

National Training Requirements

SWITZERLAND

Specialty

Clinical Pharmacology and Toxicology

(Klinische Pharmakologie und Toxikologie /
Pharmacologie et toxicology cliniques /
Farmacologia e tossicologia clinica)

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Note: This is not a legally binding document. Any current official regulations must be obtained from the responsible National Medical Association or other organisation in charge of the training of medical specialists.

Specialist in Clinical Pharmacology and Toxicology

Continuing Education Program from 1 January 2016

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*<https://www.fmh.ch/bildung-siwf/fachgebiete/facharzttitel-und-schwerpunkte/pharmakologie-toxikologie.html>
(Swiss Institute for Continuing Medical Education)*

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Specialist in Clinical Pharmacology and Toxicology

Training program

1. General

1.1 Description of the subject area

"Clinical Pharmacology and Toxicology" is a medical-scientific discipline whose goals are to promote effective, rational, adapted, safe, and controlled human pharmacotherapy, and the effective and rational management of intoxications in humans. Doctors in Clinical Pharmacology and Toxicology are committed to ensuring that every individual patient, with the right medication, receives the right dose of the right drug at the right time and with the least possible risk of undesirable effects or toxicity and at the lowest possible risk and the lowest possible cost. Clinical Pharmacology and Toxicology combines clinical expertise with basic experimental medical science, especially pharmacology and toxicology, and advances medical knowledge through research aimed at improving the efficacy and safety of clinical drug therapy and treatment of intoxications.

1.2 Goals of the further education

The training should provide the candidate with the necessary knowledge, skills and abilities for a self-reliant, specialist activity in the field of clinical pharmacology and toxicology in authorities, industry, hospital, private practice and community.

2. Duration, structure and other provisions

2.1 Duration and structure of the training

2.1.1 The training lasts 6 years and is structured as follows:

- 2 to 3 years General Internal Medicine or Paediatrics or Anesthesiology (not subject-specific)
- 3 to 4 years Clinical Pharmacology and Toxicology (subject-specific)

2.1.2 Non-specialist further education

- At least one year must be completed at a recognised continuing education institution in category A (General Internal Medicine), A1/A2 (Anaesthesiology) or 3 or 4 (Paediatric and Adolescent Medicine).
- In addition to the compulsory 2 years in General Internal Medicine or Paediatric and Adolescent Medicine or Anaesthesiology, non-specialist continuing education can be credited with up to 12 months of further education in the following fields: Psychiatry and Psychotherapy, Medical Oncology, Neurology, Dermatology, Allergology and Clinical Immunology, Endocrinology/Diabetology, Gastroenterology, Haematology, Infectiology, Intensive Care, Cardiology, Nephrology, Pulmonology, Rheumatology, Occupational Medicine.
- It is recommended to complete the non-subject-specific advanced training prior to the subject-specific further education.

2.1.3 Specialist further education

- At least one year of specialised training must be completed at recognised continuing education establishments of category A.
- An experimental pharmacological/toxicological research activity can be credited to the subject-specific further education for up to 1 year. An MD/PhD training can also, but not in addition, be credited for a maximum of 1 year. The activity does not have to be in the area of the intended

specialty title. It is advisable to ask the title committee beforehand. Research activity is not considered a training activity of the category A.

- Continuing education periods for the specialist title Pharmaceutical medicine—provided they have been completed at recognised further education centres for pharmaceutical medicine—can be recognised for specialist training as a specialist in clinical pharmacology and toxicology for a maximum of one year (does not replace the required A year).

2.2 Further provisions

2.2.1 Fulfillment of the learning objectives or learning contents / logbook:

Fulfillment of the learning objectives according to Section 3. Each candidate regularly keeps a logbook which contains the learning objectives of the training and in which all required learning steps are documented (including courses, further education, congress visits, etc.).

2.2.2 Congress participation

Attendance of at least 2 clinical-scientific congresses, one of which must be in Clinical Pharmacology or Clinical Toxicology. The list of congresses recognised by the professional society can be found on the website of the specialist society (www.clinpharm.ch). At least 25 credits must be earned.

At least one presentation (presentation or poster) of own clinical-pharmacological or clinical-toxicological research results at a national or international clinical science congress.

2.2.3 Courses

The candidate must have successfully completed at least 3 courses in "Good Clinical Practice" recognised by swissethics (Swiss Ethics Committees for Human Research) (<http://www.swissethics.ch/fortbildung.html>).

2.2.4 Publication/scientific paper:

Publication of at least three scientific papers in the field of Clinical Pharmacology/Toxicology in medical journals, at least two of which must be published in peer-reviewed journals or accepted for publication, in hard copy and/or full-text online. For at least one paper, the candidate must be first, second or last author. A dissertation at a university faculty is also considered a publication. Original work including meta-analyses and reviews as well as detailed, carefully referenced case reports are accepted. The text, without references, has a size of at least 1,000 words. The topic of the dissertation does not have to be in the field of the specialty title.

