TRAINING AND DEVELOPMENT RULES of the Pharmaceutical Society of Hesse, Public Corporation

in accordance with the resolution of the Delegates Assembly of the Pharmaceutical Society of Hesse (*Landesapothekerkammer Hessen*) dated 20 June 1996, approved by the Hessian Ministry for the Environment, Energy, Young People, Families and Health (*Hessisches Ministerium für Umwelt, Energie, Jugend, Familie und Gesundheit*) on 2 August 1996, published in *Pharmazeutische Zeitung* (PZ) no. 38/1996, pp. 3527 *et seq*., most recently amended by the resolution of the Delegates Assembly of the Pharmaceutical Society of Hesse on 17 June 2024, approved by the Hessian Ministry for Family Affairs, Senior Citizens, Sport, Health and Care (*Hessisches Ministerium für Familie, Senioren, Sport, Gesundheit und Pflege*) on 28 June 2024, published in PZ no. 29/2024, pp. 67 *et seq*. and *Deutsche Apotheker Zeitung* (DAZ) no. 29/2024, p. 65.

§ 1 Purpose of training and development

The purpose of training and development is to enable pharmacists who have qualified in the profession to gain further knowledge and skills in fields and areas for which specialist titles can be used.

§ 2 Fields and areas of training and development

(1) Pharmacists may pursue training and development in the following specialist fields:

1. Field: General pharmacy
2. Field: Clinical pharmacy
3. Field: Pharmaceutical analysis and technology
4. Field: Drug information
5. Field: Toxicology and ecology

(2) In the areas of prevention and health promotion, nutritional advice, homeopathy and naturopathy, oncology pharmacy, geriatric pharmacy, hospital medication management, infectious diseases and paediatric pharmacy, training and development may be pursued to obtain the right to use an additional title.

§ 3 Titles

The following titles are determined for the fields specified in § 2:

1. Certified general pharmacist (*Fachapotheker für Allgemeinpharmazie*)
2. Certified clinical pharmacist (*Fachapotheker für Klinische Pharmazie*)
3. Certified pharmacist for pharmaceutical technology (*Fachapotheker für Pharmazeutische Technologie*)
4. Certified pharmacist for pharmaceutical analysis (*Fachapotheker für Pharmazeutische Analytik*)
5. Certified pharmacist for drug information (*Fachapotheker für Arzneimittelinformation*)
6. Certified pharmacist for toxicology and ecology (*Fachapotheker für Toxikologie und Ökologie*)

§ 4 Type, content and duration of training and development

(1) Training and development may commence after the trainee has been licensed to practice as a pharmacist or has obtained approval to practice as a pharmacist on a temporary basis.

(2) Training and development serves to deepen knowledge and skills in developing, manufacturing, testing, certifying and dispensing medicines, and providing information and advice on medicines and the supply of medicines. It also covers the interrelationships between humans and the environment in relation to medicines as well as poisons and other substances harmful to health and their detection, along with the action necessary to redress and prevent damage.

(3) The content, duration and scope of training and development is based on the provisions of the Annex to the Training and Development Rules. The periods of training and development given therein constitute the minimum duration. Any interruption to the training and development cannot be credited towards the duration of training and development. The training and development shall not be considered interrupted if it is continued at a minimum of 19 hours per week. Annual leave in accordance with collective bargaining agreements shall not constitute an interruption.

(4) Training and development in specialist fields and areas shall generally be conducted on a full-time basis or – if justified by personal circumstances – on a part-time basis and at the primary place of employment. Part-time training and development must cover at least 19 hours per week. The overall duration and quality must meet the requirements for full-time training and development. Part-time training and development shall only be credited if it has been confirmed as eligible by the Pharmaceutical Society of Hesse (hereinafter the "Pharmaceutical Society").

(5) The Pharmaceutical Society must be notified of the commencement, schedule, interruptions and all changes relating to the training and development; such notification must be made within one month in writing using the prescribed form. In the cases laid out in § 7 (4), the trainee must also notify the authorised pharmacist of these changes.

(6) Participation in the seminars offered by the Pharmaceutical Society is mandatory. If seminars are held by other bodies, the trainee may request that the Pharmaceutical Society recognise them as equivalent and they may be attended in lieu of the seminars offered by the Pharmaceutical Society. Such recognition must generally be obtained before the start of the seminar. No separate request for recognition is required for training and development seminars offered and recognised by other societies or recognised by the Federal Chamber of Pharmacists (*Bundesapothekerkammer*, "BAK"). These are considered recognised.

(7) If the Annex to these Training and Development Rules stipulates that a written paper (project paper) must be completed for a given field or area, this must be prepared in consultation with the instructor on a topic constituting one of the learning objectives.

§ 5 Use of titles

(1) Pharmacists who are accredited in one or more field(s) may use the title of their primary field of practice. If they have more than one field of practice, they may use a maximum of two titles of the fields in which they are primarily active. The Pharmaceutical Society may grant exemptions in exceptional cases on the conditions stipulated in section 46 (3) of the Health Care Professions Act (*Heilberufsgesetz*).

(2) In principle, the eligibility to use a title shall remain in place even if the title of a field or area is subsequently changed. Titles conferred pursuant to previously valid versions of the Training and Development Rules that are no longer included in the Training and Development Rules may continue to be used.

§ 6 Authority to conduct training and development

(1) Training and development in the specialist fields shall be conducted at approved training and development centres and units at universities under the management of pharmacists authorised by the Pharmaceutical Society.

