SwAPP
Swiss Association of Pharmaceutical Professionals
CH-3000 Bern

SwAPP Speciality Diploma Clinical Pharmacology

Implemented by the SwAPP Board on January 1, 2009. Last revised Nov 11th, 2014

Theoretical training

Subject	Hours
Non-clinical pharmacology and toxicology	8
Role of clinical pharmacology trials within the clinical development plan	8
Regulatory requirements	8
Design, execution and analysis of early phase human studies	36
Ethical principles and practices in volunteer studies	8
Good clinical practice in clinical pharmacology or How2GCP certificate	8
Drug safety	8
Freely chosen courses in any field of clinical pharmacology	38
Other core fields of pharmaceutical medicine	30
Total hours	152

Non-clinical pharmacology and toxicology
Preclinical tests of pharmacology and toxicology
Preclinical data required for early human and long-term toxicology
In-vitro and in-vivo animal pharmacology
Animal toxicology study design and kinetics
Differences in drug behaviour between animals and humans

Role of clinical pharmacology trials within the clinical development plan
Clinical pharmacology requirements in regulatory submission and in the summary of product characteristics
Application of clinical pharmacology knowledge across development program

Regulatory requirements
Relevant and current regulations
Pharmacology & toxicology data needed for Phase 1 studies
Components of clinical development plan (Europe)
Components of regulatory submission (Europe)
Regulatory and legal requirements in human studies

Design, execution and analysis of early phase human studies
Purpose and methods for investigation of drug in humans
Reasons and need for healthy volunteer studies
Maximise information obtained and minimise risks to study subjects
Human pharmacokinetics, pharmacodynamics & pharmacogenetics
Selecting appropriate dose ranges
Biological variation in normal population

Ethical principles and practices in volunteer studies
Basic principles of protection of research subjects
Information to participants and informed consent
Ethical review of studies from first-in-human to large clinical trials

Good clinical practice in clinical pharmacology or How2GCP (see www.swapp.ch)
ICH GCP principles throughout the drug development program

Drug safety
Basic principles of drug safety
Drug safety in early phase clinical trials

Freely chosen courses in any field of clinical pharmacology
Courses in any of the above fields

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 specialty area, maximally 1 year in other fields of pharmaceutical medicine.

The practical training must cover as many of the specialty topics as possible.
It must be documented in a written summary signed by the applicant's supervisor.

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