HIGHER EDUCATIONAL INSTITUTION OF UKOOPSPILKA
«POLTAV UNIVERSITY OF ECONOMICS AND TRADE»

Educational and Scientific Institute of International Education
Department of commodity science, biotechnology, expertise and customs

SYLLABUS
educational disciplines
« **Standardization and certification goods and services** »
on 2022-2023 educational year

Course and semester study	4 course, 8 semester
Educational program/specialization	"Biotechnology"
Specialty	162 "Biotechnologies and bioengineering"
Branch of knowledge	16 "Chemical and bioengineering"
Degree higher education	bachelor

Name of the NPP that leads this discipline, scientific degree and academic title, position

Nadiia Hnitii

Senior Lecturer of the Department of Commodity Science, Biotechnology, Expertise and Customs

Contact phone	+38-066-771-20-32
Electronic address	nadyagnitiy@gmail.com
Schedule educational classes	http://schedule.puet.edu.ua/
Consultations	ocular http://www. http://www.tpt.puet.edu.ua/ online: by email, mon-fri with 10.00-15.00
Page remote course	https://el.puet.edu.ua/

Description educational disciplines

Goal study academic discipline	Acquisition future specialists systematized of knowledge in industry general scientific technical and practical foundations, fundamental methodological and organizational provisions standardization and certification products, goods and services in Ukraine and in the world for achievement at practical activity tall final results
Duration	4 loans EKTS/120 hours (lectures 16 hours, practical occupation 32 hours, independent work 72 hours)
Forms and methods teaching	Lectures and practical occupation in audience, independent work outside schedule
System current and final control	Current CONTROL: visiting occupations; protection home task; discussion material occupations; implementation educational tasks; reports with essays and their discussion; testing; current modular work Final CONTROL: test (FMK)
Basic knowledge	Availability of knowledge with standardization and certification products
Language teaching	English

List competencies, which provides given educational discipline, softwarethe results teaching

Software the results teaching	**Competencies, which ones should master getter**

• Be able to apply the provisions of regulatory documents regulating the procedure for product certification, production attestation, requirements for the organization of quality management systems at enterprises, rules for drawing up technical documentation and conducting technological processes based on the knowledge gained during practical training. PR04.	• Skills of performing safe activities (ZK06).
• To be able to analyze regulatory documents (state and industry standards, technical conditions, instructions, etc.), to compile separate sections of technological documentation for biotechnological products of various purposes, to analyze technological situations, to choose rational technological solutions. PR05.	• The ability to carry out the analysis of regulatory documentation necessary for the implementation of engineering activities in the field of biotechnology . (SK03).

Thematic plan educational disciplines

Name topics	Kinds works	Task independent work in cuttopics
Module 1. Order application systems standards and state supervision by their compliance		
Topic 1. The main ones concept and general provisions standardization	Visiting occupations; protection home task; discussion material occupations; implementation educational tasks; task independent works; testing	Prepare reports on topics: "History development standardization in the world and in Ukraine", "Problems standardization in Ukraine on modern stage", "Principles state politicians in industry standardization".
Topic 2. Activity with international and regional standardization	Visiting occupations; protection home task; discussion material occupations; implementation educational tasks; task independent works; testing	Prepare reports on topics: "The most famous consortia and professional organization, what are developing standards, sphere their activity", "Activity scientific and technical Commission in within the framework Eurasian advice standardization, metrology and certification"
Topic 3. Activities with national standardization	Visiting occupations; protection home task; discussion material occupations; implementation educational tasks; task independent works; testing	Prepare reports on topics: "Problem harmonization of Ukrainian standards with European ones and international", "The role of standardization in ensuring quality and safety products"