(2) The authorisation to conduct training and development can be granted on request if the pharmacist is suitably qualified. They must have extensive knowledge and experience in their field and/or area that enable them to provide comprehensive training. The authorisation may only be granted for fields and areas in which the pharmacists already hold a title.

(3) The authorised pharmacist is required to conduct the training and development in person and ensure that its timing and content complies with these Training and Development Rules. The instructor must be employed at the training and development centre for at least half of the weekly working hours determined in accordance with collective bargaining agreements.

(4) Upon request, authorisation is granted to pharmacists for a period of up to six years. The authorisation may be renewed. Applicant pharmacists must specify the field or area and training period for which authorisation is sought. The Pharmaceutical Society maintains a list of authorised pharmacists that specifies the training and development centre and the authorisation for the specialist field or area and the scope and period of validity of the authorisation. The list shall be made public.

(5) In consultation with the authorised pharmacist, trainees draw up a training plan that must be submitted to the Pharmaceutical Society at the latest three months after commencement of the training relationship. If the trainee fails to submit the training plan to the Pharmaceutical Society on time, the period until submission of the training plan will not be credited towards the training period. The trainee and the authorised pharmacist should hold at least two meetings per year, which should be appropriately documented.

(6) The training authorisation may be revoked or withdrawn on the conditions laid down in sections 48 to 50 of the Hessian Act on Administrative Procedure (*Hessisches Verwaltungsverfahrensgesetz*).
The authorisations granted to authorised pharmacists shall expire upon termination of their employment at the respective training and development centre.

§ 7 Training and development centre

(1) In consultation with the supervisory authority, the Pharmaceutical Society of Hesse shall issue a policy on the approval of training and development centres. A training and development centre is an establishment approved by the Pharmaceutical Society where trainees acquire specialist knowledge, experience and skills.

(2) The management of the training and development centre applies to the Pharmaceutical Society for approval. The application must fully identify the training and development centre with valid address for service and the specialist field for which approval is being sought. The request must include a written declaration by the authorised pharmacist that the requirements for the training and development centre's material and human resources in accordance with § 6 have been met.

(3) Approval is usually granted indefinitely. It expires on the conditions laid down in sections 3 and 4 of the German Pharmacy Act (*Apothekengesetz*). The approved training and development centre will be announced.

(4) If trainees do not work at the training and development centre of their authorised pharmacist, the trainee's workplace and the workplace of the authorised pharmacist must be approved as training and development centres before the training commences. In this case, a prerequisite for due and proper training and development is a written agreement between the authorised pharmacist and the trainee's employer that the trainee will be given the opportunity to deepen and broaden their theoretical knowledge and practical experience and skills in accordance with the instructions given by the authorised pharmacist. The authorised pharmacist must submit the declaration on the written agreement to the Pharmaceutical Society at the latest three months before commencement of the training relationship. § 6 (5) sentence 2 shall apply *mutatis mutandis*.

§ 8 Issue of certificates on the training and development

(1) The authorised pharmacist shall issue a certificate to the trainee pharmacist on the period of training completed under their tutelage. The certificate must detail:

1. the duration of the training period completed and interruptions in the training,

2. the knowledge and skills imparted and acquired during this period of training on the basis of the agreed training plan. Confirmation that the training plan has been completed must be attached as an annex to the certificate.

(2) In the case of seminars offered by the Pharmaceutical Society, the Pharmaceutical Society shall issue those in attendance who are participating in training and development a certificate stating the duration of attendance at the seminar and interruptions. If seminars are held by other persons or entities, a corresponding certificate must be submitted.

(3) If the employer is not the trainee's authorised pharmacist, the employer must issue the trainee a certificate stating the duration of the training periods completed and interruptions in the training and development. Self-employed trainees must truthfully confirm these periods and interruptions themselves.

§ 9 Accreditation

(1) Persons who have completed training and development by passing the examination may use a title pertaining to a specialist field in accordance with § 3.

(2) Eligibility to use the additional titles laid down in § 2 (2) shall be conferred on the basis of the certificates and evidence submitted and an examination by the Pharmaceutical Society.

§ 10 Examination committees

(1) The Pharmaceutical Society forms examination committees to conduct the examination. The members of the committees and their deputies are appointed by the Executive Committee. Decisions are adopted by examinations committees comprising a minimum of three members, of which two must be accredited in the specialist field or area being the subject of the examination.

(2) The Executive Committee appoints the chairpersons of the examinations committees and their deputies, who should be accredited in the specialist field or area being the subject of the examination.

(3) The examinations committees adopt decisions by a majority vote in closed sessions. In the event of a tie, the chairperson shall have the deciding vote. The members of the examination committees decide independently and are not bound by instructions.

(4) An objection may be lodged against the decision of the examination committees within one month of announcement; the Executive Committee shall decide on the objection.

(5) The members and deputy members of the examination committees are appointed for a term of four years. They shall remain in office until new appointments are made to the committees.

(6) The examination committee may inspect the project paper.

§ 11 Admission to examinations

(1) The Pharmaceutical Society decides on admission to examinations. Admission shall be granted if the training and development has been duly and properly completed and documented by certificates, attestations and evidence and the written paper in accordance with § 4 (7) has been submitted at the time of application. An objection may be lodged against refusal to grant admission within one month of such refusal being announced; the Executive Committee shall decide on the objection.

(2) The admission may be revoked or withdrawn on the conditions laid down in sections 48 to 50 of the Hessian Act on Administrative Procedure.

