Human Capital Outlook Implications for Skills Development in the Pharmaceutical Sector

The Adequacy of Higher Education and Training Provision for API and Biotechnology Manufacturing Skills Requirements

Final Report

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Acronyms

AIDS	Acquired Immune Deficiency Syndrome
API	Active Pharmaceutical Ingredient
ASGISA	Accelerated Shared Growth Initiative for South Africa
BSc	Bachelor of Science
CHAI	Clinton Health Access Initiative
CHIETA	Chemical Industries Education and Training Authority
CSIR	Centre for Scientific and Industrial Research
CSIR (India)	Council of Science and Industrial Research
DHET	Department of Higher Education and Training
DNA	Deoxyribonucleic acid
DOL	Department of Labour
DST	Department of Science and Technology
DTI	Department of Trade and Industry
EIA	Enzyme immunoassay
ELISA	Enzyme-linked immunosorbent assay
EMCM	Electrical, Manufacturing, Chemical and Mechanical (engineering)
EPI	Expanded Immunisation Programme
EPO	Erythropoietin
FIEST	Federal Institute of Education, Science and Technology
FYP	Five-Year Plan
GMP	Good Manufacturing Practice
HC&HS	Health Care and Health Sciences
HCT	HIV Counselling and Testing
HEIs	Higher Education Institutions
HEMIS	Higher Education Management Information System
HET	Higher Education and Training
HIV	Human Immunodeficiency Virus
Hons	Honours
HRD-SA	Human Resource Development Strategy – South Africa
IICB	Indian Institute of Chemical Biology
IICT	Indian Institute of Chemical Technology
IIMs	Indian Institutes of Management
IITs	Indian Institutes of Technology
IMS	Intercontinental Marketing Services (Health)

IPAP	Industrial Policy Action Plan
ISIC	International Standard Industrial Classification
mAbs	Monoclonal Antibodies
MIP	Manufacturing Incentive Programme
MRC	Medical Research Council
MTSF	Medium-Term Strategic
NCST	National Committee on Science and Technology
NIPER	National Institute of Pharmaceutical Education and Research
NIPF	National Industrial Policy Framework
NPC	National Planning Commission
NQF	National Qualifications Framework
NRF	National Research Foundation
NSC	National Senior Certificate
NSDS	National Skills Development Strategy
PEPFAR	President's Emergency Plan for AIDS Relief
PG	Post Graduate
PhD	Doctor of Philosophy
QA	Quality Assurance
QC	Quality Control
R&D	Research and Development
RIA	Radioimmunoassay
SARS	South African Revenue Services
SERC	Science and Engineering Research Council
SET	Science, Engineering and Technology
SETAs	Sector Education and Training Authorities
TAI	Tax Allowance Incentive
TIFAC	Technology Information Forecasting and Assessment Council
TIMSS	Trends in International Mathematics and Science Study
TPM	Total Pharmaceutical Market
TSP	Tourism Support Programme
UG	Undergraduate
WHO	World Health Organisation

Chapter 1: Introduction and Background

The National Industrial Policy Framework (NIPF), which was adopted by cabinet in 2007, sets out government's approach to South Africa's industrialisation trajectory and a vision for the industrial economy for both the short-medium and medium-long terms.[1] The policy framework recognises that four complementary sets of policies are necessary for the successful implementation of an industrial policy: a supportive macroeconomic and regulatory environment; skills and education; traditional and modern infrastructure; and support for technological effort.

The Industrial Policy Action Plan (IPAP) 2 is a three-year implementation plan that follows from NIPF and IPAP 1. Its purpose is to expand production in value-adding sectors with high employment and growth multipliers that compete in export markets as well as in the domestic market against imports.[2] One of these priority sectors is the pharmaceutical sector. The action plan identifies the following key growth opportunities for the pharmaceutical sector:

- Domestic production of active pharmaceutical ingredients (API) for key ARVs
- Local production of reagents for AIDS / HIV diagnostics, [3]under licence.
- Domestic production of vaccines under licence.
- Domestic production of biological medicines such as erythropoietin and monoclonal antibodies.
- Removing regulatory barriers and constraints to clinical research in South Africa.

These growth opportunities are identified against the backdrop of the multiple challenges that the sector faces, one of which is lack of key skills in new drug design, pharmaceutical formulation and biotechnology. The policy action further points to a problem of excessive supply of graduates with conventional skills and knowledge that are not relevant to a knowledge-based

[1] Department of Trade and Industry, *The National Policy Framework*.

[2] National Assembly statement on Industrial Policy Action Plan (IPAP2) by Dr Rob Davies, Minister of Trade and Industry, 18 Feb 2010

[3] Manufacturing under license refers to a product manufactured by one organisation with the authorisation of the organisation that owns the intellectual property of the product and/or process design. In the simplest sense, manufacturing under license is a form of technology transfer where the designing organisation or intellectual property owner or so-called licensor typically provides assistance to the manufacturing organisation (the licensee), for example, by providing formulation and process documentation, staff and training in return for royalty payments.

economy and for feeding into the growth opportunities identified. A need to plan and develop appropriate skills for the successful implementation of IPAP 2 is therefore critical.

1.1 Project Scope and Objectives

The Department of Trade and Industry (**the dti**) commissioned Ilangabe Lase Africa to conduct research into human capital outlook implications for skills development in the pharmaceutical sector, with a specific focus on IPAP-2-identified growth opportunities (IPAP 2 areas) for the pharmaceutical sector. The objectives of the research were:

- To verify and validate the requirements and supply of critical skills for IPAP growth opportunities (IPAP areas) for the pharmaceutical sector
- To assess the adequacy of education and training provision in addressing IPAP core skills requirements
- To present a case study of a successfully implemented growth path for the pharmaceutical sector in any of the world economies that had similar growth and skills challenges as well as opportunities in the past
- To make recommendations on skills planning and development strategies for IPAP 2 areas.

The focus is on the first four of the five identified IPAP-2–growth opportunity areas.

It is important to note upfront that the purpose of this research was not to conduct an analysis of the South African pharmaceutical industry, the relevant legislative framework, nor the appropriateness of the incentive schemes available to the sector. These areas are covered in this report with a view to providing a broad background overview of the sector.

1.2 Respondents

Nineteen companies were sampled through a purposive sampling methodology. The sample consisted of two categories: *category 1* – ten pharmaceutical companies with production facilities locally – the majority of these were generic manufacturers; and *category 2* – nine innovator companies. In addition to pharmaceutical companies, a sample of 19 stakeholders comprising trade associations, government departments, research organisations and higher education institutions was drawn.

1.3 DATA COLLECTION METHODS

- **Mailed questionnaire:** A questionnaire was developed and emailed to pharmaceutical companies to complete. Follow-up calls were made to all companies to confirm receipt of the questionnaire. Those who could not be reached by telephone were sent emails. Following several telephone calls and email reminders, six completed questionnaires were received, five from category 1 companies and one from category 2 companies. Of those companies that did not return completed questionnaires, four formally communicated their decisions not to participate in the study, while others did not.
- **Qualitative interviews** were successfully conducted with 17 of the targeted stakeholders. Additional interviews were also conducted with companies that are already involved in the IPAP 2 growth opportunities – Biovac Institute, Bioclones and Fine Chemicals Corporation.
- **Secondary Data** were obtained from various documents, *inter alia* sector research reports, international studies, websites and academic publications.
- **Statistics:**
  - NSC Examinations – Report of the Department of Education on the 2010 National Senior Certificate Examination Results
  - HEIs enrolments: Higher Education Management Information System (HEMIS); organised according to the Classification of Educational Subject Matter of 1989
  - HEIs graduates: Department of Higher Education and Training HEMIS office

1.4 REPORT STRUCTURE

The rest of the report is structured as follows:

Chapter 2 provides a brief overview of the South African pharmaceutical sector, including its structure, key players, size and value, exports and imports, regulatory environment and incentives.

Chapter 3 presents the current status of IPAP growth opportunities within the South African pharmaceutical sector in terms of an overview of the specific areas, current market size, value and key players.

Chapter 4 presents generic manufacturing processes for the four IPAP 2 areas and assesses core skills/competencies, qualifications and specialisations that are required for IPAP growth opportunity areas.

Chapter 5 discusses research findings on the adequacy of higher education and training (HET) provision in addressing API and biotechnology manufacturing qualifications and skills requirements, and strategies that support the growth of the sector.

Chapter 6 presents case studies of successfully implemented growth paths for the pharmaceutical sector by progressive economies that had similar growth/skills challenges to South Africa. Countries of which case studies are presented are India, Brazil and Cuba.

Chapter 7 concludes the reports and outlines lessons from the case studies and a comprehensive list of recommendations on strategies for planning and developing skills for IPAP 2 areas as well as the pharmaceutical sector as large.

Chapter 2: The Pharmaceutical Sector Overview

The purpose of this chapter is to provide a brief overview of the South African pharmaceutical sector in terms of its structure, players, value, imports, exports and challenges. This overview is important in setting up the context within which the IPAP 2 objectives/vision for the sector should be understood.

2.1 Pharmaceutical Sector Definition and Classification

The pharmaceutical sector is classified under the broader chemical sector in the South African industrial classification system. The chemical sector consists of various subsectors as described in the table below.

Table 1: Chemical Sector Classification[4]

CHIETA Chambers	CHIETA Subsectors	DTI's Strategic Subsectors
Petroleum and Base Chemicals	Petroleum	Liquid Fuels and Associated Products
	Base Chemicals	▪ Commodity Organic Chemicals ▪ Primary Polymers and Rubbers ▪ Commodity Inorganic Chemicals ▪ Fine Chemicals
Fast-Moving Consumer Goods and Pharmaceuticals	Fast-Moving Consumer Goods	Consumer Formulated Chemicals
	Pharmaceuticals	Pharmaceuticals
Explosives and Fertilisers	Explosives	Bulk Formulated Chemicals
	Fertilizers	
Speciality Chemicals and Surface Coatings	Speciality Chemicals	Speciality and Functional Chemicals
	Surface Coatings	
Glass	Glass	Not Part of the Chemical Industry

The inclusion of the pharmaceutical sector within the chemical industry is in line with the International Standard Industrial Classification (ISIC)[5] Revision 3.1. This has been superseded

[4] CHIETA: Chemical Sector Skills plan 2008, updated.

by ISIC Revision 4, which separates the pharmaceutical sector into a category of its own. This was done to accommodate non-chemical pharmaceuticals, which could not be classified as chemicals because of their nature.

The ISIC Revision 4 classification, "Manufacture of pharmaceuticals, medicinal chemical and botanical products" includes the following:

- Manufacture of medicinally active substances
- Processing of blood
- Manufacture of medicaments
  - Antisera and other blood fractions
  - Vaccines
  - Diverse medicaments including homeopathic preparations
- Manufacture of medical diagnostic preparations
- Manufacture of radioactive in-vivo diagnostic substances
- Manufacture of biotech pharmaceuticals

For the purposes of this study, the ISIC Revision 4 classification of the pharmaceutical sector will be adopted. This classification is ideal in that it is all-inclusive and covers the growth opportunities identified in the 2010/11 to 2012/13 IPAP 2 for the pharmaceutical industry.

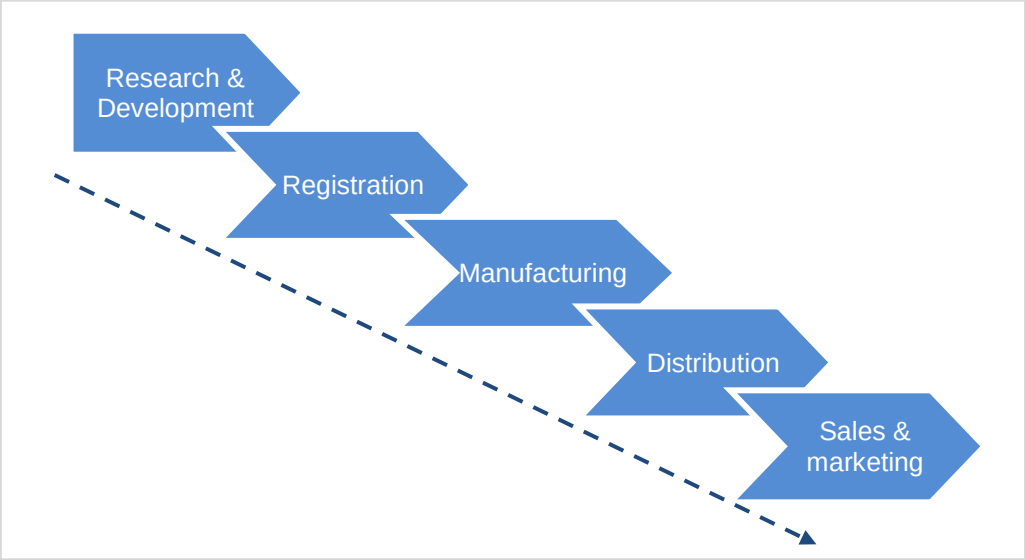
2.2 Structure and Key Players

The pharmaceutical industry is a knowledge-intensive sector, comprising research and development (R&D), manufacturing, sales and marketing of pharmaceutical products. Figure 1, below, summarises the key activities in a 'generic' pharmaceutical value chain.

In the South African context, there is very little research and development work, but the majority of both innovator and generic companies have a modified value chain wherein the R&D components as well as manufacturing are largely not applicable.

[5] International Standard Industrial Classification of All Economic Activities, Rev.4, United Nations Statistics Division; The International Standard Industrial Classification of All Economic Activities is a United Nations system for classifying economic data.

Figure 1: Pharmaceutical Value Chain



The sector can very broadly be divided into the R&D, or innovator / ethical drug industry, and the generic industry, although the boundaries between the segments have blurred significantly in the last few years, and a new hybrid model is gaining prominence. This is partly because of declining innovator pipelines, and slowing pharmaceutical industry growth in the developed economies (especially of innovator products) and the entry of innovator companies into the fast-growing generic segment, especially in the so-called emerging markets.

As a fairly developed market with sophisticated consumers and world-class clinical skills, as well as being the gateway into Africa, South Africa is host to subsidiaries of the leading large global multinational corporations (innovator and generic), large listed, and small privately held local companies. There are a number of companies that have also formed joint ventures (for example, Venture Pharm and Dr Reddy's Laboratories) with, or act as pure distributors for international companies.

The role-players in the pharmaceutical industry can broadly be classified as follows:

- Innovator/multinational/foreign-owned importers, distributors and marketers
- SA-owned manufacturing companies with plants
- Multinational manufacturing or packaging plants
- Importers of generic medicines, repackagers, marketers and distributors
- Suppliers of biological products,
- Government-funded research organisations, including universities

- Clinical trial units of universities, private medical practices and private organisations.

According to CHIETA, the pharmaceutical industry is one of the biggest beneficiaries of discretionary grants and the third-largest contributor of skills development levies. There are 112 pharmaceutical companies that pay skills development levies.[6] Based on the requirement of the Skills Development Levies Act which requires all organisations with a payroll exceeding R500 000 per annum to pay a 1% skills development tax on their payroll, it can be assumed that this is the number of registered pharmaceutical companies in South Africa.

- Aspen has operations in over 100 countries, aannd owns 5 manufacturing facilities locally and several internationally,
- Adcock is the largest manufacturer of OTC medicines in SA, and has 4 local manufacturing facilities and 1 overseas
- Cipla Medpro has 1 local manufacturing facility, and has a licensing, supply and technology agreement with Cipla India.

The top ten corporations by value in South Africa include Aspen Pharmacare, Pfizer, MSD, Adcock Ingram Healthcare (Pty) Ltd, Sanofi Aventis, Astra Zeneca and Cipla Medpro.[7] The three biggest local companies are Aspen Pharmacare with 15.4% value market share, Adcock with 9.5% and Cipla Medpro with 5%.[8] Aspen and Adcock have international operations, mostly on the continent, with the former also being active in North and South America, Australasia and Europe.

2.3 Size and Value

South Africa has a growing and dynamic pharmaceutical industry comprising a number of global innovator R&D companies, some of which also operate hybrid models with own generic divisions, and fully fledged generic companies. Strategically, the industry is positioned to supply many of the African markets. Compared with other African countries, the South African industry has the two largest manufacturers on the continent – Aspen Pharmacare and Adcock Ingram, with the former being a global top-ten generic company.

Although the South African pharmaceutical industry comprises only 0.2% of the world pharmaceutical market,[9] it is the largest in Africa and is estimated to be worth about R 21.0 billion at ex-manufacturer's prices as at June 2010, of which generic drugs accounted for 57%

[6] CHIETA Sector Skills Plan 2009-2010, www.chieta.org.za.

[7] IMS TPM 2010

[8] Ibid.

[9] Deloitte (2010), *Insights into the high-level financial contribution of the Pharmaceutical Industry in South Africa* report for the Pharmaceutical Task Group.

by volume and about 24% by value.[10] The future growth of the sector is projected at a compound annual growth rate of 22% between 2010 and 2013.[11]

The industry serves both the private sector market, which caters for about 15% of the population, and the public sector tender system, which caters for the remaining 85%. In 2009, it was estimated that the public sector purchased about R4 billion[12] worth of pharmaceuticals. These were a mix of essential drugs such as ARVs, TB drugs, vaccines and other commonly used medicines for common ailments like high blood pressure and diabetes, among others.

The private sector buyers, on the other hand, are a diverse group and include dispensing doctors, retail pharmacies, wholesalers, private and mine hospitals, and group buyers who supply funded health care programmes.

2.4 Exports and Imports

Although South Africa has a competitive industry, it is beset and bedevilled by critical and severe skills shortages, and by a lack of competitive and well-developed supporting industries. Consequently, the country is a net importer of pharmaceuticals, unlike similar developing countries like India and Brazil. Currently, South Africa imports the bulk of its pharmaceuticals from the following countries: India, Germany, USA, France, and UK and exports to mainly African countries including Kenya, Nigeria, Zambia, etc.[13] Total imports in 2010 amounted to R15.1billion, up from R13.5 billion in 2009,[14] an increase of 11.85% over a 12-month period.

Although the closure of plants by multinationals has been viewed as a key contributor to the industry's contraction and subsequent increase in imports, the latter is a complex and multi-factorial issue that can be attributed to the following:

- the lack of local investment in new manufacturing plants,
- a scarcity of critical skills,

[10] IMS TPM 2010

[11] Yasmin Mahomedy (2010), *Research Report on the Manufacture of Pharmaceuticals,* Who Owns Whom (Pty) Ltd, Johannesburg.

[12] DTI Data

[13] Deloitte (2010), *Insights into the high-level financial contribution of the Pharmaceutical Industry in South Africa* report for the Pharmaceutical Task Group.

[14] DTI – Pharmaceutical Trade Data

- an unfavourable pharmaceutical investment environment when compared with global centres of excellence like Singapore and Puerto Rico (tax regimes, incentives, skills bases etc.),
- a complex regulatory and policy environment,
- the dominance of India and China in the critical area of API supply,
- weak related and supporting industries,
- smaller population/market size,
- Global trend towards consolidation and merging.

Consequently, South African pharmaceutical manufacturers and formulators are reliant upon a high volume of imports, estimated at between 60-90% of the inputs for their drugs, mainly from India and China in the case of generic products, or from other overseas manufacturers.[15]

The increase in imports is evident in the declining exports. Total exports in 2010 amounted to R937million, down from R1.31 billion in 2009.[16] There was an average annual growth of 13% in exports between 1992 and 2009. This declined sharply, by 40%, in 2010. It is worth noting in the context of IPAP 2 that an industry that is considered to be non-competitive and with no prospects for growth, local company Aspen Pharmacare is a top ten global generic company and supplies international buyers such as Clinton Health Access Initiative (CHAI) and a host of PEPFAR and Global-Fund–funded programs on the continent.

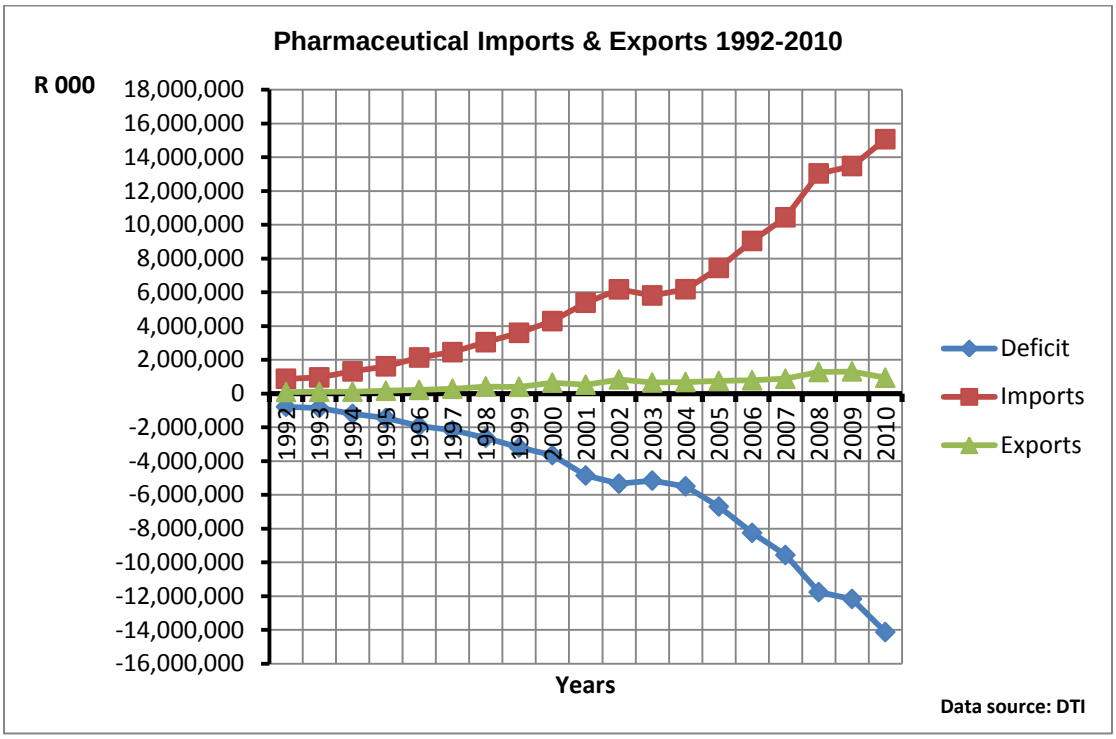
Given the imbalance between imports and exports, the trade deficit widened significantly between 2003 and 2010, bringing the total deficit in 2010 to R14.1 billion, up from R5.2 billion in 2003.[17]

[15] Maloney C and Segal N (2007), *The Growth Potential of Pharmaceuticals Sector in South Africa*, research undertaken for the Department of Trade and Industry, Genesis, Johannesburg

[16] DTI – Pharmaceutical Trade Data

[17] Ibid.