2.2.5 Crediting foreign training:

Foreign training is eligible under Art. 33 WBO. At least 2 years of specialised training must be completed in Switzerland. For the crediting of foreign continuing education, it is advisable to obtain the approval of the title committee beforehand.

2.2.6 Part time

All training can be completed part-time (at least 50%) (Art. 32 WBO).

3. Content of further education

The teaching of the most important learning objectives is recorded in the logbook.

The general course catalogue, which is an appendix to the WBO, is binding for all subject areas and serves as the basis for the continuing education concepts of the individual further education institutions.

These include, in particular, ethics, health economics, pharmacotherapy, patient safety and quality assurance (Art. 16 WBO).

3.1 Basic knowledge

- General pharmacodynamics: Pharmacological and toxicological mechanisms of action
- General pharmacokinetics and toxicokinetics: absorption, bioavailability, protein binding, distribution including transport, clearance including biotransformation, elimination
- Pharmacogenetics and genomics / polymorphisms of drug-metabolising enzymes and drug transporters / genetic toxicology
- Mechanisms of adverse drug reactions (ADRs) and drug interactions
- Basis of Pharmacoepidemiology
- Principles of "Evidence-Based Medicine"
- Basic knowledge of medical statistics

3.2 Clinical drug trials

- Basic knowledge of drug development
- The different study phases (phase I–IV) of clinical trials
- Special trials: bioequivalence studies, interaction studies, studies with therapeutic proteins, QTc studies
- The different types of studies and their significance
- Good Clinical Practice (GCP), Good Laboratory Practice (GLP)
- Planning, implementation and publication of clinical trials
- Statistics in clinical trials
- Legal basis for research involving humans

3.3 Clinical drug use

- Detailed knowledge of pharmacotherapy
- Rational selection and prescription of drugs
- Proper dosage and dose adjustments (individualization)
- Adherence and non-adherence
- Causes of insufficient or absent drug reactions, drug resistance and non-responders
- Evaluation of effectiveness of alternative medical procedures (complementary and alternative medicine)
- Clinical Pharmacology of new and experimental forms of therapy
- Investigation of adverse drug reactions and intoxications

3.4 Quality control and safety of drug therapy

- Methods of quality assurance of pharmacotherapy
- Efficient and optimal use of information resources
- Assessment of the quality and validity of published clinical studies
- Assessment and clinical success control of drug effects
- Measurements of drug concentrations and dose adjustment (therapeutic drug monitoring, population kinetics)
- Structured detection of adverse drug reactions and interactions; Information of the registration authorities (pharmacovigilance)
- Abuse and drug dependence
- Drug information of doctors and other health professionals

3.5 Individualisation of drug therapy

- Drug therapy in pregnancy and lactation
- Drug therapy in paediatric patients
- Drug therapy in old patients

- Drug therapy for organ diseases (e.g. cardiac, hepatic and renal insufficiency)
- Drug therapy in addiction patients (e.g. alcohol, tobacco)
- Drug therapy and nutrition
- Drug therapy and genetics
- Drug combination therapies

3.6 Clinical toxicology

- Toxicodynamics and Toxicokinetics
- Intoxications with drugs
- Detailed knowledge of the most important intoxications with foreign substances and their treatment
- Rational application of primary and secondary decontamination measures
- Chronic intoxications and environmental toxicology
- Drug abuse
- Antidotes

3.7 Medicines and society

- Ethical aspects of drug testing and therapy, in particular familiarity with the principles of medical ethics, mastery of methods for supporting ethical decision-making, and addressing medical ethics issues that arise in typical situations (informing subjects and patients prior to the investigation, research in humans, explanation of diagnoses, dependency relationships, patient's provisions)
- Medicines legislation; cooperation with regulatory authorities
- Legislation on research in humans
- Cost of drug therapy in hospital and practice
- Medicines and environment
- Correct communication and information about medicines in media and society
- Health-economic aspects, in particular rational use of diagnostic, prophylactic and therapeutic agents in healthy and diseased

3.8 Patient safety

- Knowledge of the principles of safety management in the examination and treatment of sick and healthy as well as competence in dealing with risks and complications. This includes, amongst other things, identifying and managing situations that increase the risk of adverse events.

3.9 Proof of practical skills

- Proof of carrying out at least 300 consultations within the framework of subject-specific training; of these, 10–30% have to be pharmacovigilance reports and 10–30% therapeutic monitoring assessments.
- Proof of planning and execution of at least one clinical pharmacological drug trial with patients and/or healthy volunteers.

