MINISTRY OF HEALTH OF UKRAINE
ODESSA NATIONAL MEDICAL UNIVERSITY

Department of Pharmacy Organization and Economy
with post-diploma specialization

APPROVED

Vice-rector for scientific and pedagogical work

_____ Eduard BURYACHKIVSKY

September 1st, 2024

WORK PROGRAM IN THE DISCIPLINE

MODERN MEDICAL DEVICES

Level of higher education: second (master's degree)

Field of knowledge: 22 "Health care"

Specialty: 226 "Pharmacy, industrial Pharmacy"

Educational and professional program: "Pharmacy, industrial pharmacy"

2024

The working program is compiled on the basis of the educational and professional program "Pharmacy, industrial pharmacy" for the training of specialists of the second (master's) level of higher education in the specialty 226 "Pharmacy, industrial pharmacy" of the field of knowledge 22 "Health care", approved by the Academic Council of ONMedU (minutes No. 10 dated 27/06/2024).

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The working program was approved at the meeting of the Department of Pharmacy Organization and Economy with post-diploma specialization
Minutes No. 1 dated August 29, 2024.

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Approved by the subject cycle methodical commission for pharmaceutical disciplines of ONMedU
Minutes No._1 dated August 30, 2024.

Head of the subject cycle methodical commission

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Revised and approved at the meeting of the department_____
Minutes No. ___ of "___" _____ 20__
Head of Department _____
(signature) (First Name Surname)

Revised and approved at the meeting of the department _____
Minutes No. ___ of "___" _____ 20__
Head of Department _____
(signature) (First Name Surname)

1. Description of the Discipline:

Name of indicators	Field of knowledge, specialty, specialization, level of higher education	Characteristics of the discipline
The total number of: Credits: 3.0 Hours: 90 Content modules: 1	Branch of knowledge 22 "Health care" Specialty 226 "Pharmacy, industrial pharmacy" Level of higher education second (master's degree)	*Full-time education, selective discipline*
		Year of training: 4
		Semesters VIII
		Lectures (0 hours)
		Seminars (0 hours)
		Practical (30 hours)
		Laboratory (0 hours)
		Independent work (60 hours)
		Final control - test

2. The Purpose and Objectives of the Discipline, Competencies, and Program Learning Outcomes.

Purpose : to increase students' knowledge of a comprehensive review of the obtaining and characterisation of modern medical devices (class I, II, III), especially for therapeutic, diagnostic and monitoring purposes. The course reveals the fundamental scientific and legal principles related to the development, receipt and evaluation of new medical devices, especially those intended for direct contact with the human body. Also will provide students with the necessary background to understand the standard characterisation methods used in the biological evaluation of medical devices and risk management.

Objectives:

1. Study the principles of operation of modern medical devices.
2. Familiarize students with innovations and recent developments in medical technology.
3. Develop skills in selecting and operating medical devices for various clinical situations.
4. Master the rules for quality control and safety of medical devices.
5. Foster competencies in evaluating the effectiveness and rational use of medical equipment.

The process of studying the discipline is aimed at forming elements of the following competencies:

- **General (GC):**

GC 02. Knowledge and understanding of the subject area and understanding of professional activity.

GC 09. Ability to use information and communication technologies.

GC 11. Ability to apply knowledge in practical situations

- **Special (SC):):**

SC 04. The ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to people who are studying.

SC 12. Ability to ensure proper storage of medicinal products of natural and synthetic origin and other products of the pharmacy assortment in accordance with their physicochemical properties and the rules of Good Storage Practice (GSP) in health care institutions.

SC 13. The ability to organize the activities of the pharmacy to supply the population, health care facilities with medicines and other products of the pharmacy assortment and to implement appropriate reporting and accounting systems in them, to carry out product analysis, administrative record keeping taking into account the requirements of pharmaceutical legislation.

SC 24. Ability to use knowledge of regulatory and legal acts of Ukraine and recommendations of appropriate pharmaceutical practices in professional activities.