Figure 2: Imports and exports 1992-2010



2.5 Policy and Regulatory Environment

The South African healthcare and pharmaceutical sectors have undergone momentous policy and regulatory changes since the advent of democracy in 1994. These changes sought to address the disparities of the past, while at the same time striving to address the constitutional obligation of the state in terms of Section 27 of the South African Constitution.[18] The resultant policy and regulatory framework had the sole intention of improving universal access to safe, efficacious and affordable quality healthcare services. It is within the context of these policy and regulatory reforms that the South African pharmaceutical sector should be understood. Below, we list and summarise the key regulations that are critical to understanding the changes that have occurred in the sector since 1994.

a) **The National Drug Policy of 1996:** The stated goal of the National Drug Policy was "to ensure an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa and the rational use of drugs by prescribers, dispensers and consumers"

[18] **The South African Constitution** – "Everyone has the right to have access to – a) health care services, including reproductive health care". Section 27 (1) (b) of the Constitution further mandates the state to "take reasonable legislative and other measures within its available resources to achieve the progressive realisation of the right"

b) **Medicines and Related Substances Control Act of 1997 (as amended):** This act provided for mandatory generic substitution, for the establishment of the Medical Control Council (MCC), for the setting of single exit price regulations, for the regulation of dispensing fees for pharmacists and logistics fees, for International benchmarking, and for pharmaco-economic evaluations, among others.

c) **Single Exit Price regulations (2003):** These flowed from the Medicines Act and were promulgated with the aim of controlling the prices of medicines.

d) **The Patent Act of 1978, amended in 2002:** This act covers and deals with all issues related to intellectual rights such as trademarks, patents, copyrights among others. It was amended to include provisions for early working, and the Bolor provision, which is supportive of the early entry of generic medicines.

Alongside the above regulations, it is important to note that like much of the developing world, South Africa is also grappling with the inherent conflict between its health and industrial policies and their objectives. If not carefully managed, this conflict has the potential to affect access negatively and inhibit the growth of the local pharmaceutical industry.

In addition, it should be noted that globally the pharmaceutical sector is one of the most heavily regulated industries, given the need for authorities to ensure that the products to which the public are exposed are safe, efficacious and of good quality.

2.6 Government Incentives

The pharmaceutical industry is a very high technology industry that requires massive capital outlays for plant construction and plant upgrades. Further, given the evolving nature of pharmaceutical science and continuing current Good Manufacturing Practices (cGMPs), investments in the sector, and the accompanying skills training, capacity building is a never-ending process. To this extent, governments around the world have accepted the need for targeted and catalytic interventions that help to not only sustain but also grow the sector and enhance its competitiveness.

The South African government similarly has incentive schemes that are very important to the growth of the sector and particularly to promoting and supporting local manufacturing. These incentives are governed by the Income Tax Act No 58 of 1962 as amended and the Revenue Laws Amendment Act 29 of 2008.

DTI has two incentives programmes that are relevant to the pharmaceutical sector as far as IPAP 2 growth opportunities for the sector are concerned. These are summarised below:

i. **Section 12i Tax Allowance Incentive (12i TAI):** This is a fairly new incentive scheme in the form of a structured tax allowance programme based on investment in new manufacturing assets and skills training. The 12i TAI was formulated with the explicit aim of accelerating economic growth in the industrial sector in support of the objectives of IPAP 2. It puts an emphasis on job creation, skills training and energy efficiency. The objectives of the incentive programme are to support the following:[19]

   - Investment in manufacturing assets, to improve the productivity of the South African manufacturing sector;
   - Training of personnel, to improve labour productivity and the skills profile of the labour force.

The 12i incentive programme targets greenfield and brownfield projects as well as projects that are classified under *'Major Division 3: Manufacturing'* according to the Standard Industrial Classification (SIC) of all industrial activities.

ii. **Enterprise Investment Programme (EIP):** An investment programme was launched in 2008 with the aim of providing sector-specific financing in order to stimulate growth. EIP has two sub-programmes, namely the Manufacturing Investment Programme (MIP) and the Tourism Support Programme (TSP). The aim of MIP is to stimulate growth within the manufacturing sector, in line with the National Industrial Policy Framework objectives.[20] The support is offered in the form of an investment grant of up to 30% of the value of investments in machinery, equipment, commercial vehicles, land and buildings for new and expansion/upgrading projects.

In addition to the DTI incentive programmes, the Department of Science and Technology (DST) also runs a research and development tax incentive programme: The Research and Development (R&D) Tax Incentive Programme[21] was introduced in November 2006, in terms of Section 11(d) of the Income Tax Act. It is administered by the Department of Science and Technology (DST) in conjunction with the South African Revenue Service (SARS). The aim of

[19] Programme Guidelines – Enterprise Investment Programme: Manufacturing investment Programme, issued March 2009, www.thedti.gov.za.

[20] Ibid.

[21] Department of Science and Technology, www.dst.gov.za.

the scheme is to encourage innovation and scientific and technological research in South Africa and is targeted at all South African enterprises irrespective of size and the sector.

2.7 DRIVERS OF GROWTH

The growth of the South African pharmaceutical sector, especially the generic segment, has been largely driven by the following factors:

- Patent expiries of many blockbuster[22] molecules
- The HIV/AIDS epidemic and a treatment programme that is the largest in the world
- Increasing acceptance and use of generic medicines
- An increase in diseases of lifestyle
- An aging population requiring chronic care
- A greater number of people now accessing health services
- A shrinking health budget and the need to contain costs.

In the next chapter, the pharmaceutical sector IPAP 2 growth opportunities are discussed, and some of the drivers of growth, especially with respect to HIV/AIDS, are discussed in detail.

[22] A blockbuster molecule is a drug product with sales of US$1 billion or more per annum.

Chapter 3: IPAP 2 Growth Opportunities

The previous chapter highlighted some of the key challenges facing the pharmaceutical sector, which include a contracting local manufacturing sector vis-a-vis increasing imports and a widening trade deficit, a shortage of skills, the HIV/AIDs pandemic and government's spending on HIV/AIDs treatment as well as the urgent need to put more people on treatment. These constitute a good enough justification for promoting local production as advocated by IPAP 2.

This Chapter provides a brief overview of the current markets of the above-stated IPAP 2 growth opportunities for the South African pharmaceutical sector.

3.1 APIs for Key Antiretroviral Drugs

According to the United Nations' AIDS 2009 HIV and AIDS estimates, South Africa had 5.6 million people living with HIV, making it one of the top five countries in sub-Saharan Africa with the highest HIV prevalence and epidemic.[23] Over the past five years, the country has undertaken a rapid scale-up of antiretroviral therapy (ART) and now runs the biggest treatment programme in the world.[24] The country has a comprehensive plan for the management, treatment, care and support of HIV and AIDS, which has enrolled over 1.4 million people on ARV treatment in the public sector[25] and an estimated 100 000 in the private sector.[26] It is estimated that the AIDS treatment plan will expand to treat between two and three million people over the next decade.[27] This will lead to increased imports for both finished formulations and APIs, leading to an increasing trade deficit.

The 2010 ARV tender[28] value was ZAR4.16 billion. Given that the API constitutes between 70 and 90% of the finished product,[29] the APIs required to fulfil this tender are estimated to be around R3 billion. Currently, local manufacturers of ARVs import all the APIs required for the

[23] Global Report: UNAIDS Report on Global AIDS Epidemic, 2010; WHO Library Cataloguing in Publication Data.

[24] South African Department of Health

[25] Minister of Health's Budget Vote Speech, June 2011

[26] 2010/11 to 2012/13 Industrial Policy Action Plan, DTI, February 2010.

[27] Guthrie T et al. (2010); *The long run costs and financing of HIV/AIDS in South Africa*; Report prepared for aids 2013 Costs and Financing Working Group; Washington, DC; Results for Development Institute.

[28] RT71-2010MF – The Supply and Delivery of Antiretroviral Drugs to the State for the period 01 January 2011 to 31 December 2012.

[29] Maloney C and Segal N, (2007); *The Growth Potential of Pharmaceuticals Sector in South Africa*; research undertaken for the Department of Trade and Industry; Genesis, Johannesburg.

manufacture of finished formulations.[30] From an industrial policy point of view, this situation is untenable in the long run, and is a very strong motivation and imperative for the local production of these APIs.

3.2 Reagents for HIV and AIDS Diagnostics

Given the high burden of HIV/AIDS in the country, and the importance of HIV testing in the management of the disease, the consumption of clinical diagnostic kits is considerable. The 2009 government rapid test kit tender (RT41-2009ME) called for almost 12 million rapid test kits (screening and confirmatory) valued at R52 million at the time of award.[31] The volumes increased significantly with the advent of the HIV Counselling and Testing (HCT) campaign initiated by the Ministry of Health in April 2010. While there are very few figures available for private sector usage, there are multiple private companies that offer testing services to large corporations, testing millions of people each year. The minister of health reported to Parliament in his recent budget vote speech that since the HCT campaign was introduced in April 2010, 11.9 million people had tested for HIV.[32]

As with pharmaceutical products, the bulk of the diagnostic products on the market are imported, with the major local suppliers sourcing products from China, India and South Korea. The unassailable fact is that very much as with HIV / AIDS medications, the country imports the bulk of what it uses, and there is a great opportunity under IPAP 2 to redress this.

There are some private companies, research institutions and universities that are already researching, developing and manufacturing diagnostics locally, although not much was revealed about their endeavours during this research. In implementing IPAP 2 objectives for the pharmaceutical sector, it will be worth learning more about what they are doing with a view of learning from their experiences and determining how they can be involved.

3.3 Vaccines

Globally, vaccines have emerged as one of the most important, successful and affordable public health tools. The first ever expanded immunisation programme was introduced by the World Health Organisation in 1974 with the intention to vaccinate all children below the age of one

[30] D Walwyn (2008); Briefing note for the pharmaceutical industry; proposed support for the local manufacture of active pharmaceutical ingredients; prepared for the Department of Trade and Industry.

[31] National Treasury Contract Management; http://www.treasury.gov.za/divisions/sf/ostb/default.aspx

[32] Minister of Health's Budget Vote Speech, June 2011

against what were then leading killer diseases. The programme has evolved since then to include new vaccines against newer threats. The South African government also introduced an Expanded Programme of Immunisation (EPI) in 1995. The programme initially covered polio, diphtheria, tuberculosis, pertussis, measles and tetanus. Subsequently, other vaccines for Hepatitis B, Heamophilus influenzae, pneumococcal and rotavirus were introduced.

South Africa imports the bulk (estimated at R1billion in 2010)[33] of the vaccines used in the EPI and in the private sector. Prior to this, there had been a measure of vaccine production, but this was terminated in 2001 with the closure of the State Vaccine Institute, the South African Institute for Medical Research and the National Institute for Virology due to a lack of the requisite technology, funding, ability to keep up with a rapidly changing field, and constantly evolving internationals standards.[34]

In 2003, the Biovac Institute was established as a Public Private Partnership between the Biovac Consortium and the Department of Health. The Biovac Consortium includes South African entity Biovac Holdings, as well as Heber Biotec of Cuba and VaxIntel of the United Kingdom. Biovac Institute is the only human vaccine manufacturing facility in the country, and one of only two on the African continent. The company is currently working on a number of R&D projects and is gearing up to commence local manufacturing by 2013.[35]

Given the extent of the government EPI, vaccine manufacturing presents a significant opportunity under IPAP2 for companies like Biovac and others that aim to produce vaccines locally.

3.4 Biological Medicines

Genius Biotherapeutics (formerly Bioclones) is the only South African local biological R&D company currently involved in commercial biosimilar[36] production. They, together with their partners, currently produce erythropoietin (EPO) using their own technology and licensed cell lines. The API is manufactured locally and formulation and filling are done by a local partner. Their only product so far is Erythropoetin, and they have various other biosimilars under development including Dendritic Cell Vaccines (DCVs) and oral vaccines.

[33] SARS data 2010

[34] Health Systems Trust, http://www.hst.org.za/news/20031008; BIOVAC, www.biovainstitute.co.za

[35] Interview with Biovac Institute (CEO, R&D director and HR director)

[36] Biosimilar medicines are follow-on versions of original biological medicines. They are independently developed after the patent protecting the original product has expired.

The South African private market for Erythropoietin (EPO) was estimated at R150 million in 2010.[37] In this market, Bioclones is competing against Roche and Janssen Cilag, which together have about 98% of the market. The two companies also have 99% of government tender business, while Bioclones has only 1%.[38] Perhaps no case demonstrates the need for IPAP 2 more than the Erythropoetin public market situation in South Africa. Although Bioclones' prices are competitive when compared to the two innovators, they remain at a disadvantaged position because their product is in the form ampoules, while the market prefers pre-filled syringes. IPAP 2, in leveraging state procurement, and in trying to support local manufacturers who have invested heavily in technologies that are sorely needed in the country, needs to facilitate dialogue among the relevant state departments, which will lead to a review of tender award criteria.

[37] IMS 2010.

[38] Interview with Bioclones.

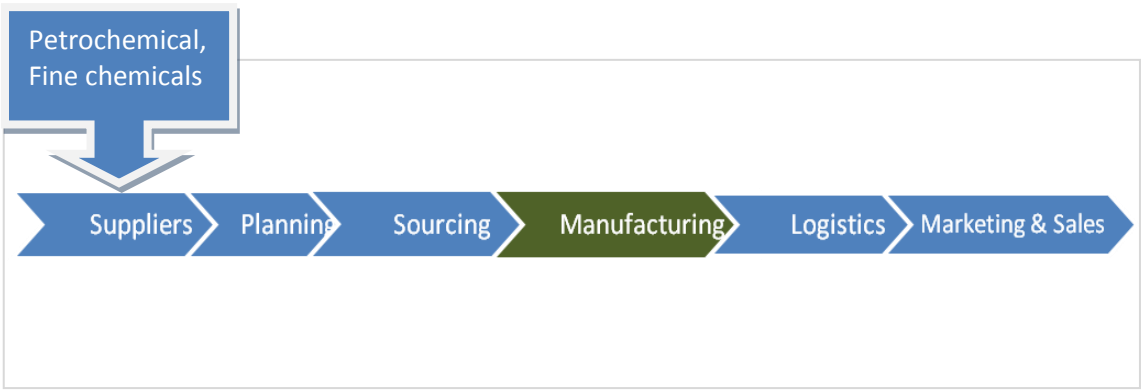
Chapter 4: Skills Requirements for IPAP 2 Areas

One of the critical factors for the success of IPAP 2 objectives for the pharmaceutical sector is the availability of relevant skills in adequate numbers and quality. IPAP 2 growth opportunity areas are complex and therefore require highly qualified and skilled human resources. This chapter aims to identify IPAP 2 core skills requirements. It starts with an overview of what the manufacturing processes for the four IPAP areas will entail. Then it outlines requisite core qualifications, areas of specialisation and the required skills sets.

4.1 Manufacturing Processes

Worldwide, there is a move away from stand-alone manufacturing plants to clustering. The development of clusters in the manufacturing sector results in a co-locating of opportunities, a shared supply chain infrastructure and a more efficient use of resources like energy and utilities, and warehousing and logistics. It brings together the manufacturing synergies of suppliers and makes the outsourcing of services easier. Figure 3, below, shows the complete value chain of a typical pharmaceutical manufacturer. The most important suppliers, who are critical to the success of the industry, are the petrochemical and fine chemicals suppliers, as they account for the largest percentage of required raw materials.

Figure 3: Pharmaceutical Manufacturing Value Chain



In the discussion of skills gaps in South Africa, it is important to consider the whole value chain first, because addressing the skills shortage in the core pharmaceutical sector in isolation will result in a non-viable sector, since it requires many other related and supporting industries and skills. These include planners, petrochemical and fine chemical technicians, machinery and equipment suppliers, tooling, logistics personnel, and so forth.

Broadly, the requisite skills for any type of manufacturing in the pharmaceutical industry include the following:

- **Research and Development**: Chemists – pharmaceutical, medicinal, synthetic, analytical and organic; Biologists – microbiologists (quality control), molecular biologists (vaccines and biological)
- **Manufacturing/GMP:** Plant engineers -– chemical, process, mechanical; and artisans
- **Regulatory:** Production and regulatory pharmacists
- **Quality Assurance:** QC personnel – pharmacists, chemists and microbiologists
- **Data management:** Data managers and IT personnel.

Below, we outline the manufacturing processes for the IPAP 2 growth opportunity areas and detail the skills that are required. In constructing these manufacturing process chains, we have taken broad generic processes. Processes may vary from one manufacturer to the other, and much of the detail is part of the trade and proprietary secrets of the companies concerned. However, the generic process and the skills required are generally similar.

4.1.1 Active Pharmaceutical Ingredient Manufacturing

APIs are the active chemical or biologic substances responsible for the clinical effect of drugs. In the manufacture of drug products, they are mixed with inactive substances (like binding agents and colourants) to produce the final drug dosage form in the form of tablets, pills, syrups and so forth. For example, paracetamol would be the active pharmaceutical ingredient in Panado or Painamol[39] tablets or syrup.

APIs are made from synthetic (man-made) compounds (mainly derived from petrochemical or organic material) or from plant extracts and microorganisms (usually bacteria, e.g. *Penicillium* spp for the production of penicillin). The API manufacturing process may involve chemical synthesis, microbial synthesis, extraction from plant or animal sources, or some combination of the above.[40] The most common method of manufacturing APIs involves reacting organic chemicals together (organic synthesis).[41] Organic synthesis is a special branch of chemical synthesis and is concerned with the construction of organic compounds (APIs are organic compounds) via organic reactions.

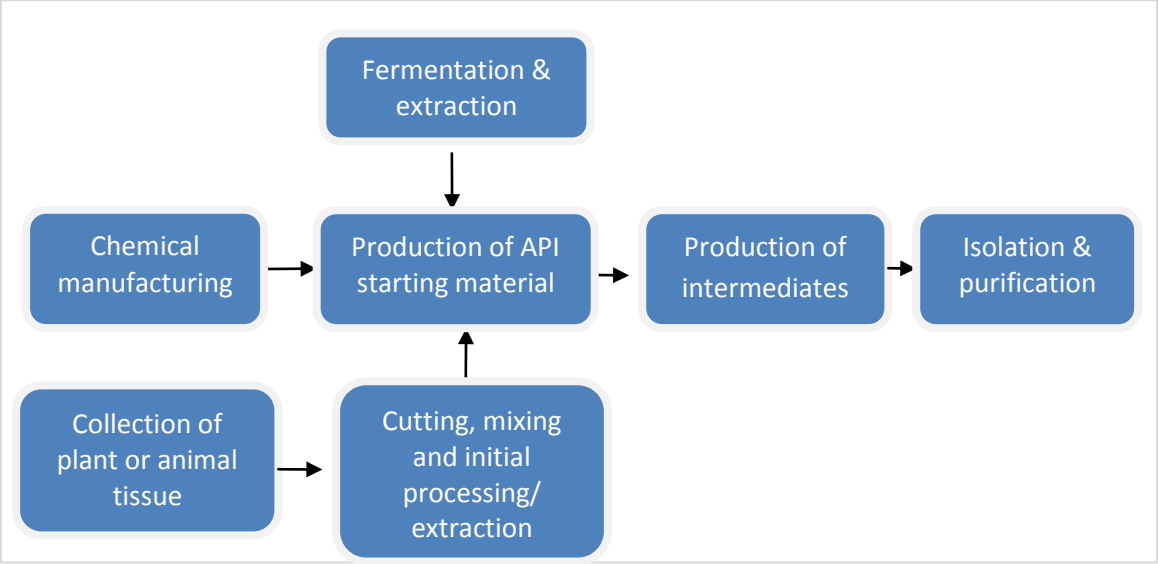
[39] Panado is a registered trademark of Adcock Ingram.

[40] Campell J J, (2008), Understanding Pharma: The professional's guide to how pharmaceutical and biotech companies really work, 2nd edition, Pharmaceutical Institute, United States of America.

[41] http://en.wikipedia.org/wiki/Organic_synthesis.

The information above is illustrated for ease of understanding by the flowchart in Figure 4, below. The flowchart shows that raw materials may be other chemicals (usually from petrochemical refining processes), plant or animal extracts, and micro-organisms. These are then reacted together with other compounds, eventually making the required API, which is purified to the required standard at the end.

Figure 4: Manufacturing Process for Active Pharmaceutical Ingredients



The chemical processes used may be common to many different APIs, differing only in terms of their starting materials. API manufacturing requires a large number of personnel trained in many different disciplines, for example, chemists (organic / medicinal / analytical), pharmacists, chemical and process engineers, and so forth. These disciplines are discussed in greater detail below. It is also important to note that API manufacturing requires a strong petrochemical industry as well as access to high-purity fine chemicals.

4.1.2 Biological Medicines and Vaccines

Biological preparations (biologicals) are made from living organisms or from their by-products through a series of complex genetic manipulations. They include monoclonal antibodies, interleukins and vaccines. They are used to prevent, diagnose, treat or relieve symptoms of a disease.

The manufacture of biological medicines and vaccines utilises biotechnology processes and demands a sophisticated and very expensive infrastructure in the form of clean (sterile) rooms; specialised equipment, all backed by highly advanced scientific (e.g. molecular biology /

pathology, biochemistry, genetic engineering) skills. Biotechnology utilises several technologies and tools with the major ones being:[42]

- Bioprocessing technology
- Cell culture
- Recombinant DNA technology
- Monoclonal antibodies
- Cloning
- Protein engineering
- Biosensors
- Nano-biotechnology
- Microarrays.

Below, the first four technologies that are considered core to the biotechnology industry and which South Africa could consider for IPAP 2 are discussed.

a) **Bioprocessing technology:** This is the oldest of the biotechnologies and uses living cells (usually unicellular microorganisms e.g. yeast and bacteria) or the molecular components of cells' manufacturing machinery (DNA or enzymes) to produce desired products. Microbial fermentation is a form of bioprocessing. The Biovac Institute (Cape Town) currently uses this bacterial fermentation technology for its developed vaccines and for those in development.

b) **Cell culture:** Cell culture technology is the growing of cells outside of living organisms. These cells may originally be derived from plants, insects or mammals. Vaccines and other biologicals are now being made using cell culture techniques e.g. Genius Biotherapeutics (formerly Bioclones) (in Cape Town) currently uses mammalian cell culture (baby Chinese Hamster Ovary) in the production of its erythropoietin biosimilar product.

c) **Recombinant DNA Technology:** Recombinant DNA is the foundation of modern biotechnology, and this entails the joining – or recombining – of two pieces of DNA from different organisms. It is widely used in vaccine and insulin manufacture.

