A Private Sector Perspective

Analysis of Training Needs in the Generic Medicines Sector in the South African Development Community

Study commissioned by the Southern African Generic Medicines Association

June 2014

SAGMA
Southern African Generic Medicines Association
Access to affordable quality medicines

Supported by

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ANALYSIS OF TRAINING NEEDS
IN THE GENERIC MEDICINES SECTOR

conducted for the

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As part of the Global UNIDO Project:

Strengthening the local production of essential medicines in developing countries through advisory and capacity-building support

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ACRONYMS

API	Active Pharmaceutical Ingredient
ARIPO	Africa Regional Intellectual Property Organization
ARV	Antiretroviral drug
AU	African Union
AUC	African Union Commission
BA/BE	Bioavailability/Bioequivalence
BAPW	British Association of Pharmaceutical Wholesalers
BABE	Bioavailability, Bioequivalence
CAGR	Compound Annual Growth Rate
CDDDP	Centre for Drug Discovery Development and Production (Nigeria)
CE	Continuing Education
CePAT	USP Center for Pharmaceutical Advancement and Training
CENQAM	Centre for Quality Assurance of Medicines (NWU - South Africa)
cGMP	current Good Manufacturing Practice
CL	Compulsory Licence
CPD	Continuing Professional Development
CTD	Common Technical Document
DLO	Detailed Learning Objective
DRC	Democratic Republic of Congo
DTI	Department of Trade and Industry (South Africa)
EDL	Essential Drugs List
EDP	Executive Development Programme
FAPMA	Federation of African Pharmaceutical Manufacturers' Associations
FDA	US Food and Drug Administration
FDC	Fixed Dose Combination
FEAPM	Federation of East African Pharmaceutical Manufacturers
FIP	International Pharmaceutical Federation
FMP	Fundamental Management Programme
GCP	Good Clinical Practice
GDF	Global Drug Facility
GDP	Good Distribution Practice
GLC	Green Light Committee
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GSB	Graduate School of Business, University of Cape Town (RSA)
GWP	Good Wholesaling Practice
GxP	(general term for) Good (Anything...) Practice quality guidelines and regulations
HEI	Higher Education Institution
HR	Human Resource
HVAC	Heating, Ventilation and Air-Conditioning
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICP	International Cooperating Partner

ICT	Information and Communications Technology
IFC	International Finance Corporation
IP	Intellectual Property
IPAT	Industrial Pharmacy Advanced Training Program (KSP-SLF)
IPTU	Industrial Pharmacy Teaching Unit (KSP-SLF)
ISO	International Organization of Standardization
ISPE	International Society for Pharmaceutical Engineering
KSP	Kilimanjaro School of Pharmacy
LDC	Least Developed Countries
LPP	Local Pharmaceutical Production
M & A	Mergers and Acquisitions
M & E	Monitoring and Evaluation
MCAZ	Medicines Control Authority of Zimbabwe
MDP	Management Development Programme
MoU	Memorandum of Understanding
MUHAS	Muhimbili University of Health and Allied Sciences (Tanzania)
NIPER	National Institute of Pharmaceutical Education and Research (India)
NMRA	National Medicines Regulatory Authority
NWU	North-West University (RSA)
OTC	Over-The-Counter
PFE	Premises Facilities and Environment
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PIM	Partnership in International Management
PMPA	Pharmaceutical Manufacturing Plan for Africa
PQ	Prequalification
PQM	Promoting the Quality of Medicines
PSCM	Pharmaceutical Supply Chain Management
QC	Quality Control
R & D	Research and Development
REC	Regional Economic Community
RIIP	Research Institute for Industrial Pharmacy
RSA	Republic of South Africa
SADC	Southern African Development Community
SAGMA	Southern African Generic Medicines Association
SARUA	Southern African Regional Universities Association
SCM	Supply Chain Management
SET	Science Engineering and Technology
SLF	Saint Luke Foundation (Tanzania)
SLP	Short Learning Programme
SMD	Senior Management Development
SME	Small and Medium Enterprises
SMPIC	Small and Medium Pharmaceutical Industry Centre (India)
SOP	Standard Operating Procedures
SSA	Sub-Saharan Africa
SSC	Sector Skills Council

ToR	Terms of Reference
TRIPS	Trade- Related Aspects of Intellectual Property Rights
TUT	Tshwane University of Technology (RSA)
UCT	University of Cape Town (RSA)
UNISA	University of South Africa
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
UNISA	University of South Africa
UP	University of Pretoria (RSA)
USAID	United States Agency for International Development
USB	University of Stellenbosch Business School (RSA)
USP	United States Pharmacopeial Convention
UWC	University of Western Cape (RSA)
UZ	University of Zimbabwe
WAPMA	West African Pharmaceutical Manufacturers Association
WBS	Witwatersrand Business School (RSA)
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

The pharmaceutical industry operates in a highly dynamic environment in which companies can only maintain their viability and competitiveness through a labour force which is highly skilled and keeps up to date with new developments and innovations. The Southern African Generic Medicines Association (SAGMA) represents manufacturers and distributors of generic medicines in the Southern African Development Community (SADC) and is an important contributor to continent-wide efforts to promote local pharmaceutical production (LPP). SAGMA is acutely aware of the constraints faced by local producers in terms of human capacity and a shortage of knowhow. Thus, the main objective of this project was to consult SAGMA members on their training needs in order to identify and prioritize topics for capacity building programmes; to identify the preferred format and duration of the training programmes; as well as users' willingness to pay. It also set out to map current offerings by different local and international trainers and institutions and to identify new service providers for future collaboration.

The study was carried out by use of an electronic questionnaire sent to different categories of stakeholders, follow up telephone interviews and a desktop review of training service providers. When the feedback was assessed, information, management and business skills and practical technical training were all ranked as being of equal importance by the majority of companies (69%). However, wholesalers rated management and business skills training as the most important (100%), followed by information (50%). Although these skills categories are in line with what trainers and institutions can provide, there may still be a disconnect with the actual content of training provided. Priorities identified in the training category were mostly related to implementing quality systems, preparing for regulatory inspections and capacity building for business management. These needs point to an industry in its infancy which requires assistance to grow to the next level.

The majority of companies indicated a willingness to pay for their employees to attend short courses and workshops. However, their training budgets were very modest in comparison with international standards. The preferred format for course delivery was short workshops (of less than three days duration) and part-time modular courses with two to four contact sessions. The most popular delivery modes were workshops (75%) and DVD-packaged self-learning material (63%). Most trainers and institutions were already offering contact learning although they expressed willingness to develop self-learning material.

Pharmaceutical industry-related training available in Southern Africa is largely focused on regulatory affairs and quality matters, neglecting other operational issues such as formulation development, plant engineering and supply chain management. Very little training is directed specifically at wholesalers and distributors. There is broad coverage of good quality executive education in the region, particularly from South African business schools, although these courses are not specific to the pharmaceutical industry. Mapping of short courses in the region showed them to be

concentrated in South Africa and Tanzania. Intellectual Property (IP) protection, international patent law and Trade and Related Aspects of Intellectual Property Rights (TRIPS) flexibilities, as well as pharmaceutical engineering and plant operations, are underserved priority areas and yet they are at the heart of LPP policies and strategies.

In summary, there is a lack of synchronisation between the training needs of industry and what is currently on offer. This study makes several recommendations on the steps SAGMA should take in order to meet the training needs of its members and to bridge training/skills gaps.

1.1 INTRODUCTION

Since the 1970s, African Governments and several international organizations, including the United Nations Industrial Development Organization (UNIDO), have been advocating the establishment and expansion of local pharmaceutical production (LPP) in Sub-Saharan Africa (SSA). Since 2006, UNIDO has been implementing a global programme to strengthen the local production of essential medicines in developing countries, focusing on Africa. There are various reasons for this, including an aim to reduce dependence on imported drugs (and attendant trade imbalances), to create employment and to improve access to essential medicines[1].

Given the numerous obstacles faced by manufacturers in the region, including lack of access to capital, insufficient technically skilled personnel and the high cost of purchasing and maintaining equipment, it is frequently thought that pharmaceutical manufacturing enterprises may not be financially viable, particularly in the face of competition from India and China[2]. A simulation by Guimier et al[3], however, has shown that domestic pharmaceutical producers in SSA have the potential to be financially viable if the prevailing political environment is stable, the companies gain a significant market share via competitive pricing, and if they produce a diversified portfolio of drugs. A modest reduction in drug prices for the population as a result of increased LPP was also demonstrated.

Political and economic developments on the continent over the past decade have made SSA an ever more attractive investment destination[4]. The region is enjoying an increasingly stable democratic and political environment and a demographic shift is fuelling an economic upturn. The pharmaceutical industry in Africa is projected to experience a compound annual growth rate (CAGR) of 10.6% through to 2016 by which time spending in the industry will reach US$30 billion[5]. The South African pharmaceutical market, the largest in the region, was valued at US$3.8 billion in 2011 and is projected to grow at a CAGR of 9.2% to US$7 billion by 2018[6].This phenomenal growth will be stimulated by a burgeoning middle class on the continent, increased spending on healthcare and a shift in the disease burden towards chronic and non-communicable diseases[7].

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1 Jean-Marc Guimier, Evan Lee, Michel Grupper. The evidence base for domestic production and greater access to medicines. 2004. DFID Health Systems Resource Centre. September 2004.
2 Warren A. Kaplan and Richard Laing. Local production: Industrial policy and access to medicines. An Overview of Key Concepts, Issues, and Opportunities for Future Research. 2003.
3 Jean-Marc Guimier, Evan Lee, Michel Grupper The evidence base for domestic production and greater access to medicines. 2004. DFID Health Systems Resource Centre. September 2004.
4 McKinsey Global Institute – Lions on the Move: The progress and potential of African economies. June 2010.
5 Africa: A ripe opportunity. Understanding the pharmaceutical market opportunity and developing sustainable business models in Africa. A White Paper on Africa. (not dated). IMS Health.
6 GBI research. Emerging Pharmaceutical Market in South Africa to 2017 - Proposed Introduction of New Drug Regulatory Agency (SAHPRA) to Accelerate Drug Registration Process http://www.marketresearch.com/GBI-Research-v3759/Emerging-Pharmaceutical-South-Africa-Proposed-7025791/ (accessed 11 April 2013).
7 Sub-Saharan Africa Pharmaceutical Yearbook. http://www.frost.com/sublib/display-report.do?id=M868-01-00-00-00 (accessed 2 May 2013).

Politically, the push for LPP by African governments gathered momentum over the past decade and resulted in the development and adoption in April 2007 of the Pharmaceutical Manufacturing Plan for Africa (PMPA) by the Conference of African Ministers of Health. The PMPA was subsequently endorsed by the African Heads of State and Government in Accra, Ghana in July 2007[8], and, in November 2012, the PMPA Business Plan was adopted in Addis Ababa, Ethiopia. The main objective of the Plan is to promote 'industrial development and safeguard / protect public health by [...] the production of quality medicines and the development of an international GMP compliant industry in Africa'.

Nonetheless, for companies in SSA to achieve sustainable competitiveness, they need to institute international quality systems. This will open up lucrative international and national tendering markets which frequently require WHO prequalification or registration as a member of either the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), or the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S)[9].

To reinforce manufacturing quality and to operate an acceptable Good Practice (GxP) system, human resources are key. These resources should be well trained to meet the rigorous demands of product design and quality assurance. Continuing training is also a requisite for maintaining the production of quality medicines and international competitiveness. Reinhardt has highlighted the many challenges which African pharmaceutical companies face and the need to build capacity, especially in human resources[10].

The PMPA recommends various strategies for achieving the goals of LPP. Among these is the strengthening of partnerships, collaboration and business linkages, and strengthening national and regional pharmaceutical manufacturers' associations. While regional associations such as the West African Pharmaceutical Manufacturers Association (WAPMA), the Southern African Generic Medicines Association (SAGMA), and, more recently, the Federation of East African Pharmaceutical Manufacturers (FEAPM) have been in existence for a while, the first continent-wide body, the Federation of African Pharmaceutical Manufacturers Associations (FAPMA) was launched only in January 2013. Its mission is 'to facilitate collaboration between regional pharmaceutical manufacturing associations, to address the common challenges faced by the industry and to enhance opportunities towards self-sufficiency through advocacy and partnership with other stakeholders in promoting the production of quality, affordable medicines'[11].

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[8] *AUC – UNIDO. Pharmaceutical Manufacturing Plan for Africa. Addis Ababa. November 2012.*
[9] *ibid*
[10] *Reinhardt J. Building capacity for local pharmaceutical production (LPP) in Africa. Conference on 'Innovation in healthcare without borders'. Brussels, 16-17 April 2012.*
[11] *http://www.sagma.net/Activities/fapma.html (accessed 22 May 2013).*

SAGMA represents manufacturers and distributors of generic medicines in SADC and is a response to continent-wide efforts to promote LPP. Its vision is to 'create a vibrant and self-sustaining generic pharmaceutical manufacturing industry in the SADC and achieve self-sufficiency in the local production and provision of affordable quality generic medicines in the region'[12]. This aim should be pursued by promoting the sector's interests vis-à vis outside parties and providing services to members.

The Association is acutely aware of the constraints faced by local producers in terms of human capacity and a shortage of knowhow. One of its key strategic objectives is to address the task of improving skills and technical expertise in the generic pharmaceutical industry in Southern Africa in a comprehensive manner. This is to be achieved by enhancing and formalizing a capacity building programme with partners and service providers which includes training workshops falling into three categories:

1) Information sharing; for example, on the requirements of World Health Organization (WHO) Prequalification and Good Manufacturing Practice (GMP) in general;

2) Business Investment; for example, financial management and strategic planning; and

3) Practical training in technical topics such as implementation of quality standards and tablet coating.

SAGMA has organized or facilitated participation for members in the following workshops:

- A workshop jointly conducted by the Promoting the Quality of Medicines (PQM) programme of the US Pharmacopeial Convention (USP),, the Global Drug Facility (GDF), the Green Light Committee (GLC), and the World Health Organization (WHO) to inform manufacturers about the WHO Prequalification Programme, the technical assistance provided on achieving prequalification, and the outlook for the global TB medicines market.
- A workshop on Intellectual Property Rights and Local Pharmaceutical Manufacturing in the Southern African Region organized in collaboration with the United Nations Industrial Development Organization (UNIDO) and United Nations Conference on Trade and Development (UNCTAD).

