What is the value of the industrial pharmacist?

Dr Ralph Tettey-Amlalo

BPharm, MSc, PhD (Rhodes), MBA (Henley)

23 October 2016 - Durban ICC - 2nd National Pharmacy Conference

Pharmaceutical Industry

Where does it start and end?

What really is an industrial pharmacist?

WHO - Industrial Pharmacist

Research and development - Pharmacists contribute to research, and their expertise in formulation development is of particular relevance to the biological availability of active ingredients.

Manufacture and quality assurance - The pharmacist's broad knowledge of the pharmaceutical sciences ensures an integrated approach to quality assurance (including good manufacturing practice) through the validation of the various stages of production and the testing of products before release.

Drug information - The pharmacist has the knowledge and expertise to provide detailed information on medicines to members of the health professions and the public. Also, pharmacists provide an information service within the company.

Report of a WHO Consultative Group, New Delhi, India, 13-16 December 1988

WHO - Industrial Pharmacist

Patent applications and drug registration - The pharmacist is ideally qualified to understand and collate the diverse information required for patent and authorization submissions.

Clinical trials and post-marketing surveillance - The pharmacist has the knowledge of drugs and health care provision required to facilitate collaboration between companies, health professionals and governments in relation to clinical trials and surveillance.

Sales and marketing - The pharmacist, whose professional ethics demand a concern for the interest of patients, can make a contribution to proper marketing practices related to health care and to the provision of appropriate information to health professionals and the public.

Management - The inclusion of pharmacists in all levels of management promotes an ethical approach within management policies.

Industrial Pharmacist - South Africa

- Not defined by guidance documents per se:
  - Good Pharmacy Practice
  - Pharmacy Act 53 of 1974
    - Regulations relating to the practice of pharmacy
  - Medicines and Related Substances Act, 1965 (Act 101 of 1965)

- However, it is inferred:
  - Manufacturing
    - Radiopharmacist (Specialist Pharmacist)
  - Wholesaler
  - Clinical
    - Clinical Pharmacist (Specialist Pharmacist)
    - Pharmacokineticist (Specialist Pharmacist)

Research & Development

- **Formulation Pharmacist / Scientist**
  - Research focused
  - Drug discovery / Drug design / Drug delivery
  - Laboratory scale batches
    - Engineering
    - Stability Studies
    - Data analysis / Technical Reports / Presentation / Publications

- **Technology Transfer Pharmacist**
  - From laboratory batches to 1/10th commercial batches
  - Validate consistency surrounding parameters in product development
    - Engineering / Manufacturing / Processing Times / Holding Times etc.
    - Stability Studies
  - Batches are normally used in clinical trials and samples for drug registration

Clinical Trial

- **Clinical Trial Registration Pharmacist**
  - Clinical Research Organisation (CRO)
    - Main duties to prepare documents for the purposes of conducting clinical trials to the Medicines Control Council (MCC)
  - Study protocol
    - Design, planning and implementation
  - Study initiation
    - Collation of site information
    - Perform site inspection
  - Study registration with the MCC
    - Submission of protocol and supporting documents
    - Approval from ethics committee
  - Protocol lifecycle management
    - Amendments to protocol

Clinical Studies

- **Clinical Research Pharmacist**
  - Activated post approval from MCC (Ethics)
    - Main duties to conduct clinical trials as per protocol submitted for approval
  - Responsibilities
    - Similar to that of a retail / hospital pharmacist however in a clinical setting
    - Manages record keeping, shipping, ordering, receiving, storage, retention/destruction and related inventory activities in compliance with good clinical practices and the requirements of individual study sponsors
    - Participates in study initiations, monitoring and closeout visits, quality assurance audits and other related meetings with study sponsors and their representatives, regulatory agencies and others
    - Ensures the accuracy and integrity of products prior to their dispensing to study participants
    - Reads, interprets and processes prescriptions for investigational medications; clarifies orders with prescribers as needed

Regulatory Affairs

- **Regulatory Pharmacist**
  - Submits a dossier containing quality, safety and eficacy data to the MCC for the purposes of evaluation to obtain registration
  - Medicine registration
    - Dossier compilation
      - MBR1, MRF1, CTD, eCTD
    - Dossier evaluation
      - Thorough understanding of clinical and quality standards
      - Close collaboration with R&D / Technology Transfer
    - Responding to queries from the health authority
  - Ammendements to registered medicines
    - Label updates, manufacturing and testing updates and site changes
  - Artwork design and approval
  - Promotional / Marketing meterial approval

Medicine Control Authority
Health Authority

- **9 Committes**
  - Pharmaceutical & Analytical, Complementary Medicines, Clinical, Biological Medicines, Names and Scheduling, Clinical Trials, Veterinary Clinical, Legal and Pharmacovigilance
- **Quality (Pharmaceutical & Analytical) and Clinical Evaluation/Clinical Trials**
  - Product Dossier evaluation (quality, safety and efficacy)
  - Guidelines and policies
- **Inspectorate Pharmacists**
  - Conduct GMP inspections of facilities

Manufacturing

- **Warehouse Pharmacist**
  - **Good Warehouse Practice (GWP)**
    - Reciept and release of materials
      - Printed packaging, raw mateirals and components
    - Monitoring storage and temperature conditions
- **Dispensing Pharmacist**
  - **Good Dispensing Practice (GWP)**
    - Reciept, dispensing of raw materials
    - Balancing of S6 register
    - Storage conditions
- **Production/Packing Pharmacist**
  - **Good Manufacturing Practices (GMP)**
    - Planning and coordinating of manufacturing processes
    - Compliance to cGMP guidelines to ensure conformance of manufacturing and packaging processes
    - People management and training