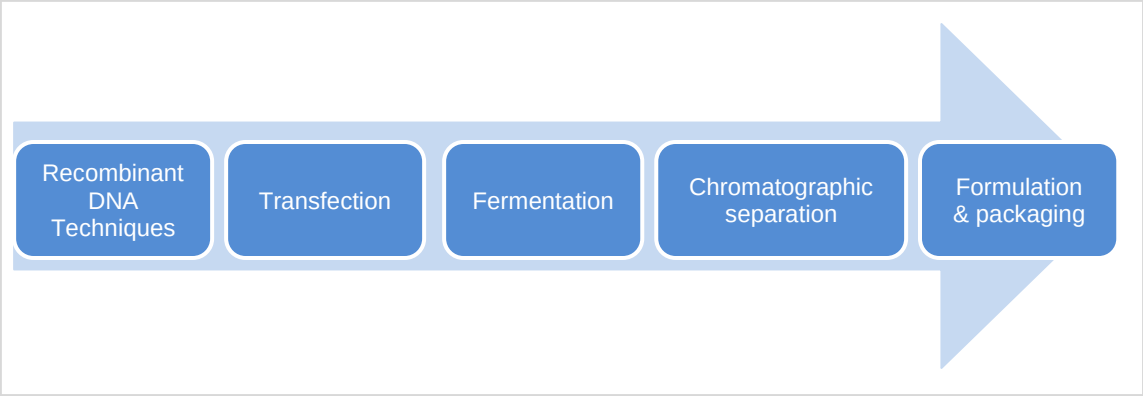
d) **Monoclonal Antibodies:** This technology uses immune system cells to make proteins called antibodies, which help the body to destroy foreign invaders such as viruses or

[42] Guide to Biotechnology 2008, Biotechnology Industry Organization; http://www.bio.org

bacteria. Monoclonal antibodies, popularly referred to as mAbs, make powerful diagnostic tools and potent new biological drugs used in the treatment of serious disabling and life threatening conditions, like disabling rheumatoid arthritis and many cancers.

The most recent technologies in the manufacture of biologicals entail the use of recombinant DNA transferred and grown into (prokaryotic) cells, then into fermented matter. Fermentation is done for the cells to multiply, thereby increasing the amount of product made. Thereafter, purification and separation of the target biologicals are performed using standard chromatographic (chemical separation) techniques. This process is illustrated in Figure 5, below. The flowchart shows how recombinant DNA is transferred into cells, which are then multiplied in fermenting vats, after which the target substance (cytokine or antibody) is purified by chromatographic separation, and then formulated for use.

Figure 5: Manufacturing Process of Biological Medicines using Recombinant DNA Technology



In the vaccine attenuation method, the virus is seeded and multiplies in incubators. It is then mixed with beads and grown on the beads (this has been found to be an efficient way of increasing the virus population. Thereafter the virus is separated out / purified and then 'killed' or 'weakened' by means of heat treatment – a process called attenuation. This renders the virus 'harmless', but it is still able to cause the body to produce antibodies when it is administered. The attenuated virus is then purified (separation) and freeze-dried (lyophilisation) to a powder, which is formulated for use. Figures 6 and 7, below, illustrate the common generic processes for vaccine manufacture.

Figure 6: Process for Vaccine Manufacture using Cell Culture Technology

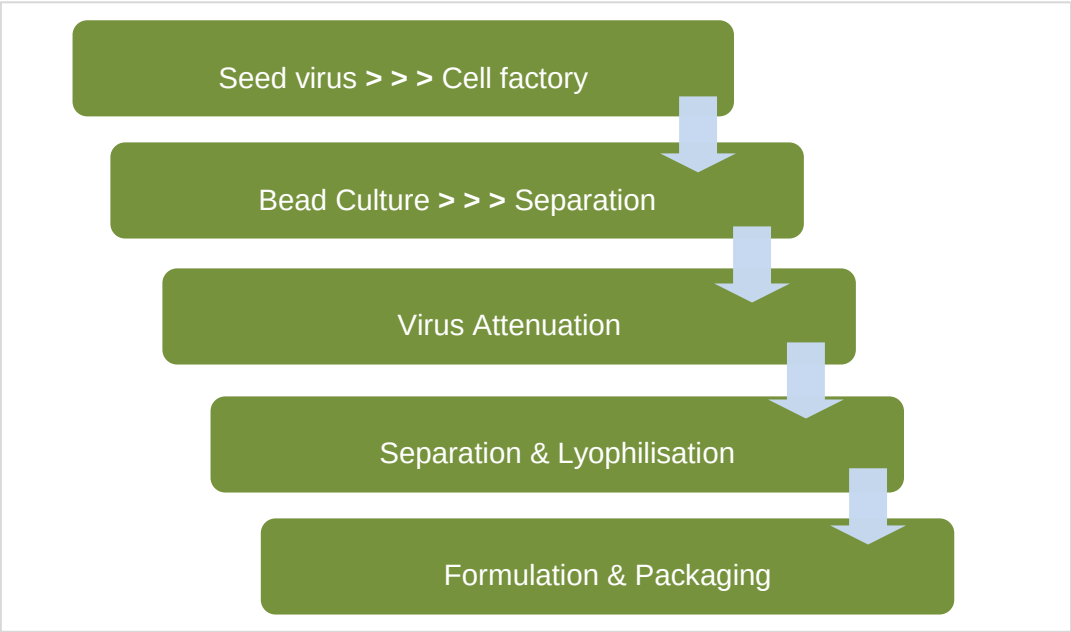
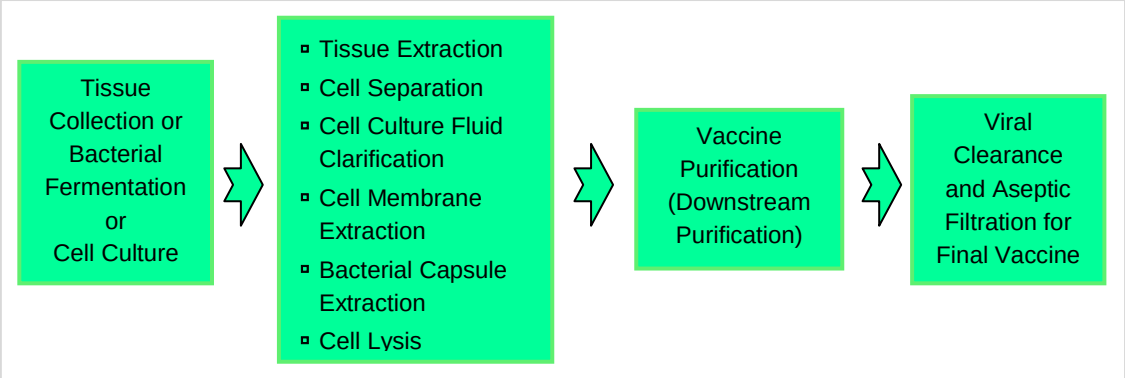


Figure 7: Process for Vaccine Manufacture using Bioprocessing Technology



The newer method of vaccine manufacture involves the use of animal or human cells, which allows for a faster and more pure virus by-product. This is shown in Figure 7 - the virus is inoculated into cells and then allowed to multiply. Thereafter, the cells are broken up and viral particles are purified out. These viral particles can cause an antibody reaction when administered but are not as functional/virulent as the complete virus, and hence they are non-infective.

Local companies Biovac and Genius Biotherapeutics have developed their own technologies for the manufacture of vaccines and biosimilars (generic biologics) respectively. Some of these technologies have even been licensed out to foreign companies.

The important disciplines in the manufacture of biological products are molecular biology, virology, microbiology, immunology, chemistry (immune, biochemistry, etc.), pharmacy and process engineering. There are inherent risks of contamination and potential disease transmission, so safety is also an important support discipline.

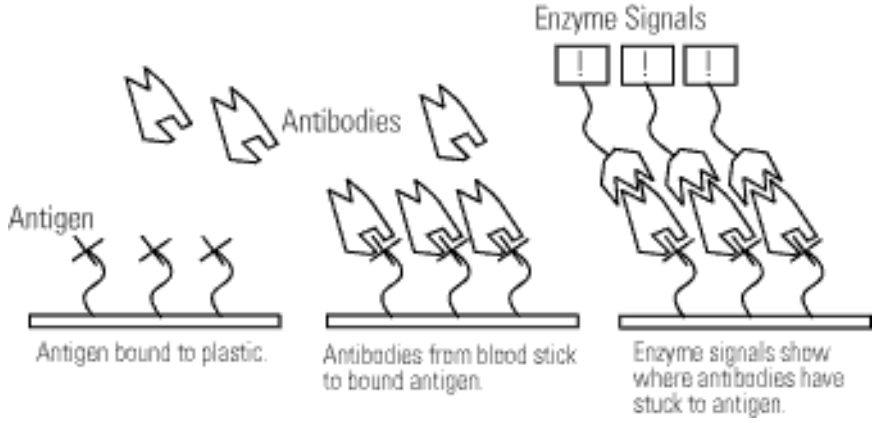
4.1.3 Diagnostic Reagents

Diagnostic assays are used to determine the presence or absence of a substance (e.g. illicit drug) or disease (e.g. HIV / AIDS or prostate cancer). Most of the diagnostic assays use reagents that rely on the immune reactions of certain marker compounds, with the target substances residing blood or urine (generally called biomarkers). The common diagnostic techniques are the following:

a) Radioimmunoassay (RIA) which uses a radioactive (nuclear) element as the traceable binding substance. However use of this technique requires specialised facilities and equipment.

b) Enzyme immunoassay (EIA), which uses various enzymes (proteins found in the body that facilitate reactions) as labels that can cause colour changes, e.g. the ELISA test, which is used for HIV testing, or the glucose test kit used for testing for sugar diabetes.

Figure 8: How Rapid Test Kits Work



This scheme shows how the Enzyme Immunoassay (EIA) kit works. The antigen is isolated from monoclonal antibodies and attached to the strip; when i reacts with antibodies (from fluid that is infected), they bind, and an enzyme reaction occurs changing the colour of the strip. If the fluid is uninfected, there is no antigen-antibody reaction and hence no colour change.

For the purposes of IPAP 2, it is prudent for this area to be developed in conjunction with the vaccine and biological industries as the manufacturing processes are virtually identical to those

discussed in Figure 4, above. The major steps are similar except that the monoclonal antibodies are isolated and then loaded onto diagnostic cassettes or sticks (so-called diagnostic reagent strips), which when exposed to appropriate samples, react in the presence of the target substances, for example, the HIV virus in the case of infection with HIV. Most diagnostics are packaged with the requisite chemicals (reagents or buffers), and for proprietary reasons the reagents are not usually generic. The reagents may include ammonium molybdate reagents, alkaline-iodide reagents, acid zirconyl reagents, chloride reagents, iodide reagents, molybdate reagents, and potassium permanganate reagents. Biologists (mainly microbiologists and molecular biologists) play a critical role in the manufacture of diagnostic reagents.

4.2 Skills Requirements: Identified Opportunities

As used in this section and throughout the document, the words listed below are defined as follows:

- **Skill** – proficiency, competence or ability to perform a task; this is usually gained by on-the-job training and experience and as an add-on to an academic qualification
- **Discipline** – practice or training in a specific academic area e.g. pharmacy or chemistry
- **Specialisation** – highly skilled academically in the discipline e.g. holder of a postgraduate qualification in an area
- **Qualification** – academic credentials that make someone suitable to perform a particular task
- **Function** – activity associated with a task

IPAP 2 skills requirements can be divided into the following two groups based on the similarities of the growth opportunity areas:

- Skills for active pharmaceutical ingredients (bulk drugs) manufacturing – chemistry and engineering are the cornerstones of this area
- Biotechnology skills – the biological sciences (molecular and microbiology) and engineering are cornerstone areas.

Biotechnology skills cover the following three areas: vaccines, reagents and the manufacturing of biological / biosimilar medicines

Within the specific skill areas, there are common or cross-cutting skills, and these include skills in disciplines such as chemistry, biochemistry, microbiology, engineering, and pharmacy. Core API and biotechnology manufacturing skills requirements fall within the following categories:

- Biological Sciences
- Physical Sciences (Chemistry)
- Life Sciences
- Engineering

While the processes and technologies for IPAP areas differ, the base skills and specialisation requirements are to a large extent similar. There are however differences in emphasis and nuanced applications of the competencies depending on the final product and the complexity thereof. In this section, we present the skills and academic qualifications requirements according to the functions/operational areas that are common to all manufacturing environments.

Table 2, below, defines functions and skills requirements for the manufacture of API and biotechnology products.

Table 2: Description of Functions Involved in API and Biotechnology Manufacturing

Process Areas	Functions and skills
Process Development	▪ Researching the relevant properties of a product and synthetic pathway in order to optimise production to increase efficiency and improve effectiveness. ▪ Requires thorough knowledge of chemical and physical properties as well as a multi-disciplinary team with competencies in chemistry, physics, computer science, mathematics, and engineering sciences.
Process Design	▪ Design of processes for desired physical and / or chemical transformation of materials, i.e. how will the product be made? The process design decision has two major components: a technical (or engineering) component and a scale economy (or business) component. The technical component includes selecting equipment and selecting a sequence for various phases of operational production. ○ **Block Flow Diagrams (BFD)**: simple flow diagrams indicating major material or energy needs. ○ **Process Flow Diagrams (PFD)**: More complex diagrams of major unit operations as well as flow lines. They usually include a material balance, and sometimes an energy balance, showing typical or design flow rates, stream compositions, and stream and equipment pressures and temperatures. ○ **Piping and Instrumentation Diagrams (P&ID)**: Diagrams showing all pipelines with their piping class (carbon steel or stainless steel) and pipe size (diameter). They also show valving, along with instrument locations and process control schemes. ○ **Specifications**: Written design requirements of all major equipment items.
Regulatory Affairs	Overall responsibility for: ▪ Compliance with legislation and GMP / GLP guidelines. ▪ Keeping an audit trail and the relevant documentation for regulatory authorities.
Validation	The documented act of demonstrating that a procedure, process, and activity will consistently lead to the expected results. It often includes the qualification of systems and equipment and various stages, i.e. ○ Cleaning Validation. ○ Process Validation. ○ Analytical Method Validation. ○ Computer System Validation.
Quality Assurance / Control	**Quality control** – testing of products to uncover defects, and reporting to and advising management, who make the decision to allow or deny their release. **Quality assurance** – steps to improve and stabilise production, and associated processes, to avoid or minimise issues that lead to the defects in the first place.
Plant Operations / Manufacturing	Support and maintain the necessary infrastructure used in manufacturing, e.g. heating, ventilation and air conditioning systems, equipment calibration, plumbing, etc.
Plant Maintenance	Methods, strategies, and practices used to keep an industrial factory running efficiently. The general aim of plant maintenance is to create a productive working environment that is also safe for workers.
Management	Planning, organising, staffing, leading and controlling an organisation in the

Process Areas	Functions and skills
	deployment of all resources available so that entity achieves its goals.

4.2.1 API Manufacturing Skills

API manufacturing requires good synthetic, separation and analytical chemistry skills. The holders of these qualifications should be at master's, doctoral and post-doctoral levels for a globally competitive manufacturer. They would be supported by large numbers of highly experienced technicians and assistants with science, engineering, information technology and management diplomas and bachelor's degrees. In addition to academic qualifications, the support team should have additional API-specific training. The core disciplines in API manufacturing are the following:

- Biological sciences – microbiology
- Chemistry – analytical, medicinal, organic, process
- Phytochemistry
- Pharmacy – regulatory
- Engineering – process, chemical, maintenance

Table 3 outlines the key industrial skills and academic qualifications required for generic API manufacturing involving total synthesis.

Table 3: Qualifications and Skills Requirements for API Manufacturing

Functions	Requisite academic qualifications	Industrial skills requirements
Process development	▪ MSc & PhD Synthetic & Organic Chemistry ▪ MSc & PhD Molecular Biology ▪ BSc Chemistry ▪ BSc & MSc Microbiology ▪ MSc Organic Chemistry ▪ PhD Chemical Engineering ▪ BSc & MSc Electronic Engineering ▪ BSc Mechanical Engineering, ▪ BSc IT ▪ Diploma, BSc, MSc Analytical Chemistry	▪ Process Chemistry ▪ Biosynthesis ▪ Process Microbiology ▪ Process Engineering
Process Design	▪ PhD Chemical Engineering ▪ MSc & PhD Organic & Synthetic Chemistry ▪ PhD & MSc Microbiology ▪ MSc & PhD Virology ▪ MSc & PhD Molecular Biology ▪ PhD Chemistry ▪ MA Law	▪ Process Design ▪ Process Chemistry ▪ Process Microbiology ▪ Analytical Chemistry R&D ▪ Technology Transfer
Regulatory Affairs	▪ BSc Chemistry ▪ B Pharmacy	▪ Manufacturing and Controls ▪ Technology Transfer
Validation	▪ BSc Mechanical Engineering ▪ MSc Chemical Engineering ▪ Diploma, BSc, MSc Analytical Chemistry ▪ Diploma, BSc, MSc Engineering (General) ▪ BSc Chemistry; BSc Microbiology ▪ Diploma IT; BSc IT	▪ Process Engineering ▪ Equipment Validation Engineering ▪ Process Validation ▪ Cleaning Validation ▪ Computerised Systems Validation
Quality Assurance & Control	▪ BSc Analytical Chemistry	▪ Good Manufacturing Practice (GMP) for API Manufacturing
Plant Operations/ Manufacturing	▪ BSc Chemical Engineering ▪ PhD Organic Chemistry ▪ MSc Chemical Engineering ▪ MSc Electrical Engineering ▪ MSc Mechanical Engineering ▪ MSc Microbiology ▪ Diploma, BSc Chemistry ▪ BSc chemistry; BSc Engineering ▪ B Pharmacy	▪ Process Engineering ▪ Chemical Operations ▪ Environmental Engineering ▪ Operational Safety and Industrial Hygiene
Plant Maintenance	▪ BSc Electrical Engineering ▪ BSc Mechanical Engineering ▪ MSc IT ▪ BSC Electronic Engineering	▪ Maintenance Engineering ▪ Maintenance Planning ▪ Plant Safety

Management	▪ BA Management (Project) ▪ MBA ▪ BA Logistics Management ▪ BA & MA Law	▪ Pharmaceutical Project Management ▪ Materials Management ▪ IP Management / Licensing

4.2.2 Biotechnology

The manufacturing processes using different biotechnology technologies as illustrated in Figures 5, 6 and 7 require specialised skills in the biological sciences, especially molecular biology and separation chemistry.

The core disciplines for the manufacture of biotechnology products are the following:

- Biological sciences – microbiology, molecular biology, immunology (vaccinology / virology specialisations)
- Analytical chemistry
- Pharmacy
- Engineering – process, chemical and maintenance.

The pharmacy skills required include regulatory, formulation, validation, production, quality assurance and quality control. The other scientists require good chromatography, fermentation, and cell culture and purification skills. Within these disciplines, one would typically require postgraduates at master's, doctoral and post-doctoral levels. Table 4, below, details the industrial skills and academic qualifications requirements for biotechnology based on generic manufacturing processes presented in Figures 4, 5, 6 and 7.

It should be noted that some of these disciplines cut across API and biotechnology production, with the exception of the core biotechnology skill areas listed above. From regulatory affairs function through to management, skills and qualifications requirements are similar for both API and biotechnology manufacturing.

Table 4: Qualifications and Industrial Skills Requirements for Biotechnology Manufacturing

Functions	Requisite academic qualifications	Industrial skills requirements
Process Development	▪ MSc, PhD Molecular Biology; ▪ Diploma, BSc Biochemistry ▪ BSc Chemical Engineering, ▪ BSc Mechanical Engineering ▪ Diploma, BSc, MSc Analytical Chemistry ▪ BSc, MSc, PhD Microbiology; BSc, MSc, ▪ PhD Virology	▪ Process Engineering ▪ Applied Process Microbiology
Process Design	▪ BSc Mechanical Engineering ▪ MSc, PhD Biotechnology ▪ MA Law ▪ Diploma, BSc Microbiology	▪ Process Design ▪ Technology Transfer ▪ Process Microbiology
Regulatory Affairs	▪ B Pharmacy ▪ BSc Chemistry	▪ Technology Transfer
Validation	▪ BSc Mechanical Engineering ▪ Diploma, BSc, MSc Analytical Chemistry ▪ Diploma, BSc Engineering ▪ BSc Chemistry; ▪ BSc Microbiology ▪ Diploma, BSc information technology	▪ Process Engineering ▪ Equipment Validation Engineering ▪ Process Validation ▪ Cleaning Validation ▪ Computerised Systems Validation
Quality assurance & control	▪ BSc Analytical Chemistry ▪ BSc Biochemistry ▪ Diploma Data Management	▪ Good Manufacturing Practice (GMP) for Biological Products ▪ Data Management
Plant Operations/ Manufacturing	▪ BSc Chemical Engineering ▪ MSc, PhD Molecular Biology ▪ B Pharmacy ▪ MSc Chemical Engineering; ▪ MSc Electrical Engineering; ▪ MSc Mechanical Engineering ▪ BSc, MSc, PhD Biochemistry	▪ Fermentation ▪ Process Engineering ▪ Purification ▪ Operations Safety & Industrial Hygiene
Plant Maintenance	▪ BSc Electrical Engineering ▪ BSc Mechanical Engineering ▪ BSc Electronic Engineering	▪ Maintenance Engineering ▪ Maintenance Planning ▪ Plant Safety
Management	▪ Project Management ▪ MBA ▪ BA Management; ▪ BA Logistics Management ▪ BA, MA Law	▪ Materials Management ▪ IP Management / Licensing

Chapter 5: Research Findings

This chapter presents findings of desk and primary research on the adequacy of higher education and training provision for IPAP skills requirements. Findings are presented according to the following areas:

a) Respondents' comments on IPAP 2 opportunities for the pharmaceutical sector

b) The relevance of qualifications offered by HEIs to API and biotechnology manufacturing

- Respondents' perceptions on the relevance of HET provision and the availability of skills for API and biotechnology manufacturing
- The relevance of qualifications offered by HEIs – review of qualification offerings as presented in HEIs' prospectuses and the SAQA database of registered qualifications and unit standards

c) Adequacy of public HEIs' enrolment and output quantities

d) Other findings

e) Summary of strategies that support the growth of the sector and are supportive of the IPAP-2-identified growth opportunities for the sector

f) Recommendations for addressing the HET provision gap.

5.1 Respondents' Comments on IPAP 2 Opportunities

The aim of this study was not to determine respondents' opinions about IPAP-2-identified opportunities for the pharmaceutical sector. However, by way of giving an introduction and background, the overview and rationale for IPAP 2 were discussed, and respondents had interesting views about the policy, which we have deemed necessary to report herein.

All interviewed stakeholders considered the promotion of local production through IPAP 2 to be a good policy initiative. The following factors were considered necessary in supporting the successful implementation of the policy:

- Developing the right incentives for companies that aspire to pursue identified opportunities
- Developing a policy and legislative framework that is supportive of local production

- Addressing capacity problems within the MCC
- Addressing the problem of skills shortages.