Program learning outcomes (PLO):

PLO N03. Have specialized knowledge and skills/skills for solving professional problems and tasks, including for the purpose of further development of knowledge and procedures in the field of pharmacy.

PLO 11. Determine the advantages and disadvantages of drugs of natural and synthetic origin of various pharmacological groups, taking into account their chemical, physicochemical, biopharmaceutical, pharmacokinetic, pharmacodynamic features and the type of dosage form. Recommend to consumers medicinal products and other products of the pharmacy assortment with the provision of advisory assistance and pharmaceutical care.

PLO 15. Predict and determine the influence of environmental factors on the quality and consumer characteristics of medicinal products of natural and synthetic origin and other products of the pharmacy assortment, organize their storage in accordance with their physical and chemical properties and the rules of Good Storage Practice (GSP).

PLO 36. Plan and implement professional activities on the basis of normative legal acts of Ukraine and recommendations of proper pharmaceutical practices

As a result of studying the academic discipline, the student of higher education must:

- **know:**
- Regulation of the production and circulation of medical devices
- Classification and purpose of modern medical devices.
- Basic technical characteristics and principles of operation of medical devices.
- Modern Technologies and Materials in Medical Devices
- Internet of Things (IoT) in healthcare: smart medical devices.
- Aspects of quality control and certification of equipment.

- **be able to**:
- Classify medical devices according to various characteristics.
- Describe the principles of operation of different types of medical devices.
- Analyse the technical characteristics of medical devices.
- Evaluate the safety and effectiveness of medical devices.
- Select optimal medical devices for specific applications.
- Develop marketing strategies for medical devices.
- Carry out quality assessment of medical devices.
- Solve problems related to logistics and storage of medical devices.

3. Content of the Discipline

Topic 1. Fundamentals and Classification of Medical Devices. Definition and classification of medical devices. History of medical technology development. Regulation of the production and circulation of medical devices Regulation of medical devices in various countries. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. The US Food and Drug Administration (FDA).

Topic 2. Conformity assessment of medical devices. Risk management . Identifying, assessing and mitigating risks associated with medical devices**.** Quality Management Systems (QMS).The role of QMS in ensuring product conformity**.** Key components of a compliant QMS.Clinical evaluation and testing:Requirements for preclinical testing; Clinical Trials and Efficacy Evaluation**;** Post-marketing clinical follow-up (PMCF) Documentation Requirements: Technical documentation and project dossiers; Declaration of Conformity (DoC)**;** Notified Bodies and Certification: The role of

notified bodies in conformity assessment; Certification processes for obtaining CE marking and other regulatory approvals**.** Post-marketing surveillance and vigilance: Monitoring and reporting of adverse events; Corrective and Preventive Actions (CAPA). A conformity assessment of the medical device, declaration of conformity. CE marking of conformity.

Topic 3. Modern materials and technologies used in the manufacture of medical devices. Biocompatible materials: Metal, ceramics, polymers and composites, Material design, fabrication and synthesis (Electrospinning, 3D printing, hydrogelation/gelation, lithography etc. Microstructures and Properties of materials: Bulk and surface properties of materials, Influence of microstructure and environment on fatigue and fracture of materials. Biomaterials for tissue engineering and drug delive. Sensor technologies in medical devices.

Topic 4. Diagnosis and Monitoring diagnostic medical devices. Diagnostic medical devices. Medical Imaging Devices: X-ray systems Computed tomography (CT) scanners, magnetic resonance imaging (MRI) machines, ultrasound devices, nuclear medicine imaging.

Topic 5: Intelligent Medical Systems. Internet of Things (IoT) in healthcare: smart medical devices. wearable devices, smart homes for the sick. Wearable diagnostic devices: fitness trackers, ECG monitors, Smartwatches with health monitoring capabilities. Blood pressure monitors. Continuous glucose monitoring (CGM) systems, Remote patient monitoring technologies o Artificial intelligence in diagnosis and treatment.

