SLOVENSKO
OGRODJE
KVALIFIKACIJ

Upravljalec/upravljalka v proizvodnji farmacevtskih učinkovin

Selected qualifications

Name of qualification	Upravljalec/upravljalka v proizvodnji farmacevtskih učinkovin
Translated title (no legal status)	Operator in pharmaceutical ingredients manufacture
Type of qualification	Nacionalna poklicna kvalifikacija, SOK raven 3
Category of qualification	Poklicna kvalifikacija
Admission requirements	• at least education at SQF level 2 • one year of work experience in the pharmaceutical industry, which the candidate proves with the employer's reference letter
ISCED field	Field Zdravstvo in socialna varnost
ISCED subfield	subfield farmacija

Qualification level

SQF 3
EQF 3

Learning outcomes

The candidate is able to:

- prepare, carry out and control own work in accordance with the quality standards of work in the pharmaceutical industry,
- perform the biosynthetic process of fermentation of an individual product from the beginning of the process of batching of raw materials and perform all subsequent phases until the final packaging of the product under the supervision of the superior,
- carry out the final stage of packaging of each product, where it is crucial that the product is properly packaged and labeled, thus ensuring further quality (stability and traceability on this product) under the supervision of a superior,
- during the work process, to ensure proper storage of input raw materials that are incorporated into the process, as well as proper storage of the final product under the supervision of a superior,
- during the implementation of the process, responsibly and accurately fill in the production documentation, thus ensuring the recording of all prescribed parameters during work, and check for possible deviations of the actual parameters from those prescribed under the supervision of a superior,
- in its work, constantly observe and ensure work with guidelines of good production and good storage practice in the production of active pharmaceutical ingredients,
- maintain personal hygiene and cleanliness of the workplace,
- take care of the equipment it uses, from the point of view of control, minor maintenance and final cleaning of the equipment, thus ensuring the smooth operation of production,
- communicate with superiors and colleagues and take into account the business ethics and values of the company,
- safely perform work in the EX environment (where explosion zones are prescribed due to the possible presence of solvent vapors) in chemical syntheses, with emphasis on knowledge of all laws applicable to work in such an environment, and comply with regulations for health, environment and equipment or overall production with a focus on the highest quality and safest work performed.

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

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.

VERIFICATION METHOD

Practical assessment with oral defense.

Condition for obtaining certificate

Candidates demonstrate attainment of the knowledge, skills and competences defined in the catalogue of standards of vocational knowledge and skills.

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/npk/48230211