While local production was considered a good policy initiative, some respondents questioned the process followed in identifying opportunities for the pharmaceutical sector. In this regard, respondents made the following comments:

- There was no consultation with the broader industry; therefore, the IPAP vision for the pharmaceutical sector might not be shared by the entire industry
- There has not been an evaluation of IPAP 1, and therefore, the basis and rationale for IPAP 2 are not known
- China and India dominate API manufacturing, and South Africa does not have the capability and capacity to compete with them in terms of prices and production efficiencies. Furthermore, SA does not have the highly skilled personnel and technology required for API manufacturing
- There will come a point when HIV/AIDS is no longer a major problem therefore, the long-term plan should be to produce APIs for other types of finished formulations
- Manufacturing biological medicines (vaccines excluded) in particular is very expensive and should not be a priority.

All six manufacturing companies that participated in the study indicated an interest in pursuing the identified opportunities, provided that government develops the right incentives and supportive environment.

5.2 Relevance of HET to IPAP Skills Requirements

The responsiveness of education and training to labour skills demands is a problem that affects a number of countries. A study conducted by the Australian Department of Education and Science Training reported that university teachers and academics expressed concern that the quality of SET education in schools was limiting their capacity to graduate students who are suitably qualified to meet the high expectations of industry. In the UK, it is reported that the links between education and the vocational training system and the labour market are weak and result in a mismatch between demand for and supply of skills by training institutions. On the other hand, a country like Germany is perceived to have an education system that is highly oriented toward the labour market. Apprenticeships are a common phenomenon in Germany,

and since employers are directly involved in the provision and delivery of apprenticeships, it is estimated that about 50% of apprenticeships end up in regular jobs.[43]

The relevance of HET in South Africa has been under the spot light in recent years, with some of the key national policies and strategies such as the Human Resource Development strategy identifying it as one of the major contributors to the mismatch between the supply of and demand for skills. With specific reference to the pharmaceutical sector, the Department of Labour's report on skills for the chemical sector reported that there is little focus on pharmaceuticals manufacturing by academic institutions.[44]

The South African public higher education landscape consists of 23 public universities, categorised into 6 comprehensive universities, 11 traditional universities and 6 universities of technology. The traditional universities offer theoretically oriented university degrees; universities of technology offer vocationally oriented diplomas and degrees, while comprehensive universities offer a combination of both types of qualifications.[45] South African HET is intended to supply high skills for the labour market and to generate knowledge that is of social and economic benefit[46] to the country.

Below, we present research findings on the relevance of HET provision to API and biotechnology manufacturing skills requirements. We start by presenting the perceptions of respondents as shared during face-to-face interviews; then, based on the qualifications and skills requirements identified in the previous chapter, we determine the relevance of qualifications offered by HEIs.

5.2.1 Perceptions on the Relevance of HET Provision

Seventy-five percent of respondents perceived HET as being not responsive to industry and IPAP skills needs, particularly in terms of relevance and quality. For example, one of the participating manufacturing companies stated that internships and new graduate recruits joining their company are all generally below the standard requirements of the company.

[43] Wagner, Karin (1998), The German Apprenticeship System after Unification. Discussion paper. Social Science Research Centre, Berlin.

[44] Van Zyl R (2008), South African Chemical Sector Report on Skills Development and Government's New Economic Policy Priorities; research conducted by the HSRC and Ozone Business Consulting for the Department of Labour.

[45] Kraak, Andre (2008). *Human Resources Development Review 2008.* Cape Town. Human Sciences Research Council. ISBN 978-0-7969-.203-8.

Those who were of the view that HET provision is relevant qualified this by stating that the theory taught is relevant but lacks industrial practicality and applicability. For example, one manufacturer reported that HET is sound; however, not on par with industry skills requirements. Specifically, the quality of analytical chemistry and chemical engineering graduates was perceived as relevant but falling short of industry's expectation of a national diploma or bachelor's graduate.

One manufacturer stated that the key skills / specialisations that are lacking for the production of biologicals are production, regulatory, QA and QC pharmacists and medical biotechnology scientists with specialisations in chromatography and cell purification. Another argued that, generally, there is a shortage of regulatory and analytical chemistry and validation skills in South Africa. Other manufacturers identified skills shortages in the areas of formulation and filling, engineering (chemical, process and production), biotechnology and chemistry (analytical, organic and process). Interestingly, four companies reported that they have some of these skills within their companies.

The perceptions of manufacturing companies that participated in the research were informed by difficulties in finding suitable candidates for advertised vacancies as well as the perceived competencies of new recruits.

Hard-to-fill Vacancies

Participating manufacturers reported to have advertised a number of vacancies in the last 12 months that proved difficult to fill. Table 5 shows that the top three vacancies that were reported as difficult to fill were regulatory pharmacists; artisans and engineers. Other vacancies were for validation, quality assurance and control as well as analytical chemistry.

Table 5: Hard-to-fill Vacancies

Hard-to-fill Vacancies / Skills	Number of Companies
Regulatory pharmacists	5
Artisans	3
Engineers	3
Validation	2
QA&C	2
Analytical Chemists with GMP	2
Plant Operators	1
R&D Scientists	1
Vaccine Production	1

The top three reasons that were given by companies for difficulties in filling certain vacancies were a) competitors were also recruiting for the same vacancies and offering higher salaries, and b) lack of core skills required and c) lack of relevant work experience.

Table 6: Reasons why Vacancies were Hard to Fill

Reasons	No of responses
Other employers were recruiting for the same vacancies & offering higher salaries for the same position	5
Candidates lacked core skills	4
Candidates did not have relevant work experience	3
Applicants lacked breadth of relevant skills	1
Applicants lacked relevant qualifications & skills	1
Applicants demonstrated poor motivation	1
There were insufficient applications received	1

The effects of recruitment difficulties on companies were reported as detrimental to business operations; forcing companies to abandon projects that had already commenced or were in the pipeline; incurring extra costs for intensifying recruitment efforts; losing business opportunities or having to incur training costs for recruiting less qualified, inexperienced and unskilled candidates. Out of the 113 candidates that were recruited, 63% had no relevant work experience.

In addition to difficulties with filling vacancies, the relevance of HET provision was judged based on the respondents' perceptions of the competencies of graduate recruits.

Perceived competencies of graduate recruits

Process design, process development and validation were the top three skill areas where graduate recruits were considered not to have the expected competencies. This was argued in view of the fact that while graduate recruits do not have work experience, there is a certain level of competency based on qualifications that is expected by recruiting companies.

Table 7: Perceived Competencies of Graduates

Functional Area	Not competent
Process Design	5
Process Development	4
Validation	4
Regulatory Affairs	3
QA & QC	3
Plant operations	3
Plant maintenance	3
Materials Management	2
R&D	1

5.2.2 Determining the Real Relevance of HET Provision

In chapter 4, we argued that the manufacture of API and biotechnology products (vaccine, reagents for diagnostics and biological medicines) requires highly specialised science and engineering skills, preferably at postgraduate level, supported by multidisciplinary teams of technicians, engineers, IT specialists, regulatory pharmacists and managers. We reviewed the SAQA database of unit standards and prospectuses of individual universities to determine whether they offer requisite qualifications for API and biotech production. Table 8, below (more detailed information is presented in Table 9), shows that out of 20 requisite qualifications, HEIs offer 16, i.e. 80%. BSc Biotechnology, BSc Microbiology, PhD Biotechnology and BSc Biochemistry are the top four qualifications offered by 91%, 82%, 82% and 73% of traditional universities, respectively. The following findings are notable:

- Although there are ten traditional universities and nine that offer the BSc Biotechnology and PhD respectively, only one offers the MSc.
- An MSc and a PhD in Molecular Biology are offered by only one university.
- Only one university offers an MSc in analytical chemistry. Traditional universities in particular offer analytical chemistry as a compulsory module for chemistry degrees.
- Organic and synthetic chemistry are also not offered as qualifications but as core courses for chemistry degrees.
- Virology and Vaccinology qualifications are also not offered. Few traditional universities offer these courses as core courses within specific medical degrees.

Table 8: Summary – HET offering in IPAP Relevant Science Qualifications

Required Academic Qualifications	Level	Traditional Universities		Comprehensive Universities		Universities of Technology	
		No.	%	No.	%	No.	%
Biochemistry	BSc	8	73%	3	50%	Not applicable	
Biotechnology	BSc	5	45%	-	-		
	MSc	4	36%	-	-		
	PhD	3	27%	-	-		
	BSc	10	91%	4	67%		
	MSc	1	9%	5	83%		
	PhD	9	82%	5	83%		
Analytical Chemistry	ND	-	-	2	33%	4	67%
	BSc	-	-	-	-	Not applicable	
	MSc	1	9%	-	-		
Organic & Synthetic Chemistry	MSc	-	-	-	-		
	PhD	-	-	-	-		
Microbiology	BSc	9	82%	3	50%		
	MSc	7	64%	3	50%		
	PhD	7	64%	3	50%		
Molecular Biology	MSc	1	9%	-	-		
	PhD	1	9%	-	-		
Virology or Vaccinology	MSc	-	-	-	-		
	PhD	-	-	-	-		
Pharmacy	B	6	55%	-	-		

Table 9: Academic Offering of IPAP Relevant Science Qualifications

Required Academic Qualifications	Biochemistry	Biotechnology			Chemistry			Analytical chemistry			Organic & synthetic chemistry		Microbiology			Molecular biology		Virology & vaccinology		Pharmacy
Level	BSc	BSc	MSc	PhD	BSc	MSc	PhD	ND	BSc	MSc	MSc	PhD	BSc	MSc	PhD	MSc	PhD	MSc	PhD	B
North West	x				x		x		No offered		There is no university that offers organic or synthetic chemistry as a qualification. These specialisations are offered only by traditional universities as compulsory subjects/modules for chemistry degrees		x	x	x			other universities offer medical virology		x
Rhodes	x	x	x	x	x		x						x	x	x					x
UCT	x	x			x		x			x			x	x	x	x	x	x		
Free State	x				x		x						x	x	x					
Fort Hare	x				x		x						x	x	x					
UKZN	x				x		x						x	x	x					x
Limpopo	x	x			x		x						x							x
Pretoria	x	x	x	x	x		x						x	x	x				x	
Stellenbosch					x	x	x						x	x	x					
UWC		x	x	x			x							x	x					x
WITS			x		x															x
Nelson Mandela	x				x		x	x	Not offered				x	x	x					
UNISA							x													
Joburg	x				x		x	x					x							
Venda							x						x	x	x					
Zululand	x				x		x						x	x	x					
Walter Sizulu					x			x												
Cape Peninsula		x	x	x				x												
Central																				
Durban		x	x	x				x												
Mangosuthu								x												
Tshwane		x	x	x				x												
Vaal		x	x					x												

All engineering requisite qualifications, with the exception of the National Diploma in General Engineering, are offered. From Table 10, below (detailed information presented in Table 11), it can be observed that the number of traditional universities offering relevant engineering degrees is low, with more than 9 degrees being offered by less than 40% of universities.

Table 10: Summary – HET offering in IPAP-Relevant Engineering Qualifications

Required Academic Qualifications	Level	Traditional Universities		Comprehensive Universities		Universities of Technology	
		No.	%	No.	%	No.	%
Chemical Engineering	BSc/B	7	64%	2	33%	Not applicable	
	MSc/M	4	36%	-	-		
	PhD/DSc	3	27%	-	-		
Electrical Engineering	BSc/B	3	27%	3	50%		
	MSc/M	3	27%	1	17%		
Electronic Engineering	BSc/B	3	27%	-	-		
	MSc/M	2	18%	-	-		
Engineering	BSc/B	4	36%	-	-		
	MSc/M	4	36%	-	-		
	ND	-	-	-	-	-	-
Mechanical Engineering	BSc/B	5	45%	4	67%	Not applicable	
	MSc/M	4	36%	2	33%		

BSc Chemical Engineering was found to be the only engineering qualification being offered by 64% of traditional universities.

Table 11: Academic Offering of IPAP-Relevant Engineering Qualifications

Required Academic Qualifications	Chemical Engineering			Electrical engineering		Electronic engineering		Engineering (general)			Mechanical engineering		Information Technology		
Level	BSc/B	MSc	PhD	BSc	MSc	BSc	MSc	BSc	MSc	ND	BSc	MSc	ND	BSc	MSc
North West	x	x	x	x	x	x					x	x	x	x	x
Rhodes															
UCT	x	x	x	x	x			x	x		x	x		x	x
Free State	x														
Fort Hare															
UKZN	x					x		x	x		x				
Limpopo	x														
Pretoria	x	x	x				x	x	x		x	x		x	x
Stellenbosch	x	x		x	x	x	x	x	x		x	x		x	x
UWC															
WITS															
Nelson Mandela				x	x						x	x			
UNISA	x										x				
Joburg	x			x							x	x			
Venda															
Zululand															
Walter Sizulu				x							x				
Cape Peninsula	x	x	x												
Central															
Durban	x	x	x												
Mangosuthu	x														
Tshwane	x	x	x												
Vaal	x	x	x												

Other identified qualifications for supporting functions – for example, law and management are generally offered by the majority of universities.

The information presented above demonstrates that the qualifications offered by HEIs are relevant to API and biotech production requisite qualifications. It should be noted though that these qualifications are relevant only to the extent that they provide the requisite foundation in scientific theory and laboratory skills. The criticism levelled against HET by respondents was that although the required qualifications are offered by the HEIs, they are generic and not suitable for pharmaceutical manufacturing.[47] Two of the six participating manufacturing companies estimated that it takes about three years to develop a university postgraduate recruit into a capable API or biotech manufacturing specialist.[48]

Having established the relevance of academic offerings in terms of qualifications, we proceed to determine the relevance of HET provision in requisite skills for API and biotech products manufacturing. In line with the conclusion above, we argue that while the offering is evidently relevant in establishing a grounding in scientific theory and laboratory skills, it falls short of preparing graduates for immediate industrial application upon leaving university.

[47] Feedback from stakeholder interviews.

[48] Technical Report for Cabinet on the Production of Anti-retroviral Active Pharmaceutical Ingredients, Version 3, 16 March 2010.

Table 12: API and Biotech Manufacturing Core Skills Requirements

Functions	API skills requirements	Biotech skills requirements
Process Development	▪ Process Chemistry ▪ Biosynthesis ▪ Process Microbiology ▪ Process Engineering	▪ Process Engineering ▪ Applied Process Microbiology
Process Design	▪ Process Design ▪ Process Chemistry ▪ Process Microbiology ▪ Analytical chemistry R&D ▪ Technology Transfer	▪ Process Design ▪ Technology Transfer ▪ Process Microbiology
Regulatory Affairs	▪ Manufacturing and Controls ▪ Technology Transfer	▪ Technology Transfer
Validation	▪ Process Engineering ▪ Equipment Validation Engineering ▪ Process Validation ▪ Cleaning Validation ▪ Computerised Systems Validation	▪ Process Engineering ▪ Equipment Validation Engineering ▪ Process Validation ▪ Cleaning Validation ▪ Computerised Systems Validation
Quality Assurance & Control	▪ Good Manufacturing Practice (GMP) for API Manufacturing	▪ Good Manufacturing Practice (GMP) for Biological Products ▪ Data Management
Plant Operations/ Manufacturing	▪ Process Engineering ▪ Chemical Operations ▪ Environmental Engineering ▪ Operational Safety and Industrial Hygiene	▪ Fermentation ▪ Process Engineering ▪ Purification ▪ Operations Safety & Industrial Hygiene
Plant Maintenance	▪ Maintenance Engineering ▪ Maintenance Planning ▪ Plant Safety	▪ Maintenance Engineering ▪ Maintenance Planning ▪ Plant Safety
Management	▪ Pharmaceutical Project Management ▪ Materials Management ▪ IP Management / Licensing	▪ Materials Management ▪ IP Management / Licensing

There is no university in South Africa that offers pharmaceutical manufacturing or API and biotech manufacturing training for the skills identified in the previous chapter and presented in Table 12, above.

We further argue that the HET curriculum is not geared to industry skills requirements but more to academia (teaching and research). This argument is also supported by respondents' perceptions as captured below:

> *"Current internships and new graduates are all below industry standard and require skills training of up to 12 months."*
>
> *"Pharmacy curricular not supportive of industry manufacturing sector; no regulatory skills."*
>
> *"There is no training in API."*
>
> *"There are no PhD analytical chemists with GMP and validation knowledge in South Africa."*
>
> *"HET is too theoretical and lacks industry interface."*
>
> *"Pharmacy schools produce community pharmacists who do not have relevant pharmaceutical manufacturing knowledge."*
>
> *"Industry is too small to influence university curriculum development."*
>
> *"Education and training are not particularly relevant to industry needs; in particular, there are no manufacturing skills. As a result of the prevalent mismatch, most graduates leave for the European market to seek employment opportunities after obtaining their degrees."*

Consider the aims and exit outcomes of the following qualifications as stated on the SAQA-registered qualifications database:

Example 1: Analytical Chemistry (National Diploma)

Aim: to teach students basic principles and techniques of chemical quantitative and qualitative analysis, quality control of raw materials and finished products, and research and development; and their application thereof.

For practical experience and applicability, learners are required to complete a 6-month practical hands-on laboratory skills component with up-to-date equipment and to gain direct exposure to the work situation.

Career opportunities: Employment opportunities exist in research and development laboratories, industries such as detergents, petroleum, plastics, food, metals, pulp and paper, and pharmaceutical and educational institutions. Graduates may be employed in a laboratory or a production environment.

Key skills acquired:

- Chemical quantitative and qualitative analysis
- quality control and assurance
- conduct routine tests on raw materials, products or environmental samples
- prepare basic chemical compounds.

Example 2: Biotechnology (MSc)

Aim: To provide qualifiers with:

- A high level of technical and research skills that will enable them to address important issues and problems in the fields of plant, animal and microbial molecular biology as well in the medical and agricultural sciences.
- Specialised knowledge and insight in the field of molecular biology that will enable them to make a contribution to science and society by promoting the continual development of a high level of knowledge and expertise in South Africa and internationally.
- An attitude of life-long learning, thereby ensuring continuing self-development and the development of their specialist field.

Exit outcomes:

The graduate must be able to:

- Plan and execute, under supervision, an original research project that demonstrates the ability of the graduate to apply both basic knowledge and a wide range of recommended DNA technologies, in addressing a specific question.
- The ability to analyse and critically assess data must be demonstrated.
- Carry out, and report on, comprehensive literature studies relating to the field of research specialisation.
- Write research reports in both a format that is acceptable for submission as a dissertation, and in the format of a publication, and present the research results within a scientific forum.

Example 2: Biochemistry (MSc)

University 1	University 2:
Aim: to provide qualifiers with the skills to –	**Aim: to train learners to –**
▪ Independently undertake original research in biochemistry ▪ Take responsibility for the scientific inputs and outputs of biochemical research projects ▪ Teach and communicate in the discipline of biochemistry and the life sciences.	▪ become conversant regarding the execution of independent basic and applied research ▪ Be able to formulate and defend a research project proposal ▪ Be able to write a dissertation and compile from it a research article based on independent research in the field of biochemistry.
Exit Outcomes	**Exit outcomes**
▪ Compare and integrate own results with that of relevant biochemical literature ▪ Plan and independently undertake a biochemical research project under expert supervision ▪ Participate in public awareness programs on specific and general aspects of biochemistry ▪ Supervise undergraduate practical training ▪ Appreciate community needs for biochemical research.	▪ Show an ability to do quality research under the supervision of a study leader ▪ Develop the research skills that comply with the further developed skills in presenting research results orally ▪ Publish a prescribed number of publications accepted by NATED-rated journals ▪ Develop an advanced ability to identify and solve problems that require critical and creative thinking ▪ Utilise opportunities for continued personal intellectual growth, efficient economic activity and positive contributions to society.

Despite the shortfall of HET in equipping students with industry-relevant skills, some universities have identified the need to introduce some industry-tailored qualifications. The University of Pretoria (Department of Engineering) was found to be the only institution that is making headway in developing qualifications that are responsive to industry. The university offers two postgraduate qualifications in process design, which are aimed at equipping candidates to become specialist practitioners in process evaluation and design in the process industry. The approach followed is that a fundamental understanding of the underlying principles should be complemented by an ability to apply these concepts in a practical environment, where the

acquired skills will enable graduates to use tools in the design and decision-making process. The programmes are prepared and presented in collaboration with invited experts from industry and accommodate candidates with an interest in research as well as those who require professional know-how for direct application in industry. These programmes are:

- **BEng Honours Process Design (process modelling and control group):** compulsory modules taught are Product Design, Process Control System Development, Process Integration and Separation Technology
- **MEng Process Design (Bioprocessing):** aimed at developing engineers and scientists for employment in industries that rely on biotechnology to drive their operations. Compulsory taught modules are:
  - Bioprocessing – specific application of biotechnology in the mining, agriculture, bio-fuels, pulp and paper, medical and pharmaceutical industries
  - Reactor Design
  - Product Design
  - Separation Technology.

Experience from around the world also demonstrates the need for educational institutions that bridge the gap between theoretical knowledge and industrial application. For example, one of the leading pharmaceutical training institutions in the United States is the Stephens Institute of Technology in Hoboken, New Jersey. This institution offers industry-specific training in various sectors of the economy. For the pharmaceutical sector, the Institute offers a Master of Science or engineering degrees in pharmaceutical manufacturing to students who have a base bachelor's degree in science, engineering, technology, pharmacy, or other non-technical disciplines. The pharmaceutical engineering master’s program offers core and elective courses, a selection of which are presented below:

Core Courses:

Introduction to Pharmaceutical Manufacturing

Validation and Regulatory Affairs in Pharmaceutical Manufacturing
Modelling and Simulation of Pharmaceutical Manufacturing Systems
Engineering Economics & Cost Analysis
Introduction to Project Management for the Pharmaceutical Industry

Electives:

Biopharmaceuticals Product Development and Upstream Production Systems
Pharmaceutical Mixing
Risk-Based Compliance in the Pharmaceutical Industry
Process Safety Management
Good Manufacturing Practice in Pharmaceutical Facilities Design
Bioprocess Technology in API Manufacturing
Validation of Computerised Systems
Bio-pharm Facilities Design
Design of PAT Systems for Pharmaceutical Manufacturing
Sustainable Design for Bio-Pharma Facilities
Chemical Technology Processes in API Manufacturing
Environmental Systems (HVAC) in Healthcare Manufacturing
Regulation and Compliance in the Pharmaceutical Industry
Process Analytical Technology (PAT) in Pharmaceutical Operations
Quality in Pharmaceutical Manufacturing
Contemporary Concepts in Pharmaceutical Validation

The course is offered to candidates aspiring to enter the pharmaceutical industry, and is well supported by the leading multinational pharmaceutical companies.