Topic 6: Implantable Medical Devices and Active Implantable Devices. Artificial Pacemaker, Implantable cardioverter defibrillator, artificial joints, breast implants, cochlear implants, contraceptive Intra-Uterine Devices (IUDs), bone, muscle, and joint fusion hardware. Hip implants Intraocular lenses. Biomaterials for implants. Various implantable medical devices.

Topic 7. Rehabilitation and Orthopedic Devices. Prosthetics and orthotics. Rehabilitation robots. portable robots such as the ARGO (ARGO Xtreme Terrain Robotics, ON, Canada), EKSO (EKSO Bionics, CA, USA), Indego (Parker Hannifin Corp., OH, USA), ReWalk (ReWalk Robotics, Inc., MA, USA) and WPAL (Fujita Health University, Aichi, Japan). Exoskeletons: technologies and prospects. Types of Exoskeletons. Powered Exoskeletons. (Static and Dynamic exoskeletons). Passive Exoskeletons Static exoskeletons need actuators to run continuously in order for them to function. Dynamic exoskeletons. Pseudo-Passive Exoskeletons

Topic 8. Modern medical devices and technologies used in ophthalmology. Emerging Technologies in Ophthalmology: Artificial intelligence in diagnostics. Smart contact lenses. Vision's drug-eluting contact lens. Intraocular lenses. Glaukos' trio of ophthalmic drug delivery devices. Sight Sciences' surgical systems for glaucoma, dry eye disease. Clearside Biomedical's injectable suspension therapy. Patient Monitoring and Home Care Devices: Mobile apps and at-home diagnostic tools. Remote monitoring systems for progressive conditions. Compliance with ophthalmic device safety standards

Topic 9. Cybersecurity in medical devices quality system considerations. Safety and ethics. Major medical device security standards and regulations affecting medical device security standards, including EO 14028, FDA Pre-Market Approval Guidelines for Medical Device Cybersecurity Standards, IEC 62304, IMDRF standards, ISO/IEC 27001, and AAMI TIR97. Ethical aspects of using modern medical technologies. The impact of medical devices on patient privacy.

Topic 10. Trends in Medical Device Development. Future Perspectives Micro- and nano-devices in the medicine. Development of genetic engineering and its connection with medical devices. Personalized medical devices. Telemedicine and remote monitoring. Bioprinting of organs and tissues.

4. The structure of the Discipline

Names of topics		Number of hours				
	Total	Including				
		lectures	Seminars	practical classes	lab classes	ISW
Topic 1. Fundamentals and Classification of Medical Devices.	8	-	-	2	-	6
Topic 2. Conformity assessment of medical devices. Risk management	8	-	-	2	-	6
Topic 3. Modern materials and technologies used in the manufacture of medical devices	10	-	-	4	-	6
Topic 4. Diagnostic medical devices. Medical Imaging Devices	10	-	-	4	-	6
Topic 5. Intelligent Medical Systems	10	-	-	4	-	6
Topic 6. Implantable Medical Devices and Active Implantable Devices.	10	-	-	4	-	6
Topic 7. Rehabilitation and Orthopedic Devices	10	-		4	-	6
Topic 8. Modern medical devices and technologies used in ophthalmology	8	-	-	2	-	6
Topic 9. Cybersecurity in medical devices quality system considerations.	8	-	-	2	-	6
Topic 10. Trends in Medical Device Development *Current test control Control of practical skills. Test*	8	-	-	2	-	6
Total	**90**	**-**	**-**	**30**	**-**	**60**

5. Topics of lectures / seminars / Practical Classes / laboratory classes

5.1. Topics of lectures

Lectures are not provided

5.2. Topics of seminar classes

Seminar classes are not provided

5.3 Topics of practical classes

No	Topic name	hours
1.	Topic 1. Practical class1 . Fundamentals and Classification of Medical Devices.	2
2.	Topic 2. Practical class 2. Conformity assessment of medical devices. Risk management	2
3.	Topic 3. Practical class 3. Modern materials and technologies used in the manufacture of medical devices	4
4.	Topic 4. Practical class 4. Diagnostic medical devices. Medical Imaging Devices	4
5.	Topic 5. Practical class 5.	4