4. Exam Regulations

4.1 Exam objective

It is examined whether the candidate fulfils the learning objectives listed in section 3 of the training program and is thus able to independently and competently care for patients in the field of clinical pharmacology and toxicology.

4.2 Subject matter of the exam

The subject matter covers the whole Catalogue of Learning Objectives under section 3 of the training program.

4.3 Review committee

The Examination Board is elected by the Executive Board of the Swiss Society for Clinical Pharmacology and Toxicology. A new election takes place every 2 years. Re-election is possible.

The examination committee consists of at least 3 persons.

The language regions must be adequately represented.

The examination committee has the following tasks:

- Organization and implementation of the exams;
- Preparation of questions for the written exam;
- Designation of experts for the oral exam;
- Evaluation of the exam and notification of the exam outcome;
- Determination of examination fees;
- Periodic review or revision of the examination regulations;
- Granting access to the test documents;
- Statements and information in the objection procedure.

4.4 Exam

The exam consists of a written and a practical exam.

4.4.1 Written exam

The candidate will answer in writing a total of 120 multiple-choice questions and short-answer questions on the different chapters of the training content (see section 3 of the training program) within 4 hours.

4.4.2 Practical exam

The candidate will conduct a consilium in the field of clinical pharmacology or clinical toxicology and will discuss a published scientific paper. After a preparation time of 90 minutes, the candidate is examined orally by the members of the examination board on the basis of (1) the consilium, (2) of the scientific work and (3) some regulatory questions for 30 minutes.

4.5 Grading

4.5.1 Time of exam

It is advisable to take the specialist examination not earlier than in the last year of the mandatory training.

4.5.2 Admission

Only those are admitted to the exam who have a Swiss or Swiss-recognised foreign doctor's diploma. For the practical examination, only those are admitted who have passed the written exam.

4.5.3 Time and place of exam

The specialist exam takes place once a year. The date, place and deadline for registration will be published at least 6 months in advance on the SIWF website and in the Schweizerisches Ärztezeitung (SÄZ; Swiss Medical Journal). The date and place of the practical examination will be communicated to the candidate after having passed the written exam.

4.5.4 Exam report

A report on the practical exam will be created.

4.5.5 Exam language

Written exam: in English. Answers to short-answer questions can also be given in one of the national languages.

Practical exam: Documents and written questions in English, oral questions and answers in German, French or—in agreement with the candidate—in English. Examinations in Italian are permitted if the candidate so requests and an Italian examiner is available.

4.5.6 Examination fees

The Swiss Society of Clinical Pharmacology and Toxicology levies an examination fee, which is determined by the Examination Board and published together with the announcement on the SIWF website.

The examination fee is payable upon registration for the examination. If the registration is withdrawn, the fee will only be refunded if the registration has been withdrawn at least four weeks before the written examination date. If withdrawn at a later date, the fee will be refunded only if the registration was withdrawn for important reasons.

4.6 Evaluation criteria

Both parts of the exam are graded “passed” or “failed”. Passing the written exam is a prerequisite for admission to the practical exam. The specialist exam is passed if both parts of the exam are passed successfully. The final assessment is “passed” or “not passed”.

4.7 Announcement of the examination result, repetition of the exam and appeal

4.7.1 Announcement

The result of the written examination as well as the final assessment will be announced to the candidate in writing, along with information on the right to appeal.

4.7.2 Repetitions

The specialist examination can be repeated as often as required, whereby only the part not passed must be repeated.

4.7.3 Appeals

The decision on the non-admission to the specialist examination can be appealed within 30 days, the one on the failure of the written exam or the entire exam within 60 days from the announcement of the exam results; appeals are to be filed with the Appeals Commission (EK WBT) (Art. 23 and 27 WBO).

5. Criteria for the recognition and classification of training centers

5.1 Requirements for all training institutions

- The accredited training institutions are led by a responsible person responsible for training, who holds the specialist title for Clinical Pharmacology and Toxicology. In exceptional cases, equivalent qualifications may suffice in accordance with Art. 39 (2) WBO.
- The director is responsible for the adherence to the training program.

