



FACULTY OF PHARMACY MEDICAL UNIVERSITY SOFIA

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DEAN:

/prof. Al.Zlatkov, DSc/

DEPARTMENT “ORGANIZATION AND ECONOMICS OF PHARMACY”

SYLLABUS of Medical Devices

INCLUDED IN “PHARMACY” EDUCATION CURRICULUM

DEGREE OF EDUCATION: “MASTER”

CREDITS (ECTS): 3

ANNOTATION

The role of medical devices in the fields of medicine, healthcare and pharmacy is of great importance. Recent innovations have led to an ever-increasing variety of such products which help improve the quality and effectiveness of health systems. Comprising a wide range of products, from gauze to complicated life-support systems and medical technology, the sector of medical devices plays an important role in diagnostics, prevention, follow-up of treatment of disease, as well as improving the quality of life of patients.

Purposes of the course teaching – to introduce students to the main legal requirements, included in the regulation of medical devices, clinical trials, market access and approval, classification, safety requirements and the main classes of medical devices. To provide students with education regarding their use in treatment, prophylaxis and diagnosis of diseases through practical applications of theoretical concepts.

To provide practical knowledge, which would support students in developing their team-work skills and capacity.

Structure of the program – The program for the course has been separated in two modules. The first module includes terminology, definitions, main requirements of the two main European Regulations in Medical devices, including materials, design and clinical studies, Bulgarian legislation, types of regulatory control, as well as data characterizing the global, European and Bulgarian market of Medical Devices.

The second module focuses on specific groups of medical devices, as per the national regulation and the way it classifies these medical devices according to their reimbursement status with public funds. The aim is to introduce students to the practical aspects and local regulatory requirements, reinforcing their knowledge base and giving them specific skills. The emphasis is on operating with national and public registers, assessing the characteristics and functionality of medical devices in specific areas.

Acquired Competences – At the end of the course, students are expected to know the main regulatory requirements for medical devices in the EU and Bulgaria, as well as the main classes of medical devices and their application in prevention, treatment, prophylaxis and diagnosis of diseases, as well as storage requirements and more. Additionally, students would be able to show competency in different software and programs, required for certain medical devices. They will have the ability to familiarize themselves with sources of information, data-bases, registers. Such competences are important for the field of medical devices and would enable them in their professional realization in distribution, pharmacy practice in both community and hospital pharmacies as well as clinical trials pertaining to medical devices.

English language training

SYLLABUS

1. Medical devices as a part of the healthcare and pharmaceutical systems.
2. Legal basis. Common European and Bulgarian Legal framework in MDs. European regulations.
3. Bulgarian legislation for medical devices. Law of Medical Devices and supporting regulatory documents.
4. Definitions of standards. Conformity assessment. ISO. International standards for medical devices.
5. Regulatory access of Medical Devices to the market.

6. Medical devices as a health technology – Assessment, Pricing, Reimbursement.
Patient access.
7. Medical Devices based on digital technologies. Digital transformation in the field.
8. Design of medical devices. Materials and technologies applied the manufacture process – metal, ceramic, polymer, adhesive, covering and biological materials.
9. Colloquium 1.
10. Medical devices reimbursed by the budget of the NHIF.
11. Medical devices reimbursed by the budget of Medical Treatment facilities.
12. Medical Devices reimbursed by the state’s republican budget, outside the scope of the mandatory health insurance.
13. Medical equipment and software.
14. Colloquium 2.
15. Summary.

Date

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