

# SwAPP Specialty Diploma Clinical Pharmacology

Implemented by the SwAPP Board on January 1, 2009.

## 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
Relevant literature and publications	8
Freely chosen courses in any field of clinical pharmacology	38
Other core fields of pharmaceutical medicine	30
<b>Total hours</b>	<b>160</b>

### **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](http://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

**Relevant literature and publications**

Read literature and relevant publications in field  
Statistical methods & analyses  
Pharmacokinetic models & analyses

**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**

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.