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CERTIFICATE SUPPLEMENT (*)

Austria

1. TITLE OF THE CERTIFICATE (DE) (1)

Lehrabschlussprüfungszeugnis Pharmatechnologie

(1) in original language

2. TRANSLATED TITLE OF THE CERTIFICATE (EN) (2)

Certificate of Apprenticeship “Pharmaceutical Technology” (f/m)

(2) This translation has no legal status.

3. PROFILE OF SKILLS AND COMPETENCES

Specialist areas of competence:

Pharmaceutical technology foundations and good manufacturing practice
The professional is familiar with the fundamentals of pharmaceutical technology, starting with the substances used, the materials of which the plants are made, the apparatus, machines and production plants used for the manufacture of medicinal products, up to their packaging and storage, including the specialist vocabulary of the industry. In his/her work in production or packaging, he/she takes into account the current state of the art and new trends in pharmaceutical technology in order to be able to guarantee the legal requirements of the responsible authorities for product quality in addition to the in-house specifications.
Based on the understanding of the prescribed quality requirements for the production of medicinal products with regard to product, consumer and environmental protection, the application and implementation of the guidelines of "good manufacturing practice" (GMP) in his/her own field of activity is part of the daily work flow for the production of medicinal products for the professional.
He/she follows the specifications of the checked/validated documents for all his/her activities, which are derived from the individual elements of a GMP-compliant quality management system (QMS), in order to ensure reproducible product quality, avoid contamination and guarantee the traceability of the in-house process steps. The professional also knows about the measures to achieve counterfeit protection for the company’s products.

Pharmaceutical technology processes
The pharmaceutical technology expert, with his/her activities, contributes to ensuring that all quality management specifications in accordance with cGMP (current good manufacturing practice) are adhered to and implemented in pharmaceutical production. During ongoing operations, he/she operates and monitors various apparatus, machines and production plants.
Before the start of production, the professional cleans the company-specific equipment, apparatus, machines and production plants with suitable cleaning processes to avoid cross-contamination. When entering or leaving the individual cleanroom zones and the associated different cleanrooms (in accordance with the zone concept), he/she uses the respective airlocks and follows the applicable personnel hygiene regulations. Depending on the type of medicinal products produced in the company (solid, semi-solid, liquid or sterile dosage forms) and the associated pharmaceutical technology processes, the professional operates and monitors the company-specific apparatus, machines and production plants after production has started and ensures safe and trouble-free operation.
He/she also operates and monitors apparatus and machines for the packaging and proper storage of the manufactured products. He/she detects faults in apparatus, machines and production plants and initiates appropriate measures to remedy them. The professional operates and monitors automation equipment and uses the sensors and measuring devices required for this purpose to measure status variables in production plants (e.g. temperature, pressure, flow rate, filling level, pH value, etc.) as well as the devices for recording, processing, transmitting and displaying the measured values in order to run pharmaceutical production in an automated manner.
In addition, he/she controls and monitors production plants with the help of the company-specific process control system, using the various options for controlling and monitoring the production process and ensuring product quality. The professional records various operating data, such as operating status variables and process notes in accordance with operational requirements and checks them for completeness and correctness.
In addition, the professional uses the methods provided in the company for continuous improvement to show possibilities for optimisation.

Quality management
The pharmaceutical technology expert carries out recurring, product-specific in-process controls for quality inspection in accordance with internal company regulations. He/she takes samples, prepares them and carries out basic laboratory work. This includes the analysis of specified physical and chemical quantities such as viscosity and density as well as visual controls. The professional prevents uncertainties and external influences as well as other possible sources of error.

He/she documents all occurring deviations from regulations (standard operating procedures (SOPs), batch documents such as manufacturing instructions, in-process controls (IPCs), packaging instructions, test instructions, cleaning instructions, etc.) in the entire production process in the corresponding records, informs the responsible supervisor(s) immediately and participates in deviation management.