However, the choice of workshops and format was not informed by members' needs. It is consequently necessary to identify and prioritize the training needs of members in order to design and deliver relevant offerings at affordable rates and in an accessible and convenient format and platform. In future, workshops should reflect the priorities identified by the present study.

[12] *SAGMA website - http://www.sagma.net*

1.2 OVERVIEW OF THE PHARMACEUTICAL INDUSTRY IN SOUTHERN AFRICA

The Southern African Development Community (SADC) is a regional economic community (REC) comprising 15 Member States - Angola, Botswana, Democratic Republic of Congo (DRC), Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe. It was formally launched in 2002 and has an estimated total population of 281 million[13] and a combined GDP of over US$ 650 billion, 60% of which is generated by South Africa[14].

SADC's major health challenges are a high burden of HIV and AIDS, tuberculosis (TB) and malaria, and non-communicable diseases, especially diabetes, hypertension and cancer[15]. Whilst few of the countries in the region have procurement policies which favour domestic suppliers in government tenders, most such 'local' suppliers are in effect importers of products manufactured in Asia rather than local pharmaceutical producers. They face many barriers to growth including inadequate public financing, weak procurement and supply chain management, insufficiently qualified personnel, inadequate infrastructure, weak regulatory and quality assurance mechanisms and unaffordable prices, all of which impact on the size of the market and financial viability of producers and competitiveness[16].

The median per capita expenditure on health in the SADC region is US$32 (range US$10 – US$400), of which 12.5% (median) was spent on medicines. The public spend on medicines ranges between US$1.7 million to US$51.7 million per country[17].

As a result of large trade deficits partly attributable to the import of medicines, SADC is promoting the regional production of pharmaceuticals as part of its industrialization agenda. The SADC Pharmaceutical Business Plan 2007 – 2013 was initiated with the main objective of improving availability and ensuring sustainability of medicine supplies and expanding access to affordable, quality, safe, and efficacious essential medicines, including African traditional medicines[18]. The Plan proposes various strategies to achieve this objective, three of which are directly relevant to capacity building and training. These are:

1. Rationalizing and maximizing the research and production capacity of local and regional generic pharmaceutical industries;
2. Developing and retaining competent human resources in the pharmaceutical sector; and
3. Strengthening regulatory capacity, supply and distribution of basic pharmaceutical products.

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[13] http://www.sadc.int/files/6213/6267/6607/Selected_Indicators_2011_with_charts06March2013_FINAL.pdf (accessed 11 May 2013).
[14] *Ibid - sadc.int*
[15] *The SADC Pharmaceutical Business Plan 2007 – 2013. SADC Secretariat. 2007. Gaborone*
[16] *The SADC Pharmaceutical Business Plan 2007 – 2013. SADC Secretariat,.2007. Gaborone*
[17] *ibid*
[18] *The SADC Pharmaceutical Business Plan 2007 – 2013. SADC Secretariat. 2007. Gaborone.*

With regard to regulatory capacity within the region, 11 of the 15 SADC countries have legal provisions for licensing local manufacturers and 10 out of 15 have Good Manufacturing Practice (GMP) guidelines at country level. In practice, however, local production takes place in only four countries, South Africa, Zimbabwe, Zambia and Tanzania. In 2009, it was reported that there were 101 domestic manufacturers in the SADC region of which the majority (42) were based in South Africa[19]. About 60% of the pharmaceutical companies in the region were found to be GMP compliant: 39 out of 42 in South Africa, 14 out of 14 in Zimbabwe[20], 2 out of 6 in Zambia, and 2 out of 7 in Tanzania[21].

All SADC members, with the exception of Seychelles, are members of the World Trade Organization (WTO)[22] and over half have domesticated articles of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which provides that Member States shall respect minimum standards of intellectual property protection, including patent protection. Nonetheless, as at 2008, only some two-thirds of SADC Member States had incorporated into national law TRIPS flexibilities on compulsory licensing, parallel importing and the Bolar provision which allows the manufacturing of test-batches of a product before the patent expires for regulatory purposes. It seems therefore that countries and the pharmaceutical industry in the region are not making use of international legal instruments to promote LPP.

There are two major sub-sectors of relevance to this study in the private pharmaceutical sector in Southern Africa. These are manufacturers on the one hand and wholesalers or distributors on the other. Some enterprises incorporate both manufacturing and wholesaling or distribution activities and, at present, manufacturers can be broken down into four different categories[23]:

1. Subsidiaries of large transnational companies such as Pfizer and GSK which manufacture branded products for regional markets
2. Global generics manufacturers such as Cipla, Ranbaxy (Indian) and Sandoz (Swiss). Operating with a global manufacturing strategy, they can form local alliances for ease of entry into the region but have global value chains which they use to channel raw materials and infrastructure to compete at local and regional levels

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[19] WHO. 2009. Baseline assessment of the pharmaceutical situation in Southern African Development Community countries. WHO press. Geneva.
[20] Note: Anecdotal evidence suggests that this has probably changed as a result of the economic meltdown in Zimbabwe from 2006 – 2009.
[21] WHO. 2009. Baseline assessment of the pharmaceutical situation in Southern African Development Community countries. Fact Book 2009. WHO. Geneva.
[22] http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (accessed 18 May 2013)
[23] Health Nutrition Population Brief #3. Pharmaceuticals: Local Manufacturing. 2004.

3. Manufacturers of generics with predominantly national operations, which include Varichem and Adcock in Zimbabwe and South Africa respectively. They are dominant players in their home markets and are beginning to export into the region. They adhere to GMP and are off-patent drug manufacturers; and
4. Small-scale local manufacturers which are generally small companies with modest portfolios that do not meet GMP standards and serve only local or regional markets. They have a combination of early generation prescription and Over-The-Counter (OTC) products. These products may also be sold in the informal sector.

At the moment, SAGMA's membership is dominated by manufacturers. Future growth, however, probably lies in the recruitment of wholesalers and distributors who warehouse finished products from local and transnational producers. Some wholesalers, particularly in South Africa, are involved in bulk breaking and re-packaging prior to distribution.

In most of Southern Africa, companies in the pharmaceutical sector experience high employee turnover mainly as a result of brain drain to South Africa or to Organisation for Economic Co-operation and Development (OECD) countries. This means that the available pool of labour is usually low-skilled. In a study published in 2009, the World Health Organization (WHO) reported that the median number of pharmaceutical personnel in SADC countries, including registered pharmacists and technicians, and including those working in the pharmaceutical industry, was 803 (range 61 – 20,162)[24]. Pharmaceutical companies find themselves with a continuous need to hire and train new employees and also to build the capacity of those who are already employed.

In addition to the challenges of human capital, manufacturing operations and priorities in the industry are continuously changing and shifting[25] due to technological developments aimed at increasing efficiency while concurrently reducing costs. All these dynamics are ultimately aimed at improving competitiveness in an industry which is increasingly competitive.

[24] *WHO. 2009. Baseline assessment of the pharmaceutical situation in Southern African Development Community countries. WHO press. Geneva.*
[25] *UNIDO. 2011. Pharmaceutical sector profile – Zimbabwe. Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries.*

2.1 PROJECT SCOPE AND OBJECTIVES / TERMS OF REFERENCE

The challenges of local pharmaceutical production in Africa are multi-faceted but the lack of management and technical capacity within companies has been identified as a key priority for enhancing viability and improving quality and competitiveness. In the light of this finding, UNIDO and SAGMA contracted a pharmaceutical expert whose mandate was to:

2.1 Consult members and identify and prioritize topics for training programmes; the preferred format and duration of such programmes; as well as willingness to pay

2.2 Map current offerings by different local and international trainers and identify new service providers for future collaboration; and

2.3 Map public and private institutions which offer industrial pharmacy programmes and courses in related disciplines such as pharmacology, engineering, and chemistry, as well as business management and allied programmes. Comparisons of the types of programmes offered, fees, duration and relevance were to be made.

The overall goal was to propose a focused capacity building programme which would meet the needs of members, attract new members and also provide revenue for SAGMA. The topics addressed by the programme should also take into account the needs of all relevant stakeholders, including wholesalers and manufacturers, whether members or non-members of SAGMA. This would, it was hoped, help to build a more cohesive and member-driven association which is responsive to members' diverse needs and interests.

2.2 METHODOLOGY

In consultation with the SAGMA Secretariat, the key informants were identified and broken down into members or potential members; training service providers, including both institutions and private providers; and national industry associations. Questionnaires were designed for each of the three categories and administered electronically via www.surveymonkey.com. To increase response rate, telephone calls were made weekly as a follow-up. Telephone interviews were conducted where necessary for clarification and for obtaining further inputs from respondents. The questionnaires were in English and were also translated into Portuguese and French. Higher Education Institutions (HEIs) were identified from the Southern African Regional Universities Association (SARUA) web site (www.sarua.org) and private service providers were identified from online searches and suggestions by the SAGMA Secretariat and industry executives. Information on the various training opportunities available was obtained from university web sites. In some cases, key institutions were contacted and requested to complete the electronic questionnaire with telephone interviews carried out as follow up.

2.3 DATA COLLECTION

An electronic questionnaire was felt to be the most appropriate instrument for data collection since this was a practical way of surveying the perceptions of busy senior managers spread across a wide geographical base. Access to the questionnaire was via an electronic link embedded in a covering letter sent via the SAGMA Secretariat. The link is part of the web-based survey monkey tool (www.surveymonkey.com). It was used as a format to capture completed responses which could be automatically submitted as soon as a respondent had completed the questionnaire. Interviews were also carried out with selected key informants mainly to seek clarity on the capacity building programme currently in place and any additional information.

A desktop review of programmes offered by various regional and international training service providers and institutions was made and used for the mapping exercise. In some cases, key institutions were contacted and requested to complete the electronic questionnaire with telephone interviews then made as follow up.

3.1 RESEARCH FINDINGS

Below is a summary of responses from the different stakeholders contacted for this study. While the response rate was generally satisfactory, only one of the national associations contacted responded. This is noteworthy because, in the previous structure, SAGMA and national associations were seen to be targeting the same membership resulting in apparent tensions. This has now been largely resolved with SAGMA being re-configured as a regional association of national pharmaceutical associations. It should also be emphasized that, in most SADC countries, national pharmaceutical industry associations are weak precisely because the domestic private sector is weak.

Table 3.1: Response rate to the questionnaire

Stakeholder	Questionnaire	Interview (oral or e-mail)
SAGMA members & potential members	X (22 responded)	X (some key informants)
National associations	X (1 responded)	
Training providers: technical	X (9 responded of which 6 HEIs & 3 private)	
Training providers: business schools	X (no respondents)	X (responded by e-mail)
Training providers: international agencies	X (no respondents)	X (responded by e-mail)

HEI = Higher Education Institute

3.1.1 SAGMA MEMBERSHIP

The beneficiary company survey showed that nine respondents were willing to join SAGMA. When questioned as to the value it would bring them, 91% of these companies cited political advocacy, 83% cited networking and cooperation and 85% cited international contacts; 75% cited technical advice and 69% cited training workshops.

None of the trainers surveyed was a member of SAGMA but 75% - or six - showed interest in joining. The study revealed that the most valued SAGMA offerings were networking and international contacts for establishing collaboration. Thus there appears to be an untapped market for SAGMA both within the trainers sector and the wholesaling arena.

3.1.2 RESPONSE FROM SAGMA MEMBERS AND POTENTIAL MEMBERS

There were 22 respondents from the pharmaceutical industry, that is, members and potential members of SAGMA. Seven of the 22 were already members and seven others expressed interest in joining. Of the 22 respondents, six were wholesalers, eight manufacturers, four consulting firms and four others from retail or marketing enterprises. The respondents were predominantly male, that is, 73.7%, with virtually all in executive management positions. English was the language of choice for 95.5% of the respondents. The only non-English speaking respondent was Portuguese-speaking from Mozambique despite the fact that investment in the local pharmaceutical industries in Lusophone countries is growing. This shows that SAGMA's profile is currently recognized only in the English-speaking countries of SADC.

3.1.2.1 Respondent company profiles and their current training activities

The majority of companies (70%) employed at least five people. Of these companies, 45% employed between 50 and more than 200 people. In the wholesaler sub-category, two-thirds employed more than 50 people, which is to be expected as wholesaling is a labour-intensive, low-skilled business. The requirements of small-sized enterprises for training and their capability to support training appear to be limited, as is their ambition to grow. The size of the labour force in this case does not correlate to the demand for high-end skills training. However, the training needs of less skilled shop-floor employees, such as packers and cleaners, who play an important role in Good Wholesaling Practice (GWP), should not be underestimated.

The majority (80%) of companies reported that all technical employees from medium rank upwards had access to reliable broadband internet connection. This would facilitate e-learning programmes, an important training tool, since video conferencing is not really an option as only a quarter of companies had video conferencing facilities. In view of this, it was surprising that only 47% of respondents were currently using e-learning platforms. Various reasons were cited for low usage of Information and Communications Technology (ICT) in accessing training, including no

broadband infrastructure (20%), the cost of internet usage (32%), and limited time for non-core activities (37%). It can be inferred from this that training is considered a 'non-core' activity. It is also likely that not many training providers are using e-learning platforms. In addition, it was found that regional HEIs do not currently have e-learning or digital material available.

About 56% of the companies did not have a career development and training strategy and policy in place despite the fact that 66% of them had existing capacity for carrying out development and training programmes. This means that their training courses were not being informed by policy and needs assessments. The implication is that training programmes are unlikely to be sustainable as they are dependent on the vagaries of management.

The respondents cited attending various in-house and external courses on executive business management, regulatory compliance, WHO Prequalification, pharmaceutical technology, and pharmaceutical supply chain management (PSCM) in the preceding three years. The last two courses were the most popular, with 38% of respondents having attended them. The categories of employees most likely to have attended the courses were those in executive management positions (47%) and operational (shop-floor) personnel (42%). The study noted that the courses were selected by management and not based on any needs and capacity assessments. Additionally, there is a general concern that technical and operational staff are being sidelined for various reasons such as cost of training and workload demand despite the fact that building their capacity is critical to improving quality and increasing productivity.

The issue of management attending technical training workshops was highlighted by key informants as being problematic as there is no real value addition to companies' day-to-day activities. The study observed that this is probably happening because there is no communication with the target audience on Detailed Learning Objectives (DLOs), learning activities and expected outcomes of the programmes.

