BOARD NOTICE 173 OF 2019

THE SOUTH AFRICAN PHARMACY COUNCIL

SCOPE OF PRACTICE AND QUALIFICATION FOR SPECIALIST PHARMACISTS IN INDUSTRIAL PHARMACY

The South African Pharmacy Council (Council) intends to request the Minister of Health to publish the *Regulations relating specialist pharmacists* to make provision for:

(a) *inter alia* the category of Specialist Pharmacists: Industrial Pharmacist
(b) the scope of practice of the abovementioned specialist pharmacists; and
(c) in terms of Sections 33 and 49(mA) to provide the required qualifications for the specialist pharmacists.

The qualifications and proposed scope of practice for the other categories of Specialist Pharmacists were published for comment in Board Notice 152 of 2014, published on 12 December 2014.

The qualification and the proposed scope of practice of the Industrial Pharmacist are published herewith for public comment prior to the said request to the Minister of Health.

SCHEDULE

1. Industrial Pharmacy:

    (a) Scope of practice for the specialist pharmacist in Industrial Pharmacy; and
    (b) Qualification for the specialist pharmacist in Industrial Pharmacy.

In this notice "the Act" shall mean the Pharmacy Act, 53 of 1974 (as amended), and any expression to which a meaning has been assigned in the Act shall bear such meaning.

Interested persons are invited to submit within 60 days of publication of this notice, substantiated comments or representations on the qualifications and scope of practice to the Registrar, The South African Pharmacy Council, Private Bag X40040, Arcadia, 0007, or Fax 0865063010 or email: BN@sapc.za.org (for the attention of the Senior Manager: Legal Services and Professional Conduct).

TA MASANGO
REGISTRAR

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To obtain the full content of this Board Notice please visit the 'Proposed Legislation' section on the South African Pharmacy Council's website:
https://www.pharmcouncil.co.za/Legislation_Proposed

South African
Pharmacy Council
www.sapc.za.org

SCOPE OF PRACTICE AND QUALIFICATION FOR SPECIALIST PHARMACISTS IN INDUSTRIAL PHARMACY

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SPECIALITIES FOR PHARMACISTS

AIM AND GOALS

To enable pharmacists to specialise and to meet advanced pharmaceutical care and the service needs of the country.

The goals for creating specialist pharmacists are to:
(a) recognise expertise in pharmacy;
(b) create a career framework, being career progression and job satisfaction;
(c) move the profession forward;
(d) achieve better outcomes for patients;
(e) establish a referral system within the pharmacy profession;
(f) manage risk and public safety; and
(g) support the training of academics (teaching staff).

PRINCIPLES

(a) The creation of specialist pharmacists must be needs driven;
(b) The speciality in pharmacy must be based on advanced knowledge in the field of specialisation;
(c) The speciality in pharmacy must be based on advance practical experience in the field of specialisation;
(d) The speciality will be recognised if the postgraduate degree is pharmacy related; and
(e) Broad specialist pharmacist would be created with an allowance to create sub-specialities within the broad category when that sub-speciality has been well established in practice.

INDUSTRIAL PHARMACISTS

SCOPE OF PRACTICE

(a) Perform acts and services pertaining to the profession of a pharmacist
(b) Control both intrinsic and extrinsic quality of a product taking into account patient health and safety
(c) Manage knowledge and transfer of research evidence into practice
(d) Provide strategic leadership for manufacture of medicine, warehousing and supply chain management
(e) Design, develop and interpret quality systems for implementation of GMP
(f) Provide education and training relating to industrial pharmacy
(g) Provide pharmaceutical leadership and guidance in directing the business

QUALIFICATION – PROFESSIONAL MASTER'S DEGREE IN INDUSTRIAL PHARMACY

SYNOPSIS

The South African Pharmacy Council (hereafter referred to as Council) envisages designing and developing a curriculum for a professional Master's Degree in Industrial Pharmacy for the purposes of enabling registration as a specialist with a postgraduate qualification in compliance with Council requirements.