§ 12 Examination

(1) The Pharmaceutical Society shall set the examination date. The candidate must be invited to the examination at least two weeks before the set examination date. Examinations generally take place once or twice per year. An employee of the office may be present at all times during the examination.

(2) The examinations in the specialist fields shall be oral examinations. They should last up to 60 minutes for each candidate. No more than three candidates should be examined simultaneously. The examination must be invigilated by the chairperson of the examination committee. A record of results must be drawn up and signed by the members of the examination committee. The examination in the specialist areas may also be a written examination.

(3) The knowledge acquired is proven by means of an oral presentation to the examination committee. After the examination, the examination committee decides by a majority vote whether the candidate has successfully completed the training and development and has acquired the prescribed specialist or additional knowledge in their selected field or area.

(4) If a candidate does not pass the examination, the examination committee may extend the prescribed training period by between three and a maximum of 12 months. It may also impose specific requirements as to the content of the training and development.

(5) If the candidate fails to appear for the examination without good cause or abandons it, the candidate shall be deemed to have failed the examination. If good cause exists, the examination shall be deemed not to have taken place.

§ 13 Examination decision

(1) Candidates will be notified verbally of the result after the examination has finished. The chairperson of the examination committee must forward the record of results to the office without undue delay.

(2) After the training and development examination has been completed, the Pharmaceutical Society shall issue the candidate a written notice that they have passed or failed the examination.

(3) The Pharmaceutical Society shall issue candidates who have passed the examination a certificate conferring the right to use the specialist title.

(4) Candidates may lodge an objection against the notification of the Pharmaceutical Society in accordance with paragraph (2) within one month of notification.

§ 14 Examination resits

Candidates may resit an examination they have failed a maximum of twice, in each case at the earliest three months thereafter. §§ 10 to 13 shall apply *mutatis mutandis* to examination resits.

§ 15 Accreditation in the case of a differing training course

(1) Upon request, the Pharmaceutical Society shall accredit persons who have completed training that differs from the training course laid down in § 4 if that training and development is equivalent. § 9 (1) and § 13 (2) to (4) shall apply *mutatis mutandis*.

(2) Training and development differing from § 4 that has not been completed or is not equivalent may be completed in accordance with the provisions of these Training and Development Rules subject to full or partial crediting of the training periods completed to date. The Pharmaceutical Society shall decide on the crediting of training periods completed to date. § 9 (1), § 10 and § 13 (2) to (4) shall apply *mutatis mutandis*.

§ 16 Training and development outside the Federal Republic of Germany

(1) The Pharmaceutical Society shall, upon request and in accordance with the requirements of points (d) or (g) of Article 10 of Directive 2005/36/EC, accredit any person who is a citizen of a member state of the European Union or another signatory state to the Agreement on the European Economic Area or a contracting state that Germany and the European Union have contractually granted a corresponding legal claim (European states or contracting states) and holds evidence of formal qualifications within the meaning of point (c) of Article 3(1) of Directive 2005/36/EC in respect of completed training and development. Sentence 1 shall also apply to persons holding evidence of formal qualifications recognised by a European state or contracting state if the holder has gained three years of professional experience in the recognising state and has been certified by that state.

(2) If the proven duration of training and development falls at least one year short of the corresponding training period or the content of such training and development differs substantially from the respective content in accordance with these Training and Development Rules, applicants must, at their discretion, either undertake an adaptation period or take an aptitude test. In the cases specified in sentence 2 of paragraph (1), the Pharmaceutical Society shall decide on the compensation measures; in this case, applicants shall have no discretionary options. Compensation measures will not be required if the knowledge acquired by the applicant in the course of their professional work and continuing professional development compensates for the substantial difference, or if the applicant's professional qualifications meet the criteria for a measure adopted in accordance with Article 15(2) of Directive 2005/36/EC.

(3) Participation in standard training and development shall be prescribed as the adaptation period. The applicant shall bear responsibility for choosing an approved training and development centre. The Pharmaceutical Society shall decide on a case-by-case basis as to the duration and content of the training and development and participation in accompanying seminars; training periods completed and content covered to date shall be taken into consideration. §§ 4 and 8 shall apply *mutatis mutandis*.

(4) §§ 10 to 14 shall apply *mutatis mutandis* to the aptitude test. The test shall be limited to those areas in which the content of the applicant's own training and development falls short of the training and development governed in these Training and Development Rules.

(5) The training periods completed by a citizen of a European state or contracting state that have not yet resulted in evidence of formal qualifications in accordance with paragraph (1) shall be fully or partly credited in accordance with § 15 (2) towards the training periods stipulated in these Training and Development Rules.

(6) § 15 shall apply *mutatis mutandis* to the evidence of formal qualifications of third-country nationals.

(7) The Pharmaceutical Society shall within one month provide the applicant with confirmation of receipt of the documents and shall indicate which documents, if any, are missing. It shall decide on the application at the latest within three months from submission of complete documents. This deadline may be extended by one further month.

§ 17 Revocation and withdrawal of accreditation

The accreditation in a specialist field may be revoked or withdrawn on the conditions laid down in the Hessian Act on Administrative Procedure.

§ 18 Entry into force and transitional provisions

(1) The Training and Development Rules shall enter into force on the day after their promulgation.