	Intelligent Medical Systems	
6.	Topic 6. Practical class 6 Implantable Medical Devices and Active Implantable Devices.	4
7.	Topic 7. Practical class 7. Rehabilitation and Orthopedic Devices	4
8.	Topic 8. Practical class 8. Modern medical devices and technologies used in ophthalmology	2
9.	Topic 9. Practical class 9. Cybersecurity in medical devices quality system considerations.	2
10.	Topic 10. Practical class 10. Trends in Medical Device Development. *Current test control.Control of practical skills*	2
	Total	**30**

5.4. Topics of laboratory classes

Laboratory classes are not provided.

6. Independent Student Work

No	Title of the topic / types of assignments	hours
1.	Topic 1. Fundamentals and Classification of Medical Devices. Independent Study of the Material for Topic 1. Preparation for the practical class	6
2.	Topic 2. Conformity assessment of medical devices. Risk management Independent Study of the Material for Topic 2. Preparation for the practical class	6
3.	Topic 3. Modern materials and technologies used in the manufacture of medical devices Independent Study of the Material for Topic 3. Preparation for the practical class	6
4.	Topic 4. Diagnostic medical devices. Medical Imaging Devices Independent Study of the Material for Topic 4. Preparation for the practical class	6
5.	Topic 5. Intelligent Medical Systems Independent Study of the Material for Topic 5. Preparation for the practical class	6
6.	Topic 6. Implantable Medical Devices and Active Implantable Devices. Independent Study of the Material for Topic 6. Preparation for the practical class	6
7.	Topic 7. Rehabilitation and Orthopedic Devices Independent Study of the Material for Topic 7. Preparation for the practical class	6
8.	Topic 8. Modern medical devices and technologies used in ophthalmology Independent Study of the Material for Topic 8. Preparation for the practical class	6
9.	Topic 9. Cybersecurity in medical devices quality system considerations. Independent Study of the Material for Topic 9. Preparation for the practical class	6
10.	Topic 10. Trends in Medical Device Development Independent Study of the Material for Topic 10. Preparation for the practical class	6
	Total	**60**

7. Teaching methods

Practical classes: Discussion, role-playing games, solving situational problems, case studies, solving calculation problems, practicing practical skills, and completing individual assignments.

Independent work: independent work with the recommended basic and additional literature, with electronic information resources.

8. Forms of control and assessment methods (including criteria for evaluating learning outcomes)

Current control: oral survey, control written works, evaluation of individual assignments, defense of the results of practical works, evaluation of reports, evaluation of activity in the class, testing (pen-and-paper or computerized), evaluation of required skills
Final control: Test

Evaluation of the current educational activity in a practical class:

1. Evaluation of theoretical knowledge on the topic of the class:
- methods: survey, solving a situational clinical problem;
- the highest grade available is 5, the lowest passing grade is 3, the failing (unsatisfying) grade is 2.
2. Evaluation of practical skills on the subject of the lesson:
- methods: standardized and include control of vocabulary, grammar, and communication skills;
3. The highest grade available is 5, the lowest passing grade is 3, and the failing (unsatisfying) grade is 2.

The grade for one practical class is the arithmetic mean of all components and can only be a whole number (5, 4, 3, 2), which is rounded according to the statistical method.

