MINISTRY OF HEALTH OF UKRAINE
ODESSA NATIONAL MEDICAL UNIVERSITY
Department of pharmacy organization and economy with post-diploma specialization

Syllabus of the discipline " Modern medical devices"

Scope of the academic discipline	Total number of hours per discipline: 90 hours, 3 credits Semesters: VIII 4th year of study
Days, time, place of the discipline	According to the schedule of classes Department of pharmacy organization and economy with post-diploma specialization Odesa, str. Oleksii Vadaturskyi, bldg. 37, 2nd floor, room 212
Teacher(s)	Head of the department, PhD in Pharmacy, Assoc.prof. Oksana BIELIAIEVA senior teacher Oksana STEPANOVA
Contact Information	Help by phone: (048) 777-98-18 senior teacher Oksana STEPANOVA oksana.stepanova@onmedu.edu.ua Oksana BIELIAIEVA oksana.belyayeva@onmedu.edu.ua Odesa, str. Oleksii Vadaturskyi, bldg. 37, 2nd floor, Department of pharmacy organization and economy with post-diploma specialization, room 212 *Face-to-face consultations*: from 14.30 to 16.00 every Tuesday, from 9.00 to 13.00 every Saturday. *Online consultations*: from 14.30 to 16.00 every Tuesday, from 9.00 to 13.00 every Saturday. The link to the online consultation is provided to each group during the classes separately.

COMMUNICATION

Communication with applicants will be carried out in the classroom (distance learning). During distance learning, communication is carried out through the Microsoft Teams platform, as well as through e-mail correspondence, Viber messengers (through groups created in Viber for each group, separately through the group head).

ABSTRACT OF THE EDUCATIONAL DISCIPLINE

The subject of the discipline is the principles of development, classification, functioning and application of modern medical devices in the diagnosis, treatment and rehabilitation of patients. Particular attention is paid to the analysis of the latest technologies, materials and quality management systems in the production of medical devices and the evaluation of the effectiveness and safety of medical devices in various healthcare areas.

Prerequisites: introduction to pharmacy, pharmaceutical law and legislation, fundamentals of economics in pharmacy, pharmacology, drug technology, ethics and deontology in pharmacy, information technology in pharmacy, world pharmaceutical distribution, psychology of communication.

Post-requisites: pharmaceutical management and marketing, organization and economics of pharmacy, pharmacoeconomics, social pharmacy, evaluation of medical technologies, pharmaceutical logistics.

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The purpose of the discipline: to increase students' knowledge of a comprehensive review of the obtaining and characterization 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 characterization methods used in the biological evaluation of medical devices and risk management.

Objectives of the discipline:

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.

Expected results:

As a result of studying the discipline the student should:

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.

DESCRIPTION OF THE ACADEMIC DISCIPLINE

Forms and methods of teaching.

Forms of study.

The discipline will be taught on a full-time basis in the form practical classes (30 hours); organization of independent work of students (60 hours).

Teaching methods:

Practical classes: verbal methods: conversation, explanation, discussion, discussion of problem situations; visual methods: illustration (including multimedia presentations*);*

Practical methods*:* test tasks, solving situational tasks, and case studies on the tasks defined by modern issues.

Independent work: independent work is based on: work with the recommended basic and additional literature, with electronic information resources, preparation for practical classes and case studies.

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 deliver. 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.

The list of 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.

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/

EVALUATION

Forms and methods of current control:

- oral control: individual questioning on the issues of the relevant topic;
- written control: assessment of solving situational tasks (including calculations), assessment of individual tasks;
- test control: assessment of test tasks on topics