3.1.2.2 Current use of training service providers / Institutions

Local universities or professional associations account for only 10% and 5% respectively of current providers of training for the pharmaceutical sector, with private providers being the dominant players. This points to weak linkages with HEIs in particular. However, the institutions themselves are also viewed as being out of touch with industry needs and not flexible enough to institute workplace training programmes. Such perceptions were also recently noted in a study in South Africa of the adequacy of HEI curricula to produce job-ready graduates for the pharmaceutical industry[26].

[26] *Department of Trade and Industry (DTI). 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.*

Of the six universities which took part in this survey, three-quarters said that they currently work with industry but on an *ad hoc* basis and with individual companies. Sixty-seven percent (67%) provide training, 66% offer consulting services to individual companies and all of them are engaged in providing expert advice or training to government departments. The universities had no collaboration with professional associations. However, most (83%) of the universities indicated willingness to collaborate with professional associations and 67% were willing to be involved in an inter-institutional and multilateral training centre. They cited perceived lack of interest from industry (25%), poor financial viability of programmes because of lack of government subsidies (37%), and lack of laboratory facilities and faculty (38%) as barriers faced in offering courses to industry.

At present, 94% of companies are interested in training provided by international organizations, especially the United States Pharmacopeial Convention (USP) and WHO, which are regarded as reliable and providing international best practices. This indicates that increased collaboration between SAGMA and FAPMA to draw on expertise such as that in the USP Center for Pharmaceutical Advancement and Training (CePAT) in Ghana is likely to yield positive results. The study observed that university and international programmes have more credibility because they are accredited for Continuing Professional Development (CPD) and certification purposes.

3.1.2.3 Willingness to pay

About 95% of the companies pay for their employees to attend short courses and workshops but only 37% contribute towards registration for academic qualifications such as a diploma or degree. This may be because of the financial costs and impact of time off from work (study leave) for employees undertaking formal studies. However, 84% of the respondents encourage staff to study towards formal qualifications - presumably in their free time. Three-quarters of the respondents indicated that they had an annual budget ring-fenced for training. Fifty per cent (50%) of the respondents had a budget of just over US$1,000 per annum, a figure far short of ideal although the bigger companies had larger training allocations. Two-thirds of the respondents were eligible for skills development levies disbursed by government agencies. However, only half these companies had actually received the levies in the past year and, of those who did, 30% received amounts ranging from US$1,000 to US$20,000. The majority of companies received amounts of less than US$1,000 which they deemed insufficient as training support.

When probed on willingness to pay for the training of employees, 11 of the 15 respondents indicated that they were willing to pay for external training. Seven respondents were non-committal. Seventy-three percent (73%) predictably selected the lowest tier of willingness, which was to pay between US$150 and US$300 per individual per day, and 26% selected US$300 to over US$500 per individual per day.

The training providers indicated a spread of charges, with 29% charging US$150 to US$300 per person per day; 29% charging US$300 to US$500; and more than US$500 per day is charged by 29% of the respondents. However, they indicated that the cost structure is not fixed but is determined by the number of participants, course material provided, and the duration of training.

3.1.2.4 Preferred format and delivery platform

In relation to the preferred format and delivery methods, short workshops (less than three days) and part-time modular courses with two to four contact sessions per year were equally popular (56%). The most popular delivery modes of training were workshops (75%) followed by DVD-packaged self-learning material (63%). Workshops are seen as providing opportunities for networking and information sharing of particular importance to executives. DVD material is more popular than internet courses and webinars because of its portability and convenience, that is, a DVD can be viewed anywhere, including outside work and can be kept as reference material.

3.1.3 RESPONSE FROM TRAINING SERVICE PROVIDERS AND INSTITUTIONS

Of the nine training institutions and companies who formally responded to the survey, five were Departments and/or Schools of Pharmacy at Higher Education Institutions (HEIs) or universities; one was a Business Development Office of a University Graduate School of Business and three were private sector service providers. There were three South African universities (Tshwane University of Technology (TUT); University of the Western Cape (UWC) and University of Pretoria (UP)), one Zimbabwean (University of Zimbabwe (UZ)) and one Tanzanian (Muhimbili University of Health and Allied Sciences (MUHAS)) specially chosen to cover the geographical spread of SADC and also because of their recognized current engagement with the pharmaceutical industry. Four Graduate Business Schools, the University of South Africa (UNISA), Tshwane University of Technology (TUT), University of Stellenbosch Business School (USB), University of Cape Town (UCT) and University of Pretoria (UP) were also approached. UNISA and UCT gave their responses informally rather than by completing the questionnaire. Of the private service providers, one, Quadpharm, was based in South Africa, LearnWright in the USA and PharmaSystAfrica in East and West Africa. The preferred language of all the respondents was English.

Over half of the service providers had more than 10 employees and two institutions had more than 20. However, although this might appear to indicate their capacity to train, it is likely that these staff numbers included support and part-time staff and this would explain why, later in the survey, lack of capacity to deliver training was cited as a limitation. Seventy-eight per cent (78%) of the trainers already had some engagement with the pharmaceutical industry. Their training courses are, however, catering mainly to technical personnel or departments of medicine registration in the companies This is also evident from the number of trainers giving courses on quality and related

topics (up to 85% of respondents) compared with those offering training to distributors and wholesalers (no more than 40%).

There is then an oversupply of trainers in regulatory and quality affairs while other important operational issues like pharmaceutical procurement, wholesaling and distribution and practical shop-floor functions are neglected. PharmasystAfrica is the only company specialized in procurement training and Pharmaceutical Supply Chain Management but it does not have a footprint in many SADC countries and currently works only in Tanzania and Liberia. Moreover, it works mainly with public procurement systems as opposed to the private sector.

The Business Schools approached are known to offer good quality accredited short courses. For example, USB offers Management Development Programmes in Namibia, South Africa and Nigeria while UNISA has online courses and is the largest long-distance learning university in Africa. However, there was no evidence that these HEIs offer training specific to the pharmaceutical industry although the study observed their willingness and flexibility to engage with the industry.

3.1.3.1 Current format and delivery platform

Of the HEIs offering technical programmes, three institutions offer a short course of no more than five days, one offers a month-long course, one offers a year-long modular course with regular week-long contact sessions and one offers a part-time 12 month course with weekend lectures. This format matches industry preferences as it allows for employee day release without compromising production.

In terms of cost, trainers quoted from US$150 to over US$500 per individual per day. The study was not able to obtain costs from Business Schools who required specific information before supplying a quote. Nonetheless, costs for management training would probably be much higher than for technical training. For example, in 2013, UNISA was charging US$2,500 for the Fundamental Management Course, US$5,000 for the Advanced Project Management Course and US$6,000 for the Executive Management Programme. These costs do not include examination fees and levies.

Fifty-six percent (56%) of the trainers, and particularly the private providers, indicated that they had online programmes available. However, from the potential beneficiaries' angle, web-based programmes might not be as convenient as DVD self-learning material. Trainers need to show flexibility to enable them to provide for SAGMA members who have ICT resource constraints.

3.1.4 TRAINING PRIORITIES

Companies were asked to break down their needs into short term, such as 6 – 18 months, medium, from 18 – 60 months and long term (more than 60 months) priorities. To qualify for inclusion, topics selected had to have been prioritized in the short-term category by at least 50% of the respondents. The training providers were asked about their readiness to provide training in the short-term and they were then matched with the topic and corresponding ability to fulfil it.

Appendices 1, 2, and 3 show the responses in a consolidated format. In view of the poor response rate, the single questionnaire received from a national association has been excluded as it shows the needs of only one country. In the case of manufacturing companies, 69% ranked the three priority areas of information; management and business skills; and practical technical training as being of equal importance. However, all the wholesalers prioritized management and business skills training and half prioritized information sharing.

3.1.4.1 Information

The priority areas for information-sharing sessions are shown below in Table 3.2. There are many providers of training on regulatory and quality systems. Assessing the quality of the programmes provided was not part of this study although many of these trainers are accredited. The problem may be that, in the absence of harmonized National Medicines Regulatory Authority (NMRA) guidelines within SADC, most of the courses are country specific. Intellectual Property (IP) protection, international patent law and TRIPS flexibilities are at the heart of LPP policies and strategies yet they are underserved priority areas.

Table 3.2: Priority areas identified for information-sharing sessions by pharmaceutical companies and wholesalers and number of trainers able to provide training in these topics

TOPIC	COMPANIES (aggregated)	WHOLESALERS	NO. OF TRAINERS
Introduction to pharmaceutical quality assurance systems e.g. GMP*, GDP*, GWP*, etc.	X	X	4
Documentation Management and Control	X	X	2
IP protection	X	X	1
cGMP* for production supervisors/ laboratory personnel / executives	X	X	4
TRIPS flexibilities	X	X	0
Preparing for NMRA* inspection		X	4
Introduction to international patent law		X	0
Environmental control and monitoring		X	1
Overview of regulatory affairs		X	6

GMP = Good Manufacturing Practice; GDP = Good Distribution Practice; GWP = Good Wholesaling Practice; cGMP = current Good Manufacturing Practice; NMRA = National Medicines Regulatory Authority

3.1.4.2 Management and business skills

Demand for training in management and business skills was evident in the responses to the survey. There are, however, few independent trainers in this area and Business Schools fail to provide programmes of direct relevance to the pharmaceutical industry.

Table 3.3: Priority areas for training in the management and business skills category

TOPIC	COMPANIES (aggregated)	WHOLESALERS	NO. OF TRAINERS
Strategic planning / Business planning	X	X	1
Operations and general management	X	X	1
Financial management and investment	X	X	1
Pharmaceutical supply chain management	X	X	1
Marketing	X	X	3

3.1.4.3 Pharmaceutical validation

Pharmaceutical validation was ranked as a low priority overall although it is one of the most critical areas for practical intervention to improve the quality of products. It is also worth noting that, while the cost of the training might act as a

barrier to participation, the perceived cost of implementing specific programmes is an even bigger barrier. Implementing a quality system is perceived as costly in terms of external consultants needed to assist with preparations, time to design and enforce Standard Operating Procedures (SOPs), requisite upgrading of equipment and modification of the plant and then fees paid to the International Organization for Standardization (ISO) certification agencies. This explains why pharmaceutical validation was a low priority.

The study observed that existing trainers are unlikely to offer hands-on training since a mock industry set up is required. The existing trainers are private and they currently conduct didactic lectures on pharmaceutical validation which are long on theory and short on shop floor practice. Effective training on pharmaceutical validation should involve working in a simulated factory environment such as a sterile manufacturing unit or tableting and packing facility with the requisite QC equipment. It is recommended that SAGMA initiates talks with the Kilimanjaro School of Pharmacy (KSP), MUHAS and TUT to look at the possibility of accessing mock industry facilities there.

Table 3.4: Priority areas for training in pharmaceutical validation

TOPIC	COMPANIES (aggregated)	WHOLESALERS	NO. OF TRAINERS	COMMENTS
Analytical methods validation for NMRA compliance	**X**		5	Lectures without simulated environment practicals
Laboratory control system		**X**	4	Lectures without simulated environment practicals
Environmental control and monitoring		**X**	0	Requires walk through inspection in simulated typical environment

3.1.4.4 Regulatory compliance

Regulatory compliance is an area popular with trainers because it involves workshops on the administrative and logistical processes involved in attaining NMRA compliance. The fact that it was ranked low by beneficiary companies may indicate that there is a lack of strategy to build portfolios. Although outside the remit of this study, this issue is worth investigating further as it may impact on the long-term planning and positioning of enterprises and their training needs.

Table 3.5: Priority areas for training in regulatory compliance

TOPIC	COMPANIES (aggregated)	WHOLESALERS	NO. OF TRAINERS	COMMENTS
Dossier compilation for NMRAs*	**X**	**X**	4	
Applied cGMP for pharmaceutical and related industries	**X**	**X**	3	This requires walk through demonstrations in an industry set up
Risk management	**X**	**X**	3	
Bioavailability and bioequivalence testing		**X**	4	No practical laboratory based course offered by these trainers

NMRA = National Medicines Regulatory Authority

3.1.4.5 Pharmaceutical technology

Pharmaceutical technology was ranked as the lowest priority with just two specific topics cited. This is surprising because, if companies are to build up their portfolios, they require competence in advanced pharmaceutics and formulation.

It may be that this and the attendant technologies are seen as expensive 'nice-to-haves' or as being suitable for outsourcing. However, in the long run, outsourcing may be unsustainable and it is potentially detrimental to building relevant in-country capacity for innovation since most of the outsourcing is to Indian companies. In any case, companies need to have skilled personnel in order to make the right decisions on what aspects to outsource and also in order to interpret results and make production decisions.

The study observed that the shortage of trainers in this field should also be a cause for concern because it points to weak formulation sciences within the HEI sector, a phenomenon which will, in the longer term, hinder industry growth. This should be the subject of further investigation.

Table 3.6: Priority areas for training in pharmaceutical technology

TOPIC	COMPANIES (aggregated)	WHOLESALERS	NO. OF TRAINERS
Water sampling and testing	**X**		4
Drug product stability and shelf-life	**X**		3

3.1.4.6 Distribution and wholesaling

In relation to distribution and wholesaling, many needs were prioritized under this topic and this is unsurprising in view of the marked lack of training specifically for these industry actors. There is also generally little overlap between the wholesalers and other companies.

Table 3.7: Priority areas for training in distribution and wholesaling

TOPIC	COMPANIES (aggregated)	WHOLESALERS	NO. OF TRAINERS	COMMENTS
Ensuring product safety and security	**X**	**X**	2	
Vendor and contract supplier qualification	**X**		1	
Systems for product recall and returned goods	**X**		2	
Good Distribution Practices	**X**		1	
Environmental control and monitoring		**X**	2	
Handling and distributing food supplements, additives and herbal medicines		**X**	1	
Warehouse management		**X**	2	
Distribution & storage of cold chain and controlled drugs		**X**	1	
Building internal monitoring and auditing		**X**	2	
ICT to support wholesaling supply chain		**X**	1	Engage with ICT departments in HEIs

3.1.5 MAPPING OF SOUTHERN AFRICAN TRAINING PROVIDERS

The mapping of HEIs in Southern Africa offering training directly related to the technical needs of generic pharmaceutical manufacturers, including short courses, indicated that trainers are by and large concentrated in South Africa. Table 3.8 lists institutions offering training in pharmacy and related disciplines such as pharmacology, chemistry and engineering. The majority of training available in Southern Africa is formal, that is, structured, full-time programmes leading to academic qualifications. Although the main focus here is on short courses catering to the needs of personnel in the pharmaceutical industry, this mapping of institutions also reveals areas where pharmaceutical personnel could take time off work to enrol and pursue higher degrees and levels of education. Indeed, personnel in most pharmaceutical companies in developed countries are holders of advanced degrees in their fields.

