



2019 COURSE SCHEDULE

1. A Day in the Life of a Regulatory Affairs Pharmacist or Officer

Date: 20 August 2019

Open to ALL BPharm, BSc, BTech graduates and professionals interested in pursuing a career in Regulatory Affairs in the Pharmaceutical Industry

1 day course

An introductory course giving an overview of Regulatory Affairs:

- South African Legislation: Medicine Act & Pharmacy Act
- Exposure to SAHPRA & relevant guidelines
- Legal requirements to market medicines in South Africa
- Medicine product filing: Common Technical Dossier
- Medicine product file life-cycle: Variations
- Brief overview of Responsible Pharmacist duties within the pharmaceutical industry
- Quality Assurance/ control
- Inspections
- Pharmacovigilance
- Marketing

2. Regulatory requirements of Specific SADC & Other Africa countries

Date: 12 June 2019

1 day course

Comprehensive training on the regulatory requirements in the following African specific countries:

i.e Botswana, Namibia, Zimbabwe, Zambia, Mozambique, Malawi, Mauritius, Ghana, Nigeria, Kenya, Uganda, Tanzania and Ethiopia

3. Variations to marketing authorisations in the EU

Date: To Be Confirmed Based on Demand

1 day course

- An introduction to the European Commission system for Variations
- The Current Variations Regulations of the EC and procedures in practice
- Review of latest requirements
- Pharmaceutical and Clinical Variations
- Practical advice on the preparation and submission of Variation applications

4. Professional information for medicines for human use and patient information leaflet training

Date: To Be Confirmed Based on Demand

2 day course

Compilation of the professional information and patient information leaflet with the implications of the latest published regulations:

- South African Legislation
- SAHPRA/ MCC guidelines
- Clinical variations utilising EMA variation classification
- Amendments & General information/ Referencing System
- SR-PINS/ URSNS
- Safety & Medicines Safety Alerts
- Relevance of CCDS & PSURs/ PBRR

5. All You Need To Know: Pharmacovigilance

Date: To Be Confirmed Based on Demand

1 day course

- International Trends/ Pharmacovigilance Planning - ICH
- Post registration ADR Reporting
- PBRR/ PSUR/ Medicine Safety Alert
- Implications of: Recalls; labelling updates & variations



6. Product QC Release by the Pharmacist & Non-Pharmacist: "Ethical" & Complementary Medicine

Date: To Be Confirmed Based on Demand

Half day course

- Release related to regulatory requirements
- Product Batch Document review
- Certificate of Analysis review
- In-house procedure for release
- Practical examples

7. Marketing Code

Date: To Be Confirmed Based on Demand

1 day course

- Legal Framework
- Marketing Code of Practice
- International Arena on the Marketing of Medicines
- Examples
- Workshop - Regulatory Affairs Compliance

8. Biosimilars vs Generics

Date: To Be Confirmed Based on Demand

1 day course

- Difference between Biosimilars and Generic drug
- Difference between Biosimilars and Biologics
- International arena
- Local requirements
- Practical Application of Guidelines
- Are Biosimilars Interchangeable

9. Inspection readiness

Date: To Be Confirmed Based on Demand

1 day course

Detailing MCC/ SAHPRA and SAPC compliance requirements during an audit:

- MCC/ SAHPRA and SAPC Legislation
- Legal Compliance during an inspection
- PICS Guideline

10. Duties of the Responsible Pharmacist & Deputy Responsible Pharmacist

Date: To Be Confirmed Based on Demand

2 day comprehensive course

To enable the responsible pharmacist to:

- Gain an understanding of the key legal responsibilities of a Responsible Pharmacist
- Practical aspects to assist with regulatory activities
- Opportunity for you to participate in interactive discussions and exchange experiences with other delegates

11. Comprehensive training on ZA CTD compilation

Date: To Be Confirmed Based on Demand

A 5 day extensive course

An extensive course on ZA CTD compilation Module 1 – Module 5 & submission strategies:

- New Chemical Entities
- Generics
- Complementary Medicines
- Veterinary