Table 1: Summary of the proposed qualification

Master of Pharmacy in Industrial Pharmacy	
Duration:	Two years
Entry criteria:	Bachelor's Degree in Pharmacy or Equivalent
HEQSF-level:	**Level 9**
Field (CESM)	**09** Health Sciences and Social Services
Sub-field:	0911 Curative Health
SAQA-credits:	240 credits
Qualification type:	Professional, exit-level, career-orientated, whole qualification
Final assessment and evaluation:	1. The following components of the curriculum must be passed in accordance with the rules and regulations specific to the relevant Higher Education provider: (a) All course modules (compulsory and electives) (b) Work Based Learning components (WBL) (c) Relevant research project (d) A comprehensive portfolio of evidence for each candidate to be submitted to the accredited provider. 2. To register as a specialist after obtaining the professional Master's Degree, candidates must complete 2 years of practical exposure/internship/experience in a relevant environment and/or field of study.
CPD requirements for annual re-registration:	As required by Council
Professional status:	Registration with Council as a practising Industrial Pharmacist
Articulation:	PhD or Professional Doctoral Degree

QUALIFICATION OUTLINE:

1. QUALIFICATION TITLE:

Master of Pharmacy in Industrial Pharmacy

Abbreviation: MPharm (Industrial Pharmacy)

2. QUALIFICATION TYPE:

Professional Master's Degree

3. FIELD AND SUB-FIELD:

- Field: [09] Health Sciences and Social Services
- Sub-field: [0911] Curative Health

4. LEVEL:

NQF **Level 9** (Master's Degree)

5. CREDITS:

Total credits: 240

6. RATIONALE FOR THE QUALIFICATION:

The South African Pharmacy Council (SAPC) as the statutory body regulating pharmacists and pharmacy support personnel seeks to develop a speciality in Industrial Pharmacy at an intermediate postgraduate level.

The Master's degree in Pharmacy (Industrial Pharmacy) was developed to meet the requirements of the pharmaceutical industry in South Africa to facilitate enhancement of local pharmaceutical production (LPP) for the manufacture and registration of medicines, medical devices and In Vitro Diagnostic Medical Devices (IVD). These products are required to meet relevant quality, safety and efficacy standards and are manufactured under applicable regulations promulgated and administered by health authorities / regulators which set minimum standards for activities involved in all stages of the lifecycle of products and materials. Furthermore, the intention is that this will contribute positively to the Industrial Policy Action Plan of the government.

From the perspective of the Department of Health, the pharmaceutical industry should be viewed as central to the so-called industrial health complex i.e. economic activities which form the basis for goods production and services related to the provision of health services. Therefore, the development of the sector will contribute to the development of skilled industrial pharmacy professionals.

The SAPC has recognised the need for the development of a specialization for pharmacists at MPharm level to ensure that the growth of the industry is accommodated and to create career opportunities for pharmacists in the pursuit of the SAPC Vision 2030, the National Skills Development Strategy

(NSDS), the Human Resource Development Strategy for South Africa, the requirements of the New Growth Path, the Industrial Policy Action Plan, and the outcomes of the Medium-Term Strategic Framework.[1]

The existence of this specialisation does not preclude pharmacists with a Bachelor of Pharmacy Degree practising in the areas of manufacture, registration of medicines, medical devices and IVD. Pharmacists should continue to perform the acts pertaining to the scope of practice of a pharmacist. Industrial pharmacists should be competent to take a leading responsibility in all activities that relate to the theory and practice of industrial pharmacy and must do so in compliance with the requirements of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), the Pharmacy Act, 1974 (Act 53 of 1974) and other applicable legislations.

The rationale for the Master of Industrial Pharmacy postgraduate qualification is to educate and train industrial pharmacist postgraduates who on completion of a qualification would be able to register with the South African Pharmacy Council as specialists in order to improve industrial pharmacy practice in South Africa. Postgraduates must be holders of a Bachelor of Pharmacy (or equivalent qualification) and following completion of a professional Master's degree may articulate to a Doctoral Degree. Graduates will be skilled to work in the pharmaceutical industry at the technical and managerial level and it is envisaged that they will have sufficient knowledge and competencies to drive innovation and competitiveness within the industry and thus enhance pharmaceutical production in South Africa and the rest of our continent, with associated positive economic and social spin-offs for industrial growth as well as human social development.