(2) Any person who has already commenced the "Pharmaceutical analysis" or "Pharmaceutical technology" training as at the date these Training and Development Rules enter into force may complete their training in accordance with the Training and Development Rules in the version dated 8 March 2017 or may switch to the "Pharmaceutical analysis and technology" training course. In the case of switching courses, the Pharmaceutical Society shall decide on recognising seminars already attended.

Annex to the Training and Development Rules for the Pharmaceutical Society of Hesse

1. Specialist field: General pharmacy

General pharmacy is the field of pharmacy that deals with the supply of medicines and medical devices to treat and prevent diseases and illnesses. It primarily includes providing drug information and advising patients and health care professionals, medication management to optimise medication therapy, and the quality-assured manufacture, testing and storage of medicines.

Learning objective:

Broader and deeper knowledge, experience and skills for pharmacy practice, including acquiring management expertise and soft skills, in particular

- with respect to assessing, selecting and applying medicines, including identifying, resolving and preventing adverse drug reactions,
- with respect to researching and assessing information on medicines and medication therapies, and deriving suitable actions and recommendations,
- with respect to in-pharmacy medication and interaction management aimed at optimising medication therapy in view of success, safety and concordance,
- in pathology and medication therapy,
- in the quality-assured production of medicines at pharmacies,
- in assessing, promoting and implementing measures to prevent diseases and promote health, including physiological-chemical and other screening procedures,
- for targeted communication with patients, nursing staff, doctors and other health care professionals,
- for managing pharmacy employees,
- in the foundations of quality-assured work at a pharmacy and to implement and refine quality management.

Duration and conduct of training:
The training period amounts to 36 months at a public pharmacy, including attending a minimum of 120 hours of seminars approved by the Pharmaceutical Society and preparing a written paper (project paper) with content that must comply with the learning objectives.

Training and development periods that may be credited:
Up to 12 months of training and development in

- clinical pharmacy

Up to 6 months of training and development in

- pharmaceutical technology, or
- pharmaceutical analysis, or
- drug information, or
- public health care.

2. Specialist field: Clinical pharmacy

Clinical pharmacy is the field of pharmacy that deals with supplying medicines and other specialist medical products to all patients in accordance with section 14 of the German Pharmacy Act, and providing the associated pharmaceutical advice. Certified clinical pharmacists ensure the effective, safe and cost-efficient use of medicines and medical devices in the area they supply. Their tasks include in particular managing procurement, producing, testing, distributing and storing medicines and providing information and advice on them, controlling consumption, providing patient-related clinical/pharmaceutical services and developing and implementing measures to ensure optimal medication therapy.

Learning objective:

To acquire and hone in-depth knowledge, skills and competences so that the certified clinical pharmacist:

- has detailed knowledge with regard to the clinical application of medicines used in hospitals,

- makes individual and general therapy recommendations pursuant to evidence-based criteria and the patient's individual parameters,
- provides pharmaceutical care for hospital patients as part of medication management,
- makes individual and general recommendations to nursing staff in dealing with and applying medicines,
- applies and develops various target group-specific communication techniques to advise and train patients, doctors, nursing and pharmaceutical staff, and to manage meetings,
- produces and tests various forms of medicines (in the quality required in line with pharmaceutical science), medical devices and in vitro diagnostics, and documents the production and test processes,
- ensures qualitative and economical management of medical supplies,
- plays an instrumental role in deciding on the hospital's choice of medicines and ensuring that these are assessed taking into consideration effectiveness, safety and cost,
- researches, assesses, communicates and documents medical and pharmaceutical information, in particular in relation to medicines,
- assesses the correct handling and application of the medical devices, in vitro diagnostics and dietary foods procured from the respective pharmacy,
- documents pharmaceutical services in a suitable form,
- is aware of the statutory and operational framework of the hospital and health care system, and aligns the activities of the pharmacy within this framework,
- performs operational and strategic management tasks with respect to the provision of pharmaceutical services,
- helps select and implement suitable measures to increase the safety of medication therapy,
- is familiar with the pharmacist's tasks in conducting clinical trials,
- identifies, collects and assesses information about pharmaceutical risks and takes adequate steps to mitigate risk,
- works in the hospital's antibiotic stewardship team/performs tasks in accordance with the German Infection Protection Act (*Infektionsschutzgesetz*) and advises doctors and nursing staff on the selection and application of anti-infectives and disinfectants,
- cooperates in quality assurance with respect to all pharmaceutical-related processes in the hospital.

Duration and conduct of training:

36 months at a hospital pharmacy, a pharmacy supplying a hospital or a Bundeswehr hospital pharmacy, including attending seminars and proof of having performed practical activities at the training and development centre. A project paper must be written during the training period. It is only necessary to switch to a different training and development centre if the centre's approval is restricted.

Training and development periods that may be credited:

Up to 12 months of training and development in
- general pharmacy, or
- drug information, or
- pharmaceutical technology, or
- pharmaceutical analysis

Up to 6 months of training and development in
- public health care, or
- theoretical and practical education.

3. Specialist field: Pharmaceutical analysis and technology

Pharmaceutical analysis and technology is the field of pharmacy that deals with the development, production, testing and quality assurance of medicines and medical devices on an industrial scale. In doing so, it is particularly important to:
- convert a substance or mixture of substances into a pharmaceutical form capable of therapeutic application in order to achieve optimal effectiveness, tolerance and stability,

- develop, validate and apply suitable production techniques and establish these on a commercial production scale,
- characterise, specify, test, assess and document the pharmaceutical quality of active ingredients, excipients, starting materials, medicinal preparations and medical devices in observance of the legal framework,
- develop, validate and apply analytical procedures in accordance with the generally accepted state of the art in science and technology, and
- develop, implement and apply suitable quality assurance procedures.

