



## ACADEMIC STANDARD FOR THE DISCIPLINE „MEDICAL DEVICES”

### 1. Aim of the education on the subject

The aim of the education on the discipline "Medical Devices" is to introduce students to the legal regulations concerning medical devices, including research and classification, market entry, safety, as well as their nomenclature, types, and intended uses; their characteristics; conditions and methods of use; changes that may occur during use and storage; procedures for their acceptance, packaging, and transportation; and the methods for storing medical devices in the wholesale trade facilities and community and hospital pharmacies, to preserve their original qualities and properties.

The aim complies with:

- University mission and concepts.
- Scope and credit rating of the discipline as listed in the curriculum.
- Qualification characteristics of the specialty.
- Academic degree (Master of Science).

The aim complies with the place of the discipline in the specialty allocated by significance and chronology in the curriculum. During the overall training course, it is foreseen that the students would individually analyse the potential applications of medical devices in practice or the methods of applying the most common types. By the end of the practical exercises, students should be familiar with the terminology, key definitions, and legislative requirements in the EU and Bulgaria related to medical devices. They should also be able to handle the primary classes of medical devices used in medical practice and their application for the prevention, treatment, and diagnosis of diseases.

### 2. Educational content of the discipline

The topics and study hours of the lectures, practical exercises, and course tasks are listed on the website of the University. Their content is arranged in chronological order so that each next

lecture and related exercises use already covered matter and terms. Thus, unnecessary overlapping and the presence of “gaps” between disciplines, associated with the educational plan, is avoided.

### **3. Prerequisites**

The medical devices sector plays a crucial role in the diagnosis, prevention, monitoring, and treatment of diseases, as well as in improving the quality of life of people with disabilities. Regulatory requirements for medical devices, which establish market access rules, aim to ensure consumer safety on one hand and to stimulate innovation in the sector on the other.

The innovativeness and wide variety of these products significantly contribute to enhancing the quality and effectiveness of healthcare. An article, instrument, apparatus, or machine that is used in the prevention, diagnosis, or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological, or metabolic means.

The course on "Medical Devices" is extremely important for pharmacists, as it provides them with the knowledge and skills necessary for the proper consultation, storage, and distribution of these products. This contributes to better patient care and enhances safety in medical practice.

### **4. Academic resources**

The academic staff of the section includes two habilitated lecturers, three non-habilitated lecturers with a scientific degree “doctor” and the relevant scientific specialty, and two non-habilitated lecturers. Five of the staff members have acquired a specialty in organization and economics of distribution and pharmacy practice, and two are enlisted and undergoing postgraduate training in the specialty.

The lectures are presented by a habilitated lecturer (Professor and Associate Professor) with a PhD degree in the relevant doctoral program. Up to 30% of the lectures are assigned to non-habilitated lecturers with an academic degree in the relevant PhD program. The practical exercises are led by non-habilitated lecturers (assistant professor, senior assistant professor). The non-habilitated lecturers have an academic educational qualification degree MSc in Pharmacy and have been employed after a competition.

## **5. Material assets**

The students and postgraduate students are trained in auditoriums and two seminar halls, where various medical devices are discussed and categorized.

## **6. Lectures as part of the Curriculum**

The lectures are prepared and presented as multimedia presentations, supplied to the students either in an electronic version or as a hard copy. The supplied lectures' scope and format depend on the leading lecturer's choice.

## **7. Practical exercises**

They are conducted in groups. The practical exercises are completed with methodological guidelines, manuals, and tests. The students must solve individual and team tasks.

The practical exercises aim to check:

- Student's preparation
- Results (acquired knowledge and skills) of the practical exercise.

As a methodological form, the priority is given to teamwork and team discussions. It is possible to assign tasks to the students to elaborate and defend their thesis (presentation) on a topic defined by the lecturer during the preceding exercise. After that a discussion with a group of students is organized where the presenting student defends his/her thesis.

## **8. Information resources. Main publications. Websites**

The lecturer is obliged to have developed lectures on the subject and to present them, along with training tests and other training materials, in electronic format.

A list of relevant recommended literature on each component of the subject (lectures, exercises) is provided, with priority given to accessible sources, which will be outlined as the "main literature." Internet resources can also be recommended, providing appropriate materials for the student's preparation.

### ***Main literature***

Петкова В., Петрова Г., Камушева М., Манова М., Савова А., Гетов И, Димитрова М., Ташков К., Миткова З, Лебанова Хр., Андреевска К., Грекова Д., Тодорова А., Гетова-Коларова В, Милушева П., Герасимов Н., Благоев В., Медицински изделия: учебник за студенти по фармация. София: [Таурус адвертайзинг], 2024.