7. PURPOSE:

The Master of Pharmacy in Industrial Pharmacy is a 240 Credit degree at NQF level 9. The purpose of this Professional Master's Degree is to educate and train highly specialised pharmacists for the pharmaceutical industry in accordance with National Skills Development Strategy (NSDS) phase III[2], the Human Resource Development Strategy for South Africa[3] and the requirements of the Industrial Policy Action Plan[4]. Following completion of the qualification learners should have the requisite attributes, skills and knowledge to contribute to the development and advancement of pharmaceutical knowledge at an innovative level in the core areas of industrial pharmacy and practice and successfully integrate all essential elements into the practise of industrial pharmacy. The core fields of study identified as the basis of the envisaged curriculum include:

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[1] Medium Term Strategic Framework: 2014-2019 - DPME
www.dpme.gov.za/keyfocusareas/outcomesSite/Pages/default.aspx

[2] http://led.co.za/sites/default/files/cabinet/orgname-raw/document/2012/nsds_3.pdf

[3] http://www.hrdcsa.org.za/sites/default/files/documents/Microsoft%20Word%20-%20HRDSA%20strategy.doc.pdf

[4] http://www.thedti.gov.za/news2013/ipap_2013-2016.pdf

(a) manufacture and control, export, import and distribution of medicines, medical devices and IVD,
(b) design and maintenance of pharmaceutical manufacturing facilities,
(c) quality management systems,
(d) governance, regulation, control, post marketing surveillance and law enforcement,
(e) general management of facilities and
(f) research and development.

Graduates of these degrees must be able to systematically and creatively deal with complex issues, design and critically appraise analytical writing, make judgements using data and information at their disposal and communicate their conclusions clearly to both specialist and lay audiences, demonstrate self-direction and originality in tackling and solving problems, act autonomously in planning and implementing tasks with a professional orientation, and continue to advance their knowledge, understanding and skills relevant to industrial pharmacy. The Master's degree may articulate vertically with a doctoral level degree.

8. RULES OF COMBINATION:

This qualification has been designed by the South African Pharmacy Council and will be registerable with Council as a specialisation.

Due to the competency based nature of the curriculum work based learning will be integrated in the curriculum.

Successful completion of the degree will require:

(a) Completion of compulsory and elective coursework requiring a high level of theoretical engagement and intellectual independence. Candidates must demonstrate an ability to apply knowledge to complex and appropriate industrial pharmacy problems.

(b) An independent study component comprised of credits at NQF level 9 (90 credits minimum) of either a single research or technical project (mini-thesis / dissertation) or a series of smaller projects (case studies) demonstrating innovation or professional expertise.

The knowledge mix required for the envisaged programme is listed in Table 2. The different types of learning are integrated across Exit Level Outcomes (ELO) with the purposes of ensuring the design of an integrated and multidisciplinary curriculum to meet the requirements of post-modern educational programme design. All learning areas are compulsory except disciplinary learning or elective courses that can be offered to a value of 18 credits. Disciplinary learning integrated within professional development (18 credits) should be informed by the field of study of the specific elective course to be studied.

Table 1: Knowledge Mix

LEARNING TYPES	ELO01 Pharmaceutical knowledge and knowledge production	ELO02 Specialised Pharmaceutical and Research Skills	ELO03 Professional Development	ELO04 Pharmaceutical Ethics and Statuary Responsibilities and Accountability	TOTAL CREDITS
Compulsory learning	72				**72**
Disciplinary learning (Elective)	18		18		**36**
Practical learning	30				**30**
Situational Learning				24	**24**
Research		90			**90**
TOTAL	**120**	**90**	**18**	**12**	**240**

9. ACCESS TO QUALIFICATION:

The minimum admission requirement to the qualification is a four-year Degree in Pharmacy (NQF level 8) or equivalent and registration with the SAPC as a pharmacist.