With regard to part-time courses aimed at the industry, most are targeted at persons employed in the medicine registration departments of companies or NMRAs, or clinical research, that is, concerned with designing and

monitoring clinical trials. This is both because of the size of the current market and because these courses do not require expensive laboratory infrastructure, equipment and consumables.

The University of the Western Cape (UWC) in South Africa offers an online course towards a Masters Degree in Regulatory Sciences. The course is organized along the lines of a professional Masters or MBA and incorporates a visit to the Food and Drug Administration (FDA) Head Office in the USA. Key participants in the survey pointed out that this course was far too expensive and took participants out of their environment for prolonged periods thus compromising production priorities. In addition, they also thought any such course should be more relevant to the African registration environment rather than to FDA requirements.

The University of Stellenbosch in South Africa currently offers a postgraduate diploma in Pharmaceutical Medicine while Tshwane University of Technology (TUT) offers a part-time postgraduate one year B.Tech.(Pharmaceutical Science) degree. The Department of Pharmacology at the University of Pretoria has a similar full-time programme to train clinical research associates. The curricula of these programmes include regulatory affairs, GMP and GCP (Good Clinical Practice) and are primarily aimed at clinical research associates, NMRA employees and, to some extent, management.

Table 3.8: Public institutions in Southern Africa offering Industrial Pharmacy and related programmes

South African and Tanzanian universities are the only ones offering short courses and online courses which personnel in the pharmaceutical industry can benefit from although the Medicines Control Authority of Zimbabwe (MCAZ) also offers relevant short courses in its laboratory. Brief details are given below. The other programmes listed below could be utilized by pharmaceutical personnel wishing to achieve formal qualifications or advanced degrees in their field.

SADC member state	Institution	Programmes offered	Notes
Angola	University Agostinho Neto	Pharmacy Mechanical engineering	Formal degree training in pharmacy and other sciences relevant to industry, e.g. mechanical engineering. Part-time courses or continuing education courses in pharmaceutical sciences not available
Botswana	University of Botswana	Chemistry Mechanical engineering	Part-time courses or continuing education courses in pharmaceutical sciences not available
Democratic Republic of Congo	University of Kinshasa	Pharmacy (Pharmaceutical Sciences) Chemistry	Part-time courses or continuing education courses in pharmaceutical sciences not available
	University of Lubumbashi	Engineering Chemistry	Part-time courses or continuing education courses in pharmaceutical sciences not available
Lesotho	National University of Lesotho	B. Pharm.	Part-time courses or continuing education courses in pharmaceutical sciences not available
Madagascar	University of Antananarivo	Chemistry Masters in Pharmacology Masters in Physical Chemistry Masters in Natural Products Chemistry	Part-time courses or continuing education courses in pharmaceutical sciences not available

Malawi	University of Malawi	B. Pharm.	Part-time courses or continuing education courses in pharmaceutical sciences not available
	Mzuzu University	Chemistry	Part-time courses or continuing education courses in pharmaceutical sciences not available
Mauritius	University of Mauritius	Chemistry	Part-time courses or continuing education courses in pharmaceutical sciences not available
Mozambique	Universidade Eduardo Mondlane	Chemistry	Part-time courses or continuing education courses in pharmaceutical sciences not available
	Universidade Pedagogica	Chemistry	Part-time courses or continuing education courses in pharmaceutical sciences not available
Namibia	University of Namibia	Chemistry	Part-time courses or continuing education courses in pharmaceutical sciences not available
Seychelles	University of Seychelles	Chemistry	Part-time courses or continuing education courses in pharmaceutical sciences not available
South Africa	North-West University (South Africa)	B.Pharm. M.Sc. Pharmaceutics, M.Sc. Pharmaceutical Chemistry Ph.D. (Pharmaceutical sciences) Engineering	
		Short courses in pharmaceutical formulation for industry personnel	Short learning programmes (SLP) aimed at persons with industry experience (a B.Pharm. degree is a requirement). Of relevance here are the SLP for Tablet and Capsule Manufacturing and Quality Assurance in the Pharmaceutical Manufacturing Industry. Duration varies from 3 months to 1 year. The short courses are given as distance learning and consist mostly of module work. The primary method of course delivery and communication is online, in

		English, through the universities educational platform, *eFundi*
Stellenbosch University (South Africa)	Postgraduate diploma in pharmaceutical medicine Engineering	Diploma aims to expand knowledge and skills in pharmaceutical medicine specifically non-clinical and clinical drug development, regulatory affairs, marketing of pharmaceutical products and drug safety / pharmacovigilance. The programme extends over two years and is presented by means of contact sessions as well as self-study assignments
Tshwane University of Technology (South Africa)	Degrees in Pharmaceutical Sciences: B.Tech., M.Tech. and D. Tech. Industrial Engineering	The B.Tech. course is aimed at persons who would like to enter the clinical research environment as clinical trial monitors. It is a part-time course
	Short course: An introduction to managing and monitoring clinical trials	A short course in introduction to managing and monitoring clinical trials including topics such as preparing regulatory and ethical submissions and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), GCP, and other relevant guidelines, regulations and legislation
University of the Western Cape (South Africa)	B.Pharm. M. Pharm. M.Sc. (Pharmaceutical Science) Ph.D. D. Pharm.	
	M.Sc. (Regulatory Sciences)	The MSc. in regulatory sciences is offered together with Hibernia College, Dublin, Ireland. It has online delivery and is designed to allow busy professionals to fit their studies around work. The duration is two years. Approx. costs €12,000 for the M.Sc.

			Regulatory Sciences (partial scholarships available)
	University of the Witwatersrand (South Africa)	B.Pharm., B.Sc.Honours (Pharmacology), M.Sc.(Med.) Research M.Sc.(Med.) Pharmaceutical Affairs Industrial Engineering	The M.Sc. (Med.) Pharmaceutical Affairs includes modules on Pharmaceutical Production, Management, Medicines Control, Regulatory Affairs and Medicines Registration, and Pharmacoeconomics. Short courses in engineering sciences available
	University of Pretoria (South Africa)	B.Sc., M.Sc., Ph.D. (Pharmacology), M.Pharm.(Med) Clinical Pharmacology Engineering	Trains clinical research associates and clinical trial monitors
	University of KwaZulu Natal (South Africa)	B. Pharm., M.Pharm. Engineering	All formalized training. No short courses.
		M. Pharm. (online)	Offers an online M.Pharm. aimed at producing professionals who can practise in the area of pharmacoeconomic evaluations, clinical pharmacy services and drug utilization reviews.
	Rhodes University (South Africa)	B.Pharm. M.Sc.(Pharm.) M.Pharm. Pharm.D. Ph.D. D.Sc. Engineering	All formalized training. No short courses.
Swaziland	University of Swaziland	Chemistry	No part-time courses or continuing education courses in pharmaceutical sciences offered

Tanzania	Kilimanjaro School of Pharmacy (KSP) - Saint Luke Foundation (SLF) (Tanzania)	Basic Technician Certificate in Pharmaceutical Sciences Technician Certificate in Pharmaceutical Sciences Ordinary Diploma in Pharmaceutical Sciences	
		Short training programme covering Drug Development, Drug Manufacturing, Regulatory Affairs and Quality Compliance (Industrial Pharmacy Advanced Training Program - IPAT)	IPAT is an advanced training programme for professionals with a background in pharmacy or related sciences with a focus on the pharmaceutical industry. These four modules are offered in a single programme. Each course has 45 contact hours as well as associated homework assignments and examinations.
	Muhimbili University of Health and Allied Sciences (Tanzania)	Diploma in Pharmaceutical Sciences B. Pharm. M. Pharm. M.Pharm. (Industrial Pharmacy) M.Pharm. (Quality Control and Quality Assurance) M.Pharm. (Hospital and Clinical Pharmacy) M.Pharm. (Pharmacognosy) M.Pharm. (Medicinal Chemistry)	
		Short courses in Industrial Pharmacy	MUHAS offers a short course (usually three days) in industrial pharmacy covering qualification and validation in Pharmaceutical

			Manufacturing, Pharmaceutical Analysis (method development and validation), Pharmaceutics (fluid bed drying, granulating and coating, granulation and tableting), Quality Assurance and Quality Control.
Zambia	University of Zambia	Pharmacy	No part-time courses or continuing education courses in Pharmaceutical Sciences appear to be available.
Zimbabwe	University of Zimbabwe	Bachelor of Pharmacy	No part-time courses or continuing education courses in Pharmaceutical Sciences appear to be available. Part-time courses offered for dispensary assistants
	Harare Institute of Technology (Zimbabwe)	Bachelor of Pharmacy B. Tech. (Hons.) Pharmaceutical Technology Engineering	No part-time courses or continuing education courses advertised
	Medicines Control Authority of Zimbabwe		The Medicines Control Authority of Zimbabwe (MCAZ) is a public institution responsible for regulation of pharmaceutical and medical devices in Zimbabwe. MCAZ's laboratory is used to offer training/short courses for the pharmaceutical industry on topics including analysis and quality control of samples. No online training is available; set schedules for training available.
	National University of Science, and Technology (Zimbabwe)	Chemistry, Engineering	No part-time courses or continuing education advertised

Short courses and online courses relevant to industrial pharmacy include that offered by North-West University (NWU) in South Africa in Pharmaceutical Formulation, the Advanced Training Programme in Industrial Pharmacy offered by the Kilimanjaro School of Pharmacy (KSP) – St Luke's Foundation (SLF) and Pharmaceutics, Pharmaceutical Manufacturing and Analysis courses offered by the Muhimbili University of Health and Allied Sciences (MUHAS), both in Tanzania.

The last two programmes were cited by the Pharmaceutical Manufacturing Plan for Africa (PMPA) as being strategic to capacity building and growth of local pharmaceutical production. Both are focused on industrial pharmacy and are aimed at persons already working in the industry. The Kilimanjaro School of Pharmacy (KSP) – St Luke's Foundation (SLF) offers an advanced training programme in industrial pharmacy under its Industrial Pharmacy Teaching Unit (IPTU) in collaboration with Purdue University and Howard University, USA. The Industrial Pharmacy Advanced Training Program (IPAT) consists of four courses - Drug Development, Drug Manufacturing, Regulatory Affairs, and Quality Compliance. Each course has 45 contact hours as well as associated homework assignments and examinations. IPAT is flexible in that upon enrolment the student is given six years to complete the programme which includes practical assignments that can be carried out at the student's workplace. KSP plans to expand IPAT to offer a Purdue University Masters Degree and the current curriculum of four, two-week courses in Industrial Pharmacy will then be augmented by six additional courses and a research topic for a thesis.

So far, 45 participants from seven African countries - DRC, Ghana, Kenya, Lesotho, Nigeria, Tanzania and Uganda - have successfully completed the programme. IPTU has a fully equipped mock production facility for training students. The costs of the programme are reasonable (less than US$1,800 per module) and could be within reach of most pharmaceutical companies. However, air flights and accommodation may add to the expenses. Currently, UNIDO provides scholarships to selected applicants.

The Pharmaceutical Research and Development Laboratory at Muhimbili University of Health and Allied Sciences (MUHAS) in Tanzania has some bench-top equipment for formulation development and offers short courses in qualification and validation in Pharmaceutical Manufacturing, Pharmaceutical Analysis (method development and validation), Pharmaceutics (fluid bed drying, granulating and coating, granulation and tableting), Quality Assurance and Quality Control. Action Medeor, a German aid agency, is also involved as a collaborating partner and sponsor. The short-course programmes cover several aspects of pharmaceutical production, from drug discovery to quality assurance and regulatory affairs. They also occasionally run short courses in specialized areas; one example of this was a three-day course in tablet coating run by the pharmaceutical company, BASF.

The Research Institute for Industrial Pharmacy (RIIP) at North-West University in South Africa incorporates the Centre for Quality Assurance of Medicines (CENQAM). This is a WHO Prequalified Laboratory for the purpose of monitoring the quality of medicines and a WHO Collaborating Centre for the Quality Assurance of Medicines. It houses analytical equipment for pharmaceutical quality control and has capacity to provide short-course training for pharmaceutical personnel.

Tshwane University of Technology in Pretoria, South Africa has a Department of Pharmaceutical Science which trains pharmacists (through a joint programme with the University of Limpopo MEDUNSA Campus also in South Africa). In addition, and of relevance to this study, is their B. Tech. (Pharmaceutical Science) programme which is available at postgraduate level and is aimed at entrants into industry. The programme runs for the whole year with Saturday lessons. It consists of six modules covering clinical trial management, quality systems (Good Clinical Practice - GCP) and cGMP, biopharmaceutics, registration of medicines and formulation. The students conduct simulated practicals in class. The programme is popular with persons already employed in the pharmaceutical industry, particularly clinical research associates and medicine registration personnel.

TUT has a strong pharmaceutical sciences grounding with well-equipped laboratories and a mock factory with tableting, dissolution and other pharmaceutical production apparatuses as well as a sterile manufacturing facility for undergraduate teaching. There is the possibility of expanding the B.Tech. (Pharmaceutical Science) programme to have more practical pharmaceutical science content and practicals in the mock factory. Such an offering would then target shop floor technical personnel in industry and would be available in a variety of delivery formats. SAGMA could facilitate this process through its members and international partners.

Elsewhere in SADC, only formal training at undergraduate and postgraduate level in other professions required by the pharmaceutical industry, notably chemistry and engineering disciplines, is available. From the available evidence, none of these universities currently offers short training courses relevant to Industrial Pharmacy.

The study noted a report recently commissioned by the South African Department of Trade and Industry (DTI) on the Pharmaceutical Industry in South Africa in which the respondents from industry bemoaned the fact that university graduates are inadequately equipped to work in industry and that the science, engineering and technology, and pharmaceutical curricula are not an adequate response to industry needs[27]. The PMPA also cited this problem as being continent-wide and a likely barrier to development of the pharmaceutical industry if not urgently addressed[28].

[27] *Department of Trade and Industry (DTI). 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.*
[28] *AUC – UNIDO. Pharmaceutical Manufacturing Plan for Africa. Addis Ababa. November 2012.*

In relation to short courses, the study observed that current training is skewed towards regulatory affairs and clinical trial management. There is a need for additional short courses in Industrial Pharmacy, business topics such as Supply Chain Management, and informative topics such as the requirements for WHO Prequalification. Moreover, the current offerings in Industrial Pharmacy could be expanded to include more advanced subjects such as Quality by Design principles and bioavailability and bioequivalence (BA/BE) testing. Practical components could be strengthened through partnering with KSP-SLF, MUHAS, TUT and NWU all of which have mock industry facilities.

