SwAPP
Swiss Association of Pharmaceutical Professionals
CH-3000 Bern

SwAPP Speciality Diploma Study Management

Implemented by the SwAPP Board on January 1, 2009, last revised on Nov 10th, 2015.

Theoretical training

Subject	Hours
Pharmaceutical development	6
Ethics and law	7
Human pharmacokinetics	4
Clinical studies	25
Auditing / inspection / fraud	6
Pharmacovigilance	12
Communication	4
Marketing authorization of medicinal products	3
Project management	10
Other core fields of pharmaceutical medicine	23
Total hours	100

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
- Risk 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

At least 3 years composed as follows: At least 2 years in the speciality area, covering as many of the above topics as possible. Evidence must be given in at least two of the following topics: responsibility or responsible involvement in planning, conducting, analyzing or reporting of different types of clinical studies. Maximally 1 year in other fields of pharmaceutical medicine.

For further requirements please refer to the current SwAPP Life Long Learning (LLL) Program on the SwAPP Webpage.

Recognition of Certificates in Clinical Trial Management and Clinical Research

A successful completion of the following courses are recognized as fulfilling the specific theoretical requirements for this diploma (100 hours):

- CAS Clinical Trial Management (Clinical Trials Center of the University Hospital and the University of Zurich)
- DAS Management of Clinical Trials (Clinical Trial Unit of the University Hospital and the University of Geneva)
- DAS in Clinical Trial Practice and Management (Clinical Trial Unit of the University Hospital and the University of Basel)
- CAS in Clinical Research I (Clinical Trial Unit of the University Hospital and the University of Basel)
- CAS in Clinical Research II (Clinical Trial Unit of the University Hospital and the University of Basel)

No additional exam by SwAPP will be required for candidates who have successfully completed the final exam of the above mentioned courses in Basel or Zurich or at least 5 of 7 existing examinations of the modules of the DAS Clinical Trials Management of Geneva.
The final exams of the CAS and the DAS are each recognized with 3 credit points.