10. LEARNING ASSUMED TO BE IN PLACE:

A four-year Degree in Pharmacy (NQF level 8) in which the knowledge mix listed in Sections 10.1 – 10. 8 are covered:

10.1 Professional and ethical practice
10.2 Communication skills and self-management
10.2 Anatomy and physiology
10.3 Pharmaceutics
10.4 Chemistry and Pharmaceutical Chemistry
10.5 Forensic Pharmacy
10.6 Pharmacy practice (including aseptic experience, standard operating procedures, GMP and quality assurance [QA])
10.7 Pharmacology
10.8 Research methodology

Candidates have to comply with all theoretical requirements set by Council for registration as a specialist industrial pharmacist.

11. EXIT LEVEL OUTCOMES (ELO) AND THEIR ASSOCIATED ASSESSMENT CRITERIA:

11.1 The envisaged ELO were framed against the Level Descriptors of SAQA and formulated by integrating the scope of practice as indicated in below, with the scope and depth of the level descriptors on level 9 of the NQF.

The envisaged Scope of Practice of an Industrial Pharmacist includes but is not limited to the following roles:

(a) Procurement: Ordering, receipt, storage and inventory control of active pharmaceutical ingredients (API) and related materials (including excipients and packaging).

(b) Manufacture: Production and quality control of pharmaceuticals according to "Good X Practise" GxP [where X- represents Manufacturing (GMP), Laboratory (GLP), Wholesaling (GWP) and many other practices].

(c) Quality Managements systems (QMS) including but is not limited to.

(i) Quality Manual for the implementation and maintenance of the QMS as per the QA/GXP/ International Organisation for Standardisation (ISO) requirements
(ii) Functional checks of instruments, equipment and devices and ensuring quality by designing of pharmaceutical products.
(iii) Quality risk management
(iv) Management Responsibility
(v) Monitoring and Measurement Management
(vi) Risk Management
(vii) Finished Product Release and distribution

(d) Good Governance for Medicines (GGM): including but not limited to:

(i) Compilation and filing of registration dossiers for market authorization / medicine registration, engaging with the medicines regulatory authority;
(ii) Ongoing compliance with regulation and post marketing surveillance requirements

(e) Health and safety including but not limited to: implementation and compliance with the Occupational Health and Safety Act.

(f) Provision of information and consultation including but not limited to: Communication of technical information to various stakeholders including other professionals, policymakers and lay people.

(g) Advocacy and lobbying including but not limited to: promoting access to quality medicines, medical devices and IVD for patients through interaction with other pharmacists, healthcare professionals and regulatory authorities

(h) Business management and entrepreneurship including but not limited to: Start up and manage a pharmaceutical enterprise

(i) Research and development: including but not limited to

(i) Research into new and better processes and processing, technologies and/or methods relevant to industrial practice and adoption and application of best practice;
(ii) Development and testing of formulations and dosage forms including commonly used dosage forms and/or novel technologies relevant to the market; and
(iii) Implementation, conduct and monitoring of all phases of clinical trials.

11.2 EXIT LEVEL OUTCOMES

ELO 0109 (120 Credits): Typically, candidates at this level will be able to integrate and apply specialist knowledge in the establishment, critical evaluation, monitoring and managing Corrective and Preventative Action (CAPA), problem solving and change control. Such activities should be performed by making autonomous decisions relating to complex organisational or professional issues. Such knowledge including but not limited to;

(a) Manufacture, export, import and distribution, of medicines, medical devices and IVD
(b) Design and maintenance of pharmaceutical manufacturing plants,
(c) Quality management systems,
(d) Governance of medicines, medical devices and IVD (Regulation, control, post marketing surveillance and law enforcement),
(e) Management; and
(f) Research and development.

