

SwAPP Speciality Diploma Regulatory Affairs

Implemented by the SwAPP Board on January 1, 2009.

Theoretical training

Subject	Hours
Clinical aspects of drug development	8
CH regulatory submissions of drugs	24
CH regulations and laws	16
EU regulatory submissions of drugs and biologics	8
US regulatory submissions of drugs and biologics	8
Variations and change control	8
Reimbursement and Pricing in CH	8
Pharmacovigilance	8
Good manufacturing practices	4
Good distribution practices	4
Promotion of pharmaceutical products in CH	4
Special regulations: generics, biologics, orphan medicinal products, pediatrics, medical devices	4
Relevant literature and publications	8
Freely chosen courses in any of the above fields	30
Other core fields of pharmaceutical medicine	18
Total hours	160

Clinical aspects of drug development

Biostatistics and interpretation of study results
Ethical and regulatory aspects of drug development
Patent protections
Medical writing

CH regulatory submissions of drugs

Duties and responsibilities of the regulatory bodies
Organisation of the CTD (Common Technical Document): modules 1-5
Granularity document
Certificate of suitability of the pharmacopoeial monograph (CEP)
European Active Substance Master File (ASMF)
Risk management plan
Pharmacopoeial monograph
From regulatory approval to market: reimbursement and pricing
Monitored release
Post-marketing procedures
Helvetisation of regulatory documents

CH regulations and laws

ICH Guidelines: M4, M4Q, M4S, M4E, E3
Heilmittelgesetz (HMG)
Arzneimittelzulassungsverordnung (AMZV)

Verordnung Arzneimittel (VAM)
Verordnung über die vereinfachte Zulassung von Arzneimitteln (VAZV)
Heilmittel-Gebührenverordnung (HGebV)
Swissmedic procedures and guidelines

EU regulatory submissions of drugs and biologics

Duties and responsibilities of the regulatory bodies
Components of regulatory submission
Regulatory and legal requirements for human studies
Steps and requirements from regulatory approval to market
Monitored release
Post-marketing procedures

US regulatory submissions of drugs and biologics

Duties and responsibilities of the regulatory bodies
Components of regulatory submission
Regulatory and legal requirements for human studies
Steps and requirements from regulatory approval to market
Monitored release
Post-marketing procedures

Variations and change control

Variation procedures in CH, EU and US
Renewing a regulatory submission
Variations for regulatory submissions
Group revisions

Reimbursement and pricing in CH

CH Spezialitätenliste, Mittel- und Gegenstände Liste
Submission
Pricing strategies
Price adjustments

Pharmacovigilance

Basic principles of drug safety
Definitions and classifications of adverse events
Drug-drug interactions, overdose, dependence and addiction
Definitions, legal requirements, interpretation and reporting of adverse events in clinical trials, observational studies and post-marketing
Epidemiologic methods
Crisis management

Good manufacturing practices

Rules and regulations for the production and packaging of medication
EU and FDA requirements
Swissmedic legal requirements
Quality assurance, quality control and quality management
Process management
Quality risk analysis
Computer system validation

Good distribution practices

Rules and regulations for the production and packaging of medication
EU and FDA requirements

Swissmedic – Legal requirements
Quality assurance, quality control and quality management
Complaints and recalls
Process management
Quality risk analysis
Quality control in biotechnological processes
Computer system validation

Promotion of pharmaceutical products in CH

Legal requirements, Pharmacodex
CH legal article Heilmittelgesetz Art. 33
Promotion in different media
Arzneimittelwerbeverordnung
Surveillance by authorities

Special regulations: generics, biologicals, orphan medicinal products, pediatrics, medical devices

Current regulations and requirements
Classification of medical devices (class 1, 2, 3)
Reporting requirements
Materiovigilance

Relevant literature and publications

Read literature and relevant publications in the field
Statistical methods & 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 be in as many of the above topics as possible. Evidence must be given for: responsibility or responsible involvement for every process in connection with a regulatory submission, resubmission, renewal and variation of a product, approval of labelling and leaflets, helvetisation of regulatory documents, monitored release procedures. Involvement in post-marketing surveillance, quality assurance, quality control and quality management of drug distribution.