No short courses relevant to the direct operations of wholesalers such as short courses on Good Wholesaling Practice and Supply Chain Management are available in the SADC region. Nor are there any specific courses offered in the region on plant operations for artisans and pharmaceutical engineers. There is therefore a disconnect between pharmacy on the one hand and engineering sciences on the other hand.

In general, public institutions charge relatively low fees compared with private institutions and their offerings are of assured quality as they are accredited by the higher education quality standards authorities. In addition, public institutions may be more accessible and their training is more sought after as it is recognized for Continuing Professional Development credits and credentialing. These institutions are also amenable to partnering with international agencies and the private sector. There is clear potential when negotiating with other HEIs within SADC to design and offer short courses in Industrial Pharmacy as well as other areas which are currently neglected, especially wholesaling, Supply Chain Management, and engineering.

3.1.5.1 Private institutions offering industrial pharmacy-related training

A mapping of private institutions within SADC offering training to the pharmaceutical industry in Southern Africa was conducted using online searches and discussions with key informants. Six of the organizations identified are based in South Africa and one organization, Stratdigm Consultancy, is based in Zimbabwe. They are mainly active in their respective countries although some expressed willingness to carry out training in the wider region. Since training fees are quoted on the basis of various metrics such as number of delegates and duration of the course, exact figures cannot be given here. The range of training offered is described in Table 3.9.

Table 3.9: Private institutions in Southern Africa offering pharmaceutical industry related training

ORGANIZATION	COURSES OFFERED					MODE OF DELIVERY	
	GMP	SCM	RA	QC/QA	FD	ONLINE	CONTACT
SGS	X	X					X
Health Science Academy	X		X	X			X
PZC Healthcare	X						X
PharmOut	X			X		X	X
BC Compliant	X					X	X
Quadpharma	X		X				X
Stratdigm	X				X		X

Key: GMP (Good Manufacturing Practice), SCM (Supply Chain Management), RA (Regulatory Affairs), QC/QA (Quality Control/Quality Assurance, FD (Formulation Development)

As discussed earlier, training programmes are currently skewed towards regulatory affairs and GMP and are offered through contact sessions which may not be convenient because participants will have to incur travel and accommodation costs as well as time away from the workplace. In addition, in the absence of harmonization, their training material might not be relevant from country to country. To drive local pharmaceutical production towards achieving international standards and competitiveness, a more diverse range of training is required with distance learning or e-learning options.

The study observed that there is a lack in the region of private providers of training aimed at artisans and engineers working in the industry, as well as for wholesalers. The advantage of using private providers is that they can design and develop programmes at short notice whereas HEIs have to go through a long bureaucratic process. They can also be more creative and flexible in migrating to online courses in a short period of time.

3.1.5.2 Training for artisans and engineers in the pharmaceutical industry

Training in engineering was found to be generally confined to structured programmes leading to academic qualifications at universities and technical institutions. Anecdotal evidence indicates that most engineers working in the pharmaceutical industry in Africa achieved their skills by way of mentoring and apprenticeships. To support LPP, additional skills which may be required could include fabrication, tooling design and plant operations and maintenance. The study noted that there are short courses offered by the University of the Witwatersrand and the Tshwane University of Technology. The former has a five-day Fabrications Applications engineering course which covers quality assurance in welded fabrication, quality control during manufacture, plant facilities, welding jigs and fixtures and health and safety. Such a course may serve as a refresher course for participants from the pharmaceutical industry or serve as a platform for more advanced training. Historically, most engineering courses in

South Africa are targeted at mining but the study observed that institutions are willing to collaborate with industry and, with lobbying by SAGMA, courses directed at the pharmaceutical industry could be developed.

3.1.5.3 Institutions offering business and management development training

The results of mapping short courses in management and business skills available to the pharmaceutical industry in the region are shown in Table 3.10. A similar situation to that of technical skills training was noted, whereby short courses were mostly available in South Africa. While other African countries do offer management and executive development programmes, these are structured programmes such as MBAs and have thus been excluded from the mapping.

Table 3.10: Short courses in management development and institutions offering them in Southern Africa

Institution	Management development	Executive development	Project management	Others
University of Stellenbosch Business School (USB)	Executive development programme (EDP) (*two modules each of two weeks duration*) Senior management development (SMD) *(three modules each of five days duration*)	Master Class in Strategy (*two day course*) Commercial negotiation *(three day course)*	Fundamentals of project management (*five day course*) Project management (*five day course)* Project management for engineers *(five day course)*	Supply Chain Management (SCM) *(three day course)*
Witwatersrand Business School (WBS)	Master of management in strategic marketing Certificate programme in marketing management *(five modules each of three day blocks spread over four months)* Product strategy and brand management *(three day course)* Strategic marketing management *(four day course)*	International Executive Development Programme *(four week course)* Thinking and planning strategically *(four day course)*		
UNISA (Graduate School of Business Leadership)	Fundamental Management Programme (FMP) *(one year, distance and e-learning education)*	Executive Development Programme (EDP) *(one year, distance education)*	Advanced project management *(one year, distance education)*	
University of Cape Town Graduate School of Business (GSB)		Strategic marketing in emerging economies *(four day course)* Strategic thinking and execution for growth *(three day course)*		Bio business course including the topics: from science to business; from molecule to market; and biopharma research management *(online delivery- webinar series)*
Tanzania Business School	Management Development Programme (MDP) for business owners and managers *(14 day programme)*			

Most notable among the management courses are the short courses offered by USB in view of their diversity and flexibility. USB offers courses in Cape Town, Johannesburg, Gaborone, Namibia and Nigeria. The USB Master Class in Strategy is a two day course aimed at sharpening the strategic alertness of business leaders. Participants are equipped to create sustainable competitive advantages for their organizations through exposure to a combination of practical, experiential and theoretical best practices in the domain of strategic management. The commercial negotiation course at USB is offered in conjunction with the Africa Centre for Dispute Settlement, also part of USB, and this programme equips managers with skills in preparing and negotiating in a manner that ensures success.

The Witwatersrand Business School (WBS), which offers courses in both business and executive development ranging in length from 20 months to four days, is the only business school in Africa to have been admitted to the Partnership in International Management (PIM). PIM is a consortium of leading international business schools which facilitates inter-institutional cooperation, fosters the development of joint programmes and the exchange of students and staff. The University of Cape Town's Graduate School of Business (GSB) offers a Bio Business course which incorporates elements of the traditional pharmaceutical business environment. The course is delivered online through webinars and would thus be convenient for SAGMA members across Southern Africa. The fact that GSB has such a course indicates potential for developing a similar course more tailored to the generic pharmaceutical industry.

While the short courses available in Southern Africa appear comprehensive enough to cover the broad needs of executive education, a notable course available from an international business school is that offered by Duke University in the USA. The Fuqua School of Management at Duke runs a health sector management programme which includes courses in pharmaceutical management and strategy in emerging markets offered through distance and e-learning platforms and offers potential for future collaboration with HEIs in the SADC region.

3.1.5.4 Independent consultants

There are a number of independent consultants who currently offer training on an *ad hoc* basis and who serve mostly the small and medium enterprises in the region. Such consultants are generally more affordable than formal conventional service providers as they have lower overheads and they are also flexible in terms of availability and readiness to travel. One key informant suggested that seconding consultants or trainers to companies on long-term contracts (six to twelve months) with specific objectives of, for example, setting up and running a BA/BE study would be helpful, especially for companies which have little technical support. He indicated that many companies would be willing to pay for such services.

3.1.6 MAPPING OF INTERNATIONAL TRAINING PROVIDERS

Given the competitive nature of the pharmaceutical industry, Continuing Professional Development (CPD) is an indispensable strategy for keeping ahead in a global environment. There are a number of international agencies, including global health organizations, which are particularly interested and keen to support LPP in African countries. The training they offer is summarized in Table 3.11.

Table 3.11: Summary of types of training available through international organizations

ORGANIZATION	COURSES OFFERED								MODE OF DELIVERY	
	GMP	SCM	RA	QA/QC	BA/BE	HVAC	PFE	FD	ONLINE	CONTACT
USP	X		X	X						X
WHO	X		X	X				X		X
FIP			X	X				X		X
NIPER	X		X	X	X			X		X
ISPE	X	X				X			X	X

Key: GMP (Good Manufacturing Practice), SCM (Supply Chain Management), RA (Regulatory Affairs), QA/QC (Quality control/Quality Assurance), FD (Formulation Development), BA/BE (Bioavailability/Bioequivalence), HVAC (Heating, Ventilation, and Air Conditioning), PFE (Premises Facilities and Environment)
USP = United States Pharmacopeial Convention; WHO - World Health Organization; FIP = International Pharmaceutical Federation; NIPER = National Institute of Pharmaceutical Education and Research (India); ISPE = International Society for Pharmaceutical Engineering

The study observed that one shortcoming of training offered by most international organizations is that it is largely contact based. However, these organizations could be approached to develop longer term, sustainable training, such as e-learning programmes. More detailed comments on such agencies are given below.

3.1.6.1 United States Pharmacopeial Convention (USP)

The United States Pharmacopeial Convention (USP) operates a programme called Promoting the Quality of Medicines (PQM), funded by the United States Agency for International Development (USAID). PQM works with manufacturers and collaborates with international health organizations to increase the supply of quality assured medicines, specifically those used to treat diseases on the USAID priority disease list. The programme assists manufacturers to achieve WHO Prequalification (PQ) of medicines. PQM currently operates in ten African countries. In Tanzania, the programme has helped to prepare manufacturers for WHO Prequalification application and presented a number of workshops on medicine quality. In the other nine countries, PQM activities have mainly centred on strengthening regulatory authorities.

Recently, the USP launched the Centre for Pharmaceutical Advancement and Training (CePAT) in Accra, Ghana. This centre is a purpose-built facility meant to serve the training needs of pharmaceutical personnel from Sub-Saharan Africa (SSA). The programmes include comprehensive training in the QC and QA of medicines, including hands-on Laboratory Training, Laboratory Quality Management Systems and GLP, GMP certification of laboratory

personnel in QC procedures and supply chain integrity. CePAT appears to be an excellent initiative likely to positively impact pharmaceutical quality control in SSA, and SAGMA should forge alliances with it as soon as possible. The study observed that wholesalers could benefit from the training offered by CePAT on supply chain integrity and QA of medicines.

3.1.6.2 World Health Organization (WHO)

The World Health Organization (WHO) has the global mandate to ensure good quality essential medicines are available to the public. In pursuing this goal, WHO organizes various training workshops aimed at the pharmaceutical industry and also operates the prequalification (PQ) scheme which assures the quality and safety of certain types of medicines[29] purchased and distributed by the main procurement funds. The companies achieving PQ status are able to increase product market penetration as procurement funds and International Cooperating Partners (ICPs) purchase only prequalified products and usually in large quantities.

However, prequalification is currently limited to medicines and active pharmaceutical ingredients (API) used for malaria, tuberculosis, HIV/AIDS, diarrhoea (zinc-containing products) and reproductive health[30]. Moreover, few African pharmaceutical companies currently manufacture or have capacity to formulate and manufacture these items. For those that do currently manufacture products falling into this category, attaining prequalification is advantageous as it opens up new markets and, with requirements similar to those of ICH and PIC/S signatories, it can be a stepping stone towards entry into these lucrative OECD countries.

WHO also offers various training programmes for the pharmaceutical industry upon request. Previous topics have included Pharmaceutical Development with a Focus on Paediatric Formulations (Singapore, 2012); GMP for Pharmaceutical Manufacturers and GMP Inspectors (Nairobi, 2011); Quality Documentation of Generic Medicines in CTD (Common Technical Document) Format (Harare, 2011); Regulatory Assessment of Stability Studies (Ghana 2009); and Pharmaceutical Quality, Good Manufacturing Practice and Bioequivalence with a focus on Artemisinins (Tanzania 2006).

In 2012, SAGMA facilitated participation of members in a workshop that was jointly conducted by the Promoting the Quality of Medicines (PQM) programme of the US Pharmacopeial Convention (USP), the Global Drug Facility (GDF), the Green Light Committee (GLC), and the World Health Organization (WHO) to inform manufacturers about the WHO Prequalification programme, the technical assistance provided towards prequalification, and the outlook for the global TB medicines market. Such collaboration should be expanded with further activities.

[30] *WHO http://apps.who.int/prequal/ (accessed 20 May 2013).*

3.1.6.3 The United Nations Conference on Trade and Development (UNCTAD)

UNCTAD promotes 'the development-friendly integration of developing countries into the world economy'[31] and was mandated by its Commission on Investment, Technology and Related Financial Issues to engage in work related to the local manufacturing and supply of pharmaceutical products in the context of Millennium Development Goal No. 8, Target 17, which states: 'In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries'.

The Commission recommended that 'UNCTAD should, within its work programme on investment, technology transfer and intellectual property, assess ways in which developing countries can develop their domestic productive capability in the supply of essential drugs in cooperation with pharmaceutical companies'[32]. Its Intellectual Property Unit has expertise in intellectual property and its impact on Local Pharmaceutical Production in Africa, especially the use of TRIPS Flexibilities. As part of a joint SAGMA-UNIDO-UNCTAD collaboration, a 'Capacity Building Workshop on Intellectual Property Rights and Local Pharmaceutical Manufacturing in the Southern Africa Region' took place in Johannesburg in April 2013.

UNCTAD also offers a Blended Learning Course[33] which outlines how TRIPS Flexibilities can be used to promote Local Pharmaceutical Production. The course consists of a three-month e-learning module which is framed by two workshops, one at the start and the other at the end of the course.