Assessment Criteria

The achievement of these competencies will be evident when/if specialist knowledge and advanced scholarship of research and enquiry, and knowledge production are demonstrated within the context of integrated assessment and practice, within fields of learning including but not limited to:

ACC010109: Manufacturing, export, import and distribution, of Medicines, medical devices and IVDs: including but not limited to;

(a) Raw materials
(b) Final product
(c) Plant, equipment and environment
(d) Manufacturing procedures and processes,
(e) Import, export and distribution

ACC020109: Design and maintenance of pharmaceutical plants, including but not limited to;

(a) Manufacturing facilities

(b) Utilities
(c) Equipment
(d) Qualification and validation
(e) Access control

ACC030109: Quality management systems, including but not limited to;

(a) Quality control
(b) Standard operating procedures (SOP)
(c) Quality Risk Management (QRM)
(d) Management's responsibilities
(e) Technical agreements
(f) Audits
(g) Policy management

ACC040109: Medicines, medical devices and IVDs governance, including but not limited to;

(a) Licencing
(b) Production Registration and maintenance
(c) Law enforcement (compliance issues, e.g. substandard and counterfeit products, advertising, management of controlled substances)
(d) Post marketing surveillance (e.g. Recalls, adverse drug reactions, field action alert)
(e) Provision of medical information

ACC050109: Pharmaceutical Business Management, including but not limited to;

(a) Operations management including production planning and resource management (including human resources)
(b) Role of the responsible pharmacist in the management team
(c) Risk management
(d) Commercial operations management (marketing, finance and forecasting)
(e) Pharmacoeconomics and health technology assessment

ACC060109: Research and development, including but not limited to;

(a) Clinical trials
(b) Formulations development and design
(c) use of unregistered medicines in clinical trials and for named patient processes
(d) research ethics

ELO0209 (90 Credits): Typically, candidates at this level will be able to demonstrate and use a wide range of specialised skills to address complex and challenging, practical and theoretical problems within the field of industrial pharmacy, and demonstrate an understanding of the consequences of any solutions or insights generated and /or implemented. Candidates should be able to design and implement appropriate and creative solutions in addition to addressing intended and unintended consequences of all potential interventions. Candidates should also be able to design and implement cutting edge research strategies, conduct comprehensive and critical reviews of

current research and practices, utilise a range of specialised skills, discourses and technologies to produce insights and knowledge in the field of Industrial Pharmacy. Candidates should also be able to defend ideas generated during their research and communicate such ideas to a wide of audience. Such specialised skills may include but are not limited to:

(a) Root cause analysis (quality management, business management, operations and logistics, risk management, medicines government)
(b) Corrective and Preventative Action (CAPA)
(c) Monitoring and re-evaluation
(d) Quality management system and
(e) Governance of medicines

Assessment Criteria

The achievement of these attributes will be evident when/if:

ACC010209: Specialized skills are used to investigate and identify complex and challenging, problems

ACC020209: A situational analysis of a practical and/or theoretical problem in industrial pharmacy is undertaken

ACC030209: Solutions to practical and / or theoretical problems are designed and implemented

ACC040209: Monitoring, evaluation and re-evaluation of proposed solutions are performed in order to generate insight and understand intended and unintended consequences of interventions

ACC050209: Insights / lessons learnt and knowledge produced are documented and reported

ACC060209: Appropriate literature resources (i.e. reports, legislation, guidelines, policies and technical documentation) informing research and problem solving are identified and used. A comprehensive and critical review of current research and/or practice is conducted and reported.

ACC0701209: Appropriate research strategies are designed and implemented in order to produce insight and knowledge

ACC080209: Specialized skills and technologies are applied appropriately in research and problem solving

ACC090209: Communication of research findings is undertaken to audiences of diverse expertise.

