SwAPP
Swiss Association of Pharmaceutical Professionals
CH-3000 Bern

SwAPP Speciality Diploma Regulatory Affairs

Implemented by the SwAPP Board on December 17, 2010. Last revised April 18th, 2016.

Theoretical training

Subject	Hours	MEGRA Module
CH regulations, laws and submission processes	24	I-IV
Life cycle management	4	V
Pharmacovigilance	4.5	VI
Swissmedic operating approval and responsible person	4.5	VII
Promotion of pharmaceutical products in CH	4.5	VIII
Reimbursement and Pricing in CH	4	IX
Special regulations, medical devices	5.5	X
Approval of clinical trials and regulatory aspects of drug development	7	XI
EU/US regulatory submissions	7	XII
Freely chosen courses in any of the above fields	25	25 examination credits
Courses in other core fields of pharmaceutical medicine	20	3 examination credits
Total hours	110	

CH regulations, laws and submission processes
Duties and responsibilities of the regulatory bodies
Relevant laws and standards in the global environment
Swissmedic procedures and guidelines
Human Research Act (HRA)
Ordinance on Clinical Trials in Human Research (ClinO)
Heilmittelgesetz (HMG)
Arzneimittelzulassungsverordnung (AMZV)
Arzneimittelverordnung (VAM)
Verordnung über die vereinfachte Zulassung von Arzneimitteln (VAZV)
Patent protection and intellectual property rights
Processes (authorizations NAS, simplified authorizations (generics, fast track procedure, orphan drugs etc.))
Organisation of the CTD (Common Technical Document): modules 1-5
CH Module 1Relevant guidelines, Pharmacopoeias
“Helvetisierung”

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
Market surveillance, implementation Risk management plan

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
Signal detection
Electronic reporting

Swissmedic operating approval and qualified person
Rules and regulations for the production and packaging of medicinal products
Swissmedic legal requirements, Arzneimittelbewilligungsverordnung (AMBV)
Quality assurance, quality control and quality management
Inspections
Process management
Quality risk management
Complaints and recalls

Promotion of pharmaceutical products in CH
Legal requirements, Pharmacodex
Arzneimittelwerbeverordnung (AWV)
CH legal article Heilmittelgesetz Art. 33
Promotion in different media
Surveillance by authorities

Reimbursement and pricing in CH
CH Spezialitätenliste SL
Submissions to authorities
Pricing strategies
Price adjustments

Special regulations, medical devices
Current regulations and requirements
Classification of medical devices I, IIa, IIb, III
Requirements for clinical studies
Developments in EU
Materiovigilance

Approval of clinical trials and regulatory aspects of drug development
Regulatory environment, ICH E6, Human Research Act (HRA), Ordinance on Clinical Trials in Human Research (ClinO),), Declaration of Helsinki
Responsibilities Ethics Committees and Swissmedic
Submissions to ECs and Swissmedic
Clinical Trial Protocol, Investigator Brochure, Case Report Form etc.
The relevance of biomarkers, surrogate and clinical endpoints
IMPD (Investigational Medicinal Product Dossier)
Patient reported outcomes

EU/US regulatory submissions
Duties and responsibilities of the regulatory bodies
Components of regulatory submission

Steps and requirements from regulatory approval to market
Variations

Freely chosen courses in any field of regulatory affairs*
Courses in any of the above fields. Examination credits: The credits obtained from the examinations for the MEGRA Startup Plus course (28 hours total, see details below) can be claimed here and under *Courses in other core fields of pharmaceutical medicine*.

Courses in other core fields of pharmaceutical medicine
Courses in any topic of pharmaceutical medicine. Surplus examination credits from MEGRA StartUp Plus can be claimed here.

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 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.

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

Recognition of the MEGRA StartUp Plus Program

A successful completion of the MEGRA StartUp Plus Modules are recognised as fulfilling the specific theoretical requirements for this diploma (65 hours). A successful exam after modules I - X is recognised with 2 credit points each, after Modules XI and XII with 4 credit points each. Therefore, 28 credit points total can be claimed for successful examinations in all 12 modules. No additional exam by SwAPP will be required for candidates who have successfully completed examinations in all modules of the StartUp Plus Program.

Candidates with successful completion, including examinations, of all 12 MEGRA Startup Plus modules plus documentation of

- coursework in any field of pharmaceutical medicine (17 credit points)
- practical training as described above

are therefore eligible for the SwAPP Speciality Diploma Regulatory Affairs without further examination. Please apply for the Diploma under http://www.swapp.ch/education/diplomas.