



# SwAPP

Swiss Association of Pharmaceutical Professionals

CH-3000 Bern

## SwAPP Speciality Diploma Regulatory Affairs

Implemented by the SwAPP Board on December 17, 2010. Revised March 1, 2011.

### Theoretical training

Subject	Hours
CH regulations, laws and submission processes	9.5
CH regulatory submission	15
Submission and approval of clinical trials	4
Pharmacovigilance	4
Life cycle management	4
Promotion of pharmaceutical products in CH	4
Swissmedic operating approval and responsible person	4
Reimbursement and Pricing in CH	4
Special regulations, medical devices	5.5
EU/US regulatory submissions	4
Clinical aspects of drug development	4
Freely chosen courses in any of the above fields	28
Courses in other core fields of pharmaceutical medicine	20
Relevant literature and publications	10
<b>Total hours</b>	<b>120</b>

#### **CH regulations, laws and submission processes**

Duties and responsibilities of the regulatory bodies  
Relevant laws and standards in the global environment  
Heilmittelgesetz (HMG)  
ICH Guidelines: M4, M4Q, M4S, M4E, E3)  
Patent protection and intellectual property rights  
Processes (authorizations NAS, simplified authorizations (generics, fast track procedure, orphan drugs etc.)  
Veterinary products

#### **CH regulatory submission**

Organisation of the CTD (Common Technical Document): modules 1-5  
M2 (eCTD  
Granularity document  
Certificate of suitability of the pharmacopoeial monograph (CEP)  
European Active Substance Master File (ASMF)  
Risk management plan  
Pharmacopoeial monograph

“Helvetisierung”

Swissmedic procedures and guidelines

Arzneimittelzulassungsverordnung (AMZV)

Arzneimittelverordnung (VAM)

Verordnung über die vereinfachte Zulassung von Arzneimitteln (VAZV)

Monitored release

Pharmacovigilance Plan

### **Submission and approval of clinical trials**

Regulatory environment, ICH E6, Verordnung über klinische Versuche, (VKlin), Declaration of Helsinki

Responsibilities Ethics Committees and Swissmedic

Submissions to ECs and Swissmedic

Clinical Trial Protocol, Investigator Brochure, Case Report Form etc.

### **Pharmacovigilance**

Basic principles of drug safety

Definitions and classifications of adverse events

Risk management

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

Electronic reporting

### **Life cycle management**

From regulatory approval to market: reimbursement and pricing

Post-marketing procedures

Variation procedures in CH, EU and US

Renewing a regulatory submission

Variations for regulatory submissions

Group revisions

### **Promotion of pharmaceutical products in CH**

Legal requirements, Pharmacodex

CH legal article Heilmittelgesetz Art. 33

Promotion in different media

Arzneimittelwerbeverordnung (AWV)

Surveillance by authorities

### **Swissmedic establishment authorization and qualified person**

Rules and regulations for the production and packaging of medicinal products

EU and FDA requirements

Swissmedic legal requirements, Arzneimittelbewilligungsverordnung (AMBV)

Quality assurance, quality control and quality management

Inspections

Process management

Quality risk analysis

Computer system validation

Complaints and recalls

Quality control in biotechnological processes

### **Reimbursement and pricing in CH**

CH Spezialitätenliste, Mittel- und Gegenstände Liste

Submission

Pricing strategies

Price adjustments

Heilmittel-Gebührenverordnung (HGebV)

### **Special regulations: medical devices**

Current regulations and requirements  
Classification of medical devices (class 1, 2, 3)  
Requirements for clinical studies  
Materiovigilance

### **EU/US regulatory submissions**

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

### **Clinical aspects of drug development**

The relevance of biomarkers, surrogate and clinical endpoints  
IMPD (Investigational Medicinal Product Dossier)  
Patient reported outcomes

### **Freely chosen courses in any field of regulatory affairs**

Courses in any of the above fields

### **Courses in other core fields of pharmaceutical medicine**

Courses in any topic of pharmaceutical medicine  
Successful completion of a MEGRA course module (preparation of exam and successful completion of exam) is recognised with 2 creditpoints/module.

### **Relevant literature and publications**

Read literature and relevant publications in the field  
Statistical methods & analyses

## **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.

## **Recognition of the MEGRA StartUp Program**

A successful completion of the MEGRA StartUp Modules, plus the two separate modules offered by MEGRA on *EU/FDA regulations* and *Clinical Aspects of Drug Development*, are recognised as fulfilling the specific theoretical requirements for this diploma. Attendance of modules 1,4,5 and 12 gives 5.5 credit points each, all other modules 4 credit points each. A successful exam after each module is recognised with 2 credit points, 28 credit points total for all 14 modules. A total of 90 creditpoints are recognised for 14 completed modules with successful exams.

Candidates with successful completion of all 14 MEGRA modules plus documentation of

- coursework in any field of pharmaceutical medicine (20 credit points)
- study of relevant literature (10 creditpoints)
- practical training as described above

are eligible for the SwAPP specialty diploma regulatory affairs without further examination.