ELO0309 (18 Credits): Graduates achieving this outcome will be able to develop and enhance their own learning strategies to sustain independent learning, professional development and interactions. As such, the graduate should be able to operate independently and take full responsibility / accountability for their own work, and be able to lead, initiate, and implement systems while ensuring efficient resource management and good governance practice. Such specialised strategies includes, but is not limited to:

(a) independent learning
(b) accountability and responsibility
(c) leadership
(d) creativity
(e) innovation
(f) project management and
(g) entrepreneurship

Assessment Criteria

The achievement of these attributes will be evident when/if:

ACC010309: Independent learning, professional development and interaction are developed and enhanced as demonstrated by learning activities including but not limited to
;
(a) Case studies
(b) Presentations;
(c) Report writing and
(d) Simulated learning;

ACC020309: Systems are initiated and implemented to ensure efficient resource and project management and good governance of practice. Such systems must demonstrate that the candidate has an understanding of the necessary accountability, responsibility and leadership attributes required.

ELO0409 (12 Credits): Typically, graduates achieving this outcome will demonstrate an understanding of ethical standards and the legislation relevant to the pharmaceutical and healthcare industries. The candidate should take full responsibility and accountability for their decisions and actions. Such understanding may include but is not limited to the areas of ethical and statuary responsibility.

ACC010409: An understanding of ethical behaviour and pharmaceutical legislation is demonstrated and implemented.

ACC020409: The role of the responsible pharmacist in industry with respect to statutory responsibility and accountability is appreciated, understood and applied at all times.

12. CRITICAL CROSS-FIELD OUTCOMES:

The following critical cross-field outcomes form an integral part of the exit level outcomes for this qualification. Candidates must be able to:

(a) Identify and solve problems to which responses display responsible decision making following critical and creative thinking in the field of Industrial Pharmacy
(b) Work effectively with others as a member of an industrial pharmacy team, group, organisation and/or community of practice
(c) Organise and manage their activities responsibly and effectively
(d) Collect, analyse, organise and critically evaluate information in the field of industrial pharmacy
(e) Communicate effectively using visual, graphical, mathematical and/or language skills for oral and/or written presentations

(f) Critically evaluate pharmaceutical science and technology and show responsibility towards the environment and health of all

(g) Demonstrate an understanding of the world as a set of related systems by recognising that problem-solving contexts do not exist in isolation

(h) Promote personal and professional development of each candidate in the programme and social and economic development of society at large by creating an awareness of the importance of:

(i) exploring and reflecting on strategies to learn effectively
(ii) participating as responsible citizens in local, national and global communities
(iii) being culturally and aesthetically sensitive across all social contexts
(iv) exploring education and career opportunities efficiently and
(v) development of entrepreneurial skills

13. INTERNATIONAL COMPARABILITY:

The following examples are provided to illustrate the proposed competitiveness and comparability of the proposed curriculum with those of developed and developing countries.

13.1 UNITED KINGDOM

13.1.1 The University of London

The University of London has three programmes of which two are discussed here.

13.1.1.1 Drug Discovery and Development Master of Science

- This programme provides a broad overview of the drug discovery and development process and is designed for graduates of science-based curricula as preparation for either PhD-level research studies or a career in the pharmaceutical industry or regulatory body.
- Students gain hands-on experience of molecular modelling and computer-based drug design, analytical and synthetic techniques are exposed to modern platforms of drug discovery and methods of synthesis.
  The programme is 180 credits made up of three core modules (90 credits), two optional modules (30 credits) and a dissertation (60 credits). The core modules are offered in medicinal chemistry, drug discovery and development. The dissertation is written following a laboratory-based research project which is assessed at the end of the year as a written report and by oral presentation.
- The programme is delivered through a combination of lectures, tutorials and seminars supported by e-learning and practical classes. Assessment undertaken through a combination of written examinations and continuous coursework submission and assessment.

