

Procesničar/procesničarka v proizvodnji farmacevtskih učinkovin

Selected qualifications

Name of qualification Procesničar/procesničarka v proizvodnji farmacevtskih učinkovin

Translated title (no legal status) Process engineer in the production of pharmaceutical active ingredients

Type of qualification Nacionalna poklicna kvalifikacija, SOK raven 4

Category of qualification Poklicna kvalifikacija

Admission requirements At least one year of work experience in the pharmaceutical or chemical industry, which the candidate proves with authentic documents that show the time and content of the work performed (e.g. contract, reference letter from the employer, report on the work performed with the signature of the responsible person, etc.).

ISCED field Splošne izobraževalne aktivnosti/izidi

Qualification level

SQF 4
EQF 4

Learning outcomes

The candidate is able to:

- independently plan, prepare, implement and control own work in accordance with work quality standards in the pharmaceutical industry of active substances,
- carry out the biosynthesis process of fermentation of an individual product from the beginning of the batching process of raw materials and carry out all subsequent stages until the final packaging of the product,
- carry out the synthesis process of the production of the active pharmaceutical ingredient from the beginning of the raw material batching process and carry out all subsequent stages of reaction, extraction, crystallization, drying until the final packaging of the product,
- to carry out independently and with high quality the final stage of packaging of an individual product, where it is crucial that the product is properly packed and labeled, which ensures further stability and traceability of this product,
- during the work execution process, ensure adequate storage of the input raw materials that are incorporated into the process, as well as adequate storage of the finished product,
- when carrying out the process, fill out the production documentation responsibly and accurately, which ensures that all prescribed parameters are recorded during the work, and check for possible deviations of the actual parameters from the prescribed ones,
- in their work, constantly observe and ensure work with the guidelines of good production and good storage practices in the production of pharmaceutical active ingredients,
- maintain personal hygiene and workplace cleanliness,
- take care of the equipment he uses, from the point of view of monitoring, minor maintenance and final cleaning of the equipment, which ensures the smooth operation of production,
- communicate with superiors and colleagues and observe business ethics and company values,
- perform work safely in an EX-environment (where explosion zones are prescribed due to the eventual possibility of the presence of solvent vapors), in chemical syntheses while knowing all the laws that apply to work in such an environment, and comply with regulations for the protection of health and the environment, equipment and the entire production with a focus on the highest possible quality and safely performed work.

Accessors

Verification and assessment are carried out by committees for the verification and validation of national vocational qualifications, appointed by the National Examination Centre (NEC). Committee members must be licensed by the National Examination Centre. Licences may be found [here](#).

Assessment and completion

1.VALIDATION

During the guidance process the candidate prepares a portfolio, which is assessed by a committee. If the portfolio submitted by the candidate contains authentic, valid and adequate proof of the knowledge, skills and competences defined in the occupational standard, the committee may:

- validate the contents of the occupational standard in full,
- validate the contents of the occupational standard in part and define the knowledge, skills and competence to be verified,
- refuse to validate any of the contents of the occupational standard because the candidate has not provided proof of any of the knowledge, skills and competences defined in the occupational standard, in which case it will verify the occupational standard in full.

2.METHOD OF VERIFICATION

- Practical verification with an oral presentation.

Condition for obtaining certificate

The candidate demonstrates that he/she achieves the knowledge, skills and competencies specified in the catalogue of professional knowledge and skills standards.

Awarding body

Providers of procedures for identifying and validating NVQs are entered in a register of providers maintained in the collection of the national information centre for vocational qualifications. These are: vocational schools, businesses, B2B training centres, adult education centres and chambers of commerce.

URL

<https://www.nrpslo.org/podrobnosti/izvajalec-pregled/74876623>