Interdisciplinary areas of competence:

- Working in an operational and professional environment
- Quality oriented, safe and sustainable work
- Digital work

4. RANGE OF OCCUPATIONS ACCESSIBLE TO THE HOLDER OF THE CERTIFICATE [3]

Range of occupations:
Employment including in industrial and commercial enterprises in pharmaceutical and chemical production

[3] if applicable

(*) Explanatory note

This document has been developed with a view to providing additional information on individual certificates; it has no legal effect in its own right. These explanatory notes refer to the Decision (EU) no. 2018/646 of the European parliament and the Council of 2 May 2018 on a common framework for the provision of better services for skills and qualifications (Europass).

More information on Europass is available at: http://europass.cedefop.europa.eu or www.europass.at

5. OFFICIAL BASIS OF THE CERTIFICATE

Name and status of the body awarding the certificate	**Name and status of the national/regional authority providing accreditation/recognition of the certificate**
Lehrlingsstelle der Wirtschaftskammer (Apprenticeship Office of the Economic Chamber; for the address, see certificate)	Bundesministerium für Arbeit und Wirtschaft (Federal Ministry of Labour and Economy)
Level of the certificate (national or international) NQF/EQF 4 ISCED 35	**Grading scale / Pass requirements** Overall performance: Pass with Distinction Good Pass Pass Fail
Access to next level of education/training Access to the *Berufsreifeprüfung* (i.e. certificate providing university access for skilled workers) or a vocational college for people under employment. Access to relevant courses at a *Fachhochschule* (i.e. university level study programme of at least three years' duration with vocational-technical orientation); additional examinations must be taken if the educational objective of the respective course requires it.	**International agreements** Between Germany, Hungary, South Tyrol and Austria, international agreements on the mutual automatic recognition of apprenticeship-leave examinations and other vocational qualifications have been concluded. Information on equivalent apprenticeship occupations can be obtained from the Federal Ministry of Labour and Economy.

Legal basis

1. Training Regulation for Pharmaceutical Technology BGBl. II (Federal Law Gazette) No. 118/2023 (company-based training)
2. Curriculum framework (education at the vocational school for apprentices)
3. The present apprenticeship trade replaces the apprenticeship trade Pharmaceutical Technology (Training and Examination Regulation BGBl. II (Federal Law Gazette) No. 105/2008, which expired as of 30 of April 2023.

6. OFFICIALLY RECOGNISED WAYS OF ACQUIRING THE CERTIFICATE

1. Training in the framework of the given Training Regulation for Pharmaceutical Technology and of the curriculum of the vocational school for apprentices. Admission to the final apprenticeship examination upon completion of the apprenticeship period specified for the apprenticeship trade concerned. The final apprenticeship examination aims to establish whether the apprentice has acquired the skills and competences required for the respective apprenticeship trade and is able to carry out the activities particular to the learned trade herself/himself in an appropriate manner.

2. Admission to the final apprenticeship examination in accordance with Article 23 (5) of the *Berufsausbildungsgesetz* (Vocational Training Act). An applicant for an examination is entitled to sit the final apprenticeship examination without completing a formal apprenticeship training if she/he has reached 18 years of age and is able to prove acquisition of the required skills and competences by means of a relevant practical or an on-the-job training activity of appropriate length, by attending relevant courses etc.

Additional information:

Entry requirements: successful completion of 9 years of compulsory schooling

Duration of training: 3 ½ years

Enterprise-based training: Enterprise-based training comprises $^{4}/_{5}$ of the entire duration of the training and focuses on the provision of job-specific skills and competences according to Article 3 of the Training Regulation, BGBl. II (Federal Law Gazette) No. 118/2023, enabling the apprentice to exercise qualified activities as defined by the profile of skills and competences specified above (cf. job profile).

Education at vocational school: School-based education comprises $^{1}/_{5}$ of the entire duration of the training. The vocational school for apprentices has the tasks of imparting to apprentices the basic theoretical knowledge, of supplementing their enterprise-based training and of widening their general education in the framework of subject-oriented part-time instruction.

More information (including a description of the national qualification system) is available at:
www.zeugnisinfo.at and www.edusystem.at

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