Criteria for current assessment in practical classes

Score	Evaluation criteria
Excellent '5'	The applicant takes an active part in the practical lesson; demonstrates in-depth knowledge, gives full and detailed answers to questions; takes an active part in the discussion of problem situations, uses additional educational, methodological and scientific literature; is able to form his/her attitude to a particular problem; expresses his/her own views, gives appropriate practical examples; is able to find the most appropriate forms of resolving contradictions. The test tasks are completed in full, all 100% of the answers to the questions are correct, the answers to the open questions are complete and substantiated. The applicant freely solves situational tasks, confidently demonstrates practical skills on the topic of the class and correctly interprets the data obtained, expresses his/her own opinion on the topic of the task, demonstrates creative thinking.
Good '4'	The applicant participates in practical classes; has a good command of the material; demonstrates the necessary knowledge, but answers questions with some errors; participates in the discussion of problem situations, uses the main educational, methodological and scientific literature; expresses his/her own opinion on solving practical situations on the topic of the class. The test tasks are completed in full, at least 80% of the answers to the questions are correct, the answers to open questions are generally correct, but there are some errors in the definitions. The applicant correctly solves situational tasks, but makes minor inaccuracies and demonstrates more standardized practical skills on the topic of the class with the correct interpretation of the data obtained, expresses his/her own opinion on the topic of the task, demonstrates critical thinking.
Satisfactory '3'	The applicant sometimes participates in practical classes; partially speaks and asks questions; makes mistakes when answering questions; shows passive work in practical classes; shows fragmentary knowledge of the conceptual apparatus and literary sources. The test is completed in full, at least 50% of the answers are correct, the answers to open questions are illogical, with obvious significant errors in the definitions. The applicant does not have sufficient knowledge of the material for solving situational tasks, is uncertain about demonstrating practical skills on the topic of the class and interprets the data obtained with significant errors, does not express his/her opinion on the topic of the situational task.
Unsatisfactory '2'	The applicant does not participate in the practical lesson, is only an observer; never speaks or asks questions, is not interested in learning the material; gives incorrect answers to questions, shows unsatisfactory knowledge of the conceptual apparatus and literary sources. The test is not completed. The situational task is not completed.

Forms and methods of final control: test.

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

The test is taken at the last class. 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 off using the statistical method with two decimal places.

INDEPENDENT WORK OF HIGHER EDUCATION STUDENTS

- independent work with recommended literature, electronic information resources, preparation for practical classes;
- independent performance of an individual task, preparation of a report and presentation for the defense of an individual task.

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POLICY OF THE ACADEMIC DISCIPLINE

Policy on deadlines and retakes:

- Unexcused absences are made up according to the schedule of the teacher on duty.
- Absences for valid reasons are made up on an individual schedule with the permission of the dean's office.

Policy on academic integrity:

It is mandatory for students to maintain academic integrity, namely:

- independent performance of all types of work, tasks, forms of control provided by the work programme of this educational component;
- links to sources of information in case of using ideas, developments, statements, information;
- compliance with copyright and related rights legislation;
- providing reliable information about the results of their own educational (scientific) activities, research methods and sources of information.

Unacceptable in educational activities for participants in the educational process are:

- the use of family or official ties to obtain a positive or higher grade during any form of control of learning outcomes or advantages in academic work;
- use of prohibited auxiliary materials or technical means (cribs, notes, micro-headphones, phones, smartphones, tablets, etc.) during control measures
- passing the procedures for monitoring learning outcomes by fictitious persons.

For violations of academic integrity, students may be held academically liable in the following ways:

- lowering the results of the assessment of a test, class grade, test, etc;
- repeating the assessment (test, examination, etc.)
- assignment of additional control measures (additional individual tasks, quizzes, tests, etc.)
- conducting an additional check of other works by the offender.

Policy on attendance and lateness:

Health status: applicants with acute infectious diseases, including respiratory diseases, are not allowed to attend classes. Lateness to classes is not allowed. An applicant who is late for a lesson may attend it, but if the teacher has marked ‘absent’ in the journal, he or she must work it out in the general order.

Use of mobile devices:

The use of any mobile devices is prohibited. In case of violation of this item, the student must leave the class and the teacher will mark ‘absent’ in the journal, which he/she must work out in the general order.

Mobile devices may be used by students with the permission of the teacher if they are needed to complete the assignment.

Behavior in the Classroom:

The behavior of students and instructors in classrooms should be focused and calm, strictly adhering to the rules established by the Regulations on Academic Integrity and Ethics of Academic Relations at Odessa National Medical University. It must also comply with the Code of Academic Ethics and Relations within the University Community of Odessa National Medical University, as well as the Regulations on the Prevention and Detection of Academic Plagiarism in Research and Educational Activities of Higher Education Students, Researchers, and Faculty of Odessa National Medical University.