

# SwAPP Speciality Diploma

## GCP Quality Management

Implemented by the SwAPP Board on January 1, 2009.

### Theoretical training

Subject	Hours
GCP guidelines and data protection	24
Quality assurance	24
Clinical development	16
Preparation of study documents (protocol, CRF, PIC)	16
Managing SOPs	16
Monitoring and project management	24
Pharmacovigilance	8
Medical writing	8
Other core fields of pharmaceutical medicine	24
<b>Total hours</b>	<b>160</b>

#### **GCP guidelines and data protection**

Ethical and legal aspects in studies with volunteers and patients  
Good clinical practice (GCP), declaration of Helsinki  
Data protection regulations and adequate documentation  
EU clinical trial directive  
Study insurance  
Ethics committees and competent authorities

#### **Quality assurance**

Quality assurance / quality control  
Quality management systems  
Documentation  
System audits, vendor audits  
Project / investigator audits  
Communication before, during and after the audit  
Audit report  
Scientific misconduct and fraud – detection, communication  
Preparation for an inspection

#### **Clinical development**

Study phases (phase I-IV)  
Assessment of phase I and early phase II study results  
Investigational medicinal product dossier (IMPD), investigator brochure  
Study designs in consideration of ethical aspects, indication, controls, patient population, study centers  
Studies in minors and specific regulations  
Logistics of a clinical study  
Selection and training of investigators

Project management and study control systems  
Lab data: sample logistics, continuous data review  
Communication, escalation  
Methodology data collection, data management, query handling  
Basic statistics

### **Preparation of study documents**

Protocol, case report forms, patient informed consent  
Version control  
Data management/statistical plan  
Monitoring guideline

### **Managing Standard Operating Procedures (SOPs)**

Defining a SOP structure  
Writing, implementation, follow-up of SOPs

### **Monitoring and project management**

Monitoring procedures  
Methods and tool

### **Pharmacovigilance**

Definitions and classification of adverse events and adverse reactions  
Monitoring and reporting of adverse events  
Postmarketing surveillance  
Crisis management

### **Medical Writing**

Elements of a clinical study report  
Objectives and responsibilities towards regulatory bodies  
Basics of marketing authorization processes in CH, EU and USA

## **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 and conducting a GCP clinical study, a site audit and/or inspection and a sponsor audit and/or inspection.