ENTERPRISES
University of Pretoria

Manufacture and Registration of Herbal and Cannabis-Based Medicines

Presented by the Biomedical Research Centre, University of Pretoria

Unlike conventional pharmaceutical products, which are usually produced from synthetic materials by means of reproducible manufacturing techniques and procedures, herbal medicinal products (HMPs), including cannabis-based products for medicinal use (CBPMs), are prepared from materials of herbal origin, which are often obtained from varied geographical and/or commercial sources. In addition, due to the often unknown nature of the active(s) and the complexity of the phytochemical constituents, there may be high batch variability and poor quality. As a result, it may not always be possible to ascertain the conditions to which they may have been subjected. In addition, they may vary in composition and properties. Furthermore, the procedures and techniques used in the manufacture and quality control of herbal medicines are often substantially different from those employed for conventional pharmaceutical products. The quality may be affected by cultivation conditions, pests and pesticides and primary processing, among many other factors. For this reason, understanding quality management systems (including GACP, cGMP and EU-GMP), CTD compilation and the regulatory aspects of manufacturing, formulation and registration of these products is key to success in the market place.

The short course in **Manufacture and Registration of Herbal and Cannabis-Based Medicines** introduces delegates to the theory and practice of manufacturing and registering herbal medicinal products (HMPs), including cannabis-based products for medicinal use (CBPMs) in Southern Africa.

Delegates (without basic pharmacy training) will be introduced to relevant industrial pharmacy theory and practice to be gain a greater understanding / appreciation of the industry and medicine governance. Delegates will gain a basic understanding to enable them to compile and file registration dossiers (in CTD format) correctly which will lead to shorter turn-around times for registration of their products.

Course content

Module 1 – Background to Complementary and Alternative Medicines (CAMs)
- History of CAMs and the different disciplines
- History of traditional and herbal medicines
- Ethnobotany & pharmacognosy
- Field to Facility sustainable chain of custody for botanicals.

Module 2 – Background to Cannabis and Hemp
- History of Cannabis and hemp use
- National and international regulations for hemp, cannabis and CBPMs
- Introduction to pre-processing and processing of CBPMs.

Module 3 – Formulation & Manufacturing
- Pharm development and drug discovery
- Introduction to reference texts/pharmacopeia
- Pre-formulation and formulation
- Introduction to the theory and practice of industrial pharmacy
- Introduction to quality management systems - Total Quality Management (TQM, Quality by Design (QbD))
- GACP, GMP, QA and QC of herbal products.

Module 4 - Regulation of CAMs, HMPs and CBPMs
- The philosophy of Quality, Safety & Efficacy
- Introduction to the regulatory frameworks of WHO, FDA, SAHPRA and Zazibona.

Module 5 – Case study of the SA regulatory landscape
- Guidelines for GMP, P&A, Clinical studies, QSE documents for CAMs.
- Guidelines for CBD and CBMPs
- Regulations – marketing & advertising, claims.
- Introduction to the CTD modules.
- Practical compilation of dummy CTD dossiers for CAM registration (to be submitted for as formative assessment).

Module 6 - Assessment - CTD assignments due

Learning outcomes

After successfully completing this course, you will have gained;
- A clear understanding of the herbal medicine and medical cannabis regulatory framework.
- An appreciation of quality management systems for medicine production in general, complementary and herbal medicines in particular.
- A working understanding of different types of complementary and herbal medicines, their production (including basic industrial pharmacy) and release.
- Familiarity with pharmaceutical formulation and industrial pharmacy equipment for manufacturing and analysis (this may incorporate a laboratory visit or simulated learning).
- A working understanding of regulatory guidelines (WHO, MCC, EDQM) relevant to the manufacture, registration and sale of Complementary, Herbal and Cannabis-based medicines and the compilation of CoAs and CTDs.
- Practical experience of compiling a registration dossier in CTD format.

Course duration

The course will be presented for6 Weeks (6 Sessions scheduled over 6 Weeks).

Who should enrol?

- Staff from government medicine regulatory and trade departments (e.g. Department of Health, Department of Trade etc.).
- Personnel working in regulatory affairs departments of manufacturers and pharmaceutical companies.
- Entrepreneurs interested in medicine manufacturing and distribution.
- Researchers and students in medicine regulation and policy.
- Persons involved in medicine regulation, trade and policy at any level.

Admission requirements

Prospective delegates should at least have a National Senior Certificate (Grade 12).

Course fees

R8 912.50 (VAT Inclusive) per delegate
Course fee include all online course material.

Course fees must be paid in full 14 days prior to course start date. Proof of payment can be submitted to enrolments@enterprises.up.ac.za

Accreditation and certification

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Registration and enquiries

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