3.1.6.4 The United Nations Industrial Development Organization (UNIDO)

UNIDO has been implementing a global project to strengthen the local production of essential medicines in developing countries with a focus on Africa since 2006. Interventions have focused on providing advisory and capacity building services to the public sector, industry and support institutions at different levels of intervention. Aspects of the project of particular relevance to training are described below:

At continent level, UNIDO is cooperating with the African Union Commission on the implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA) and has co-authored the PMPA Business Plan (PMPA BP). It is leading the consortium of partners who will implement this Business Plan, in particular in Ghana, which serves as the pilot country for PMPA implementation. In parallel, UNIDO is working on the solution packages described in the Business Plan where training and human resource development are acknowledged as key factors in the pharmaceutical sector's development on the African continent. Other areas such as GMP improvements (GMP Road Map), incentives, access to capital, building regulatory capacity, partnerships and business linkages, technology and

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[31] http://unctad.org/en/Pages/AboutUs.aspx *(accessed 20 May 2013)*

[32] http://unctad.org/en/Pages/DIAE/Intellectual%20Property/Building-local-pharmaceutical-production--supply-capacity.aspx *(accessed 20 May 2013)*

[33] *"Intellectual Property, Public Health and Local Pharmaceutical Production"*

market data are also mentioned. UNIDO is involved in these issues and will continue to work towards expansion of training capacities in African countries as part of the PMPA Business Plan implementation.

At national level, the project supports the process of strategy building for pharmaceutical sector development and accompanies the implementation of key elements of these strategies, working with all relevant stakeholders. Training is one component and, for example, a four day GMP training course for industry in Kenya was designed and took place in 2013. There will be a follow-up three day training session for regulatory staff in 2014. A one day training course on GMP for industry executives is currently under development and will complement the technical training in order to raise awareness among senior management of the need for investment in GMP.

In addition, UNIDO has assisted institutions that support the pharmaceutical manufacturing sector. Notably, it has facilitated the establishment of the Southern African Generic Medicines Association (SAGMA) and the Federation of African Pharmaceutical Manufacturers' Association (FAPMA) and continues to support these associations in fulfilling their advocacy and service provision functions. Under the PMPA BP, associations have a role in making training accessible to companies and consequently this study is intended to assist SAGMA to make informed decisions on forthcoming training activities of relevance to the pharmaceutical industry.

Moreover, at the institutional level, UNIDO is working with the Kilimanjaro School of Pharmacy - St. Luke Foundation in Moshi, Tanzania where it sponsors a programme for professionals from the private sector and regulatory authorities which includes participation in the Industrial Pharmacy Advanced Training Program (IPAT) course. Forty-five participants have already completed the course, with a further 23 set for completion in March 2014. UNIDO is also supporting Ibadan University in Nigeria to replicate the IPAT course as part of the training available at its Centre for Drug Discovery Development and Production (CDDDP).

3.1.6.5 International Pharmaceutical Federation (FIP)

The International Pharmaceutical Federation (FIP) is a global organization representing at least three million pharmacists and pharmaceutical scientists. A special interest group exists on Formulation Design and Pharmaceutical Technology offering networking opportunities and professional development, including continuing education relevant to the pharmaceutical industry. Continuing education and training workshops include updates on Pharmaceutical Manufacturing Science and Practice, Biotechnology, QC/QA and Regulatory Affairs. A working group of particular interest to SAGMA would be the one on analytical sciences and pharmaceutical quality. This group provides educational opportunities for researchers, academics and manufacturers to develop knowledge in analytical science and pharmaceutical quality. It also provides a platform for experts in the analytical science and pharmaceutical quality disciplines to discuss the most recent progress in innovative approaches and technologies,

including separation science, spectroscopy analysis and surface analysis and to address current and future needs and challenges. SAGMA has not had any contact with FIP to date.

3.1.6.6 The National Institute of Pharmaceutical Education and Research (NIPER)

The National Institute of Pharmaceutical Education and Research (NIPER) is an autonomous body set up by the Indian Government in 1998 and based in S.A.S. Nagar (Mohali) in the State of Punjab. The Institute was conceived to provide leadership in pharmaceutical sciences and related areas not only within India but also in countries in South East Asia, South Asia and Africa. The main objectives of NIPER are to nurture and promote quality and excellence in pharmaceutical education and research and to collaborate with the Indian pharmaceutical industry to help it meet global challenges. It is a designated Centre of Excellence for Advanced Studies and Research in Pharmaceutical Sciences and, in particular, for Industrial Pharmacy. In order to keep pharmacy professionals acquainted with the latest developments in the field of pharmacy, the Institute conducts specialized training in the following areas:

- GMP/GLP validation procedures in pharmaceutical industry
- Standardization of herbal products
- Modern analytical techniques for quality assurance
- Impurity profiles of bulk pharmaceutical chemicals and their formulations
- Degradation chemistry and stability testing of drugs and pharmaceuticals
- Bioavailability and bioequivalence of pharmaceutical dosage forms
- Documentation in pharmaceutical research, development and manufacturing
- Regulatory toxicology
- Scale up techniques in the pharmaceutical industry; and
- Pharmaceutical project management

NIPER has a Small and Medium Pharmaceutical Industry Centre (SMPIC) which offers capacity building programmes to meet the needs of the Small and Medium Enterprise (SME) pharmaceutical sector. The Centre provides access to equipment on a cost sharing basis to SMEs as well as access to expert opinion of faculty members in solving specific problems for the industry.

3.1.6.7 International Society for Pharmaceutical Engineers (ISPE)

The International Society for Pharmaceutical Engineers (ISPE), with headquarters in Tampa, Florida, USA, was founded in 1980 and caters to the needs of technical and artisanal professionals in the pharmaceutical industry who deal with practical applications of science and technology. The ISPE has at least 22,000 members in 90 countries worldwide and aims to keep industry professionals informed of the latest technological and regulatory trends.

The present survey revealed that there appear to be no organizations in Africa providing training specific to pharmaceutical manufacturing such as sterile products manufacture, process analytical technology, packaging and biotechnology. ISPE is of particular relevance in this respect since it offers online (e-learning) training modules on topics which include:

- Commissioning and qualification of equipment
- Quality systems
- Regulatory compliance
- Supply Chain Management
- Critical utilities
- Engineering benchmarking standards
- Facilities and equipment
- Good Control Laboratory Practices
- Heating, Ventilation, and Air Conditioning
- Packaging
- Process analytical technology
- Product process development
- Project management
- Sterile Products Processing; and
- Sustainable Facilities

ISPE member chapters and affiliates can benefit from networking, event-workshop organization and education sharing seminars but there seem to be no member chapters or affiliates in Africa

3.1.6.8 Cogent SSC (UK)

Cogent is the Sector Skills Council (SSC) for the chemicals, pharmaceuticals, nuclear, life sciences,petroleum and polymer industries in the UK. Cogent is licensed by the UK Government to help employers in these sectors address their workforce development needs and become globally competitive. It has established 'gold standards', that is, national frameworks for training personnel with, for instance, frameworks for Process Operators, Process Setter Operators and Process Technicians. These frameworks address preparation, purification, isolation, drying and milling and packaging of pharmaceutical products in accordance with current good manufacturing practice (cGMP) and health and safety practices. Cogent also runs a structured apprenticeship programme which 'gives the learner the opportunity to work for an employer, learn on the job and build up knowledge and transferable skills'[34]. Students

[34] *http://www.cogent-ssc.com/Apprenticeships/index.php (accessed 20 May 2013).*

may gain apprenticeships as process operatives, engineering maintenance operatives (electrical, mechanical and instrumentation) and laboratory assistants. The Council is also concerned with the career pathways of graduates from the apprenticeship programmes. It provides a well-integrated capacity and career building programme. This study found that some SAGMA members are willing to be involved in work placement programmes for students. Adopting the Cogent SSC model of apprenticeships would be advisable as it is deemed successful and SAGMA can facilitate information sharing with Cogent SSC in this respect.

4.1 RECOMMENDATIONS

The case for local production of pharmaceuticals in Africa has gathered momentum over the past decade. However, the industry remains weak for various reasons such as lack of access to capital, inappropriate government policies, tariff structures which favour low-cost imports from India and China, a poor regulatory framework and a labour force which is insufficiently skilled.

Wright and others have noted that the pharmaceutical industry operates in a highly dynamic market and that companies can only maintain their viability and competitiveness by having a labour force which is highly skilled and keeps up to date with new developments and innovations[35]. Therefore, if pharmaceutical companies in the SADC region are to become regionally and globally competitive, there is a need for strategies to build and maintain the skills base of their labour force. Continuing training is also required by regulatory agencies for those companies which operate or would like to operate in a quality system such as cGMP. The US Food and Drug Administration (FDA), for example,requires that 'Under a quality system, continued training is critical to ensure that the employees remain proficient in their operational functions and in their understanding of cGMP regulations'[36].

Such training should focus on the policies, processes and procedures for all operational activities to ensure that employees remain proficient in their functions. Effective programmes for the pharmaceutical industry should be of high quality content, format and presentation[37]. The content should be composed of current, appropriate and relevant material to capacitate employees to improve their performance and overall productivity. Formal assessment to evaluate and demonstrate to what extent an employee has learned and can apply his/her new knowledge should ideally be included. It must also mitigate compliance risk by meeting the expectations of National Medicines Regulatory Authorities. In 2011, US companies spent about US$156 billion on training their employees[38]. However, research suggests that, if there is no practical follow-up or meaningful assessment, some 90% of new skills are lost within a year (decay).

This study observed that there is a need for companies to be assisted in training employees from executive level to the shop floor as well as at the human resources level. This will result in improved productivity and competitiveness as well as enhancing the business health of the enterprises and will consequently promote the local production agenda.

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[35] Wright, S., Fleisher, C.S. & Madden, E. 2008. 'Characteristics of Competitive Intelligence. Practice in R&D Driven Firms: Evidence from the UK Pharmaceutical Industry', European Business Research Forum (EBRF), Finland.

[36]Guidance for Industry: Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations. 2006.(http://www.fda.gov/cder/guidance/7260fnl.pdf)

37 http://www.ngpharma.com/article/Achieving-a-world-class-quality-training-program/ (accessed 9 May 2013).

[38]Rachel Emma Silverman. So Much Training, So Little to Show for It. Wall Street Journal. http://online.wsj.com (accessed 11 May 2013).

It is recommended that, as a starting point, companies should be encouraged to put programmes in place which are informed by policies, needs and capacity assessments. Delivery modes which are inexpensive and easily accessible should be used for capacity building. The programmes should be of high quality, meet the specific objectives and requirements of companies and NMRAs, include formal assessments and incorporate practical follow-up.

Based on the findings of this study, it is recommended that SAGMA should communicate training opportunities more clearly in future. Further, the Association should work towards setting up good quality Executive Management Programmes which are marketed separately from technical programmes. In addition, there should be a training calendar with a healthy mix of the two. For ease of reference, detailed recommendations are tabulated below.

The priorities for training identified by stakeholders are listed in Table 4.1. The respondents see these as needs which are pressing and should be met in the short term, i.e. within 6 to 18 months.

Table 4.1: Training priorities identified by respondents

General	Management and business	Pharmaceutical validation and technology	Regulatory affairs	Wholesale and Distribution
Introduction to pharmaceutical quality assurance systems e.g. GMP, GDP, GWP, etc.	Strategic planning / Business planning	Analytical methods validation for NMRA compliance	Dossier compilation for NMRAs	Ensuring product safety and security
Documentation Management and Control	Operations and general management	Laboratory control system	Applied cGMP for pharmaceutical and related industries	Vendor and contract supplier qualification
cGMP for production supervisors/ laboratory personnel / executives	Financial management and investment	Water sampling and testing	Risk management	Systems for product recall and returned goods
IP protection	Pharmaceutical Supply Chain Management	Drug product stability and shelf life	Bioavailability and bioequivalence testing	Good Distribution Practices
TRIPS flexibilities	Marketing			Environmental control and monitoring
Preparing for NMRA inspection				Handling and distributing food supplements, additives and herbal medicines
Introduction to international patent law				Warehouse management
Environmental control and monitoring				Building internal monitoring and auditing
Overview of Regulatory affairs				Distribution and storage of cold chain and controlled drugs
				ICT to support wholesaling supply chain

The tables below make more general recommendations which have been divided into delivery mode, encouraging collaboration, capacity building programming and membership broadening. These were not necessarily included in the terms of reference of the study but they were important findings which need to be addressed.

Table 4.2: Recommendations on preferred modes of delivering training

Major challenges	Recommendations
Most companies only willing and able to spend around US $300 per day per individual	Negotiate for better rates with service providers. Reduce travel expenses for companies by having training in different countries. SAGMA should promote the use of technology such as webinars and e-courses to reduce the costs of face-to-face training platforms. For example, the University of Zimbabwe has a Virtual Lecture Hall with broadband connection where trainees can congregate and link up with ongoing proceedings in South Africa or Tanzania.
DVD self-learning material is the most popular off-site learning mode	SAGMA should negotiate with trainers, especially USP, NIPER and WHO, to obtain licensing and distribution rights for quality accredited DVD training materials, which could also produce an income stream. SAGMA should have an internet shop on its website to market training material and other branded products.
The quality of courses offered and the credentials of private trainers are generally unknown	SAGMA should establish an accreditation system. This can be conducted through an education and skills development committee which reviews material offered to members. In addition, a dashboard/database of training organizations and independent consultants in the region should be developed and maintained by SAGMA. This will be a resource pool which can be tapped into by members.
Most training offered is through contact sessions	SAGMA should negotiate with providers to develop more e-learning/online courses to increase members' accessibility to courses.
Training based in Southern Africa is concentrated in South Africa	SAGMA should negotiate with HEIs to set up training nodes for members elsewhere in the region; for example in Zimbabwe, Zambia, and DRC.
Most workshops are being held in South Africa	South Africa is easily reachable by air and road as it serves as a regional hub. However, SAGMA should have a training calendar which rotates training to other countries to allow for exchange of on-the-ground challenges and experiences.