13.1.1.2 Drug Discovery and Pharma Management Master of Science

- This is a recently introduced programme started as a spin-off from a Drug Discovery Master of Science degree in response to increasing opportunities that exist for research scientists to evaluate the business potential of their generated science.
- This MSc is comprised of the scientific core of the Drug Discovery MSc and combines a broad overview of the drug discovery and development process with specialisation in management training and awareness, strategic partnering and business development skills. The programme is180 credits comprised of five core modules (120 credits) and a dissertation (60 credits). The core modules are medicinal chemistry, drug discovery and development and pharma management. The dissertation is undertaken as a business development project based on an aspect of science from drug discovery which is assessed at the end of the year as a written report and via oral presentation.
- The programme is delivered through a combination of lectures, tutorials, seminars and practical classes. Assessment is achieved through a combination of written examinations and coursework assessment. The business development project is assessed by written report and oral presentation to the class and a panel of judges comprised of scientists and business managers.
- The entry requirements are A second-class UK Bachelor's degree or higher in a related subject such as pharmacy, pharmaceutical science, pharmacology, physiology, physical science, biochemistry, biotechnology, chemistry, chemical engineering, genetics, material sciences, or a medical degree (MBBS), or an overseas qualification of an equivalent standard.

13.1.2 The University of Central Lancashire

13.1.2.1 *Master of Science Industrial Pharmaceutics: This MSc programme develops* the skills required for prospective employees in the pharmaceutical industry and has been developed following extensive discussions with the industry. The emphasis of the programme is dosage form development and manufacture.

The programme is open to students with an undergraduate degree in chemistry, pharmacy, biology, related subjects or experience equivalent to the above. The course is offered as a one-year full time course taught over three terms. A research project is undertaken the whole of the third term. Practical, industry and research skills are incorporated in all aspects of the programme.

13.1.3 University of Strathclyde

13.1.3.1 *Master of Science Advanced Pharmaceutical Manufacturing*: This course trains graduates in key aspects of modern manufacturing approaches suitable for pharmaceuticals and high value chemicals. This course is designed to produce highly-skilled graduates well-versed in continuous manufacturing science and technology to meet the growing demands for expertise in this area. Candidates are trained to take up jobs in the food, chemical and pharmaceutical industries. The course is 180 credits, 120 credits (six 20-credit taught modules) are taught in combination with practical classes after which they complete a research project at the University or at an external company or organization.

Compulsory classes include materials in which research skills, Process Analytical Technology (PAT), Quality by Design (QbD) in Continuous Pharmaceutical Manufacturing, Continuous Manufacturing of Pharmaceutical Particles and Products, and Pharmaceutical Project Management are covered. Theory and applications are taught through lectures, tutorials, seminars and web-based learning approaches.

13.2 UNITED STATES

13.2.1 University of Ephos

13.2.1.1 *Master's Degree in Industrial Pharmacy and Regulatory Affairs*: This degree in industrial pharmacy and regulatory affairs provides students with technical know-how and allows them to develop skills such as analysis and problem solving, organisation and sound application of methodology as required by the pharmaceutical industry so as to be able to enter areas of drug manufacturing and control, distribution and regulatory affairs.

Modules offered in this degree include professional skills, legal framework for drugs, drug manufacture and control, regulatory affairs and pricing, reimbursement and access and a thesis on planning for the registration and manufacture of a drug in the American context.

13.3 AFRICA

13.3.1 Kilimanjaro School of Pharmacy (KSP) / Purdue University

13.3.1.1 *Advanced Industrial Pharmacy Training Programme*: The Advanced Industrial Pharmacy Training Programme is offered at KSP in close collaboration with lecturers from Purdue and Howard Universities, USA and aims at filling a void on the continent viz., the lack of a well-educated and qualified workforce that is a key factor constraining the growth and development of the local pharmaceutical industry.

Modules covered include Drug Development, Good Regulatory Practices and Documents and Dialogues of Drug Development and Registration. Students are able to work towards a Master's degree conferred by Purdue University.

13.4 INDIA

13.4.1 Pharmacy education in India, both at the BPharm and MPharm levels, is taught as an industry- and product-oriented profession with a focus on the basic sciences. Six (6) National Institutes of Pharmaceutical Education and Research (NIPER) in India offer MS (Pharm), MTech (Pharm) and higher-level degrees. The NIPER were created with the vision of providing excellence in pharmacy and pharmacy-related education. The MPharm degree is offered in many disciplines including pharmaceutics and pharmacology. The curriculum is divided into two parts. The first is 1 year of didactic theory and laboratory course work (both and the second involves completion of a research project under the supervision of a faculty member in pharmacy in a selected discipline. Students who pursue an MPharm in industrial pharmacy may undertake research projects in the pharmaceutical industry during the second year of the course and an industrial expert is appointed as a co-supervisor who is responsible for this part of the research.

