SwAPP
Swiss Association of Pharmaceutical Professionals
CH-3000 Bern

SwAPP Speciality Diploma GCP Quality Management

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

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
Total hours	160

GCP guidelines and data protection
Ethical and legal aspects in studies with volunteers and patients
Good clinical practice (GPC), 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

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 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.

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