Learning objective:
In-depth knowledge, skills and competences in this specialist field so that the pharmacist having completed training
- develops pharmaceutical forms with the objective of achieving optimal quality, effectiveness, safety and user friendliness,
- develops, validates and applies suitable production techniques in selection of suitable materials, and establishes these on a production scale,
- develops, validates, applies and assesses physical, chemical, biological, biochemical and microbiological methods of analysis, and
- assesses the results on the basis of the data obtained and documented,
- characterises, specifies and assesses the quality of substances, mixtures of substances, starting materials, intermediate products, medicines, medical devices and packaging materials,
- takes into consideration the regulatory and legal framework,
- applies adequate quality assurance systems,
- cooperates on an interdisciplinary basis with research and development, production and quality control/assurance, marketing authorisation and management, thereby contributing specialist knowledge.

Duration and conduct of training:
36 months at a suitable pharmaceutical analysis and technology establishment, including attending seminars. A project paper must be written during the training period.
Training and development centres may include pharmaceutical companies, pharmaceutical analysis and technology laboratories, pharmaceutical institutes at universities and equivalent Bundeswehr facilities, to the extent these demonstrate that they can achieve the learning objectives. The period of training at the individual training and development centre that can be credited is based on the extent of training content covered.

It is only necessary to switch to a different training and development centre if the centre's approval is restricted.

Training and development periods that may be credited:

- Up to 12 months of training and development in toxicology and ecology
- Up to 6 months of training and development in drug information or public health care or clinical pharmacy.

4. Specialist field: Drug information

Drug information is the field of pharmacy that deals with the development, collection, processing, assessment and dissemination of information on the quality, effectiveness and safety of medicines to various target groups.

Learning objective:

To acquire and hone in-depth knowledge, skills and competences so that the certified pharmacist for drug information:

- collects scientific data and information on active pharmaceutical ingredients and medicines, assesses this and processes and disseminates the results to specific target groups,
- is familiar with the requirements for, structure and content of standardised drug information such as patient information leaflets, summaries of product characteristics, labelling and public assessment reports,
- is familiar with the fundamental requirements for the design, planning and conduct of clinical studies as well as biometric methods to evaluate clinical studies,
- interprets clinical and epidemiological studies, meta analyses, systematic reviews and medical guidelines and assesses their quality and scientific evidence,
- is familiar with the legal basis for pharmaceutical marketing authorisation, the various authorisation procedures, the fundamental structure of an application dossier for marketing authorisation and the fundamental regulatory requirements to evidence the quality, safety and efficacy of a medicine and actions to maintain or change the marketing authorisation,
- is familiar with the fundamentals of GxP, in particular good manufacturing practice (GMP), good clinical practice (GCP), good clinical laboratory practice (GCLP), good laboratory practice (GLP), good pharmacovigilance practice (GVP) and good distribution practice (GDP),

- is familiar with the structure of the national and international risk management system and the methods and procedures used to identify and assess pharmaceutical risks,
- is familiar with various forms, objectives and areas of application of pharmacoeconomic and other cost-utility studies on medicines, and assesses their quality.

In addition, certified pharmacists for drug information have knowledge, skills and competences in at least three of the following areas:
- The certified pharmacist is familiar with methods to determine the therapeutic need for new pharmaceutical substances, for the development of active ingredients, and for the process of developing new medicines.
- The certified pharmacist can differentiate medicines from other product groups such as medical devices, nutritional supplements, dietary foods, cosmetics and biocides.
- The certified pharmacist is familiar with the legal bases for medical devices, their rating and classification, the requirements for market access including clinical testing, the vigilance system for medical devices and the pricing and reimbursement mechanisms.
- The certified pharmacist is familiar with the fundamentals of project management for the purposes of planning, monitoring, managing and completing projects in connection with medicines.

Duration and conduct of training:

36 months at a suitable drug information establishment, including attending seminars. A project paper must be written during the training period.
Training and development centres may include pharmaceutical companies, scientific and academic institutions, government agencies and other institutions, to the extent these demonstrate that they can achieve the learning objectives. The period of training at the individual training and development centre that can be credited is based on the extent of training content covered. It is necessary to switch to a different training and development centre if the centre's approval is restricted.

Training and development periods that may be credited:

Up to 6 months of training and development in one of the fields specified in § 2 (1).

5. Specialist field: Toxicology and ecology

Toxicology and ecology is the field of pharmacy that deals with studies in pharmaceutical toxicology, chemical toxicology, environmental toxicology and forensic toxicology as well as the associated analytical methods used to study pharmacokinetics and clinical and chemical methods to detect substances. This includes knowledge about ecological equilibrium and its disruption by environmental contaminants.

Learning objective:

Broadening and deepening of knowledge, experience and skills, in particular:

- in the development, application and assessment of procedures for analytical toxicology,
- in the identification, quantification and assessment of the harmful effects of foreign substances in suitable model systems under defined conditions,
- in methods of chemical, biological and physical analysis,
- in pharmacokinetics and toxicokinetics,
- in the effects and impact of substances influencing ecological equilibrium,
- in the development of suitable analytical methods to identify factors causing ecological disruption,
- in the interpretation of research outcomes and the drafting of expert opinions,
- in measures to eliminate substances that are harmful to health and for the avoidance of risk,
- in the respective fields of law.