Table 4.3: Recommendations on building strategic collaboration with Higher Education Institutes in Southern Africa

Major challenges	Recommendations
University graduates in the region are not equipped to work in the pharmaceutical industry	SAGMA should have a long term strategy to engage with HEIs in order to influence curricula and increase the industrial pharmacy focus.
Involvement of HEIs and national associations in training for industry is insufficient	SAGMA needs to address barriers such as lack of interest from industry in HEIs by creating a market for HEI pharma specific training which reflects the real needs of industry. It should negotiate with HEIs to set up training nodes for members and encourage a mix of faculty from industry and university, thus combining practical experience with theory. Specifically, it should negotiate with KSP, MUHAS, University of Zimbabwe and Tshwane University of Technology (TUT) to deliver regular programmes which are based on this study's findings.
Business Schools do not offer pharmaceutical specific options in their training programmes	SAGMA should encourage HEIs/Business Schools to expand their executive business training programmes to include pharmaceutical specific topics such as mergers and acquisitions, international patent law, intellectual property rights, and Good (Anything...) Practice quality guidelines and regulations (GxP) systems. Industry representatives could be co-opted as part-time faculty members and programmes could be organized as summer or winter schools similar to mini-MBAs.
Need for training in pharmaceutical manufacturing, analysis, pharmaceutics, quality assurance and quality control	SAGMA should approach MUHAS and KSP in Tanzania as well as their sponsors to examine the scope for specialist training and scholarships. It should also examine possibilities for short training courses with the Research Institute for Industrial Pharmacy (RIIP) at North-West University and Tshwane University of Technology in South Africa.
Need for pharmaceutical specific business courses	SAGMA could approach the Graduate School of Business at the University of Cape Town to see if it could design a similar course to that on Bio Business but one more tailored to the generic pharmaceutical industry.
Need to collaborate with internationally respected HEIs with experience in pharmaceutical training	SAGMA could approach Duke University in the USA, which already has healthcare centred courses, for assistance in designing similar training tailored to the context of the Southern African pharmaceutical industry and targeting pharmaceutical executives. It should also encourage collaboration between Duke and business schools in the region.
No partnerships exist between local HEIs and international training agencies	SAGMA should coordinate training programmes delivered to the industry via international agencies and selected HEIs in order to enhance capacity in the latter and facilitate technology transfer
No institutionalizing of capacity building	SAGMA should sign a Memorandum of Understanding (MoU) to formalise relationships with selected HEIs, for example, the Kilimanjaro School of Pharmacy. This will help to institutionalise capacity building within SAGMA and also help with planning, and monitoring and evaluation of implementation.
No training available for pharmaceutical artisans and engineers	SAGMA should approach the Engineering Departments of HEIs and encourage them to design and offer short courses to artisans working in the pharmaceutical industry.

Table 4.4: Recommendations on strategic collaboration with other training providers in Africa and elsewhere

Major Challenges	Recommendations
Use of existing training expertise on the African continent is low	FAPMA should be approached to share information with SAGMA on expertise available within the continent and SAGMA should collaborate with the Federation to bring trainers to the SADC region. For example, this could include expertise from the newly opened USP Center for Pharmaceutical Advancement and Training (CePAT) in Ghana. SAGMA should consider organizing at least one continent-wide workshop jointly with FAPMA.
Information is needed on the availability and expertise of independent consultants based in Africa	SAGMA should make contact with independent training consultants and establish an online database to which they can be invited to register. Programmes and material should then be accredited for quality. Consultants who could accept longer term assignments to give in-house technical support to individual companies should also be identified and included in the database.
No organizations in Africa to provide specific technical training on topics such as process analytical technology, sterile products manufacture, etc.	Such needs are well catered for outside Africa and the International Society for Pharmaceutical Engineers (ISPE) with HQ in Florida, USA is just one such example. SAGMA should approach ISPE and negotiate to become part of an African chapter or affiliate. This would allow both SAGMA and its members to access ISPE resources and training programmes at reasonable cost. SAGMA could also broker an alliance between ISPE and Engineering Departments in selected universities and colleges to involve them in designing and delivering relevant programmes to artisans and engineering professionals in the pharmaceutical sector who are neglected in the current capacity building agenda in the region.
Limited availability of training to cater for the specific needs of wholesalers and distributors	SAGMA needs to develop specific programmes for distributors. There are few trainers in this area and initiating discussion with the British Association of Pharmaceutical Wholesalers (BAPW) and WHO is recommended to learn more about their training activities. Training institutions identified in this report, particularly those in SADC, should be approached to develop courses specifically for wholesalers and, in particular, short courses in neglected areas such as Wholesaling and Supply Chain Management.
Limited support available specifically for SMEs	SAGMA should try to replicate NIPER's Small and Medium Pharmaceutical Industry Centre (SMPIC) in India in Southern Africa and should seek assistance from ICPs and HEIs in order to achieve this.
No specific training is available for wholesalers and distributors	SAGMA should approach trainers identified in this study, particularly those in SADC, to develop courses specifically for wholesalers and should initiate discussions with BAPW and WHO for training on PSCM.

Table 4.5: Recommendations on strategic collaboration with international agencies

Major Challenges	Recommendations
Need for more technical training on medicine quality and, in particular, WHO Prequalification of medicines	SAGMA should engage with the United States Pharmacopeial Convention (USP) to assist with training of industry personnel and to identify members who need TA in order to obtain WHO Prequalification (PQ). SAGMA should build on earlier collaboration with WHO on PQ training with at least one WHO workshop organized every two years. It also needs to sensitize members to the process and utility of WHO PQ status.
Need for more information and training on technical issues such as technology transfer, regulatory frameworks, and the strategic position of the pharmaceutical industry	Several international agencies are active in these areas, in particular, UNCTAD, UNIDO and the International Pharmaceutical Federation (FIP). SAGMA should engage with these bodies with a view to training and technical assistance on issues such as technology transfer, regulatory frameworks, formulation design and pharmaceutical technology, IP/TRIPS Flexibilities, etc. There is similar potential for collaboration with the National Institute of Pharmaceutical Education and Research (NIPER) in India. SAGMA should engage with both the Indian Government and NIPER with a view to NIPER providing regular training on specialized API synthesis and characterisation, an area crucial to LPP. NIPER's Small and Medium Pharmaceutical Industry Centre (SMIPC) is also a very relevant model which might eventually be replicated in the SADC region.

Table 4.6: Recommendations to companies and SAGMA on in-house capacity building programmes

Major challenges	Recommendations
No focus on building capacity of less skilled employees, for example, artisans, packers	SAGMA and individual companies should engage with local trade and industry associations and other employee bodies to design and deliver affordable workplace training. In the case of artisans, SAGMA should negotiate with ISPE to become an affiliate and access training material for the pharmaceutical engineering sector. Build alliances with technical colleges.
Lack of (or weak) policies in place within SAGMA member organizations including capacity and career building programmes	SAGMA should collaborate with national chambers of trade and industry for training of HR personnel on capacity building policy formulation and implementation. SAGMA should assist companies to carry out needs and capacity assessments and to develop capacity building policies based on these. This could be done by having model policies developed which companies can adapt and adopt. Programmes can then be designed and implemented based on these policies.
Need for a medium to long term strategy to address skills shortages in the region.	SAGMA should examine the feasibility of collaboration with Cogent SSC (UK) with a view to helping its members design capacity and career building, as well as work placement, programmes. This will require the cooperation of HEIs, governments and employers.
Executive managers are attending programmes which are meant for technical production personnel	SAGMA should compile a calendar of all programmes for the year with clearly defined learning objectives and target audiences. It should offer a healthy mix of both management and technical training to cater for all the different target audiences. The Association should work towards offering executive management training programmes marketed separately from technical programmes. SAGMA should negotiate with business schools for the setting up of executive management courses aimed at pharma industry executives. University of South Africa (UNISA), University of Stellenbosch and University of Cape Town business schools were approached during this study and they indicated willingness to engage in such discussions.
No technical assistance available for sustained capacity building within individual companies	SAGMA should create a database of consultants. There is a need for technical assistance to second consultants for long periods to assist companies on particular tasks; for example, to set up bioequivalence validation and testing. Alternatively, SAGMA should lobby the SADC Secretariat and ICPs to set up a NIPER-like body which houses expertise and equipment which can be shared with all members. KSP and MUHAS could be used in this way and could become centres of excellence for industrial pharmacy.
Inadequate training coverage of priority areas such as Intellectual Property protection, international patent law and TRIPS flexibilities	In addition to collaboration with HEIs on these topics (see above), SAGMA should engage with independent consultants and law firms in the region on specialist subjects such as intellectual property rights, TRIPS flexibilities, and public health patent sensitive provisions in order to provide courses to its members. UNCTAD's Intellectual Property Unit could also be tapped for expertise.

Table 4.7: Recommendations to SAGMA on membership recruitment and profile raising

The pharmaceutical sector in Africa needs more champions	SAGMA should be open to both private and public institutions because both sectors in Africa are strategic in championing the Local Pharmaceutical Production agenda.
Membership of SAGMA has stagnated and it has little recognition outside English-speaking countries	Initiate an aggressive membership recruitment drive. Attend conferences in other SADC countries and market SAGMA through expos and fairs, especially in Lusophone (Angola and Mozambique) and Francophone SADC countries (DRC).
Communication with national and regional associations is poor.	Improve relations with national and regional associations by attending workshops and events organized by them.

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6.1 RESPONDENTS

Name	Organization	Country
Dr. Lloyd Matowe	Pharmaceutical Systems Africa	Tanzania
Dr. E Kaale	Muhimbili University	Tanzania
J. Carter	University of Cape Town	South Africa
Frank Taylor	LearnWright Inc.	United States of America
Joy Berry-Baker	Quad Pharma	South Africa
Desmond Nazer	Tshwane University of Technology	South Africa
Prof. Sarel Malan	University of the Western Cape	South Africa
Prof. Chiedza Maponga	University of Zimbabwe	Zimbabwe
Prof. Oppel B. W. Greeff	University of Pretoria	South Africa
Yusuf Vahed	Pharmed Pharmaceuticals (Pty.) Ltd.	South Africa
Harish Dhutia	Bytrade Tanzania Ltd.	Tanzania
Navika Minnu	Pharmed Pharmaceuticals (Pty.) Ltd.	South Africa
Fungai D. H. Kurangwa	Swazipharm Wholesalers	Swaziland
Clement Mulenga	Ngansa Pharmaceuticals Ltd.	Zambia
Denise Kamyuka	Medswana	Botswana
Noémia Maria Ossufo e Silva Muíssa Escrivão	Sociedade Moçambicana de Medicamentos	Mozambique
Peter Tshazibande	Vantage Health Group	South Africa
Maropeng Modiba	Zambezi Healthcare	South Africa
Relebohile Hlabana	Pharmaceutical Lesotho Legacy (Pty.) Ltd.	Lesotho
Rakesh Daya	Nikitas Pharmacy	South Africa
Wynn Chalira	Malawi Pharmacies Limited	Malawi
Sathvir Singh	Medivision (Pty.) Ltd.	South Africa
Pasipanodya Nyamangara	CAPS Pharamaceuticals	Zimbabwe
Vimbainashe Mukakati	Datlabs	Zimbabwe
Alagappan Murugappan	Pharmanova Zambia Limited	Zambia
Tsungi Moyo	SAGMA	South Africa
M. Khohlokwane	Tripharm Manufacturing	Lesotho
Skhumbuzo Ngozwana	Cipla Medpro	South Africa
Emmanuel Mujuru	Pharmaceutical Manufacturers' Association	Zimbabwe
Warren Makgowe	UNISA Graduate School of Business Leadership	South Africa

7.1 ANNEX

Annex 1 – Consolidated results of responses to questionnaire from companies

1. Name & Contact details		
Answer Options	**Response Percent**	**Response Count**
Name:	100.0%	22
Company:	100.0%	22
City/Town:	100.0%	22
Country:	100.0%	22
Email Address:	100.0%	22
Phone Number:	100.0%	22
answered question		22
skipped question		0

2. What is your gender?		
Answer Options	**Response Percent**	**Response Count**
Female	27.3%	6
Male	72.7%	16
answered question		22
skipped question		0

3. What is your position in the company		
Answer Options	**Response Percent**	**Response Count**
1. Executive management	72.7%	16
2.Technical e.g. Production, QC etc	13.6%	3
3. Human Resources	9.1%	2
4. Secretariat	0.0%	0
Other	4.5%	1
5. Other (please specify)		3
answered question		22
skipped question		0

4. What is your preferred language of communication		
Answer Options	**Response Percent**	**Response Count**
1. English	95.5%	21
2. French	0.0%	0
3. Portuguese	4.5%	1
4. Swahili	0.0%	0
5. Other	0.0%	0
Other (please specify)		0
answered question		22
skipped question		0

5. How many people are employed in your company		
Answer Options	**Response Percent**	**Response Count**
1. < 5 people	30.0%	6
2. 5 - 50 people	25.0%	5
3. 50 - 200 people	30.0%	6
4. >200 people	15.0%	3
answered question		20
skipped question		2

6. What sector is your company in (multiple answers acceptable)		
Answer Options	**Response Percent**	**Response Count**
Wholesaler	30.0%	6
Manufacturer	40.0%	8
Consulting	20.0%	4
Other	20.0%	4
Other (please specify)		3
answered question		20
skipped question		2

7. All our (technical) employees have reliable internet connection		
Answer Options	**Response Percent**	**Response Count**
Yes	80.0%	16
No	20.0%	4
answered question		20
skipped question		2

8. The company has a well-equipped video conference facility		
Answer Options	**Response Percent**	**Response Count**
Yes	25.0%	5
No	75.0%	15
answered question		20
skipped question		2

9. The company has affordable broadband internet connectivity

Answer Options	Response Percent	Response Count
Yes	80.0%	16
No	20.0%	4
answered question		20
skipped question		2

10. The company is eligible for skills development levy / support

Answer Options	Response Percent	Response Count
Yes	66.7%	12
No	33.3%	6
answered question		18
skipped question		4

11. Who provides the levy

Answer Options	Response Percent	Response Count
1. government department / agency	81.8%	9
2. trades association	0.0%	0
3. Other	18.2%	2
Other (please specify)		1
answered question		11
skipped question		11

12. How much of the levy was received in the past financial year

Answer Options	Response Percent	Response Count
1.None	53.8%	7
2. < $1,000	15.4%	2
3. $1,000 - $5,000	15.4%	2
4. $5,000 - $20,000	0.0%	0
5. > $20,000	15.4%	2
answered question		13
skipped question		9

13. The contact point for receiving and disseminating information on training is

Answer Options	Response Percent	Response Count
N/A	0.0%	0
1. Executive management	73.7%	14
2. individual employees	15.8%	3
3. line managers	10.5%	2
4. HR designate	26.3%	5
5. Other	5.3%	1
Other (please specify)		1
answered question		19
skipped question		3

14. How does the company communicate training opportunities to employees

Answer Options	Response Percent	Response Count
N/A	5.0%	1
e-mail	65.0%	13
staff meetings	55.0%	11
notice board	30.0%	6
Other	15.0%	3
Other (please specify)		1
answered question		20
skipped question		2

15. Does the company have a career development and training strategy and policy in place

Answer Options	Response Percent	Response Count
Yes	44.4%	8
No	55.6%	10
answered question		18
skipped question		4

