

SwAPP Speciality Diploma Study Management

Implemented by the SwAPP Board on January 1, 2009.

Theoretical training

Subject	Hours.
Pharmaceutical development	12
Ethics and law	16
Human pharmacokinetics	12
Clinical studies	32
Auditing / inspection / fraud	12
Pharmacovigilance	8
Communication	8
Marketing authorization of medicinal products	8
Project management	16
Other core fields of pharmaceutical medicine	36
Total hours	160

Pharmaceutical development

Trial medication
Manufacturing of *matching placebos* and reference medication
Randomization
Compliance and labeling and presentation of trial medication

Ethics and law

Ethical and legal aspects in studies with volunteers and patients
Good Clinical Practice (GCP), Declaration of Helsinki
Data protection

Human pharmacokinetics

Definitions of pharmacokinetic parameters (absorption, bioavailability, distribution, clearance, elimination half life, AUC)
Pharmacokinetic and metabolism in special patient groups (e.g. hepatic/renal insufficiency, pregnancy/lactation, geriatrics)
Special pharmacokinetic studies: bioavailability and bioequivalence studies, single/multiple dose studies, interaction studies

Clinical studies

General

- Study phases (phase I-IV)
- Basics and assessment of phase I and early phase II study results
- Study designs in consideration of ethical aspects, indication, controls, patient population, study centers

Preparation

- Investigational medicinal product dossier, investigator brochure

- Writing study documents (synopsis, protocol, CRF, etc.)
- Basic statistics
- Methodology of data collection
- Logistics of a clinical study
- Selection of investigators
- Investigator meeting
- Ethics committees and ministry of health
- Study insurance
- Resource planning and training of the monitors

In-study

- Monitoring
- Project management and study control systems
- Adverse events: definitions, procedures
- Lab data: sample logistics, continuous data review

Assessment

- Data management and query handling
- Basics of data management process and biostatistic evaluation

Auditing / inspection / fraud

Documentation

Audits and inspections

Fraud

Pharmacovigilance

General

- Definitions and classification of adverse events and adverse reactions
- Procedures and management

Phase I-III

- Monitoring adverse events
- Reporting adverse events (responsibilities towards ethics committees, competent authorities, communication etc.)
- Centralized/decentralized reporting procedures

Phase IV

- Reporting adverse events

Post-marketing surveillance

- Post-marketing studies
- Spontaneous reports
- Crisis management

Communication

Communicating within a study

Communication study events and study results

Escalation internal and external

Marketing authorization of medicinal products

Objectives and responsibilities regulatory authorities

Basics of marketing authorization processes in Switzerland and EU

Project management

Methods and tools

Other core fields of pharmaceutical medicine

Courses in any topic of pharmaceutical medicine

Practical training

The practical training must be in as many of the above topics as possible. Evidence must be given for: responsibility or responsible involvement in planning, conducting, analyzing and reporting of different types of clinical studies.