Duration and conduct of training:

36 months in ecology and toxicology at a government-approved diagnostic laboratory, a laboratory at an industrial company, a university institute or an equivalent Bundeswehr facility, including attending the seminars prescribed by the Pharmaceutical Society and preparing a written paper (project paper) with content that must comply with the learning objectives.

Training and development periods that may be credited:

- Up to 12 months of training and development in pharmaceutical analysis.

6. Specialist area: Prevention and health promotion

Prevention and health promotion covers action taken to prevent or delay to the furthest extent possible a disease or adverse progression leading to a disease. In the broadest sense, the aim of prevention is to maintain health or to alleviate diseases and their effects or bring about an improvement. The training and development is aimed at enabling pharmacists to act as a patient's specialist and independent advisor in the area of prevention and health promotion.

Learning objective:

Broadening and deepening of knowledge and experience, in particular:
- on the understanding of health and its influencing factors,
- on the objectives, approaches and strategies of prevention and health promotion,
- on theories and models to influence health behaviour,
- on implementing theories and models to influence behaviour and on planning interventions,
- on health promotion and preventative measures,
- in preventing drug misuse and substance abuse.

At the same time, rhetorical, teaching and educational knowledge and skills must be acquired:

- in conversation and discussion techniques,
- in appropriately conveying information to recipients, in particular with respect to helping disseminating information in the pharmacy and in working groups at adult education centres, local authorities and other institutions,
- in designing talks and presentations.

Duration and conduct of training:

At least 12 months working as a professional pharmacist, including attending at least 80 hours of approved seminars. A project paper must be written during the training period.

7. Specialist area: Nutritional advice

Nutritional advice covers advising the public on nutritional issues and is aimed at preventing the development and manifestation of nutritional diseases, manipulating their development or preventing deterioration. It therefore serves the health of individuals.

Learning objective:

Broadening and deepening of knowledge, experience and skills, in particular in:
- the legal bases,
- the German Foodstuffs and Consumer Goods Act (*Lebensmittel- und Bedarfsgegenständegesetz*),
- the German Regulation on Dietary Foodstuffs (*Diätverordnung*),
- the German Regulation on Maximum Quantities (*Höchstmengenverordnung*) and similar,
- nutrition and dietetics,
- purpose of nutrition,
- components of food,
- principles of food preparation,
- conduct of nutritional analyses including quantitative calculation,
- preparation of diet plans,
- special forms of diets for metabolic disorders,
- special forms of nutrition,
- interactions between medicines and foodstuffs,
- preventative nutritional advice,
- counselling techniques and special psychological aspects of nutritional advice.

Duration and conduct of training:

At least 12 months working as a professional pharmacist, including attending at least 100 hours of approved seminars. The training is completed by sitting an examination.

8. Specialist area: Homeopathy and naturopathy

Homeopathy and naturopathy are a special area of therapy. The term "naturopathy" is not very specific and includes all practices of complementary medicine, primarily homeopathy, anthroposophic therapies and phytotherapy. This area of training and development focuses on homeopathy and phytotherapy as key pillars of naturopathy.

Homeopathy:
In homeopathy, the original substance of mineral, plant or animal origin is only present as a trace (dilution) or in concentrations that are no longer measurable. The effect of homeopathy is nevertheless undisputed and as such it is recognised as an independent field in medicine.

Phytotherapy:
Modern phytotherapy based on natural science differs significantly from traditional herbal medicine in that instead of uncritically passing on traditional methods it strives to verify therapeutic claims by means of controlled pharmacological and clinical studies. One feature that sets it apart from "synthetic and chemical single-drug medication therapy" is the experience that in the "multi-substance mix" of a treatment using plant extracts, the various active ingredients in their "natural" composition generally interact to achieve synergy, often in the sense of achieving an overall super-additive agnostic effect.

The interest in treatments such as homeotherapy and phytotherapy reflects the fact that the public is increasingly taking a self-reliant approach to health awareness. Advice from pharmacists in their role as "health managers" is mainly sought when the issue involves:

- disorders affecting wellbeing, or
- conditions with mainly psychosomatic symptoms,
- conditions where the treatments provided in pure "orthodox medicine" are inadequate, with priority given to chronic diseases, or
- certain chronic diseases that are not "recognised" as such by the public but which involve a great deal of suffering for patients, or
- adjuvant therapy to complement conventional methods, or
- therapies using groups of non-prescription medicines that as such are obtained directly and primarily from pharmacies as the first point of contact.

Pharmacists can only take responsibility for performing these tasks once they have acquired the additional specialist knowledge required to do so.

Learning objective:

To acquire, expand and deepen knowledge, in particular
- in the principles and laws of homeopathy,
- in homeopathic remedy pictures,
- in the theory behind the independent treatment approach of homeopathy,
- in homeopathic medical histories and proving,
- in the principles of "remedy discovery",
- in processing a minimum number of example cases with the aim of independently developing and gaining an understanding of remedy pictures and the resulting therapy,
- in knowledge of key and commonly used phytopharmaceuticals and homeopathic remedies for use in naturopathic pharmacy,
- in assessing the quality, therapeutic claims and risk potential of phytopharmaceuticals on the basis of the respective product specification in relation to the criteria of Commission E or ESCOP, and in general the pharmacology of the main active ingredients of the drugs used in phytotherapy,
- in developing naturopathic concepts for use in and to redesign a pharmacy.