Manufacturing

- **Quality Assurance Pharmacist**
  - **Good Manufacturing Practice (GWP)**
    - Compliance: SOP, QMS, CAPA, Deviations, APR, BMR/BPR, Document control
    - Sampling
    - Final release or rejection of FPP
    - Site and third party audit

- **Validation Pharmacist**
  - **Good Manufacturing Practice (GWP)**
    - Validation Master Plan
    - Qualification/Validation Protocol development for equipment and process validation, technical knowledge/expertise
    - Change control for equipment or processes

- **Nuclear Pharmacists / Radiopharmacists**
  - **Specialist Pharmacist**
    - Radioactive materials
    - Reproductive Women not allowed after 6 months

Medical

- **Medical Advisors**
  - **Medical Resources**
    - Internal and external customers (HCPs)
    - Organisation of Advisory Boards
    - Present organisations in local and international meetings
    - Medical training of internal colleagues
    - Suppoting Pharmacovigilance, Regulatory and Clinical operations

- **Medical Scientific Liaison**
  - **Assists Medical Affairs**
    - Clinical Trial Development
    - Pharmacovigilance
    - Medico-Marketing Inteface
    - Regulatory Support
    - Clinical Epidemiology

Market Access

- **Market Access Associates**
  - **Pharmacoeconomics**
    - Internal pricing policies
    - Engage with funders
      - Formulary listings
      - Clinical value proposition
      - Remoive hurdles to access
        - » Risk benefit ratio
        - » Cost benefit ratio

Sales and Marketing

- **Sales**
  - **Pharmaceutical Sales Representative**
    - Engaging directly with HCPs
    - Sells benefit of medicines
      - Have knowledge
      - Discuss risk benefit ratio
      - Adverse effect discussion
- **Marketing**
  - **Marketing Manager**
    - Develops market based strategies
      - Tools for the representative force
      - Marketing materials
      - Marketing understanding
      - New product launches
      - Forecast and supply management
- **Informatic/Medical Writers**
  - Scribes

Post Marketing Survelliance

- **Pharmacovigilance Pharmacist**
  - Adverse Drug Reaction Monitoring
    - Collect quality and safety data
    - Company must have processes for collection of data
    - Submit data to the HA (Important / Must be a Pharmacist)
  - Medical Information
    - Label and off label information required by HCP

Funders

- **Clinical Policy Unit Pharmacist**
  - **Policy**
    - Clinical evidence based considerations
    - Clinical benefit/adverse benefit ratio
    - Advice for formulary inclusion
- **Formulary Pharmacist**
  - Implementation
    - Enforcement of formularies
    - Levies/Co-pays
    - Review of formulary list for new products (generics)
- **Drug Utilisation Review**
  - Review
    - Prescribing, dispensing and use of medications
    - In line with in-house policies
    - Advice patients on cheaper alternatives

Destruction Pharmacist

- **Destruction**
  - Witness
    - Reciept of medicines
    - Special storage considerations
    - Incineration
    - Desctruction certificate

Responsible Pharmacist

- **Overall Accountability**
  - All of the above
  - Supervision
  - Notify council
  - Take corrective action

Industrial Pharmacists - Any value??

- **Yes**
  - Initiate the supply chain
    - Without R&D – no medicines can be introduced in the chain
  - Maintain the supply chain
    - Throughout the lifecycle

Trends in Pharma

- **Regulated Roles**
  - Responsible Pharmacist
  - Regulatory Pharmacists
  - Clinical Pharmacists
  - Production Pharmacists
  - Quality Assurance Pharmacists
  - Dispensing Pharmacists
  - Warehouse Pharmacists
  - Nuclear/Radio Pharmacist
- **Non-Regulated Roles**
  - Formulation Pharmacist
  - Technology Transfer Pharmacist
  - Validation Pharmacist
  - Medical Advisor
  - Sales and Marketing
  - Pharmacovigilance Pharmacist

Risks and Opportunities

- **Risks**
  - Regulatory Pharmacists
  - Clinical Pharmacists
  - Production Pharmacists
- **Opportunities**
  - Formulation Pharmacist
  - Technology Transfer Pharmacist
  - Validation Pharmacist
  - Medical Advisor
  - Sales and Marketing
  - Pharmacovigilance Pharmacist

Industrial Pharmacist - Comments

Dr Michael Parker, vice chair of the Industrial Pharmacists Group at the Royal Pharmaceutical Society of Great Britain (RPSGB), says there has been a decline in the number of pharmacists entering industry in recent years. "This is partly due to the pharmacy undergraduate curriculum which tends to focus on clinical aspects and partly because there have been fewer pre-registration placements in industry and partly because there is strong competition for all jobs in the industry."

http://www.independent.co.uk/student/career-planning/getting-job/industrial-pharmacy-under-the-microscope-413983.html

Industrial Pharmacy: Under the microscope

Postgraduate Courses in Pharmacy

- Nelson Mandela Metropolitan University
  - MPharm (Industrial), MPharm (Research), PhD
- Rhodes University
  - MSc (Pharm), MPharm, PharmD, PhD, DSC
- Sefako Makgatho Health Sciences University
  - PDip (Pharmacovigilance), MPharm, PhD
- Tshwane University of Technology
  - MSc, PhD
- University of Limpopo (Turfloop Campus)
  - MPharm
- University of KwaZulu-Natal (Westville Campus)
  - MSc (Pharmacoeconomics), MSc (Health Sciences), PhD
- University of the Western Cape
  - MPharm, MSc, DPharm, PhD
- University of the Witwatersrand
  - MPharm (Pharmacy)

What is the value of the industrial pharmacist?

Thank You