Similar institutions in Africa include the St Luke's Foundation in Moshi, Tanzania, which offers an Industrial Pharmacy Advanced Training Program, which covers the disciplines of drug development, drug manufacturing, and regulatory and quality compliance in the pharmaceutical industry. The entry level for the program is a minimum bachelor's degree in pharmacy, biochemistry, chemistry, microbiology and the food technology industries. Similarly, the Muhimbili University of Health Sciences in Dar es Salaam offers training to candidates with base scientific qualifications in the following industrial competencies:

- Qualification and validation in pharmaceutical manufacturing
- Analytical method development and validation
- Fluid bed drying, granulating and coating
- Granulation & tableting

- Quality assurance and quality control.

The deficiencies of the South African HET provision of industry-focused training, and the examples of pharma-oriented postgraduate training in other countries point to an apparent need to marshal resources into developing capacity at undergraduate and postgraduate levels in four core scientific disciplines – biology, biotechnology, chemistry and engineering. Engineering in particular is at the nexus of all the IPAP growth opportunity areas and is a pre-requisite for scaling up processes to industrial magnitude. Various engineering specialisations e.g. mechanical, chemical, process, electrical, IT and others are required as essential and critical support disciplines for the growth of the pharmaceutical and biotechnology industries in South Africa.

In addition, there should be a strategy to train biologists and chemists to doctoral level, since such specialisations drive innovation. The involvement of industry in working directly with universities is an important strategy toward kick-starting industrial innovation.

5.3 Adequacy of Enrolment and Output Quantities

There is significant evidence suggesting that the output of science, engineering and technology (SET) in South Africa is low compared with other countries such as India, Australia and Brazil, to mention but a few.

Without reference to specific qualifications, all respondents thought that output quantities of SET graduates are not sufficient to meet the skills requirements of all SET-skills-dependent industries in South Africa. Participating manufacturing companies identified the areas presented in Table 13, below, as those where shortages are prevalent.

Table 13: Companies' Perceptions of the Adequacy of HEIs' Graduate Output Quantities

Functional Area	
Validation	6
Process Development	5
Process Design	5
Regulatory Affairs	5
Plant Maintenance	4
R&D	3
QA & C	3
Plant Operations	3
Materials Management	3

Cognisance is taken of the fact that respondents' perceptions were not based on hard evidence, but on companies' experiences with of recruitment difficulties. We analysed data sourced from the Department of Higher Education and Training on the HEIs enrolments and graduate output (Higher Education Management Information System - HEMIS). While this database is a good source of information, it is limiting in that data is presented according to broad categories of "Classification of Educational Subject Matter (CESM)" as defined by the Department of Education. We have therefore analysed broad categories of Engineering, Pharmacy, Pharmaceutical Science and Administration, Biological Sciences and Chemistry. API and biotech-requisite qualifications fall within these broad categories.

5.3.1 HET Enrolments and Output 2006-2008

5.3.1.1 Engineering

Table 14: Engineering Enrolments and Output, 2006-2008

Level	2006		2007		2008	
	Enrolments	Graduates	Enrolments	Graduates	Enrolments	Graduates
Cert & Diploma	22 109	2 241	21 340	2 401	21 896	2 575
Degree	10 514	1 582	11 665	1 884	12 347	2 030
PG Dip & Hons	238	117	228	89	285	120
Master's	1 375	312	1 363	280	1 416	284
Doctorate	477	73	491	56	476	49
Total	**34 713**	**4 325**	**35 086**	**4 710**	**36 420**	**5 058**
Output as % of enrolments		12%		13%		14%

As depicted in Table 14, above, an average of 35 406 students per year enrolled in all engineering fields between 2006 and 2008. The total output per year in the same period was

4 698 (13% of total enrolments) on average. Nineteen percent (876) of total output were master's graduates, while only 4% (178) were PhDs. The highest output was in electrical and electronic, mechanical and chemical engineering (EMC) undergraduate qualifications, which accounted for an average of 59% of the total engineering output per year (Table 15).

Table 15: Engineering Output 2006-2009

Field of study	2006		2007		2008		2009	
	Under grad	Post grad	Under grad	Post grad	Under grad	Post grad	Under grad	Post grad
Electrical & Electronic	2 153	240	2 323	206	2 407	186	2 394	252
	33%	22%	32%	20%	31%	17%	29%	19%
Mechanical	938	132	1 037	121	1 239	139	1 417	154
	14%	12%	14%	12%	16%	12%	17%	11%
Chemical	725	130	922	98	954	129	1 022	103
	11%	12%	13%	10%	12%	12%	12%	8%
Total EMC* Eng graduates	3 815	502	4 283	425	4 600	454	4 832	509
Total Engineering	6 473	1 094	7 305	1 007	7 828	1 115	8 374	1 355
Total EMC* Eng output as % of total engineering output	59%	46%	59%	42%	59%	41%	58%	38%

EMC* represents Electrical & electronic, Mechanical and Chemical engineering

5.3.1.2 Pharmacy, Pharmaceutical Science and Administration

According to the CESM 2008, the Pharmacy, Pharmaceutical Science and Administration categories fall within the broader Health Professions and Related Clinical Sciences category and are composed of ten different fields of study, including pharmacy. There is no way, therefore, of determining data specific to pharmacy output. Nevertheless, Table 16, below, depicts that output of the broader category as a percentage of enrolment declined from 28% in 2006 to 23% in 2008.

Table 16: Pharmaceutical Science Enrolments and Output, 2006-2008

Level of Qualification	2006		2007		2008	
	Enrolments	Graduates	Enrolments	Graduates	Enrolments	Graduates
Cert & Diploma	2	1	2	0	18	0
Degree	1 263	318	1 559	396	1 790	394
PG Diploma & Hons	176	99	57	25	82	48
Master's	396	112	379	112	321	77
Doctorate	86	10	61	11	76	9
Total	1 922	540	2 058	544	2 286	528
Graduates as % of enrolments		28%		26%		23%

5.3.1.3 Biological Sciences

Biological sciences output as a percentage of enrolments was steady at 23% per year from 2006 to 2008. The number of graduates increased from 2 095 in 2006 to 2 198 in 2009.

Table 17: Biological Sciences Enrolments and Output 2006-2009

Level	2006		2007		2008	
	Enrolments	Graduates	Enrolments	Graduates	Enrolments	Graduates
Cert & Dip	1 262	241	1 232	189	857	159
Degree	5 620	1 075	5 686	1 123	6 183	1 098
PGD & Hons	528	447	583	490	612	524
Master's	1 074	243	1 041	221	1 064	250
Doctorate	703	89	719	89	733	97
Total	9 186	2 095	9 261	2 112	9 449	2 128
Output as % of enrolments		23%		23%		23%

5.3.1.4 Chemistry

An average of 10 172 students per annum enrolled for chemistry-related qualifications between 2006 and 2008, while an average of 1 830 per year graduated in the same period.

Table 18: Chemistry Enrolments and Graduates 2006-2008

Level	2006		2007		2008	
	Enrolments	Graduates	Enrolments	Graduates	Enrolments	Graduates
Cert & Dip	2 947	406	2 858	189	2 895	440
Degree	5 896	741	5 631	1 123	5 677	834
PGD & Hons	324	234	351	490	432	275
Master's	581	143	610	221	636	156
Doctorate	502	61	561	89	587	88
Total	10 250	1 585	10 011	2 112	10 225	1 793
Output as % of enrolments		15%		21%		18%

5.3.2 Output of PhD and Master's Graduates in SET

Master's programmes and doctoral education in scientific and technical innovation play a pivotal role in a knowledge-based economy. Postgraduate education and academic research are now global endeavours, so not only nations but also supranational organisations (OECD, EU,

UNECSO, the World Bank) are developing policies to enhance the contribution of doctoral education to national and regional economic growth.[49]

The National Research Foundation estimates that for South Africa to meet its human resources requirements, the country must expand the quality and quantity of PhDs produced. It is estimated that the country will require 6 000 PhDs per annum by 2015.[50] Based on this estimation, the Department of Science and Technology also estimates that for South Africa to compete in the global knowledge economy, and to achieve standards that are internationally comparable, it requires 3 000 SET PhDs per annum to transform into a knowledge-based economy by the year 2018.[51]

Figure 9, below, shows that between 2005 and 2009, the output of PhD graduates has not been consistent. It dropped 8% from 2005 to 2006, increased by about 14% in 2007, declined again by about 8% in 2008 and increased by 14% in 2009. Despite these inconsistencies, the overall PhD output has been between 72% and 80% lower than the requirements estimated by the NRF, while SET output is between 71% and 85% lower.

The Academy of Science of South Africa (ASSA) argues that while South Africa has experienced positive growth in its production rate, the country continues to produce a very small number of doctoral graduates per million of the total population (26 doctorates per million in 2007) compared with other countries such as Portugal (569 per million), Australia (264 per million), Korea (187 per million), and Turkey (48 per million).[52]

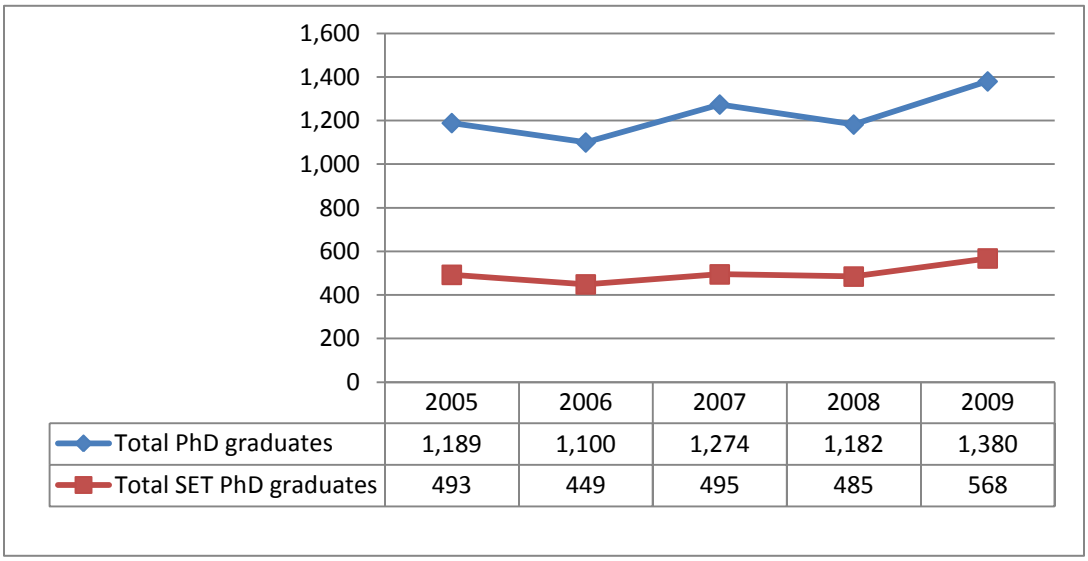
[49] The PHD Study: An evidence-based study on how to meet the demands for high-level skills in an emerging economy, Consensus Report; Academy of Science of South Africa; September 2010

[50] National Research Foundation, the PhD Project

[51] Department of Science and Technology; *Ten Year Innovation Plan*

[52] The PHD Study: An evidence-based study on how to meet the demands for high-level skills in an emerging economy, Consensus Report; Academy of Science of South Africa; September 2010

Figure 9: Output of PhD Graduates 2005-2009

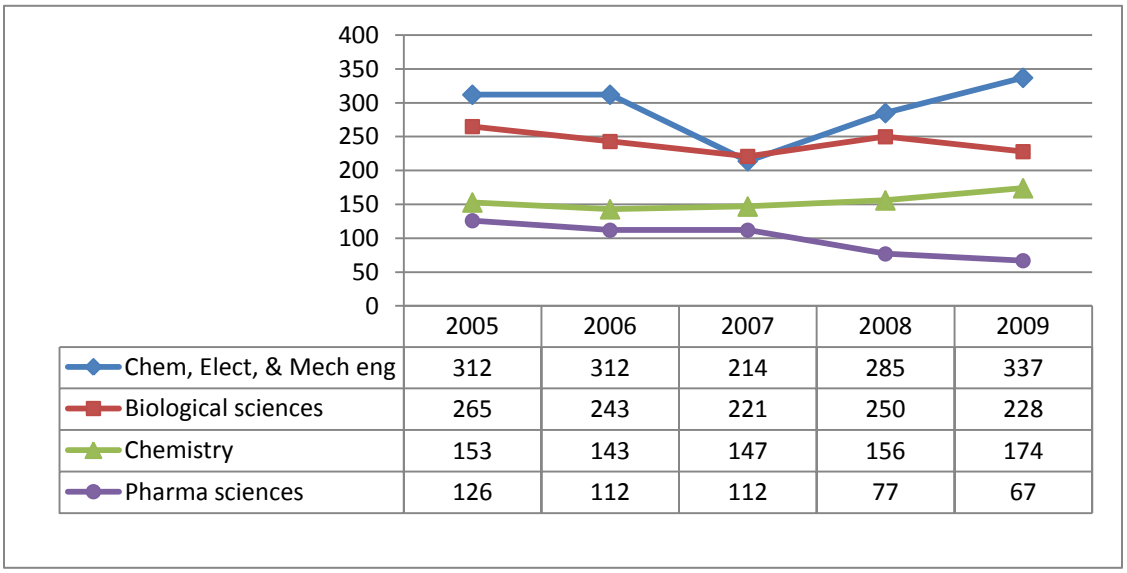


	2005	2006	2007	2008	2009
Total PhD graduates	1,189	1,100	1,274	1,182	1,380
Total SET PhD graduates	493	449	495	485	568

As illustrated in the previous chapter, the manufacturing of API and biological products requires highly specialised skills in synthetic chemistry, separation and analytical chemistry, biological sciences and microbiology. The holders of these disciplines should be at master's, doctoral and post-doctoral levels for a globally competitive manufacturer.

IPAP-relevant qualifications/disciplines produced an average of 787 masters' graduates per annum between 2005 and 2009. This in an average of 12% of all Master's graduates for that period and about 40% of the SET Master's graduates. Figure 16, below, provides output figures per discipline. It can be observed that the lowest number of graduates were in pharmaceutical science. Engineering output was the highest, with chemical engineering graduates accounting for 21% of the IPAP-relevant engineering disciplines, electrical engineering 51% and mechanical engineering 24%.

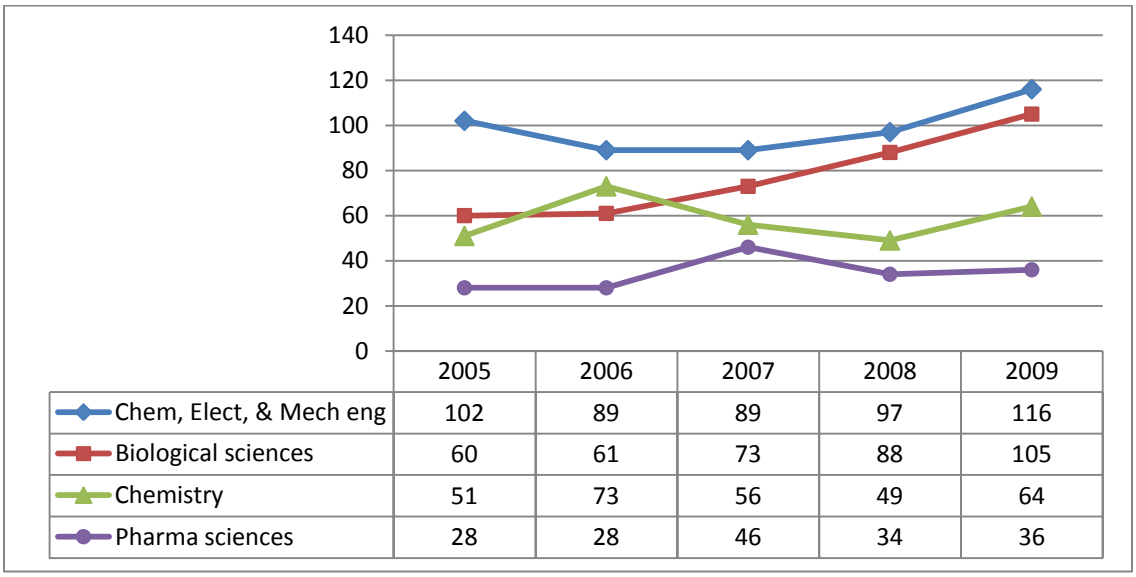
Figure 10: Master's Output in Requisite API & Biotech Qualifications 2005-2009



	2005	2006	2007	2008	2009
Chem, Elect, & Mech eng	312	312	214	285	337
Biological sciences	265	243	221	250	228
Chemistry	153	143	147	156	174
Pharma sciences	126	112	112	77	67

Doctoral graduate output averaged 269 per year.

Figure 11: Doctoral Output in Requisite API & Biotech Qualifications 2005-2009



	2005	2006	2007	2008	2009
Chem, Elect, & Mech eng	102	89	89	97	116
Biological sciences	60	61	73	88	105
Chemistry	51	73	56	49	64
Pharma sciences	28	28	46	34	36

A strategy and implementation plan for identified opportunities for the pharmaceutical sector has not been developed; therefore, the skills requirement is not known. It is therefore difficult to judge with precision whether HET output is adequate or not. However, based on the NRF's and DST's estimations of PhD requirements for South Africa, to progress towards a knowledge-based economy, and the number of industries that are competing for/dependent on SET skills, it can be argued that the numbers are not adequate.

In conclusion, the adequacy of HET provision is relevant in providing required academic qualifications for API and biotechnology manufacturing; however, it does not provide industry-specific training that prepares students for immediate industrial application upon graduating. Furthermore, the number of graduates produced by HEIs is not sufficient to meet the requirements of all SET skills-dependent industries, including pharmaceutical. Addressing the gap requires a number of strategies, which are discussed in the last section of this chapter. Successful implementation of recommended strategies will be dependent upon a number of enablers key among which is a supportive policy and legislative framework. Below, we provide key government policies that are supportive of the identified opportunities in the sector and promote the development of relevant skills.

5.4 Strategies that Support Skills for Identified Growth Opportunities

NATIONAL SKILLS DEVELOPMENT STRATEGY[53]

The National Skills Development Strategy (NSDS) outlines the national skills development priorities over a 5-year time horizon as identified by organised business and labour.[54] Unlike its predecessors, the current NSDS III will now be implemented under the custodianship and leadership of the Department of Higher Education and Training (DHET). This is mainly driven by the fact that under the new reorganisation, the Sector Education and Training Authorities (SETAs) fall under the DHET. The NSDS III is informed and guided by other overarching government programmes, including the Human Resource Development Strategy for South Africa, the requirements of the New Growth Path, the Industrial Policy Action Plan, and the outcomes of the Medium-Term Strategic Framework.[55] Below are some of the key goals of the strategy.

- **Establishing a credible institutional mechanism for skills planning:** establishing mechanisms that will provide credible information and analysis with regard to the supply and demand of skills
- **Increasing access to occupationally directed programmes:** The strategy seeks to encourage and support large corporate employers and state-owned enterprises to collaborate with the relevant education and training institutions by providing needed

[53] Department of Higher Education and Training, National Skills Development Strategy III 2010 - 2015

[54] Hoosen Rasool (2011), *Creating a National Skills Development Strategy that Works: Learning Lessons from the Mistakes of NSDS I and NSDS II;* National Skills Planning and Development Series – 2nd Research Paper, April 2010, Management College of South Africa, www.mancosa.co,za

[55] Department of Higher Education and Training, *National Development Skills Development III, 2010-2015*

training equipment and experienced staff to address specific needs. This will facilitate the relevance of education and training to industry skills needs and requirements.

The strategy further acknowledges the fact that higher and vocational education and training is still not meeting the skills demands central to social and economic development. The need to import skills – particularly the scarce skills needed for economic growth – from other parts of the world is therefore considered necessary. Thus, the information gathered by the DHET, will be used to advise the Human Resource Development Council, the Department of Home Affairs and other interested agencies on the country's skills priorities and the areas of particular shortage on an ongoing basis.

Some of the challenges identified by the strategy include the following:

- Continuing skills shortages in the artisanal, technical and professional fields that are fundamental to the development and growth of the South African economy.
- An over-emphasis on NQF level 1-3 learnerships, with insufficient progression towards more appropriate (intermediate and higher) skills required for growth sectors in a knowledge economy.
- The absence of coherent strategies within economic and industrial sectors, compounded by a lack of systematic skills development to support and sustain growth and development.

THE TEN-YEAR INNOVATION PLAN FOR SCIENCE AND TECHNOLOGY 2008-2018[56]

Drawn up by the DST in collaboration with other partners, this plan proposes a transformational path for South Africa towards a knowledge-based economy. This was done in support of government's broad developmental agenda. The plan sets out a vision for South Africa, and among other things, sees the pharmaceutical and biotechnology sectors as the sectors with the greatest potential. It therefore envisions that "Over the next decade, South Africa should become one of the top three emerging economies in the global pharmaceutical industry, based on an expansive innovation system using the nation's indigenous knowledge and rich biodiversity".

[56] Department of Science and Technology, Innovation Towards a Knowledge-based Economy – A Ten Yean Plan (2008 – 2018)

THE HUMAN RESOURCE DEVELOPMENT STRATEGY FOR SOUTH AFRICA 2010-2013

The Human Resource Development Strategy for South Africa (HRD-SA) aims to implement a key set of strategic priorities targeted at addressing the most pressing imperatives for human resource development (HRD) in South Africa, thereby stimulating other HRD-related activities in the country.

The implementation of the HRD-SA is considered as the best way to address the dilemma of the mismatch between the supply of and demand for skills in the country's labour market and the negative implications that comes with it. The strategy identifies a number of skills planning and development challenges that South Africa is faced with including:

- The need for capacity to identify demand for priority skills and formulate strategies to ensure supply
- The need to ensure the responsiveness of education and training to the government's development agenda and labour market demands for skilled human resources
- Quality of learning attainment and competency acquisition
- Quality of education and training provision.

It then proposes a set of interventions and activities formulated in response to a careful analysis of the HRD implications of the government's key development strategies including:

- The Government Programme of Action (covering all cluster priorities);
- The Medium-term Strategic Framework (MTSF);
- ASGISA;
- The National Industrial Policy Framework (NIPF);
- The Industrial Policy Action Plan (IPAP);
- The Emerging Anti-Poverty Strategy; and
- The Technology and Innovation Strategy.

In addition, the HRD-SA is based explicitly on relevant current and emerging education- and training-related strategic frameworks.

The success of IPAP 2 will largely depend on how these various human resource development strategies are integrated and implemented. In turn, the emergence of South Africa as a serious player in the knowledge economy, and the success thereof, will depend on how quickly and

effectively the country can train HET graduates with the relevant theoretical foundation, and equally important industrial relevance.