Duration and conduct of training:

At least 12 months working as a professional pharmacist, including attending at least 100 hours of approved seminars. The training is completed by sitting an examination.

9. Specialist area: Oncology pharmacy

Oncology pharmacy is the area that deals with advising, caring for and providing medicines to cancer patients. Oncology pharmacy also includes providing clinical and pharmaceutical advice to the oncologist and other health care professionals, assessing information in the area of oncology, ensuring the due and proper patient-specific production proper handling of tumour therapeutics.

Learning objective:
To acquire in-depth knowledge, skills and competences so that the pharmacist having completed training in this area:

- cares for cancer patients and advises doctors, nursing staff and other health care professionals, as well as friends and relatives in the context of tumour therapy,
- is responsible for the quality-assured, patient-specific production of cytostatic preparations in consideration of the requisite measures to protect employees and products and ensure occupational health and safety,
- researches, assesses, draws up, communicates and documents information in the area of oncology,
- contributes to the planning and conduct of studies in clinical oncology.

Duration and conduct of training:
At least 12 months at a pharmacy or establishment suitable for the purposes of training and development, including attending a minimum of 100 hours of seminars.

The following practical requirements must be demonstratively met for the examination:

- assessment and testing of at least 300 cytostatic preparations,
- production of at least 100 cytostatic preparations,
- preparation of at least three patient profiles in accordance with the SOAP methodology, of which two must include consultation with a patient,
- processing and documentation of five selected queries on cytostatic therapy from different subject areas, including giving the sources used,
- preparation of a patient information sheet,
- planning and carrying out at least one training or continuing education event on a topic relating to oncology pharmacy.

10. Geriatric pharmacy

Geriatric pharmacy is the area of pharmacy that covers support for and optimisation of the entire medication process for geriatric patients. For this purpose, potential risks in the supply of medicines are identified and recommendations are drawn up to modify the medication process. In addition, long-term medication management is used to identify, resolve and prevent pharmaceutical-related problems among geriatric patients to improve patient care and reduce subsequent costs in the health care system. One key focal point in geriatric pharmacy is the safety of medication therapy in older people.

Learning objective:
To acquire and hone in-depth knowledge, skills and competences so that the pharmacist having completed training:
- identifies, analyses, resolves and prevents pharmaceutical-related problems and improves the supply of medicines to geriatric patients with respect to effectiveness, safety, rationality and cost-effectiveness using methods from the areas of clinical pharmacy and quality management (QM),
- ensures quality-assured support for and optimises the medication process in various supply structures, including identifying, resolving and preventing medication errors relating to the institution,
- assesses the medical, pharmaceutical, social and economic significance of acute and chronic diseases in old age, in particular with respect to diseases associated with medicines,
- plans and carries out training activities for doctors, nursing staff, informal carers and patients,
- offers their services at pharmacies, in hospitals, retirement homes, care homes and outpatient facilities, and
- cooperates in an interdisciplinary team with doctors, nursing staff and relatives.

Duration and conduct of training:
12 months' full-time work at an establishment suitable for the purposes of training and development, including attending a minimum of 100 hours of seminars and a three-day placement at a care home or hospital ward specialising in geriatric medicine. One of the three placement days can optionally be completed at another suitable in-patient or out-patient care facility. A project paper must be written during the training period, which must contain the following:

- the results of a ward inspection at a care home or hospital ward specialising in geriatric medicine to identify problems that the facility has with supplies of medicines,
- documentation of training given to the nursing staff which addresses the identified facility-related problems that the care home or hospital geriatric ward has with supplies of medicines and makes recommendations for optimisation and implementation,
- results of the clinical pharmaceutical assessment of problems relating to medicines in two geriatric patients.

11. Infectious diseases

Infectious diseases is the area of pharmacy that deals with treating and preventing infectious diseases, in particular pharmacotherapy using anti-infective agents and strategies to ensure the rational use of anti-infective agents.

Learning objective:

The aim of training and development in infectious diseases is to acquire in-depth knowledge, skills and competences in this area. Pharmacists having completed training and development

- advise doctors, nursing staff and patients on the use of anti-infective agents in pharmacotherapy. This includes the appropriate selection of substances depending on substance properties, the symptoms, pathogen and infection site. Pharmacists having completed training and development draw up patient-specific dosage schedules, assess problems relating to medicines and advise on how to address these,

- assess the health care facility's hygiene standards in accordance with the statutory and normative rules and regulations. They identify potential transmission routes for key pathogens within the facility and propose measures to prevent infection, specifically in the context of using medicines. Pharmacists having completed training and development advise doctors, nursing staff and patients in handling disinfectants and on using decolonisation agents.

- are familiar with antibiotic stewardship (ABS) strategies to ensure rational use of antibiotics in hospital settings and apply these,

- applies communication techniques tailored to target groups. Pharmacists who have completed training and development then plan and carry out training and information activities with knowledge of the advantages and disadvantages of various training formats and in selection of suitable content, methods and media. They plan and chair meetings in an effective and targeted manner.

Required knowledge and experience:

The training in "infectious diseases" is aimed at pharmacists employed in hospitals and public pharmacies supplying hospitals. Before commencing training, it is recommended that pharmacists spend at least a year working (based on full-time employment) at a hospital or a pharmacy supplying a hospital.
The training is also open to other interested pharmacists who work at a suitable facility.

Duration and conduct of training:

12 months full-time at an establishment suitable for training in infectious diseases and attending a minimum of 100 hours of seminars approved by the Pharmaceutical Society.