- The director fulfils the duty of continuing education (Art. 39 WBO).
- There is a training concept that documents the teaching of the learning contents in terms of time and content (Art. 41 WBO). The training concept must be realistic and comprehensible in defining the offered training and also the with respect to the maximum number of possible training places. In particular, it describes the goals that a doctor in training can achieve over the course of a year (both for subject-specific and non-subject-specific training).
- The general learning objectives are taught according to section 3 of this program and the logbook. Special attention should be paid to the learning objectives related to ethics, health economics, pharmacotherapy, patient safety and quality assurance (Art. 16) WBO).
- A reporting system for errors (e.g. Critical Incidence Reporting System, CIRS), provided by the clinic (respectively department or institute), the hospital or the professional society, is available.
- The current editions of at least 3 of the following 6 journals are available to the trainees as print and/or full-text online editions at any time: "Clinical Pharmacology and Therapeutics", "British Journal of Clinical Pharmacology", "European Journal of Clinical Pharmacology", "Clinical Pharmacokinetics", "Drugs", "Clinical Toxicology". At the workplace or in the immediate vicinity there is a PC with a powerful Internet connection. There is an access to a library with interlibrary loan for the magazine articles and books that are not available at the training centre.
- The training centres are obliged to offer the assistant doctors the opportunity to attend the required courses (section 2.2) during the working hours.
- The training centres regularly carry out a workplace-based assessment¹ through which the state of training is documented four times a year.

5.2 Training network

If necessary, training institutions can form a training network. The training institutions joined together in a training network form a committee that coordinates the training of the candidates and, in particular, organises the rotations in the various departments. The training institutions involved regulate their cooperation by means of a contract.

5.3 Training association

Clinics, institutions or medical practices can link up to form a training association. All affiliated units then belong to a single training centre with a training concept in the corresponding category. The prerequisite is that the training concept regulates the rotation system of the assistant physicians and the senior physicians within the framework of the association, and that the director of the main centre assumes responsibility for training. A delegation of the responsibility to the associated units is permissible if governed by the training concept.

5.4 Categories of training institutions for Clinical Pharmacology and Toxicology

Due to their characteristics, training centres are classified into 2 categories (see Table).

¹ http://www.fmh.ch/bildung-siwf/weiterbildung/fuer-facharztanwaerter/arbeitsplatzbasiertes_assement.html

5.5 Classification of criteria

Characteristics of the training center	Category (maximum recognition)	
	A (4 years)	B (2 years)
Clinic, department or institute of Clinical Pharmacology and/or Clinical Toxicology in a tertiary care hospital (university or hospital centre)	+	
Clinical research department, medical service of a medicines authority		+
Drug side effects and/or toxicology information centre		+
Clinical-pharmacological, clinical-toxicological or pharmaceutical-medical department in industry		+
Clinical-pharmacological contract research organisation		+
Intensive care unit in the hospital available	+	

Medical staff	A (4 years)	B (2 years)
Director of the training institution full-time in Clinical Pharmacology and Toxicology	+	+
Director habilitated	+	
Number (without leader) of senior physicians and senior physicians with specialist diploma in Clinical Pharmacology and Toxicology, minimum (% of positions):	100%	
Trainee positions, minimum (% of positions):	200%	100%
Number ratio of trainers with specialist title to doctors in training, minimum	1:2	1:2

Practical training	A (4 years)	B (2 years)
Teaching the entire catalogue of learning objectives (see section 3 of the training program)	+	
Teaching part of the training, depending on the focus defined in the training concept of the institution		+
Minimum number of processings of clinical-pharmacological and toxicological consilia/consultations/inquiries/reports/dossiers per year per trainee	100	20
Planning and conducting clinical phase I to III trials (minimum number per year)	1	
Clinical visits with the director or another specialist in Clinical Pharmacology and Toxicology (minimum number per week)	1	

Theoretical training	A (4 years)	B (2 years)
Structured training in the specialty (training curriculum Clinical Pharmacology and Toxicology including internistic case presentations and journal club) (hours)	3 / week	3 / week
Interdisciplinary training courses with other internistic specialties (hours).	1 / week	
Other training (hours)	1 / week	1 / month
Possibility of visiting external training events during working hours (minimum number of days / year)	3	2
Training in medical ethical and health economics issues of the specialty	+	+
Opportunity for scientific work	+	desirable

6. Transitional provisions

The SIWF approved this revision of the training program on 11 June 2015 and put it into effect on 1 January 2016.

This program replaces the training program of 1 January 2001.

(Anyone who has completed all the conditions (excluding the specialty examination) in accordance with the previous program until 31 December 2018 may apply for the title as specialist according to the old provisions of the training program of 1 January)².

Revisions: 12 January 2006 (sections 2.2.1, 4, 5 and 6, approved by the ZV)
23 November 2006 (sections 2.4.1, 3.8, 5.4 and 6, approved by the KWFB)
29 March 2007 (ections 3.8 and 5.4, approved by the KWFB)
6 September 2007 (sections 3.9 and 5.4, additions patient safety approved by KWFB)

Bern, 15.10.2007/pb
WB-Programme/Klinische Pharmakologie/2007/klinische_pharmakologie_version_internet_d.doc

² https://contens30.fmh.ch/fmh/_files/pdf17/klinische_pharmakologie_2001_d.pdf