Chapter 6: Case Studies

In this chapter, we present case studies of progressive economies that had similar growth / skills challenges to South Africa, which successfully implemented growth paths for their pharmaceutical sectors. We have chosen India, Brazil and Cuba as our case study countries. We present India's case study as the main and more comprehensive one, while Brazil and Cuba are presented as shorter versions illustrating the simple but profoundly transformative and catalytic role that the state has to play in a sector like pharmaceuticals.

The Indian pharmaceutical industry is a case study that demonstrates the importance of the catalytic role that governments can play in kick-starting capital- and skills-intensive industries, and how deliberate and integrated processes of policy making and planning can successfully be leveraged for development, in the process creating self-sufficiency and sustainability in critical knowledge-based industries like the chemicals and pharmaceuticals industries.

6.1 India

India gained its independence in 1947 and became a federal democratic republic in 1950 after its constitution came into effect in January 1950. Post independence, the country was faced with a multitude of social and economic problems, *inter alia*, high unemployment, low literacy rates, a poor and unresponsive education system and pressing healthcare issues. High unemployment was particularly prevalent among the educated middle classes and was a result of a mismatch between the system of education and the needs of the economy. Historically, there was an overemphasis on literary education at the expense of neglecting specialised, technical and vocational education.[57] Healthcare challenges included a shortage of trained healthcare personnel, a high disease burden, and a lack of access to essential medicines resulting from the high prices of medicines.

The pharmaceutical industry was dominated by multinational pharmaceutical companies, many of which sold their drugs in a poor post-independence India at prices that were higher than in their home markets of the West. Further, at this stage, the nascent Indian industry could not compete, and produced less than 15 % of the finished formulations, and virtually no APIs.[58] The

[57] 2nd Five year Plan, http://planningcommission.gov.in/plans/

[58] 1st Five year Plan , http://planningcommission.gov.in/plans/

policies and strategies, as well as regulatory frameworks that followed would revolutionise the delivery of healthcare in India and catapult the Indian pharmaceutical industry into global dominance in less than four decades, and earn it the tag, 'Pharmacy of the developing world'.

It is important to note that the development of the Indian pharmaceutical industry was planned and executed within a broader system of planning and industrial development led by the government of India through the centralised economic planning system of five-year plans. Central to this process was the National Planning Commission (NPC), which drafted respective Five Year Plans (FYPs). Among others, the NPC was responsible for assessing the countries material, capital and human resources and investigating ways of augmenting them to meet the national development requirements as well as for determining the national priorities and the balanced allocation of resources.[59] The NPC's work informed the various policy and regulatory instruments that were put in place, the support given to the various industries, and perhaps more importantly, the kind of training and human resource planning and development that was needed to support the government's developmental objectives.

The FYPs were informed by investigations and recommendations of expert sub-committees and working groups, which were constituted by the NPC. Examples of such committees include the Scientific Manpower Committee, the Pharmaceuticals Inquiry Committee, the Working Group on Drugs and Pharmaceuticals (see Appendix 6 for the terms of reference and constitution of this committee), the Engineering Personnel Committee, the Scientific Instruments Committee, and others. The committees were very diverse in composition, and their members came from all relevant stakeholders, from government, industry and academia, among others. These committees were also mandated with assessing the demand for personnel and developing comprehensive recommendations on how industry-relevant skills could be built. For example, during the period that led to the second FYP, the NPC established the Engineering Personnel Committee to examine the demand for engineering personnel in relation to supply, keeping in view a perspective wider than the second five-year plan. The committee came up with the following recommendations that informed the programmes of the second FYP for the development of engineering occupations, which entailed:

- The expansion of existing facilities

[59] The National Planning Commission, www.planningcommission.nic.in

- The establishment of new facilities
- The development and expansion of apprenticeship and in-plant training schemes on a large scale
- That to improve the quality of teaching, some senior teaching posts in technical institutions should be undertaken by officers working in government departments. The existing engineering cadres in government service should be strengthened so as to provide reserves for this purpose; and
- That there should be a high-power body supported by an executive organisation with sufficient authority to take decisions on questions of policy relating to technical personnel.

Changes in Policy and Strategies of Science, Technology and Industry

Soon after independence, the government of India recognised the importance of transforming and diversifying the economy from one that was dependent on agriculture and raw materials to a modern industrialised economy. The socialist first prime minister and first chairman of the Planning Commission, Jaharwala Nehru was a great believer in the power of science and technology in transforming economies. He equated Institutes of Science of Technology to Temples at which Indians worshipped. The critical role of science, engineering and technological skills for the economic and industrial development of India was identified. The government, through its five-year planning system established programmes to build the scientific, engineering and technological skills and capabilities. Changes in policy and strategies of science, technology and industry can be examined from 1950 during the successive Five Year Plans (FYPs), mainly in five phases[60]:

Phase 1: Infrastructure Building (1950s-1960s)

This period covers mainly the first (1951-1956) and second (1956-1961) FYPs. During this phase, the foundation for science and technology as well as industry was laid. The programmes of scientific research and national institutes and laboratories were set up and enabling policies and strategies were developed.

Programmes of Scientific Research and Institutes and Laboratories

[60] Ashok J (Undated), Science, Technology and Industry Network: India's Policies and Strategies; Institute of Informatics and Communication, New Delhi University, New Delhi: India; http://www.namstct.org/ADB_RETA_Report/Dr_Ashok_Jain.pdf

The first and second FYPs pointed to an urgent need for an overhaul, diversification and reorientation of the entire education system in responding to the demands of India's economic and industrial development. Plans included improving enrolments, quality and output of education, building the capacity of teachers, developing a new and expanding an existing infrastructure (colleges, polytechnics, universities,) and establishing national research institutes. Specific focus and emphasis was placed on developing scientific, engineering and technological skills and capabilities. The government of India even took the initiative and responsibility of undertaking Research and Development (R&D) in its own laboratories under the Council of Science and Industrial Research (CSIR). During the first five-year plan, the CSIR completed work on the establishment of national laboratories for physics, chemistry, metallurgy, fuel, glass and ceramics, food technology, drugs, electro-chemistry, road research, leather, and building research[61]. The second FYP provided for the completion of buildings and the installation of the necessary equipment to enable the laboratories to function fully. These institutes and national laboratories are directly responsible for catapulting India into a global leadership position in diverse fields like pharmaceuticals, biotechnology (vaccinology), IT and general management skills. Some of these institutes and national laboratories that are relevant to SET-based industries and the pharmaceutical industry in particular include the following:

- BCG Vaccine Laboratory (1948)
- Central Drug Research Institute (1951)
- Indian Institute of Chemical Technology (first established in 1944 as the Central Laboratories for Scientific & Industrial Research; was renamed IICT in 1989 in recognition of the multidisciplinary activities and the expertise developed by the institute in the field of chemical technology[62].
- Indian Institutes of Technology[63] (IITs)
- Industrial Toxicology Research Centre (1965)
- The Glass and Ceramic Institute (inaugurated in 1950)
- The Haffkine Institute (1899)
- the Indian Institute of Science at Bangalore (1909)
- The National Chemical Laboratory (1950)

[61] 2nd Five Year Plan, http://planningcommission.gov.in/plans/

[62] Indian Institute of Chemical Technology, http://www.iictindia.org/

[63] The 1961 act lists seven institutes, which are, in order of establishment, IIT Kharagpur (1951); IIT Bombay (1958), IIT Madras (1959), IIT Kanpur (1959), IIT Delhi (1961; as IIT 1963), IIT Guwahati (1994) and IIT Roorkee (1847; as IIT 2001).

- The Indian Institute of Chemical Biology (IICB) – established in 1935 as the Indian Institute of Medical Research and renamed the IICB in 1956 when it came under the umbrella of the CSIR
- The Indian Institutes of Management (IIMs) (the first two IIMs were established in 1951).

The main function of these institutes was to look for new knowledge, fundamental or applied, examine existing industrial processes with the objective of introducing improved techniques of manufacture, and to produce standard materials, wherever possible, at reduced costs. At the same time, they would evolve new processes and new products, preferably from indigenous raw materials, and assist in the starting of new industries in the country[64].

The second FYP noted that even though the CSIR was mandated with industrial R&D, its R&D areas were derived from the frontiers of the physical, chemical and engineering sciences and not from the technology requirements of industry. This FYP identified the need for corrective action in coordinating programmes of research at national institutes and laboratories as well as at universities with the requirements of national planning.

Engineering Occupations

Expanding training facilities for engineering-related occupations started as early as the first five-year plan. The All India Council of Technical Education recommended the establishment and strengthening of a number of institutions, including the Institute of Technology, the Indian Institute of Science and a chain of new colleges and polytechnics. At the end of the first plan, significant results in the output of engineering graduates were observed. Comprehensive planning and development was also undertaken for lower-end occupations such as artisans.

Scientific Policy of 1958

In 1958, Parliament adopted a Scientific Policy Resolution as an expression of its conviction in the future contribution of science and scientific research to the country's industrial, economic and social development[65]. The aims of the scientific policy were[66]

- *to foster, promote, and sustain, by all appropriate means, the cultivation of science, and scientific research in all its aspects – pure, applied, and educational;*

[64] 2nd Five Year Plan, http://planningcommission.gov.in/plans/

[65] Ashok J (Undated), Science, Technology and Industry Network: India's Policies and Strategies; Institute of Informatics and Communication, New Delhi University, New Delhi: India; http://www.namstct.org/ADB_RETA_Report/Dr_Ashok_Jain.pdf

[66] Ministry and Science and Technology, Government of India, www.dst.gov.in/stsysindia/spr**1958**.htm

- *to ensure an adequate supply, within the country, of research scientists of the highest quality, and to recognise their work as an important component of the strength of the nation;*
- *to encourage, and initiate, with all possible speed, programmes for the training of scientific and technical personnel, on a scale adequate to fulfil the country's needs in science and education, agriculture and industry, and defence;*
- *to ensure that the creative talent of men and women is encouraged and finds full scope in scientific activity;*
- *to encourage individual initiative for the acquisition and dissemination of knowledge, and for the discovery of new knowledge, in an atmosphere of academic freedom; and, in general, to secure for the people of the country all the benefits that can accrue from the acquisition and application of scientific knowledge*.

Industry Policy and Strategy

Industry policy and strategy gave priority to capital goods and heavy industries. The importance of participation of foreign capital and technology was recognised. The 1948 industrial policy and the foreign investment policy of 1949 were put in place[67]. The industrial policy emphasised the importance of securing a continuous increase in production, its equitable distribution and the active role of government in developing industries. The objective of the 1949 foreign investment policy was to welcome foreign private investment on a selective basis in areas advantageous to the Indian economy[68]. The policy also dictated that no technology could be imported in areas where adequate local know-how was available. Examples of technologies introduced through the foreign investment routes are pharmaceuticals and fertilizers. As a result of the reluctance of foreign investors to invest in capital-intensive industries such as petroleum exploration and refining, and others, the 1948 industrial policy was revised, and in 1956, the new industrial policy was adopted. The 1956 policy enabled the emergence of state-owned corporations and the importation of technology.

At the end of this phase, the infrastructure for carrying out R&D had been laid and the opportunities for learning production technologies had been created.

According to the 10th five-year plan (2002-07), in 1947 there were only 46 engineering colleges and 53 polytechnics with an annual intake of 6,240 students. However, as a direct result of the initiatives and activities taken under the direction of, and in support of the objectives of the Planning Commission and also of increased participation by the private sector, the number of

[67] Ashok J (Undated), Science, Technology and Industry Network: India's Policies and Strategies; Institute of Informatics and Communication, New Delhi University, New Delhi: India; http://www.namstct.org/ADB_RETA_Report/Dr_Ashok_Jain.pdf

[68] Foreign Investments and Collaboration in India, India Juris, www.indiajuris.com; ebook

technical and management institutions approved or certified by the All India Council of Technical Education (AICTE) had risen to 4,791 by 2001-02, with an annual intake of 6.7 million students.

Phase 2: Reorientation of Industry and Science and Technology Strategies and Policies (1960s-1970s)

Among other objectives, the fourth (1969-1974) FYP advocated an increase in exports and self-reliance. During this phase, the science and technology as well as industrialisation strategies and policies were reoriented, a restrictive attitude towards foreign imports and collaborations was adopted, and the substitution of imported goods and technologies was encouraged[69]. Under the new policy, the R&D laboratories and institutes had to change their R&D priorities towards substitution of imported know-how and products. Thus, industry was forced to use results from local R&D. This phase therefore created a linkage between science and technology infrastructure and production.

Phase 3: Promotion of Indigenous Technologies (1970s-1980s)

Phase 3 covers the fourth and fifth (1974-1979) FYPs. Import substitution was still considered necessary for promoting the generation and utilisation of local technologies and know-how. Technologies and know-how developed by the national laboratories and institutes at laboratories or pilot plants had to be commercialised. Science and technology strategies and policies were re-examined and further reorientation was deemed necessary to address the following challenges:

- increasing interaction between research institutions and industry
- ensuring that research institutions undertook the research activities required for improving manufacturing aspects.

The National Committee on Science and Technology (NCST) was instituted and mandated to promote inter-departmental cooperation and to coordinate scientific research activities with economic and industrial plans. For the first time, a separate government department of Science and Technology was established to implement the plans and policies of the NCST. In addition, the Science and Engineering Research Council (SERC) was established to provide project funding to academic institutions for research in frontier areas of science.

[69] Ashok J (Undated), Science, Technology and Industry Network: India's Policies and Strategies; Institute of Informatics and Communication, New Delhi University, New Delhi: India; http://www.namstct.org/ADB_RETA_Report/Dr_Ashok_Jain.pdf

A number of policy changes, which had a direct impact on science and technology programmes and industry, were affected. In several areas, indigenous research moved up to production, for example in electronics, drugs and pharmaceuticals, chemicals and pesticides to mention but a few. Policy changes included the following:

- The 1970 Patent Law
- The 1973 Foreign Exchange Regulation Act
- The 1976 Technical Development Fund Scheme
- The 1977 Industrial policy
- Various R&D Tax Incentive Schemes.

At the end of this phase, linkages between science and technology and production became functional[70].

Phase 4: Moving Towards Economic Liberalisation (1980s-1990s)

During the sixth (1980-1985), seventh (1985-1990) and eighth (1992-1997) FYPs, the Indian economy moved away from the protective policy and regulatory framework to a more open and internationally connected economy. The sixth and subsequent FYPs emphasised the modernisation and liberalisation of the Indian economy. This implied the opening up of the economy to external connectivity and consequently reinterpretation of self-reliance in the context of global competition[71]. The 1980 Industrial Policy implicitly focussed attention on the need for promoting competition in the domestic market, technological upgrading and modernisation. The policy laid the foundation for an increasingly competitive export base and for encouraging foreign investment in high-technology areas[72].

The developments that followed in response to this new policy direction heightened the need for increased and new skill areas in science and technology. Significant support and funding were then awarded to new areas such as biotechnology and information technology. More R&D institutions and programmes were established and those for emerging areas were launched. The following science and technology policies and strategies were formulated. These include the 1983 Technology Policy Statement and the establishment of the Technology Information Forecasting and Assessment Council (TIFAC) in 1983. The shift during this phase from a

[70] Ibid

[71] Ibid

[72] India, 1980 Industrial Policy, http://siadipp.nic.in/publicat/nip0791.htm

singular focus on science to including a strong component of technology was significant and continues to influence India's science and technology policy framework and programmes.[73]

Phase 5: Science and Technology in Liberalised Economy (1991 onwards)

During this phase, economic liberalisation strengthened, and there was a shift of focus in government funded R&D laboratories. The focus was now directed to commercial returns on R&D, and institutes reviewed their strategies accordingly. Systems for the protection of intellectual property were strengthened, and this attracted global R&D contracts.

PROGRAMMES OF PHARMACEUTICALS

In the 50s, the Indian pharmaceutical industry was virtually nonexistent, with a few privately held Indian companies. The industry was dominated by the multinational pharmaceutical companies, most of which imported finished products into India, and sold their products at prices that were unaffordable for the majority of the Indian people. The government of India took a decision that the country had to be self-sufficient and had to take responsibility for providing affordable quality healthcare to the people of India. This decision was followed by a comprehensive, pragmatic and proactive process of policy and regulatory reform that spelled out what needed to be done and how.

Through the industrial policies that followed and the subsequent FYPs, the pharmaceutical industry was identified as one of the key chemical industry subsectors that had the potential to contribute significantly to India's economic and industrial development. Specific development programmes for the pharmaceutical industry were laid out in the second, fifth, sixth and eleventh (2007-2012) FYPs.

One of the five priority areas of the second FYP was spelled out as the *"*expansion of capacity in respect of other developmental commodities and producer goods such as aluminium, cement, chemical pulp, dyestuffs and phosphatic fertilizers, and of essential drugs". In particular, the second FYP prioritised the development of the pharmaceuticals, plastics and dyestuffs industries. Some of the key growth opportunities identified by the second FYP for the pharmaceutical industry included the following:

[73] Ashok J (Undated), Science, Technology and Industry Network: India's Policies and Strategies; Institute of Informatics and Communication, New Delhi University, New Delhi: India; http://www.namstct.org/ADB_RETA_Report/Dr_Ashok_Jain.pdf

- Synthetic pharmaceuticals – progress was planned in the direction of increased production and development from basic primary organic chemicals and intermediate products replacing the then present operations based on penultimate products.
- The industry was expected to derive considerable benefit from steps taken to develop the manufacture of dyestuff intermediates that would provide several of its raw materials.
- Vitamins – the scope for the production of vitamin A from an indigenous raw material, lemon grass oil, was to be investigated.
- Antibiotics – apart from development planned in the public sector, efforts initiated by private enterprise to establish the production of penicillin were expected to succeed.
- The existing units in the field were expected to make considerable progress in the conversion of what were then predominantly processing operations into genuine manufacturing operations.
- The pharmaceutical industry covered a wide range of products, and targets of development were indicated for a few of the more important products.
- It was expected that the investment in the private sector of the pharmaceutical industry would be of the order of about 30 million Indian Rupees (INR)

During the fifth FYP, the public sector was given a prominent role in the overall development of the drug industry. A significant step up in production in the area of antibiotics, synthetic drugs and formulations in the public sector was envisaged.

The sixth FYP programme for the pharmaceutical industry focused on state-owned pharmaceutical companies: Hindustan Antibiotics Ltd., Indian Drugs and Pharmaceuticals Ltd., Smith Stanstreet Pharmaceuticals Ltd., Bengal Chemical & Pharmaceutical Works Ltd., and Bengal Immunity Co. Ltd.

The eleventh FYP highlighted the need for an increase in the supply of science and pharmacy graduates with quality education to enable the industry to increase its manufacturing and R&D services. The plan estimated that the industry needed 1 000 trained people every year for the next ten years in order to double its exports. Furthermore, the need to incentivise R&D through tax concessions on a permanent basis was expressed. Planned interventions included the following:

- Providing financial assistance to small-scale firms to acquire GMP-compliant facilities
- To replicate the National Institute of Pharmaceutical Education and Research *(*NIPER) through five more institutes with the aim of providing human resources of the right calibre needed by the industry
- Funding the existing NIPER to modernise and expand its facilities.

Collaborations with Foreign Organisations

One of the seeds of India's competitiveness, which was clearly articulated by the NPC and the Pharmaceutical Enquiry Committee of 1954, was the need to collaborate with others and seek technical assistance. The Pharmaceutical Enquiry Committee had three key recommendations:

- Licensing technologies from outside the country
- Fostering foreign collaborations
- Promotion of bulk drugs.

Thus, India received assistance from the WHO and UNICEF in setting up The Hindustan Antibiotic Ltd. (HAL) in 1954, and from the former USSR in setting up Indian Drugs and Pharmaceutical Ltd. (IDPL) in 1961. Both companies produced predominantly bulk drugs, and it is worth noting that many of the entrepreneurs who went on to found some of the leading Indian companies were trained in these companies, especially at IDPL[74]. Another example of collaboration is the BCG Vaccine Laboratory, which was founded to produce and supply liquid Bacillus Calmette-Guérin Tuberculosis vaccines (BCG vaccine) and Tuberculins in collaboration with Statens Serum Institute (SSI) of Copenhagen, Denmark.

The role of National Chemical Laboratory in Creating the Indian Pharmaceutical Industry

Of all the government-owned laboratories and institutions that were established during the first and second FYPs, one that was to play a crucial a role in the development and growth of the Indian pharmaceutical industry was the National Chemical Laboratory (NCL). This laboratory was formed with the sole intention of undertaking research and development work to develop technologies and processes, and then transfer them to industry for commercialisation.

Over the last few decades, the contribution of the NCL to the Indian industry has been phenomenal. Some of the leading products developed (reverse engineered) at NCL and whose process and other technology for the production of APIs was licensed to the Indian pharma industry for commercialisation on a non-exclusive basis include the following molecules[75]:

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[74] Felkar, G., Choudhuri, S., Gyorgi, K. and M Goldman (1997): The Pharmaceutical Industry in India and Hungary: Policies, Institutions and Technological Development, World Bank Technical Paper No. 392

[75] Indian Pharma Industry: Decades of Achievement and Industry – Lecture by Dr Hamied on the occasion of former NCL Director, Dr Rama Rao's 70th birthday, 2 April 2005, http://www.arvindguptatoys.com/arvindgupta/avra-hamied.pdf

- Diazepam
- Salbutamol (inhaled)
- Sulfamethaxazole and Trimethoprim
- Vinblastine and Vincristine
- Atenolon and metoprolol
- Norfloxacin and Ciprofloxacin
- Omeprazole
- Etoposide and Mitoxantrone
- Mefloquine
- Zidovudine, Efavirenz, Tenofovir and other antiretrovirals – which were transferred to a number of Indian companies that today collectively dominate the global generic ARV business.

This is by no means an exhaustive list, but it serves to highlight the critical role that the NCL played in the promoting the Indian Industry, and it serves to demonstrate the critical catalytic role of government in the development of a resource-intensive industry for small and medium enterprises.

Today, many of the recipients of NCL-developed technologies and processes are internationally competitive global companies. It is doubtful though whether without this critical government support – despite their own internal scientific talent – would have had the wherewithal to develop every attractive blockbuster molecule given the huge financial resources needed to reverse-engineer medicines. Today, on the back of the commercial success founded on NCL support, they have built their own considerable research teams, and now have the financial means to develop their own products.

Today the NCL employs more than 200 scientific staff to research in various disciples including polymer science, organic chemistry, catalysis, materials chemistry, chemical engineering, biochemical sciences and process development. It houses a good infrastructure for measurement science and chemical information[76]. Further, the laboratory now:

- Trains about 400 PhD students and awards about 50 PhD degrees every year;
- Publishes over 400 research papers annually in the field of chemical sciences and over 60 patents worldwide;
- Produces the largest number of PhDs in chemical sciences within India.

[76] National Chemical Laboratory, http://www.ncl-india.org/

- Conducts cutting-edge research in the fields of biochemical sciences, organic chemistry, catalysis, polymer science and engineering, physical and material chemistry and chemical engineering science.

