Module Outline:

- **Module I:** Introduction to Pharmaceutical Medicine
- **Module II:** Non-Clinical Development of Medicines, Legal, Ethical & Regulatory Issues
- **Module III:** Clinical Development of Medicines
- **Module IV:** Pharmacovigilance, Pharmaceutical Marketing & Economics of Health Care
- **Module V:** Research Project

**Course Language:** English

**Assessment:**
All Modules must be passed with a min of 50%
Final mark to be calculated as follows:
- two 3-hr written papers: 60%
- research assignment: 25%
- oral examination: 15%

**Approval:**
The course has been approved as postgraduate Diploma by the Stellenbosch University, the DoE and by SAQA.
The four modules are also offered individually as short courses (CPD, certificate of competence)

**Location:** Cape Town

**Admission & Selection Requirements:**

For admission to the course, a candidate should hold:

- an MBChB or BChD degree,
- a B Pharm or equivalent degree, or
- a B Cur, BSc in Biological Sciences or Biomathematics degree with at least 2 years experience in drug development / pharmaceutical medicine.

**ENQUIRIES:**
Programme Coordinator:
Prof. Bernd Rosenkranz
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This 2-year, part-time course is a joint venture between the Division of Pharmacology, Department of Medicine at the Stellenbosch University Faculty of Health Sciences and the Tiervei Trial Centre. It aims to equip students with a thorough understanding and knowledge of new drug development and the principles of clinical pharmacology; pharmaceutical development and safety pharmacology; the planning and execution of clinical trials; clinical epidemiology, ethics, statistics and data management, as well as pharmacovigilance, pharmaceutical marketing and economics of health care.

The modular format and course structure (i.e. 3 full days every quarter) were specifically adopted to accommodate part-time students and those from out of town. Components of the course will be done by e-learning. The course is also open to students preparing for the Dip Pharm Med examination of the Faculty of Pharmaceutical Medicine (UK). Each module is also offered as a stand-alone short course.
MODULE I: Introduction to Pharmaceutical Medicine

Drug Discovery
- Approaches to drug discovery
- Genomics, proteomics
- Laboratory and animal testing of new compounds for biological activity
- Significance of preclinical animal data for application in humans
- Laws and patent protection

Principles of Clinical Pharmacology
- Pharmacodynamics
- Pharmacokinetics

MODULE II: Non-Clinical Development of Medicines

Pharmaceutical Development
- Formulation development
- Principles of testing formulations for bioequivalence, impurities, stability
- Preparing of placebo and clinical trial materials
- Drug delivery systems
- Good Manufacturing Practice (GMP)

Non-clinical Safety Pharmacology & Toxicology
- Toxicology of pharmaceuticals
- Comparison between the toxicology of compounds in animal models and man
- In vitro and in vivo tests to assess toxicity
- Mechanisms of tissue damage; genotoxicity

Ethical & Regulatory Issues
- Principles of drug and device regulation
- The ethical review process, Good Clinical Practice (GCP)
- Legal issues

MODULE III: Clinical Development of Medicines

Clinical Development of Medicines
- The Strategic planning, development and organization of a clinical trial from conception to finalization
- First administration of new substances to humans
- Trial designs; placebos, patient populations, sample size, randomization, end-points
- Data collection, documentation, analysis
- Monitoring and Reporting of results

Biometrics & Data Management
- Principles of clinical epidemiology
- Fundamentals of statistics

MODULE IV: Pharmacovigilance, Marketing, & Economics of Health Care

Safety of Medicines & Pharmacovigilance
- Classification and mechanisms of adverse events
- Methods of assessing and monitoring AEs

Pharmaceutical Marketing
- Principles and practice of marketing and competition
- Scientific writing and critical evaluation of publications

Economics of Health Care
- Principles of health economics and of pharmaco-economics
- Costs of clinical trial management
- Pharmaceutical Medicine in developing countries

MODULE V: Research Project

- Formulate research questions as they pertain to the discipline of pharmaceutical medicine
- Write a research protocol
- Write a literature review
- Decide on the most appropriate methodology to address the research question(s)
- Analyse the data
- Draw logical, evidence-based conclusions from the data
- Present and defend the outcomes of the research project in an acceptable scientific format