Current Evaluation Criteria at Practical Classes

Rating	Evaluation criteria
Excellent "5"	The higher education student is fluent in the material required, demonstrates versatile and deep knowledge of the program material, can perform the tasks provided for in the program successfully; has mastered the content of the required and additional literature, and has realized the interrelationship of individual sections of the discipline and their importance for the future profession; has demonstrated creative abilities in understanding and using educational program material and the ability to update and replenish knowledge independently; level of competence - high (creative);
Good "4"	The HE student has demonstrated complete knowledge of the educational program material, successfully performs the tasks provided by the program, has mastered the basic literature recommended by the program, and is capable of independent updating and renewal in the course of further education and professional activities, but makes minor mistakes, which are eliminated by the student him/herself when the examiner points them out; the level of competence is sufficient (constructive and variable);
Satisfactory "3"	The HE student does not have sufficient knowledge but knows the fundamental curriculum material to the extent necessary for further education and subsequent work in the profession; copes with the tasks provided by the program, makes some mistakes in the answers at the exam and when completing the exam tasks, but has the necessary knowledge to overcome the mistakes made under the guidance of a scientific and pedagogical worker; level of competence - average (reproductive);

Unsatisfactory "2"	The HE student does not acquire knowledge of program material, makes fundamental mistakes in the assignments provided by the program, cannot use the knowledge in further studies on their own, did not manage to master the skills of independent work; the level of competence is low (receptive-productive)

A test is awarded to an applicant who has completed all the tasks of the work program of the discipline, actively participated in practical classes, completed and defended an individual assignment and has a current average grade of at least 3.0 and has no academic debt.

The test is taken: at the last lesson before the start of the examination session - in the case of the tape system of education, at the last lesson - in the case of the cycle system of education. The grade for the test is the arithmetic mean of all components on a traditional four-point scale and has a value that is rounded according to the statistical method with two decimal places.

9. Distribution of points received by students of higher education

The obtained grade point average for the discipline for students who have successfully completed the work program of the discipline is converted from the traditional four-point scale to points on a 200-point scale, as shown in the table:

Table for converting a traditional grade into a multi-point scale

Traditional four-point scale	200-Point Grading Scale
Excellent ("5")	185 - 200
Good ("4")	151 - 184
Satisfactory ("3")	120-150
Unsatisfactory ("2")	Below 120

A multi-point scale (200-point scale) characterises the actual performance of each student in mastering the educational component. The conversion of the traditional grade into a 200-point scale is performed by the University's Information Technology Department using the Contingent programme.

10. Methodological support

- Working program on the discipline
- Syllabus
- Guidelines for practical classes
- Guidelines for independent student work
- Multimedia presentations
- Situational/case tasks
- Scenarios of role-playing games (if necessary)

11. Questions for Preparing for the Final Assessment

1. What defines a medical device according to international standards?
2. How are medical devices classified based on their function?
3. Describe the risk-based classification of medical devices.
4. Give examples of Class I, II, and III medical devices.
5. What is the significance of proper classification for regulatory purposes?
6. What are the key steps in the conformity assessment process for medical devices?
7. Explain the role of ISO 13485 in medical device conformity assessment.
8. What are the primary elements of a Quality Management System (QMS) for medical devices?

9. How is risk management applied during medical device development?
10. Describe common risk mitigation strategies for medical devices.
11. What materials are commonly used in the manufacture of medical devices?
12. How do biocompatibility considerations affect material selection?
13. What are the advantages of using smart materials in medical devices?
14. Describe the role of additive manufacturing (3D printing) in medical device production.
15. What are nanomaterials, and how are they applied in medical devices?
16. What are the main types of diagnostic medical devices?
17. How does an electrocardiogram (ECG) monitor function?
18. Describe the working principle of an ultrasound imaging device.
19. What are the benefits and limitations of magnetic resonance imaging (MRI)?
20. Explain the difference between diagnostic imaging and therapeutic imaging.
21. Define intelligent medical systems and their key components.
22. How do artificial intelligence (AI) and machine learning contribute to intelligent medical devices?
23. What are some examples of intelligent medical systems used in hospitals?
24. Discuss ethical concerns related to AI in medical systems.
25. What challenges exist in the integration of intelligent medical systems into healthcare?
26. What are implantable medical devices, and how are they classified?
27. Give examples of active implantable devices and their applications.
28. What is the role of pacemakers in healthcare?
29. How are implantable devices powered and controlled?
30. What are the potential risks associated with implantable devices?
31. What are the primary categories of rehabilitation devices?
32. How do robotic rehabilitation devices support patient recovery?
33. Describe the function and design considerations for prosthetic limbs.
34. What materials are used in orthopedic implants?
35. Discuss the importance of ergonomics in the design of rehabilitation devices.
36. What diagnostic devices are commonly used in ophthalmology?
37. How does an optical coherence tomography (OCT) device work?
38. What is the role of laser technology in ophthalmic surgery?
39. Discuss the benefits of telemedicine technologies in ophthalmology.
40. What are the latest advancements in contact lens technology?
41. Why is cybersecurity important for medical devices?
42. What are common cybersecurity threats to medical devices?
43. Describe best practices for ensuring the security of connected medical devices.
44. How do regulatory bodies address cybersecurity concerns?
45. What are the challenges of balancing cybersecurity and device usability?
46. What are current trends in the development of wearable medical devices?
47. How is 3D printing influencing the design of medical devices?
48. Discuss the role of personalized medicine in medical device innovation.
49. What is the potential impact of the Internet of Medical Things (IoMT) on healthcare?
50. How do regulatory frameworks adapt to technological advancements in medical devices?