The 1970 Patent Act

Another key government intervention that put the Indian pharmaceutical industry on a significant growth trajectory was the amendment to the Indian Patents and Design Act of 1911, which recognised both product and process patents. Patents were granted for an effective 14-year period. This acted as a major entry barrier for Indian firms to enter pharmaceutical manufacturing.

In 1970, the government of India introduced a new Patent Act, which became effective from 1972. This act recognised only process patents and not product patents. Thus, as per this Act, drugs patented in other countries could be analysed and manufactured in India using a different process, popularly known as 'reverse engineering', without paying royalties to the original patent holder[77]. Moreover, the statutory term of a patent was shortened to five years from it being granted or seven years from application, whichever was shorter.

Through the process of reverse engineering, technologies for the production of several bulk drugs (active pharmaceutical ingredients) were indigenously developed by coming up with alternative processes for patented drugs. This process led to the development of high skills in process chemistry and chemical engineering using the already available large pool of well-educated pharmaceutical scientists.

[77] Indian Pharmaceutical Industry: Surging Globally, Export-Import Bank of India, August 2007

OTHER INITIATIVES POST 1991

Establishment of the National Institute of Pharmaceutical Education and Research (NIPER)

NIPER is an autonomous body set up, under the aegis of the Ministry of Chemicals and Fertilizers in 1998 through the enactment in Parliament of the National Institute of Pharmaceutical Education Act, 1998. The original NIPER Centre was set up in SAS, Nagar, Mohali. The Government of India has declared NIPER as an 'Institute of National Importance.' The Institute was conceived to provide leadership in pharmaceutical sciences and related areas not only within the country, but also to countries in South East Asia, South Asia and Africa. NIPER is a member of the Association of Indian Universities and Association of Commonwealth Universities.

The main objectives of the institute are:[78]

- To nurture and promote quality and excellence in pharmaceutical education and research
- The toning up of pharmaceutical education and research by training the future teachers, research scientists and managers for the industry and profession
- Creation of National Centres to cater for the needs of the pharmaceutical industry and other research and teaching institutes
- Collaboration with Indian Industry to help it meet global challenges
- To carry out National / International research
- The study of sociological aspects of drug use and abuse and rural pharmacy
- Running programmes in drug surveillance, community pharmacy and pharmaceutical management.

In terms of the amended NIPER Act, 1998, the Government of India set up six new NIPERs at Hajipur, Hyderabad, Ahmedabad, Rae Bareli, Guwahati and Kolkata. New NIPERs were set up to cater for the future demand of the pharmaceutical industry for highly trained manpower for continuous growth of the pharmaceuticals sector, with increased focus on R&D, particularly after the amendment of the Indian Patent Act to comply with the WTO 2005 deadline for the country to comply with TRIPS requirements.

The institute conducts research in various areas such as medicinal chemistry, pharmaceuticals, natural products, pharmacology, toxicology, biotechnology and pharmaceutical management.

[78], Institutes of Pharmaceuticals Education and Research (NIPER), www.niper.gov.in

Establishment of the Pharmaceutical Research and Development Committee (1999)

Chaired by the Director General of the CSIR, the PRDC was set up to strengthen the pharmaceutical industry's R&D capabilities and to identify support required by the industry to undertake domestic R&D.

Pharmaceutical Policy 2002[79]

The main objectives of this policy are:

- Ensuring abundant availability within the country of good-quality essential pharmaceuticals of mass consumption at reasonable prices.
- Strengthening the indigenous capability for cost-effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.
- Strengthening the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry, and promoting the rational use of pharmaceuticals.
- Encouraging R&D in the pharmaceutical sector in a manner compatible with the country's needs, with particular focus on diseases endemic or relevant to India, by creating an environment conducive to channelling a higher level of investment into R&D in pharmaceuticals in India.
- Creating an incentive framework for the pharmaceutical industry that promotes new investment into the pharmaceutical industry and encourages the introduction of new technologies and new drugs.

De-licensing of Drugs and Pharmaceutical

Industrial licensing had already been substantially dismantled, and during the tenth FYP period, further measures were taken to pare it down. Drugs and pharmaceuticals including biotechnology were de-licensed in 2005.[80]

Factors of Success

- Government's catalytic, leadership and supportive role in the following:
  - Driving (through the NPC and its expert sub-committees) the human capital planning and development processes and plans for revolutionising the Indian educational system

[79] http://www.pharmaceutical-drug-manufacturers.com/pharmaceutical-policies/pharmaceutical-policy2002.html

[80] 11th Five Year Plan, http://planningcommission.gov.in/plans/

- Funding the establishment of scientific infrastructure and SET skills development, and R&D initiatives
- Creating a policy and regulatory environment that is supportive of the growth of the industry (the Patent Act of 1970, Drug Price Control Order 1970)
- Putting in place incentive programmes that were aimed at increasing exports;
- Promoting domestic R&D and assisting small-scale companies to be GMP compliant.

- Collaborations with international organisations for technical assistance.
- Collaboration of different government department, industry, academia and national research institutes in skills planning and development as well as in developing policies.
- Establishment of specialist education and training institutes, for example the NCL and NIPER of India (API manufacturing, biotechnology), diffuse know how to industry.
- Reorientation of the education system to ensure that it is responsive to the skills needs of the country's economic, industrial and social development.

6.2 BRAZIL

Brazil has historically imported most of its medicinal and pharmaceutical products. The value of imports has grown from $170 million in 1981 to $2 billion by 2002[81]. Over 85% of raw materials are imported (Frost.com). It is one of the fastest growing economies being the fifth most populous country in the world and the ninth largest market for pharmaceuticals[82]. The market is projected to grow to $27 billion by 2015[83].

What is interesting about Brazil is that the HIV / AIDS pandemic helped to kick start its generic manufacturing industry and this will probably trigger the growth of the local API sector, which is currently lagging behind. At the moment, and to its credit, Brazil is host to some of the biggest API factories of multinational pharmaceuticals companies like Bayer. This is testimony to Brazil's reputable science education.

In contrast, the biotech industry in Brazil is innovative and a collaboration between the Federal University of Minas Gerais and its spin-off company Biobrás led to the development and patenting of recombinant human insulin[84]. Investment in the biotech industry by government has led to the growth of strong diagnostic and conventional vaccine sectors. Ferrer et al. (2004)[85] suggested that this investment is also seen in the increase in publications in international scientific journals from 96 in 1998 to 179 in 2001, even though patent activity remains weak. Most of the publications (95%) originate from the public sector and to some extent reflect the shortage of highly trained personnel in the private sector[86].

Brazil has been able to build its biotech industry because of the government has since the 1960's put in place policies and programmes to encourage and enhance science education and infrastructure e.g. National Program for Post-Graduate Studies, Integrated Programme for Genetics (PID), and the National Biotechnology Programme (PRONAB), among others. All these programmes and policies were aimed at

[81] M Ferrer,H Thorsteinsdóttir,U Quach, P A Singer & A S Daar. The scientific muscle of Brazil's health biotechnology; Nature Biotech 22, sup. Dec 2004

[82] http://www.brasil.gov

[83] www.foxbusiness.com

[84] M Ferrer,H Thorsteinsdóttir, U Quach, P A Singer & A S Daar. The scientific muscle of Brazil's health biotechnology; Nature Biotech 22, sup, Dec 2004

[85] ibid

[86] Rezaie R, Frew SE, Sammut SM, Maliakkal MR, Daar A S and Singer PA. Brazilian health biotech – fostering crosstalk between public and private sectors, Nature Biotech 26, June 2008

a) Providing good basic education particularly in Maths and Science. The Plan for the Development of Education (PDE) was aimed to enable the creation of over 300 Federal Institutes for Education, Science and Technology (FIEST) institutes dedicated to teaching science and technology to high school students and to the training of new teachers in the public education system[87.]

b) Training more scientists. Brazil has 100 universities that publish 80% of their research internationally. In doing this, the country has built a cohort of highly trained scientists and since 2005 graduates about 9000 new PhDs annually[88]. However, like many countries, there is also no match in skills between academic courses and industry's specialised needs.

c) Promoting collaboration between public institutes, universities, and to some extent, industry into 'virtual institutes'. Collaboration between different / disparate fields is also promoted e.g. experts in agro-biotech have been used in bio-pharma innovations.

d) Changing legislation to make it easier for local scientists to work exploit Brazil's unique biodiversity in research but restrict commercialization by foreign scientists.

Key factors for success

- Sustained government support in the industry i.e. large government grants, creation of research institutes
- Strong basic education particularly in Maths and Science
- Focus on growing PhD cohort

[87] da Silva LL, Nicolelis M and Haddad F, Brazil's Option for Science Education, Scientific American, Jan 17,2008. http://www.scientificamerican.com/article.cfm?id=brazils-option-for-science-education&page=2

[88] Rezaie R, Frew SE, Sammut SM, Maliakkal MR, Daar A S and Singer PA. Brazilian health biotech – fostering crosstalk between public and private sectors; Nature Biotech 26, June 2008

6.3 CUBA

Cuba has a population of 11 million people, and is an impoverished country living under a US embargo since the 1960s. However, it boasts over 200 research institutes and more than 12,000 scientists in the country and is world-renowned for innovation, particularly in vaccine research.

The 'Scientific Cluster' known as West Havana Scientific Pole in the capital Havana is a complex of 53 research centres and their industrial offshoots that date back to the 1960s when the communist government set up the National Centre for Scientific Research (CNIC). Later the government added other institutes, the most well-known ones being the Carlos J. Finlay Institute for vaccine development (established in 1991), Centre for Molecular Immunology (CIM) (established in 1992) for research and development into monoclonal antibodies, and the Centre for Genetic Engineering and Biotechnology (CIGB)[89]. There are 14 such clusters dispersed throughout the whole island employing over 30,000 people and generating over $400 million annually from its total pharmaceutical and biotechnology exports.

The domestic pharmaceutical and biotechnological industry is strong and relevant to the population's needs and export opportunities particularly to other developing countries. Over the years, Cuba has become a leader in the development of vaccines and drugs to treat HIV/AIDS, circulatory diseases and cancer[90] . Cuba has also been involved in developing a cholera vaccine, hepatitis B vaccine, a synthetic vaccine against Haemophilus influenzae type B, and Heberprot-P, regarded as the only effective treatment in the world for diabetic foot ulcers, a cholesterol-lowering drug derived from sugar cane, the anti-coagulant, streptokinase, bone implants, among other biomedical and biopharmaceuticals [91]

Cuba's success hinges on three things:

a) Cuba spends 1.7% of its gross domestic product (GDP) on research in science and technology, outstripping the subcontinent's average spend of 0.7%[92]

[89] Science and technology - Cuba http://www.nationsencyclopedia.com/Americas/Cuba-SCIENCE-AND-TECHNOLOGY.html#ixzz1L7o1hmvK)

[90] http://www.espicom.com/Prodcat2.nsf/Product_ID_Lookup/00000336?OpenDocument

[91] Chinweizu C. http://www.scribd.com/doc/49208741/50-years-of-Cuban-Socialism-achievements-of-the-Cuban-revolution

[92] http://www.wsicubaproject.org/factbiotech.cfm

b) There is integration of research, product development, production and marketing activities in the main research institutes, the so-called “Scientific Poles” spread across all 12 provinces and integrate the efforts of researchers, university professors, business experts and innovators[93]. All innovations are owned by the state which funds all the institutes and the profits are reinvested in the sector[94]

c) A world-class comprehensive education system partly based on the Montessori principles of consistent pedagogical quality, small class size and universal school enrolment and attendance[95]. Cuba has achieved universal literacy and is ranked top in math and science achievement. Between

d) Protection of the government-led pharmaceutical ‘industry’ from competition, because Cuban communism does not allow a free market. It will therefore be interesting to see how this sheltered industry will develop when Cuba opens up and the trade embargo with the US is lifted, though this is not likely to happen soon.

Key factors for success

- Investment in a comprehensive universal education. The Cuban example shows that it is not how many financial resources a country has, but rather how they are strategically utilised.
- Creation of integrated research unit which span basic and applied research as well as production and marketing
- Lack of the free market

[93] ibid

[94] Science and technology - Cuba http://www.nationsencyclopedia.com/Americas/Cuba-SCIENCE-AND-TECHNOLOGY.html#ixzz1L7o1hmvK

[95] http://calvino.polito.it/ricerca/gasparini.en.html

Chapter 7: Lesson Learnt and Recommendations

7.1 Lessons from the Case Studies

Below are the key lessons that can be drawn from the three case studies,

- That government should assume a leadership role in driving skills planning and development initiatives, setting up necessary infrastructure for developing SET skills as well as creating a supportive and enabling policy and regulatory framework for the growth of the pharmaceutical sector
- That skills planning and development initiatives and polices should be aligned with government's industrial and economic policies. In this regard, skills planning and development should be informed by economic and industrial policies
- That there is a need for a clear vision, policies and strategies (a clear growth path) for the pharmaceutical sector to inform and guide skills planning and development activities
- That government in collaboration with industry should undertake regular reviews of the educational system to ensure that it is responsive to the country's economic and industrial development needs as well as industry's skills demands
- That successful skills planning and development requires a collaboration of institutions of higher education, research institutes and laboratories, industry and government departments
- That skills planning should be informed by credible research and undertaken by well qualified, experienced and capable experts with industry relevant expert knowledge
- That collaborative arrangements and agreements with international partners play a critical role in providing the technical assistance necessary for the development of the pharmaceutical sector.

The table below summarizes the various skills planning and development opportunity areas presented in the Indian case study, lessons learnt and appropriateness of such areas in the South African Context

Table 19: Lessons Learnt from Case Studies and their Applicability to SA

Lessons Learnt	Appropriateness for the South African Situation
Need for the assessment of a country's material, capital and human capital resources and ways of augmenting them to meet the national development requirements as well as determining the national priorities and balanced allocation of resources.	A centralised economic planning system is appropriate for South Africa, and the establishment of the National Planning Commission in South Africa will facilitate applications of the Indian case study.
There is a need to establish expert sub-committees within the NPC to facilitate investigations and recommendations in specific priority fields.	An expert sub-committee within the South African NPC could be established to handle the IPAP growth opportunity areas for the pharmaceutical sector, and these to be incorporated into Vision 2025 of the SA NPC.
Need for the establishment of programmes of Scientific Research and Institutes and Laboratories.	Existence of scientific research programs and institutes in SA which need to be strengthened with the establishment of specific pharmaceutical institutes and laboratories like NIPER.
Promotion of foreign private investment on a selective basis in areas advantageous to the economy.	Very relevant for SA, new technologies in the pharmaceutical sector can be introduced through this route.
Restrictive attitude towards foreign imports and collaborations, adoption and substitution of imported goods and technologies.	Given the current trends in globalisation and the negative impacts of such a practice, this approach is not appropriate.
Promotion of indigenous technologies through increasing interaction between research institutions and industry and ensuring that research institutes undertake activities required for improving manufacturing.	There is currently a missing link between the existing research institutions and industry. Such an approach would be quite relevant for the development of SA industry.
Identification of the pharmaceutical industry as one of the key chemical industry sub-sectors, with the potential to contribute significantly to the country's economic and industrial development.	South Africa, through IPAP, has identified the pharmaceutical sector as a priority sector which could foster economic and industrial development.
The need for an increase in the supply of science and pharmacy graduates with quality education to enable industry to increase its manufacturing and R&D services.	This is quite relevant for the SA situation and should be done with the collaboration of HEI and industry.
The importance of providing financial assistance to small-scale firms to acquire GMP compliant facilities.	This could strengthen the quality of manufacturing output from industry, and is very appropriate.
Provision of human resources of the right calibre needed by the industry through the establishment of more NIPERs.	The establishment of specific pharmaceutical education and research institutes similar to NIPER would strengthen the skills base in the

Lessons Learnt	Appropriateness for the South African Situation
	pharmaceutical sector.
Importance of collaboration with foreign organisations for the provision of foreign technical assistance.	Foreign partnership programmes already in place (see section 5.4.2) and Appendix 1, section 4.
Critical catalytic role of government in the development of a resource-intensive industry for small and medium enterprises.	The role played by the National Chemical Laboratory in the development and transfer of technologies and processes to industry for commercialisation can be taken as a key lesson by South Africa, especially in achieving the IPAP growth opportunities and in building in-house skills for local pharmaceutical companies.
Reverse engineering of API manufacturing processes leads to the development of high skills in process chemistry and chemical engineering.	The use of reverse engineering was possible because of the Indian Patent Act of 1970, which was put in place prior to the TRIPS agreement of 1995. However, with the coming into place of the TRIPS agreement, South Africa cannot use this tool in order to develop high skills in process chemistry and chemical engineering for patented medicines. It can, however, be used for off-patent medicines.

7.2 RECOMMENDATIONS

The following recommendations are made based on the research findings:

7.2.1 Importation of Skills

Globally, there is a high demand for SET skills resulting in the movement of SET-skilled workers within and across borders. Direction and destinations of movement are influenced by a number of factors, including financial benefits, personal growth opportunities and exposure, to mention but a few.

All respondents perceived skills importation as one of the quickest solutions that can be considered in the short term to meet the IPAP skills requirements. They stated that the objective should be to kick-start the process with the medium-term goal of using the imported expertise to develop local capacity. An effective skills importation programme will require the collaboration of industry and relevant government departments in reviewing the current laws and processes followed by the department of home affairs in establishing and promoting the list of scarce

resources (which Home Affairs forwards to Foreign Affairs for advertising) and identifying areas of improvement.

7.2.2 Partnerships with Overseas Organisations and Universities

Forging professional exchange / enrichment partnerships with international pharmaceutical companies, universities and research organisations can go a long way to broadening the skills of professionals and post-doctoral SET individuals; to creating opportunities for learning new skills; and to sharing knowledge and experiences. A number of individual South African pharmaceutical companies and universities already have similar partnerships. The NRF / Emory University / Scynexis Advanced Drug Discovery Program is one such initiative. Expansion of these to be inclusive of all key relevant players from industry and government, and structured to address the broader skills shortages agenda in South Africa, other than individual organisations, is one of the ways in which IPAP skills requirements can be met.

7.2.3 Increased Collaborations with Various Organisations

7.2.3.1 Collaboration between HEIs and CHIETA

The Skills Development Act Number 97 of 1998 aims among other things, to develop and improve the levels of skills in South Africa by increasing the level of investment in education and training, and ensuring the quality of such education and training. Sector Education and Training Authorities (SETAs) were established to provide a vehicle to achieve the aims of the Skills Development Act. An important function of the SETAs is the management of funds received for skills development levies as required by Act Number 9 of 1999.

Planning of skills is central to the implementation of the National Skills Development Strategy (NSDS 2). SETAs are required to respond to the NSDS 2 through the development of Sector Skills Plans (SSP).

In terms of the Skills Development Act, the CHIETA is required to prepare a Sector Skills Plan every five years within the framework of the National Skills Development Strategy.

The pharmaceutical sector is one of CHIETA's significant and strategic chambers in terms of its contribution to the economy. The pharmaceutical industry is one of the biggest beneficiaries of CHIETA's discretionary grants and the third largest contributor of skills development levies

within CHIETA.[96] Workplace Skills Planning (WSP) participation of the pharmaceutical industry, according to CHIETA executives, is satisfactory.

CHIETA is reported to have held intensive discussions involving the National Economic Development and Labour Council (NEDLAC), the Department of Trade and Industry (DTI) and industry on the manufacture of active pharmaceutical ingredients (APIs) for antiretrovirals (ARVs) and industry's orientation towards the IPAP 2 growth opportunity areas for the pharmaceutical sector. However, from a skills planning point of view, CHIETA have not seen this area emerging as a point of interaction with the SETA, where industry expresses the need to refocus skills planning in order to better address IPAP growth opportunity areas. CHIETA was of the opinion that interaction between CHIETA and the DTI would give CHIETA a more solid footing on which it would engage industry. Before the SETA landscape of 2010, CHIETA was only involved with skills planning for National Qualification Framework (NQF) levels 1 to 4, and this hampered interactions with industry and the DTI, especially with respect to IPAP growth opportunity areas, which tend to call for higher skills than covered hitherto.

According to CHIETA, in order for industry to align itself to IPAP growth opportunity areas, the proposed way forward is for:

- DTI to confirm IPAP growth opportunity investment areas
- CHIETA to discuss with industry how they can participate and act as a strategic leader in directing the industry
- CHIETA to engage the South African Pharmacy Council and Labour Affairs Association for the Pharmaceutical Industry (LAAPI) on the best approach to skills planning and development in order for industry to embark on the IPAP growth opportunity areas.

It is CHIETA's belief that there is a need for education and training to address specific industry knowledge and practical aspects in their curriculum. Communication between industry and Higher Education and Training is seen as limited and needs to be improved by creating a more solid relationship between industry and Higher Education and Training. CHIETA reported that they had established industrial occupational centres of excellence in the petroleum and engineering sectors that look at sector-specific skills training, but had not done so for the pharmaceutical industry.

The following points were also raised by CHIETA:

[96] Interviews with CHIETA executives

- Governmental interdepartmental interactions were lacking; departments work in isolation of each other.
- The Department of Science and Technology (DST) has a vacant seat on CHIETA's board, which had no consistent representation.
- Need to create a more solid partnership between CHIETA, industry and HET, and hopefully, translate this into industry-focussed research foundations.
- Lack of maturity within the industry, with no collective approach. Competitive environment does not augur well for the sharing of information and co-investment for improvements in training for the benefit of the whole industry.
- Uptake of postgraduate training by industry has not been forthcoming.
- Skills development has been focussed on developing managers. engineers, pharmacists and other technically qualified persons getting into management and thus depriving the intended areas of skill requirements.

7.2.3.2 Industry and HEIs through Trade Associations

All respondents expressed concern over the lack of collaboration between industry and HEIs. This lack of collaboration is perceived as a major contributor to the problem of the mismatch between demand for and supply of relevant skills to the industry and by extension, IPAP skills requirements. The need for industry through umbrella bodies or trade associations to facilitate collaboration was recommended. It is believed that this will create opportunities for an increased participation of industry in influencing the output of HET. Respondents also acknowledge that the pharmaceutical sector exists within a broader environment of other SET skills-dependent manufacturing industries. Exploring areas of overlap and synergies with such sectors was suggested as critical.

Suggested areas where industry can proactively contribute include the following:

- Development or review of curricular to align them with industry skills needs – this can also include the introduction of industry-specific modules
- Sponsorship of joint appointments
- Offering increased opportunities for internships and apprenticeships
- Funding of laboratory equipment and other infrastructure including capacity development of human resources
- Appointment of industry professionals as visiting lecturers; TUT has successfully done this for its pharmaceutical science programme.