Topic 4. Rules and methods of development and application national regulatory documents	Visiting occupations; protection home task; discussion material occupations; implementation educational tasks; task independent works; testing; current modular work	Prepare reports on the topics: "State supervision and departmental CONTROL by compliance standards on products", "Structure and content of standards for groups homogeneous products".
Module II. The main ones management principles and control quality		
Topic 5. Standardization as element software quality products	Visiting occupations; protection home task; discussion material occupations; implementation educational tasks; task independent works; testing	Prepare reports on topics: "World experience the use of a system approach in UNP", "Essence and types of technical control", Classification and characteristic methods evaluations equal quality products".
Topic 6. State certification system andevaluations compliance products	Visiting occupations; protection home task; discussion material occupations; implementation educational tasks; task independent works; testing	Prepare reports on the topics: "Procedure of implementation attestation production", "Factors what determine precision carrying out trials, what are held laboratory".

Name topics	Kinds works	Task independent work in cuttopics
Topic 7. Assessment compliance in Ukraine and the world	Visiting occupations; protection home task; discussion material occupations; implementation educational tasks; task independent works; testing	Prepare reports on topics: "Legislative basis assessment compliance and certification in Ukraine", "Conditions necessary for implementation certification on productions"
Topic 8. Systems management quality	Visiting occupations; protection home task; discussion material occupations; implementation educational tasks; task independent works; testing; current modular work	To prepare reports on the topics: "Main directions in industry international standardization", "Which the main ones characteristics concepts TQC, TQM and TQEM".

Informational sources

1. https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100354.pdf
2. https://europa.eu/youreurope/business/product-requirements/chemicals/classification-labelling-packaging/index_en.htm
3. https://www.ieee.org/content/dam/ieee-org/ieee/web/org/educ/eab_ops_manual_current.pdf
4. https://unevoc.unesco.org/home/ISO+standard&context=
5. https://www.greynet.org/images/GL12-PSS,_Ramasesh_and_Chowdappa.pdf
6. https://www.iso.org/foresight/biotechnology.html
7. https://bio.libretexts.org/Bookshelves/Biotechnology/Quality_Assurance_and_Regulatory_Affairs_for_the_Biosciences/03%3A_Quality_Management_Systems/3.03%3A_Section_3-
8. https://www.classcentral.com/course/patenting-bio-ipr-8559
9. https://www.careers360.com/university/indian-institute-of-technology-kharagpur/legal-and-regulatory-issues-in-biotechnology
10. https://www.coursera.org/learn/patenting-bio-ipr

Software software educational disciplines

- Package software products Microsoft Office.

Policy study educational disciplines and assessment

- Due Date and Reschedule Policy: Assignments that are submitted in violation of due dates are not respected reasons are evaluated on lower assessment (75 % from possible maximum quantity points by kind activities). Rearranging modules takes place with the permission of the leading teacher if there are good reasons (for example, hospital).
- Academic Integrity Policy: Withdrawals for ongoing module work and testing prohibited (including using mobile devices). Mobile devices are allowed to be used only under time online testing and preparation practical tasks in process occupation.
- Policy of visiting:
  attending classes is a mandatory component. For objective reasons (for example, illness, employment, internship) training may to happen in online form (Moodle) by consent with the leading a teacher

Assessment

Final rating by study academic discipline is calculated by current assessment

Kinds works	Maximum number points
Module 1 (topics 1-4): visiting classes (8 points); protection home task (8 points); discussion material classes (4 points); implementation educational tasks (8 points); task independent work (8 points); testing (4 points); current modular work (10 points)	50
Module 2 (topics 5-8): visiting classes (8 points); protection home task (8 points); discussion material classes (4 points); implementation educational tasks (8 points); task independent work (8 points); testing (4 points); current modular work (10 points)	50
Together	100

Scale assessment acquirers higher education by by the results study educational disciplines

Sum points by all species educational activity	Rating by scale ECTS	Rating by national scale
90-100	AND	Perfectly
82-89	IN	Very fine
74-81	WITH	Fine
64-73	D	Satisfactorily
60-63	IS	Satisfactorily enough
35-59	FX	Unsatisfactorily with possibility repeated drafting
0-34	F	Unsatisfactorily with mandatory repeated studyeducational disciplines