13.4.2 The JSS College in Mysore offers a two year MPharm degree in one of twelve (12) areas of specialization including but not limited to Industrial Pharmacy, Pharmaceutical Analysis, Pharmaceutical Quality Assurance and Regulatory Affairs. Candidates who have passed BPharm degree at any recognized University are eligible for admission to the qualification. The course is offered as a two-year full time degree with taught modules, a dissertation and an oral examination. No work based or experiential components apart from laboratory based practicals are included.

13.5 BRAZIL

13.5.1 The School of Pharmaceutical Sciences (FCF) at "Júlio de Mesquita Filho" São Paulo State University – UNESP offers a teaching based course founded on the principle of integration of teaching, research and community service that are considered indissociabile. The Graduate School offers three stricto sensu programs at the Master's and Doctoratal levels in Food and Nutritionarea focussing on food and nutritional science, Clinical Analysis and Pharmaceutical Sciences including research and development of pharmaceuticals and drugs and Bioprocessor and Biotechnology Engineering.

14. INTEGRATED ASSESSMENT:

A combination of integrated assessment strategies including formative and summative assessment and evaluation must be used to ensure that the purpose of the qualification is achieved. Assessment may include, but is not limited to any or all of the following approaches:

- Portfolio of evidence
- Practical experience work-place assessment
- Written and oral assessments and examinations
- Written assignments
- OSPE
- Case studies
- Journal clubs
- Self-assessment strategies, peer-group assessment and preceptor evaluation

15. CREDIT ACCUMULATION AND TRANSFER:

Candidates may apply for recognition of credits obtained as part of an incomplete qualification at the same or at a different institution, depending on the admission and articulation policies of individual institutions.

16. ARTICULATION (PROGRESSION):

Completion of a Master's Degree is an indication that the minimum entry requirement for admission to a Doctoral Degree, usually in the area of specialisation of the Master's Degree, has been achieved.

Articulation may also be horizontal and entry into other Master's level Degrees in a similar or related field, or area of specialisation may be considered.

17. MODERATION OPTIONS:

Suitable moderating options should be included in each application for accreditation so as to ensure this qualification complies with the stipulations of the Council on Higher Education (CHE), as well as the relevant Standards Generating Body (SGB) (i.e. Council). Both internal and external moderation should form an integral part of quality assurance for the provision of this qualification.

18. CRITERIA FOR THE APPOINTMENT OF ASSESSORS:

Assessors in the field of Industrial Pharmacy must have a suitable background with a proven track record and relevant experience to enable them to make sound judgement through their expert application of the assessment criteria specified for the qualification.

19. NOTES:

- All candidates must, in addition to their current registration as academic interns or pharmacists, be registered with Council for study towards the specialisation for the duration of the period of learning as specified in current relevant legislation
- The range of elective learning areas offered will be dependent on approval of the provider and SGB
- Credit values reflected for each exit level outcome listed in Table 2 should be regarded as a guideline only
- The respective assessment criteria should aim to test the achievement of specific learning outcomes for modules. Some of these criteria are likely to be practice-based, therefore providers are required to include time and space in their curriculum design for this purpose
- Following completion of the Master's Degree, a candidate may commence with the process of registration as a specialist pharmacist in Industrial Pharmacy with Council. Requirements for this registration process will be as determined by Council. (See Appendix A)

ANNEXURE A

Requirements for registration as a specialist after successful completion of a Professional Master of Pharmacy in Industrial Pharmacy qualification will be as stipulated by Council and includes but is not limited to:

(i) Registration as a pharmacist with Council
(ii) Practical training at a training site approved by Council for training, (i.e. health or manufacturing facility where pharmaceuticals are routinely handled).
(iii) Tutor or supervisor
(iv) Evaluation and panel