7.2.3.3 Pharmacy Council

The South African Pharmacy Council (SAPC) is the regulator established in terms of the Pharmacy Act, 1974 Act 53 of (1974) to regulate pharmacists, pharmacy support personnel and pharmacy premises in South Africa. SACP is tasked to protect, promote and maintain the health safety and wellbeing of patients and the public who use pharmaceutical services in South Africa

The SAPC fulfils the role of registrar and regulator or all level of pharmacists in South Africa. They develop and guide policies that coves every aspect of pharmacists' activities and delivery of services in South Africa. Together with stakeholders, they develop curricula and set standards for education at HET and FET centres and the new training academies.

The council acts as the focal point for all sectors of pharmacy management. These areas are Academic Institutions, Community Pharmacy, Consultant Pharmacy, Institutional Private, Institutional Public, Manufacturing Pharmacy and Wholesale Pharmacy.

The Future role the Council plays will change significantly with the introduction of different tiers of pharmacy support personnel who will be working under indirect and direct supervision of pharmacists. Accreditation of sites and personnel will become more critical as more of these facilities are established to meet the growing need of population who require medicines.

The Council will also need to work in close relationship with the burgeoning new training academies and institutions, which by necessity will need to develop to train all the new levels of pharmacy support personnel.

The role of the Pharmacy Council as a facilitator between intergovernmental departments and HEIs needs to be strengthened

7.2.3.4 Collaborations with Supporting and Related Industries

Pharmaceutical and IPAP skills requirements cannot be addressed in isolation without addressing skills demands in pharmaceutical supporting and related industries. A successful planning and development of requisite skills must be conducted along the whole cluster value chain and systems.

7.2.3.5 Collaboration with Research Organisations

Research organisations (MRC, CSIR) and universities are doing phenomenal work in R&D and clinical trials. This presents partnership opportunities for pharmaceutical companies for

commercialisation of work done by these institutions. In the process, the parties can investigate means by which they can develop skills of doctoral candidates or employees of partnering companies.

7.2.4 Establishment of Pharmaceutical Specialist Training Institution

To address the critical shortage of high-level scientists and technology developers, industry could pull scientists from industry, universities, research organisations and scientists from outside the country to form at least one centre of excellence that represents the broader chemical and other SET-based industries. This centre could also serve as an interface between academia and industry and offer pharmaceutical specific courses such as those offered by Stevens University of Technology presented earlier in this chapter. In addition, collaborations with relevant institutions on the continent (e.g. St Luke's Foundation and Muhibili University in Tanzania) should be explored.

7.2.5 Development of a Sector Strategy

The major weakness that was identified is the lack of a sector strategy that articulates a shared vision and growth path for the sector. In the absence of a sector strategy, any kind of sectoral planning cannot be successful. The pressing need therefore is to develop a sector strategy upon which all other strategies and initiatives can be built, including skills planning and development.

Nevertheless, sector skills development initiatives need to take the following factors into consideration:

- Demand for skills is comprised of new demand and replacement demand. New demand arises from new growth areas within industry including new ideas, new technologies and new industries. These new growth areas lead to the creation of new occupations or skills that did not previously exist. Replacement demand occurs from staff turnover, retirement, mortality and migration and creates the need to replace skills or employees lost. Capacity to determine the growth and replacement changes that are likely to happen within industry is critical for a successful skills planning and development. Furthermore, while there is general inclination to attribute skills shortages to inadequacy of education and training, it is critical to acknowledge that skills shortages emanate from a multiple of factors; for example, labour conditions, cost of recruitment, skills immigration (brain drain), technology advancement and contracting[97] out but to mention

[97] Rasool Hoosen, *Creating a National Skills Development Strategy that works: Learning Lessons from the mistakes of NSDS I and NSDS II;* 2nd research paper, National Skills Planning and Development Series – April 2010

a few. This understanding is vital to developing a skills planning and development strategy that works.

- Standardised frameworks and credible information are critical for the development of a successful skills development strategy. The HRD-SA points out that there is currently no institutional mechanism that provides credible information and analysis with regard to the supply and demand for skills Whilst there are a number of disparate information databases and research initiatives, there is no standardised framework for determining skills supply, shortages and vacancies, and there is no integrated information system for skills supply and demand across government.[98]
- Successful skills planning and development cannot be housed in a single organisation or department. It calls for a calibration of all relevant stakeholders – government departments, industry, HEIs and labour. A stakeholder analysis and mapping exercise should be undertaken to determine the various stakeholders as well as the roles that they can play in this process.
- Industry skills planning and development processes should be aligned with the government's key development priorities as well as those of other SET-dependent industries.
- Skills planning and development processes should be monitored on a regular basis and be flexible to accommodate necessary adjustments.

[98] Human Resource Development Strategies for South Africa 2010 - 2030

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Appendices

Appendix 1: Job Descriptions for IPAP Core Disciplines

In this section, we set out the job descriptions and activities of the core disciplines for IPAP skills requirements. This information has been obtained from http://www.prospects.ac.uk/

CHEMICAL ENGINEERS

Chemical engineers are involved in the development of industrial processes for the production of a diverse range of products, as well as in commodity and specialty chemicals. Relevant industries include oil and gas, pharmaceuticals, water treatment, food and drink, plastics and toiletries. Modern chemical engineering is also concerned with pioneering valuable new materials and techniques, such as nanotechnology, fuel cells and biomedical engineering.

A Chemical engineer may focus on one or more of the following: researching new products from trial through to commercialisation; managing scale-up processes from plant to full industrial-scale manufacturing; improving product lines; modifying the processing plant that produces the products; and designing and commissioning new plants.

Typical work activities may include the following

- working closely with process chemists and control engineers to ensure the process plant is set up to provide maximum output levels and efficient running of the production facility;
- designing plant and equipment configuration so that they can be readily adapted to suit the product range and the process technologies involved, taking environmental and economic aspects into account;
- instituting scale-up and scale-down processes including appropriate changes to equipment design and configuration;
- assessing options for plant expansion or reconfiguration by developing and testing process simulation models;
- designing, installing and commissioning new production plants, including monitoring developments and troubleshooting;
- optimising production by analysing processes and compiling de-bottleneck studies;
- applying new technologies;
- ensuring that potential safety issues related to the project operator, the environment, the process and the product are considered at all stages

PROCESS ENGINEERS

They develop economical industrial processes to make the huge range of products on which modern society depends, including: food and drink; fuel; artificial fibres; pharmaceuticals; chemicals; plastics; toiletries; energy; and clean water. Their work is concerned with chemical and biochemical processes in which raw materials undergo change, and involves scaling up processes from the laboratory into the processing plant. Their responsibilities may involve designing equipment, understanding the reactions taking place, installing control systems, and starting, running and upgrading the processes. Environmental protection and health and safety aspects are also significant concerns.

Specific tasks that may be performed by a Process Engineer include the following:

- assessing processes for their relevance, and assessing the adequacy of engineering equipment;
- reviewing existing data to see if more research and information need to be collated;
- designing, installing and commissioning new production units, monitoring modifications and upgrades, and troubleshooting existing processes;
- conducting process development experiments to scale in a laboratory;
- preparing reports, flow diagrams and charts;
- assessing the availability of raw materials and the safety and environmental impact of the plant;
- managing the cost and time constraints of projects;
- selecting, managing and working with sub-contractors;
- supporting the conversion of small-scale processes into commercially viable large-scale operations;
- assuming responsibility for risk assessment, including hazard and operability studies, for the health and safety of both company staff and the wider community;
- working closely with chemical engineers to monitor and improve the efficiency, output and safety of a plant;
- ensuring the process works at the optimum level, to the right rate and quality of output, in order to meet supply needs;
- ensuring that all aspects of an operation or process meet specified regulations;
- working closely with other specialists, including: scientists responsible for the quality control of raw materials, intermediates and finished products; engineers responsible for

plant maintenance; commercial colleagues on product specifications and production schedules; and the operating crew

MAINTENANCE ENGINEERS

Maintenance engineers plan the routine maintenance of equipment and machinery. They work on-site or remotely diagnosing faults and overseeing time-critical repairs. In modern, complex plants, maintenance engineers use sophisticated, computerised systems to schedule the work. They may oversee the work of teams of maintenance personnel, such as fitters and technicians. They may be involved in all stages of manufacturing. In equipment development, they work to incorporate efficient methods of maintaining new equipment or plant, and may be involved in the installation and commissioning process. Through the production phase, they work to improve the useful life of equipment and machinery. Maintenance engineers work with other professionals such as manufacturing systems engineers and production managers to improve production facilities, reduce the incidence of costly breakdowns, and develop strategies to improve overall reliability and safety of plant, personnel and production processes. Typical work activities include the following:

- designing maintenance strategies, procedures and methods;
- planning and scheduling planned and unplanned work;
- diagnosing breakdown problems;
- carrying out quality inspections on jobs;
- directing, instructing and supervising maintenance technicians and fitters;
- liaising with client departments and customers;
- arranging specialist procurement of fixtures, fittings or components;
- controlling maintenance tools, stores and equipment;
- monitoring and controlling maintenance costs;
- writing maintenance strategies to help with installation and commissioning guidelines

MECHANICAL ENGINEERS

Mechanical engineers use engineering principles to provide efficient solutions to the development of processes and products ranging from small component designs to extremely large plant, machinery or vehicles. They can work at all stages of a product, from research and development to design and manufacture, through to installation and final commissioning. Most industries rely on mechanical systems and mechanical engineering is thought to be one of the

most diverse of all engineering disciplines, with employment opportunities available in a wide range of sectors, such as the manufacturing, power, construction and medical industries.

Mechanical engineers responsibilities include the following

- designing and implementing cost-effective equipment modifications to help improve safety, reliability and throughput;
- developing project specification with colleagues, often including those from other engineering disciplines;
- developing, testing and evaluating theoretical designs;
- discussing and solving complex problems with manufacturing departments, sub-contractors, suppliers and customers;
- making sure a product can be made again reliably and will perform consistently in specified operating environments;
- planning and designing new production processes;
- producing details of specifications and outline designs;
- recommending modifications following prototype test results;
- using research, analytical, conceptual and planning skills, particularly mathematical modelling and computer-aided design;
- monitoring and commissioning plant and systems

MICROBIOLOGISTS

Microbiologists study microorganisms, including viruses, bacteria, fungi, algae and protozoa. They focus on the biology of microorganisms at both the molecular and cellular level, as well as their ecology. They also study many important practical problems in medicine, agriculture and industry, looking at how microorganisms affect us and how we can exploit them. Microorganisms affect every aspect of life on earth and, consequently, microbiologists work in a wide variety of settings, although the majority of work is laboratory-based. Microbiology is a vast subject that overlaps with other areas of the life sciences, such as molecular biology, immunology and biochemistry. Areas of specialism include basic research; medicine; healthcare; food; industry, such as pharmaceuticals, toiletries and biotechnology; agriculture; the environment; and university teaching.

Typical work activities include the following:

- observing, monitoring and identifying microorganisms;

- tracking of microorganisms in a range of environments;
- monitoring and assessing samples from a range of sources;
- using a variety of identification methods, including molecular techniques, to test samples;
- developing new techniques, products and processes;
- developing and planning methods to prevent the spread of disease;
- developing and registering new medicines, vaccines, diagnostic tests and pharmaceutical products;
- planning, implementing and evaluating new products in clinical trials;
- developing products, such as enzymes, vitamins, hormones, and antimicrobials;
- growing microbial cultures, e.g. for use in the food and beverage industry or in agriculture;
- quality control in manufacturing processes, e.g. checking for signs of contamination;
- writing up research findings and producing reports;

BIOLOGICAL SCIENTISTS

Researchers within life sciences are primarily involved in planning, conducting and analysing experiments, either with a definite end use (to develop new products, processes or commercial applications) or to broaden scientific understanding in general. Although research is often carried out on an individual basis, researchers usually work as part of a larger team and part of their job is to disseminate information to professional colleagues. This is sometimes done at international conferences or through the publication of research papers. The term 'Biological/life sciences' covers a whole range of scientific disciplines. This includes neurosciences, plant sciences, physiology, pharmacology, cancer studies, microbiology, genomics / molecular biology, bioinformatics, biotechnology and stem cell research. They are close to the medical sciences but also cross over into other areas, such as biochemistry.

The exact nature of the work depends on the level of seniority of a research post, the specific area of life sciences studied, and whether the context is industrial or academic. However, most life science researchers are involved in the following:

- devising and conducting experiments;
- processing and analysing results and data;
- communicating results to the scientific community via published papers;

- collaborating with industry/academia to apply the results of research and develop new techniques, products or practices;
- working in multidisciplinary teams

ANALYTICAL CHEMISTS

Analytical chemists typically use a diverse range of methods to investigate the chemical nature of substances. The aim of such work is to identify and understand the substance and how it behaves in different conditions. In the pharmaceutical industry, for example, analytical chemists are involved throughout the drug development process; they study the physical or chemical properties of drug substances and formulations, with a view to determining the quality and stability of drug products.

Analytical chemists may be involved in work as diverse as:

- chemical or forensic analysis;
- process development;
- product validation;
- quality control;
- toxicology;
- drug formulation and development

Specific work activities include:

- analysing samples from various sources to provide information on compounds or quantities of compounds present;
- using analytical techniques and instrumentation, such as gas and high performance liquid chromatography (HPLC), ion chromatography, electro-chromatography and spectroscopy (infrared and ultraviolet, amongst others);
- interpreting data and adhering to strict guidelines on documentation when recording data;
- reporting scientific results;
- using a range of analytical techniques, instrumentation and software;
- developing new techniques for the analysis of drug products and chemicals;
- validating methods and equipment

PRODUCT/PROCESS DEVELOPMENT SCIENTISTS:

Industries that manufacture products typically need development scientists capable of understanding and controlling the processes used to produce the final product. Development scientists work across the manufacturing industry, on products as diverse as foods, medicines, cosmetics and paints.

Process development scientists aim to optimise the performance of manufacturing systems. They are responsible for identifying and developing new processes for product manufacture, as well as implementing process controls to ensure that quality products are manufactured in a reproducible manner. They work with research scientists to develop new ideas and scientific discoveries, which can be utilised in the manufacture of new products. They also develop and improve existing products.

Specific work responsibilities for process development scientists include:

- devising new processes, or refining existing ones, to optimise the manufacturing process;
- planning, carrying out and supervising process trials in laboratories, pilot plants or factories;
- scaling up the production process, via plant trials, making changes to raw materials or components and process parameters to ensure quality is maintained during large-scale production;
- improving yields by reducing costs, for example investigating alternative materials or new machinery to improve efficiency, quality and yields in bottleneck areas;
- implementing process controls and devising test methods to assess the production process;
- validating new processes and showing that they are an improvement;
- working with product pipelines at various stages of development;
- developing formulae, specifications and label declarations, and ensuring compliance with the finished product specifications;
- advising on equipment modification to enable process changes for new product development;
- reading and writing technical reports and specifications, and maintaining appropriate records;

Appendix 2: India's Scientific Policy of 1958

Scientific Policy Resolution, 1958[99]

GOVERNMENT OF INDIA
SCIENTIFIC POLICY RESOLUTION
New Delhi, the 4th March 1958/13th Phalguna, 1879

1. The key to national prosperity, apart from the spirit of the people, lies, in the modern age, in the effective combination of three factors, technology, raw materials and capital, of which the first is perhaps the most important, since the creation and adoption of new scientific techniques can, in fact, make up for a deficiency in natural resources, and reduce the demands on capital. However, technology can only grow out of the study of science and its applications.

2. The dominating feature of the contemporary world is the intense cultivation of science on a large scale, and its application to meet a country's requirements. It is this that for the first time in human history has given common people in countries advanced in science, a standard of living and social and cultural amenities, which were once confined to a very small, privileged minority of the population. Science has led to the growth and diffusion of culture to an extent never possible before. It has not only radically altered man's material environment, but of still deeper significance, it has provided new tools of thought and has extended people's mental horizons. It has thus influenced even the basic values of life, and given to civilization a new vitality and a new dynamism.

3. It is only through the scientific approach and method and the use of scientific knowledge that reasonable material and cultural amenities and services can be provided for every member of the community, and it is out of recognition of this possibility that the idea of a welfare state has grown. It is characteristic of the present world that the progress towards the practical realisation of a welfare state differs widely from country to country in direct relation to the extent of industrialisation and the effort and resources applied in the pursuit of science.

4. The wealth and prosperity of a nation depend on the effective utilisation of its human and material resources through industrialisation. The use of human material for industrialisation demands its education in science and training in technical skills. Industry opens up

[99] India Department of Science and Technology; www.dst.gov.in/stsysindia/spr1958.htm

possibilities of greater fulfilment for the individual. India's enormous human resource can only become an asset in the modern world when people are trained and educated.

5. Science and technology can make up for deficiencies in raw materials by providing substitutes, or, indeed, by providing skills which can be exported in return for raw materials. In industrialising a country, heavy price has to be paid in importing science and technology in the form of plant and machinery, highly paid personnel and technical consultants. An early and large-scale development of science and technology in the country could therefore greatly reduce the drain on capital during the early and critical stages of industrialisation.

6. Science has developed at an ever-increasing pace since the beginning of the century, so that the gap between the advanced and backward countries has widened more and more. It is only by adopting the most vigorous measures and by putting forward our utmost effort into the development of science that we can bridge the gap. It is an inherent obligation of a great country like India, with its traditions of scholarship and original thinking and its great cultural heritage, to participate fully in the march of science, which is probably humankind’s greatest enterprise today.

7. The Government of India have accordingly decided that the aims of their scientific policy will be –

    a. to foster, promote, and sustain, by all appropriate means, the cultivation of science, and scientific research in all its aspects - pure, applied, and educational;

    b. to ensure an adequate supply, within the country, of research scientists of the highest quality, and to recognise their work as an important component of the strength of the nation;

    c. to encourage, and initiate, with all possible speed, programmes for the training of scientific and technical personnel, on a scale adequate to fulfil the country's needs in science and education, agriculture and industry, and defence;

    d. to ensure that the creative talent of men and women is encouraged and finds full scope in scientific activity;

    e. to encourage individual initiative for the acquisition and dissemination of knowledge, and for the discovery of new knowledge, in an atmosphere of academic freedom ;

and, in general, to secure for the people of the country all the benefits that can accrue from the acquisition and application of scientific knowledge.

The Government of India have decided to pursue and accomplish these aims by offering good conditions of service to scientists and according them an honoured position, by associating scientists with the formulation of policies, and by taking such other measures as may be deemed necessary from time to time.

APPENDIX 3: INDIA'S WORKING GROUP ON DRUGS AND PHARMACEUTICALS, 11TH FYP

Constitution of a Working Group on Drugs & Pharmaceuticals for Eleventh Five Year Plan (2007-12)[100]

The Terms of Reference and Composition of the Working Group are -

Terms of Reference

1. To review the status of the industry Tenth Plan targets, vis-à-vis achievements, in terms of production as well as exports, identify the reasons for major deviations, if any, bring out areas of strength and weakness of the Indian industry vis-à-vis international Drugs and Pharmaceuticals Industry.
2. To assess the structure and capability of the domestic drugs & Pharmaceutical industry in the light of the new IPR regime, identify emerging areas having specific potential for growth and competitiveness and suggest measures for putting the indigenous industry on sound footing.
3. To assess the present status of WHO-GMP (World Health Organisation – Good Manufacturing Practice) certification and suggest measures for Schedule M compliance by manufacturers of drugs and Pharmaceutical products in the country.
4. To assess the present R&D status of the Drugs & Pharmaceuticals Industry and to suggest measures for increasing the role of the industry in R&D effort, Industry-Institutional linkages, investment (including foreign) by Industry to make the drugs and Pharmaceuticals industry internationally competitive and meet the emerging challenges arising out of the WTO regime.
5. To assess the requirements of equipment / machinery and indigenous capability for fabrication of internationally competitive equipment and suggest measures for augmentation of capabilities, where necessary.
6. To assess the present employment and likely employment that will be created in the Drugs & Pharmaceuticals Industry during the Eleventh Plan period and in the perspective of 15 years.
7. To assess the present education and training facilities and infrastructure for human resource development pertaining to Drugs and Pharmaceuticals sector and to suggest measures including institutional mechanisms to strengthen it, where required.
8. To assess the existing infrastructure for Pharmaceutical industry and to suggest measures to strengthen it including investment and source of investment along with option of revival of Pharmaceutical Public Sector Undertakings.
9. To assess the present regulatory mechanism and assess need for an apex authority to control price, quality and supply of drugs.

[100] 11th Five Year Plan, http://planningcommission.gov.in/plans/

10. To review the present Drugs & Cosmetics Act and to suggest amendments to it including for ensuring GMP.
11. To review the present structure of the Indian Drugs Industry and suggest measures for improving the quality of drugs, particularly for tackling the menace of spurious drugs.
12. To benchmark the Indian Drugs and Pharmaceuticals industry against the international Drugs and Pharmaceutical industry and to suggest appropriate measures for bringing it up to international levels.
13. To make such other recommendations as are considered appropriate to make the drugs and Pharmaceuticals industry internationally competitive at the earliest
14. To suggest measures to improve the accessibility of essential medicines for common people, particularly the poorer sections of the population, and the availability of drugs for BPL families.
15. To identify steps required for facilitating implementation of the National Health Policy.

II. Composition of Working Group

1. Secretary, Department of Chemicals & Petrochemicals (DCPC) Chairman
2. Secretary, Dept. of Scientific & Industrial Research/DG, Council of Scientific & Industrial Research or his Representative Member
3. Principal Adviser (Dev. Policy), Planning Commission Member
4. Principal Adviser / Adviser (Health), Planning Commission Member
5. Additional Secretary & Financial Adviser, Dept. of C&PC (DCPC) Member
6. Joint Secretary (PI), Dept. of C&PC Member – Secretary
7. Adviser (I&VSE) Planning Commission Member
8. Chairman, National Pharmaceutical Pricing Authority Member
9. Representative of Ministry of Health & Family Welfare Member
10. Representative of Dept. of Science & Technology Member
11. Representative of Department of Bio-Technology Member
12. Director, Central Drugs Research Institute, Lucknow Member
13. Director, National Institute of Pharmaceutical Education & Research Mohali, Punjab Member
14. Representative, Pharmaceuticals Export Promotion Council, – Member
15. Representative, Indian Drugs Manufacturers Association – Member
16. Representative of Confederation of Indian Pharmaceuticals Industry – Member
17. Representative of Indian Pharmaceuticals Alliance – Member
18. Representative of Organisation of Pharmaceuticals Producers of India Peninsula –Member
19. Representative of Bulk Drug Manufacturers Association – Member
20. Chairman, Dr. Reddy's Laboratories Ltd – Member
21. Chairman, Ranbaxy Laboratories Limited – Member

22. Chairman, CIPLA Limited Mumbai Central – Member
23. Dr. Jai Prakash Narain, Lok Satta – Member
24. Dr. Ahmed Masood, Ex-Adviser (PAMD) – Member