The trainee pharmacist writes a project paper during the training period. The following practical tasks constitute the starting point for the project paper:

- optimising anti-infective agent dosage for patents on the basis of patient-specific data,
- participating in ward inspections or infectious disease counselling service and developing patient-specific recommendations for anti-infective medication therapy,
- recording and processing queries from doctors and/or nursing staff with regard to anti-infective medication therapy and conducting an anti-infective usage analysis.

The results of these tasks must be taken as the basis to draw up an optimisation plan to ensure the rational prescription of anti-infective agents for the health care facility.

The required knowledge, experience and skills are demonstrated in an interview.

12. Hospital medication management

Hospital medication management is the area of pharmacy that deals with the individual pharmaceutical and ongoing care of hospital patients and advising the doctors and nursing staff responsible for in-patient care. For this purpose, on-ward pharmacists work as part of an interdisciplinary team to continually assess and optimise the individual medication therapy with respect to its suitability, effectiveness, safety, value for money and patient adherence.
The "Hospital medication management" training and development area also covers managing the entire pharmaceutical supply process and the uninterrupted supply of medicines to patients at various points during their hospitalisation by on-ward pharmacists, who in doing so help increase the safety of medication therapy and patient safety in hospitals.

Learning objective:
To acquire and hone in-depth knowledge, skills and competences so that the pharmacist having completed training:
- sees themself as a member of an interdisciplinary team and shares responsibility for the medication therapy and the safety of medication therapy in the hospital,
- continually assesses and optimises the patient's individual medication in application of their knowledge of evidence- and guidelines-based medication therapy as well as factoring in diagnostic parameters and pharmacokinetic data,
- identifies and prioritises problems relating to medicines and in cooperation with the responsible team members and the patient takes appropriate action to optimise the medication therapy, tracks the implementation/success of this action and makes any necessary readjustments,
- ensures the uninterrupted supply of medicines and drug-related information to patients at various points during their hospitalisation and helps ensure the smooth transition of patients into out-patient care,
- provides individual and pharmaceutical-related care to patients during their hospitalisation, identifies where support is needed and advises and educates patients and their relatives on issues relating to medication therapy,
- identifies weaknesses in the hospital's overall pharmaceutical supply process and advises, educates and supports all relevant professional groups in the prescription, procurement, correct handling and risk-free application of medicines,
- is instrumental in drawing up and implementing in-house guidelines and standards for medication therapy,
- successfully applies various communication techniques in dealings with patients, their relatives, doctors and nursing staff on the ward,
- implements various strategies to boost their resilience in order to deal with stressful situations,
- applies methods of self-reflection.

Accreditation requirements

Completion of training as a certified clinical pharmacist or proof of registration for the "Clinical pharmacy" training course at the competent pharmaceutical society.

Duration and conduct of training:
12 months at an establishment suitable for the purposes of training and development (hospitals, hospital pharmacies, public pharmacies supplying hospitals) under the guidance of a pharmacist authorised to carry out training and development, including attending a minimum of 100 hours of seminars. 150 hours of clinical pharmacy work on a ward and a three-day period of "work shadowing" (*Hospitation*) must be demonstrated during the training period. The work shadowing takes place in a hospital that provides clinical pharmacy services and where pharmacists work on wards that is not the workplace of the trainee pharmacist. Furthermore, patient cases must be processed from at least five different fields of medicine. The processing of cases must be documented in a portfolio.

13. Paediatric pharmacy

Paediatric pharmacy is a specialised field of pharmacy focussed on providing pharmaceutical advice and care as well as the supply of medicines to paediatric patients.

This includes, in particular, the quality-assured manufacture of paediatric medicines, pharmaceutical advice and care for paediatric patients and their family members as well as for paediatricians and nursing staff with the aim of increasing the safety of medication therapy (AMTS) for this special patient group.
Training and development also extends to pharmaceutical advice and care for expectant/nursing mothers as well as those wishing to conceive children.

Learning objective:

To acquire and hone in-depth knowledge, skills and competences so that the pharmacist having completed training:
- can advise paediatric patients, their family members and medical professionals on all aspects of pharmaceutical care and health, while taking age-related physiological factors into account;
- can advise on typical paediatric illnesses, their clinical pictures and pharmacotherapy in the context of medical prescriptions and self-medication and is able to recognise, evaluate, avoid and solve medication-related problems and thus increase the safety of medication therapy;
- can manufacture individual medicines in the context of individual and bulk formulations in the quality required according to state-of-the-art pharmaceutical science;
- can advise paediatric patients, their family members and medical professionals on preventive measures, age-appropriate nutrition, while taking into account changing energy and nutrient requirements and special diets;
- can advise on medication therapy for women trying to conceive, during pregnancy and while nursing, as well as on other questions relating to health in these phases;
- can advise adolescents and their family members about physical changes that occur during puberty, typical illnesses in this phase of life and their medication therapy and is able to provide information about the risks of abusing medications and the dangers of addiction.

Duration and conduct of training:

12 months at an establishment suitable for the purposes of training and development (public pharmacies, hospitals, hospital pharmacies, public pharmacies supplying hospitals), including attending a minimum of 100 hours of seminars. A project paper must be written during the training period.
During the training period, the trainee prepares various formulations in paediatric dosage. The quality of at least one capsule manufacture must be verified by an external quality assurance test, e.g. Central Laboratory of German Pharmacists (ZL) round robin test.