16. Does the company have capacity development and training programmes in place

Answer Options	Response Percent	Response Count
Yes	68.4%	13
No	31.6%	6
answered question		19
skipped question		3

17. What in-house and external courses have employees been sponsored to attend in the past 3 years?

Answer Options	Response Percent	Response Count
Executive business management	31.3%	5
Regulatory compliance	37.5%	6
WHO pre-qualification	18.8%	3
Dossier compilation	31.3%	5
Pharmaceutical validation	18.8%	3
Pharmaceutical technology and related	25.0%	4
Supply chain management	37.5%	6
Other	31.3%	5
Others (please specify)		7
answered question		16
skipped question		6

18. How are these courses selected?

Answer Options	Response Percent	Response Count
1. needs assessment done	15.8%	3
2. selected by managers	73.7%	14
3. suggested by employees	21.1%	4
4. these were the one available	26.3%	5
5. Don't know	0.0%	0
answered question		19
skipped question		3

19. Which category of employees attend the training programmes

Answer Options	Response Percent	Response Count
1. N/A,	21.1%	4
2. low level technicians	31.6%	6
3. all shopfloor personnel,	42.1%	8
4. Exec management	47.4%	9
4. HR and support staff	10.5%	2
answered question		19
skipped question		3

20. The programmes are delivered by (multiple answers acceptable)

Answer Options	Response Percent	Response Count
N/A	31.6%	6
1. senior employees	52.6%	10
2. service providers	42.1%	8
3. internet courses / webinars etc	15.8%	3
4. local university	10.5%	2
5. trade association	5.3%	1
answered question		19
skipped question		3

21. Employees who are registrable (e.g. pharmacists, natural scientists etc) are supported to achieve annual Continued Professional Development (CPD) requirements

Answer Options	Response Percent	Response Count
Yes	84.2%	16
No	15.8%	3
answered question		19
skipped question		3

22. The company pays for relevant short course / conference/ workshop attendance

Answer Options	Response Percent	Response Count
Yes	94.7%	18
No	5.3%	1
answered question		19
skipped question		3

23. How many employees attended conferences / workshops in the past year?

Answer Options	Response Percent	Response Count
1. none	15.8%	3
2. 2 - 4	42.1%	8
3. > 4 - 10	15.8%	3
4. >10	26.3%	5
5. don't know	0.0%	0
answered question		19
skipped question		3

24. Employees are encouraged to study for formal qualifications (e.g. diploma or degree courses)

Answer Options	Response Percent	Response Count
Yes	84.2%	16
No	15.8%	3
answered question		19
skipped question		3

25. The company pays for such studies

Answer Options	Response Percent	Response Count
Yes	36.8%	7
No	63.2%	12
answered question		19
skipped question		3

26. How many employees are currently registered to study towards a formal qualification?

Answer Options	Response Percent	Response Count
1. none	47.4%	9
2. 2 - 4	36.8%	7
3. > 4 - 10	5.3%	1
4. >10	10.5%	2
answered question		19
skipped question		3

27. Are current capacity building programmes adequate for your needs

Answer Options	Response Percent	Response Count
Yes	52.6%	10
No	47.4%	9
If NO, explain what the inadequacies are		4
answered question		19
skipped question		3

28. Current programmes involve electronic-learning platforms (e.g. internet)

Answer Options	Response Percent	Response Count
Yes	47.4%	9
No	52.6%	10
answered question		19
skipped question		3

29. What difficulties do you encounter with the use of E-learning platforms (multiple answers acceptable)

Answer Options	Response Percent	Response Count
1. N/A	31.6%	6
2. no broadband infrastructure	21.1%	4
3. cost of internet usage	31.6%	6
4. limited time for non-core activities	36.8%	7
5. no video conferencing infrastructure	47.4%	9
answered question		19
skipped question		3

30. Please rank the priority training areas your company

Answer Options	high priority	moderate priority	low priority	Response Count
1. Informational (i.e. high-level information sharing sessions on general principles. Strategic and theoretical rather than technical / practical ideal for executives and decision makers)	11	3	2	16
2. Management and business skills	12	1	3	16
3. technical and practical (This would practical course with technical content for operational/shopfloor level employees. Training will be mainly in pharmaceutical validation & regulatory compliance.)	11	4	1	16
Other (please specify)				1
			answered question	16
			skipped question	6

31. INFORMATIONAL: Rank your company's training needs according to priority (i.e. short term priority being the most pressing needs, and long term being the least)

Answer Options	Short - term (6 - 18 months)	Medium - term (18 - 60 months)	Long-term (> 60 months)	N/A	Rating Average	Response Count
1. IP protection	10	1	1	2	1.25	14
2. TRIPS flexibilities	7	1	2	2	1.50	12
3. Introduction to WHO pre-qualification	6	4	1	2	1.55	13
4. Overview of Regulatory affairs	8	4	0	2	1.33	14
5. Computer systems validation	3	5	4	2	2.08	14
6. Designing state of the art laboratories	4	3	6	1	2.15	14
7. Documentation Management and Control	11	1	1	1	1.23	14
8. Environmental control and monitoring	6	5	2	1	1.69	14
9. Introduction to international patent law	6	3	2	3	1.64	14
10. Outsourcing clinical development and operations	3	3	4	4	2.10	14
11. Vendor & contract supplier qualification	7	4	1	2	1.50	14
12. Writing and implementing clinical protocols	3	5	2	4	1.90	14
13. Writing and implementing SOPs	8	4	2	1	1.57	15
14. Preparing for MRA inspection	7	4	1	2	1.50	14
15. cGMP for production supervisors/ laboratory personnel / executives	10	1	2	1	1.38	14
16. General overview of GMP accreditation	7	4	2	0	1.62	13
17. Introduction to pharmaceutical quality assurance systems e.g. GMP, GDP, GWP etc	12	1	1	0	1.21	14
Other (please specify)						0
					answered question	15
					skipped question	7

32. MANAGEMENT & BUSINESS SKILLS: Rank your company's training needs according to priority (i.e. short term priority being the most pressing needs, and long term being the least)

Answer Options	Short - term (6 - 18 months)	Medium - term (18 - 60 months)		Long-term (> 60 months)	N/A	Rating Average	Response Count
18. Financial management and investment	10	1		1	2	1.25	14
19. Strategic planning / Business planning	12	2		0	1	1.14	15
20. Operations and general management	10	3		0	1	1.23	14
21. Strategic HR management e.g succession planning	7	3		3	1	1.69	14
22. Marketing	9	3		1	1	1.38	14
23. Pharmaceutical supply chain management	9	3		1	1	1.38	14
24. Business risk management	6	5		2	1	1.69	14
25. Overview on corporate governance	5	4		4	1	1.92	14
26. Understanding mergers and acquisitions	2	3		5	5	2.30	15
27. Applied project management	5	5		0	3	1.50	13
Other (please specify)							0
						answered question	**15**
						skipped question	**7**

33. TECHNICAL - Pharmaceutical Validation:Rank your company's training needs according to priority (i.e. short term priority being the most pressing needs, and long term being the least)

Answer Options	Short - term (6 - 18 months)	Medium - term (18 - 60 months)		Long-term (> 60 months)	N/A	Rating Average	Response Count
28. Analytical methods validation for MRA compliance	9	2		4	1	1.67	16
29. System validation (IQ, OQ and PQ)	5	5		3	2	1.85	15
30. Process Cleaning and cleaning validation	6	4		3	2	1.77	15
31. Microbiological control and validation	5	6		3	2	1.86	16
32. Generic Drug approvals	7	3		3	2	1.69	15
33. ICH Q10: Pharmaceutical Quality system	5	5		4	1	1.93	15
34. Laboratory control system	5	5		4	1	1.93	15
35. Effective QbD (Quality by Design)	6	5		4	0	1.87	15
36. Environmental control and monitoring	4	7		3	1	1.93	15
Other (please specify)							0
						answered question	**16**
						skipped question	**6**

34. TECHNICAL - Regulatory compliance: Rank your company's training needs according to priority (i.e. short term priority being the most pressing needs, and long term being the least)

Answer Options	Short - term (6 - 18 months)	Medium - term (18 - 60 months)	Long-term (> 60 months)	N/A	Rating Average	Response Count
37. Applied cGMPs for pharmaceutical and related industries	9	5	2	0	1.56	16
38. Basics of safety testing methods	4	6	4	1	2.00	15
39. Statistical and data processing for regulatory submission	6	5	3	1	1.79	15
40. Dossier compilation for NMRAs	11	2	2	0	1.40	15
41. Bioavailability and bioequivalence testing	7	2	6	1	1.93	16
42. Pharmaceutical analysis e.g. HPLC	6	4	3	2	1.77	15
43. Strategies for compliance with cGMP auditing	6	5	3	1	1.79	15
44. CMC writing and submission	3	7	3	2	2.00	15
45. Combination product development	5	3	5	2	2.00	15
46. Control of contamination in sterile& non-sterile manufacture	6	1	6	2	2.00	15
47. Commissioning, Qualification & Validation	5	3	5	2	2.00	15
48. Risk management	7	1	6	1	1.93	15
49. Excipient GMPs	4	3	5	3	2.08	15
Other (please specify)						0
					answered question	16
					skipped question	6

35. TECHNICAL - Pharmaceutical Technology: Rank your company's training needs according to priority (i.e. short term priority being the most pressing needs, and long term being the least)

Answer Options	Short - term (6 - 18 months)	Medium - term (18 - 60 months)	Long-term (> 60 months)	N/A	Rating Average	Response Count
50. Clean room technology	4	3	6	1	2.15	14
51. Tablet coating technology	4	5	2	3	1.82	14
52. Advanced tablet press operation	4	2	5	3	2.09	14
53. Aerosol technology	4	1	5	5	2.10	15
54. Agglomeration	3	2	4	5	2.11	14
55. Packaging	4	6	3	1	1.92	14
56. Particle size reduction	3	4	4	3	2.09	14
57. Paste and high viscosity processing	4	4	5	2	2.08	15
58. Water sampling and testing	7	1	4	2	1.75	14
59. Powder mixing technology	5	2	4	3	1.91	14
60. Rheology of dispersions	3	3	6	2	2.25	14
61. Microencapsulation and particle coating	2	2	7	3	2.45	14
62. Basics of pharmaceutical formulation	5	5	3	1	1.85	14
63. Drug product stability and shelf-life	7	2	3	2	1.67	14
64. Topical product development	4	3	5	2	2.08	14
65. Spray drying technology	2	1	7	4	2.50	14
66. Suspensions and emulsions	4	3	5	2	2.08	14
Other (please specify)						1
					answered question	15
					skipped question	7

36. TECHNICAL - Distribution: Rank your company's training needs according to priority (i.e. short term priority being the most pressing needs, and long term being the least)

Answer Options	Short - term (6 - 18 months)	Medium - term (18 - 60 months)	Long-term (> 60 months)	N/A	Rating Average	Response Count
67. Cosmeceutical products, market and claims	7	5	3	1	1.73	16
68. Environmental control and monitoring	6	5	3	1	1.79	15
69. Handling and distributing food supplements, additives and herbal medicines	6	6	2	1	1.71	15
70. Good Distribution Practices	9	3	3	1	1.60	16
71. Validation of distribution computer systems	5	4	3	3	1.83	15
72. Vendor & contract supplier qualification	9	1	3	2	1.54	15
73. Ensuring product safety and security	11	0	2	2	1.31	15
74. Warehouse management	7	4	2	2	1.62	15
75. Distribution & storage of cold chain and controlled drugs	7	2	4	2	1.77	15
76. Systems for product recall and returned goods	9	3	1	2	1.38	15
77. Building internal monitoring and auditing	7	4	3	1	1.71	15
78. Understanding co-operation and franchising models	6	3	4	2	1.85	15
79. ICT to support wholesaling supply chain	6	1	6	2	2.00	15
Other (please specify)						0
					answered question	16
					skipped question	6

37. What forms should the training take (multiple answers acceptable)

Answer Options	Response Percent	Response Count
1. N/A	12.5%	2
2. workshops	75.0%	12
3. web-delivered lectures	31.3%	5
4. DVD-packaged self-learning material	62.5%	10
5. long-distance / correspondence material	31.3%	5
6. Other	6.3%	1
Other (please specify)		1
answered question		16
skipped question		6

38. What is your preferred course formats (multiple answers acceptable)

Answer Options	Response Percent	Response Count
1. < 3 day workshop	56.3%	9
2. 1-week short course	50.0%	8
3. part-time course with 2 - 4 contact sessions annually	56.3%	9
4. Other	0.0%	0
Other (please specify)		0
answered question		16
skipped question		6

39. Who would you prefer to provide the course (multiple answers acceptable)

Answer Options	Response Percent	Response Count
1. local service providers	56.3%	9
2. tertiary institutions	25.0%	4
3. international organizations e.g. USP	93.8%	15
4. national associations	37.5%	6
5. other	6.3%	1
Other (please specify)		1
answered question		16
skipped question		6

40. What is the company's total annual budget for training / capacity building

Answer Options	Response Percent	Response Count
1. none	26.7%	4
2. < $1,000	20.0%	3
3. $1,000 - $5,000	20.0%	3
4. $5,000 - $20,000	26.7%	4
5. > $20,000	6.7%	1
answered question		15
skipped question		7

41. On average how much is the company willing to pay for one individual per day of a training session

Answer Options	Response Percent	Response Count
1. $150 - 300	73.3%	11
2. $300 - 500	13.3%	2
3. > $500	13.3%	2
4. other	0.0%	0
Other (please specify)		0
answered question		15
skipped question		7

42. Are you a member of SAGMA?

Answer Options	Response Percent	Response Count
Yes - full member	46.2%	6
Yes - associate member	7.7%	1
No	46.2%	6
answered question		13
skipped question		9

43. If, you are not a member, would you consider becoming one

Answer Options	Response Percent	Response Count
Yes	77.8%	7
No	22.2%	2
answered question		9
skipped question		13

44. Rank the SAGMA offerings which are of particular interest to you

Answer Options	High priority	Medium priority	Low priority	N/A	Rating Average	Response Count
Political Advocacy	10	1	0	0	1.09	11
Legal advice	5	3	2	0	1.70	10
Fairs/exhibitions	5	2	4	0	1.91	11
Training	9	3	1	0	1.38	13
Cooperation with other enterprises	10	1	1	0	1.25	12
International contacts	11	1	1	0	1.23	13
Technical advice	9	2	1	0	1.33	12
Administrative advice	6	3	3	0	1.75	12
answered question						13
skipped question						9