

## Specialty areas for Continuous Professional Training

### *SwAPP Diploma Pharmaceutical Medicine*

Subject	Hours
Discovery of new substances	8
Pharmaceutical development	16
Preclinical development	24
Clinical development	136
Pharmacovigilance	32
Medical-scientific information	32
Registration of drugs	40
Social economics of the health sector	24
Management	24
Any topic in pharmaceutical medicine	24
<b>Total hours</b>	<b>360</b>

### *SwAPP Specialty Diploma Study Management*

Subject	Hours.
Pharmaceutical development	12
Ethics and law	16
Human pharmacokinetics	12
Clinical studies	32
Auditing / inspection / fraud	12
Pharmacovigilance	8
Communication	8
Marketing authorization of medicinal products	8
Project management	16
Other core fields of pharmaceutical medicine	36
<b>Total hours</b>	<b>160</b>

### *SwAPP Specialty Diploma Regulatory Affairs*

Subject	Hours
Clinical aspects of drug development	8
CH regulatory submissions of drugs	24
CH regulations and laws	16
EU regulatory submissions of drugs	8

and biologics	
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, biologicals, 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
<b>Total hours</b>	<b>160</b>

*SwAPP Specialty Diploma GCP Quality Management*

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>

*SwAPP Specialty Diploma Clinical Pharmacology*

Subject	Hours
Non-clinical pharmacology and toxicology	8

Role of clinical pharmacology trials within the clinical development plan	8
Regulatory requirements	8
Design, execution and analysis of early phase human studies	36
Ethical principles and practices in volunteer studies	8
Good clinical practice in clinical pharmacology or How2GCP certificate	8
Drug safety	8
Relevant literature and publications	8
Freely chosen courses in any field of clinical pharmacology	38
Other core fields of pharmaceutical medicine	30
<b>Total hours</b>	<b>160</b>

### *SwAPP Specialty Diploma Medical Marketing*

Subject	Hours
International regulations and laws	4
Swiss regulations and laws for the promotion of pharmaceutical products	16
Drug promotion surveillance by authorities, Pharmacodex group and competitors	8
Standard Operating Procedures (SOPs)	8
Promotion to the general public and to healthcare professionals	12
Medical clearing of promotion material	4
Marketing authorisations	4
Distribution and GDP	4
Sponsoring	8
Collaboration with Key Opinion Leaders, Advisory Boards	8
Rules and regulations for clinical trials, observational studies, case reports, IITs	8
Market surveillance	8
Clinical publications and ICMJE uniform requirements	8

Relevant literature and publications	16
Freely chosen courses in any field of medical marketing	14
Other core fields of pharmaceutical medicine	30
<hr/> Total hours	<hr/> 160