12. Recommended literature

Main:

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng
2. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. https://eur-lex.europa.eu/eli/reg/2017/746/oj/eng
3. Quality Management System Regulation (QMSR) Final Rule https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation
4. Personalized Medical Devices - Regulatory 2023 https://www.imdrf.org/sites/default/files/2023-09/IMDRF_PMD%20WG_N58%20FINAL_2023%20%28Edition%202%29_0.pdf
5. MDCG 2021-24 Guidance on classification of medical devices https://health.ec.europa.eu/system/files/2021-10/mdcg_2021-24_en_0.pdf
6. MDCG 2020-16 Rev.3 - Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746 - July 2024 https://health.ec.europa.eu/latest-updates/mdcg-2020-16-rev3-guidance-classification-rules-vitro-diagnostic-medical-devices-under-regulation-eu-2024-07-08_en
7. MDCG 2024-11 Guidance on qualification of in vitro diagnostic medical devices https://health.ec.europa.eu/document/download/12b92152-371f-404d-a865-93800cd5cdca_en?filename=mdcg_2024-11_en.pdf
8. Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff September 2023 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and
9. List of Medical Devices , by Product Code, that FDA classifies as Implantable, Life-Saving, and Life-Sustaining Devices for purposes of Section 614 of FDASIA amending Section 519(f) of the FDC Act Updated March 2015

Additional:

1. Trust Saidi Materials for Medi Dev.Biomedical Engineering for Africa University of Cape Town July 2019 https://www.researchgate.net/publication/347563447_Materials_for_Medical_Devices/citations
2. Cao D, Ding J. Recent advances in regenerative biomaterials. Regen Biomater. 2022 Dec 5;9:r bac098. doi: 10.1093/rb/rbac098. PMID: 36518879; PMCID: PMC9745784.
3. Nitti P, Narayanan A, Pellegrino R, Villani S, Madaghiele M, Demitri C. Cell-Tissue Interaction: The Biomimetic Approach to Design Tissue Engineered Biomaterials. Bioengineering (Basel). 2023 Sep 25;10(10):1122. doi: 10.3390/bioengineering10101122. PMID: 37892852; PMCID: PMC10604880.

13. Electronic information resources

1. U.S. Food and Drug Administration. https://www.fda.gov/
2. World Health Organization (WHO) i https://www.who.int/
3. European Medicines Agency (EMA) https://www.ema.europa.eu/en
4. European Directorate for the Quality of Medicines and HealthCare (EDQM), https://www.edqm.eu/

5. ISO 13485:2003 Medical devices – Quality management systems [Electronic resource]: 15. 15. Requirements for regulatory purposes. – Retrieved from: http://www.iso.org/iso/catalogue_detail?csnumber=36786. (Reference date of 10.12.2017).
6. Medscape search database [Electronic resource]. – Access mode: Medscape https://www.medscape.com/pharmacists.