

SwAPP Diploma Pharmaceutical Medicine

Implemented by the SwAPP Board on January 1, 2009.

Theoretical training

Subject	Hours
Discovery of new substances	8
Pharmaceutical development	16
Preclinical development	24
Clinical development	136
Pharmacovigilance	32
Medical-scientific information	32
Registration of drugs	40
Social economics of the health sector	24
Management	24
Any topic in pharmaceutical medicine	24
Total hours	360

Discovery of new substances

Basic procedure in the discovery, development, modification, appraisal and patenting of new pharmacologically active substances
Preclinical experiments and their implications on human pharmacology
New technologies in drug development
Profiling of a new substance (efficacy, safety, application)
Understanding the therapeutic index
Development of new indications

Pharmaceutical development

Principles of galenic development
Analytical methods
Manufacturing of study medication
Preparation of matching placebos and reference substances
Randomisation
Problems of compliance

Preclinical development

Knowledge of the methodology of in vitro and in vivo screening
Microbiology: methods for testing of susceptibility and resistance
Animal pharmacology and animal models
Animal pharmacokinetics
Toxicology, implications for drug development in humans

Clinical development

Ethical and legal aspects in studies in healthy volunteers and patients
Good clinical practice (GCP) for clinical trials, Declaration of Helsinki
Regulatory requirements for clinical research (Switzerland, EU, USA)

Data protection regulations
Human pharmacology and pharmacokinetics, polymorphism
Pharmacokinetics and metabolism in special patient-groups (e.g. hepatic insufficiency, renal insufficiency, pregnancy and geriatrics)
Special study designs (pharmacokinetic, bioavailability, interaction, proof of concept studies)
Investigational phases of clinical research (Phases I-IV)
Clinical development plan, investigator brochure
Biostatistics in the planning phase (estimate of number of cases, randomisation, statistical models, definition of end-points, planning of the subsequent evaluation)
Planning, setting up and implementing a clinical trial
Reporting of adverse events and serious adverse events in clinical trials
Laboratory data: data collection, logistics for samples, ongoing evaluation
Data management and biostatistics
Clinical study report, study closure, archiving
Audits and inspections

Pharmacovigilance

Definitions, classification and interpretation of adverse events
Drug interactions, overdose, drug dependence and addiction
Regulations and reporting of adverse events
Crisis management
Post-marketing surveillance
Epidemiological methods

Medical-scientific information

Rules and regulations for the promotion of pharmaceutical products
Answering medical questions
Medical clearing of promotion material
Marketing authorizations
Rules for sponsoring and collaboration with key opinion leaders, advisory boards
Rules and regulations for observational studies and case reports
Market Surveillance

Registration of drugs

Mission and responsibilities of registration authorities
Submission procedures in Switzerland, the EU and the USA
Compilation of the registration dossier
Monitored release
Pricing and reimbursement

Social economics of the health sector

Organisation of health systems
Reimbursement systems
Pharmaco-economic studies
Managed care, disease management, evidence-based medicine

Management

Structures of the pharmaceutical industry
Responsibilities of the medical department, legal position of the medical director
Personnel planning and management
Project-team management
Budgetary planning and control
Organisation of scientific symposia

Practical training

The practical training must be as broad as possible within the above topics. Evidence must be given that the candidate had responsibilities or participated in project work in clinical development, drug safety, medical-scientific information and regulatory submissions.

This document together with the Life Long Learning Programme replaces:

SwAPP Fortbildungsprogramm, 30. November 2000, and
SwAPP Diplom für Pharmazeutische Medizin – Weiterbildungsprogramm, 1. Januar 1999