### *Additional sources*

1. Григоров, Е., Медицински изделия – правно регулиране в България. МУ-Варна, Принтзоун ООД, 2015.
2. Григоров, Е., Е. Костов, Х. Лебанова, И. Гетов, Пазарно проучване на медицински изделия прилагани за аерозолотерапия, *Обща медицина*, 2013 (15) 2, 36-39.
3. Григоров, Е., Х. Лебанова, Е. Насева, И. Гетов, Проучване на нагласите за измерване на кръвно налягане сред посетителите в аптеки в София, *Сърдечно съдови заболявания*, 2012 (43) 2, 43-47.
4. Григоров, Е., Е. Костов, Х. Лебанова, И. Гетов, Проучване на нагласите за измерване на кръвна захар сред посетителите в аптеки в София, *Обща медицина*, 2012 (14) 2, 12-16.
5. Григоров, Е., Х. Лебанова, Е. Насева, И. Гетов, Пилотно проучване за измерване на общ холестерол сред пациенти с ИБС в аптеки в София, *Сърдечно-съдови заболявания*, 2012 (43) 3, 36-40.
6. Григоров, Е., Е. Костов, Х. Лебанова, И. Гетов, Характеристики на фармацевтичните услуги с добавена стойност в аптека, *Социална медицина*, 2012 (20) 4, 38-39.
7. Герасимов, Н., Ст. Сопотенски, Г. Петрова. Развитие на Европейското законодателство в областта на медицинските изделия – основа за безопасни, ефективни и иновативни медицински изделия в полза на пациентите и медицинските специалисти, *Медицински мениджмънт и здравна политика*, 2014 (45) 4, 26-41.
8. Министерство на Здравеопазването. Закон за медицинските изделия, (Обн. ДВ. бр.46 от 12 Юни 2007г.)
9. Министерство на Здравеопазването. Наредба за съществените изисквания и процедурите за оценяване на съответствието със съществените изисквания на ин витро диагностичните медицински изделия (Приета с ПМС № 184, обн. ДВ. бр.65 от 10 август 2007 г.)
10. Министерство на Здравеопазването. Наредба за условията и реда за блокиране, изтегляне и/или унищожаване на медицински изделия.(Обн. ДВ бр. 97 от 11 ноември 2008 г.)
11. Закон за лекарствените продукти в хуманната медицина (ЗЛПХМ) в сила от 13.04.2007 г. (чл. 219, чл. 225, чл. 238, § 22 от преходните и заключителните разпоредби);
12. Национален рамков договор № РД-НС-01-4 от 23 декември 2019 г. за медицинските дейности между Националната здравноосигурителна каса и Българския лекарски съюз за 2020 – 2022 г. (чл. 2, чл. 30, Глава 11).

13. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
14. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.
15. European Commission, Guidelines on medical devices, Brussels, Belgium, 2005.
16. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
17. Council Directive 90/385/EEC OF 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
18. CRDH, Medical device Use-safety: Incorporating human factors engineering into risk management, CDRH, USA, 2000
19. WHO, Medical device regulation. (Global overview and guiding principles), Geneva, 2010.

## **9. Control assignments**

Students are occupied dynamically and intensively during the semester. It is assumed that how knowledge and skills are acquired is an important factor for their depth, durability, and applicability. Students' knowledge of current control is executed through tests once per semester as a minimum. Students are provided with timely information and explanations on the control results (on the next exercise), which assists their further preparation. The results of those tests are included as a component in the final semester evaluation mark.

## **10. Individual preparation and out-of-auditorium work of the students**

The individual work is supervised by the lecturer, who advises the student on both literature sources to be studied and on methods for their understanding and adoption.

## **11. Collaboration between lecturers and students**

This collaboration is expressed in:

- Lecturer's engagements with the student and his/her preliminary preparation; current difficulties in learning the material and options to achieve better results with the implementation of individual programs.
- Use of consultation hours.
- Involving students in teams developing scientific projects, tasks, studies, etc.

## **12. Examinations**

The current evaluation marks foreseen in the educational plan of the discipline are formed by:

- Students' results from seminar exercises, individual tasks, students' work with the lecturer on scientific research and projects, etc.
- At least one (at the end of the semester) control written test or student essay.

### 13. Evaluation standards

The successful learning of the discipline „Medical Devices” of the education plan is evaluated as a compilation of evaluation marks distributed in two basic elements:

- The first one includes the student's evaluation mark for the overall semester (not more than 30%). It includes individual evaluation marks for current control (tests), for the overall and qualitative execution of the forms of individual work, foreseen in the curriculum of the discipline.
- The second one covers the evaluation mark from the exam on the discipline (not more than 70%). The rules of leading the examination are also very important, with a view to minimizing the possibility for examination results manipulation. The exam is conducted both in written and oral. The written part consists of a test that includes both open-ended and multiple-choice questions.

Clear evaluation standards are developed for the discipline.

The levels of reproducing and implementing the students' knowledge are defined as information-reproductive, technological-productive, and innovation-creative. A certain characteristic is determined on the above basis for evaluation of the theoretical component of the examination:

- **Grade F - corresponding to Bulgarian grade “Weak” - 2** is assigned to a student with scarce knowledge that cannot be a basis for further educational levels.
- **Grade D – corresponding to Bulgarian grade “Poor” - 3** is assigned to a student who reproduces the knowledge in a “ready-to-use chart” with missing certain basic moments of the developed topic; there is no preparedness to use independently the obtained knowledge and professional competences; the terminology is not learnt, and the presentation is characterized by poor wording.
- **Grade C – corresponding to Bulgarian grade “Good” - 4** is given to a student who develops the subject descriptively and reproductively, using model situations; restricted independence when using the acquired knowledge and professional competences; the presentation, though characterized by good language culture, contains improper use of certain terms.

- **Grade B – corresponding to Bulgarian grade “Very good” - 5** is given to a student who develops the issue independently, productively, unusually, searching for a new algorithm and analysis of the used referent publications; tries to define and substantiate an own thesis; adequately implements the terms of the scientific domain of the studied subject, shows good language culture.
- **Grade A – corresponding to Bulgarian grade “Excellent” – 6** is assigned to a student who independently, logically, with creative elements presents the topic; uses and interprets the relevant referent publications in a substantiated and original way; completeness and preparedness to implement the acquired knowledge and professional competences; accurate, rich language of the presentation.

At the beginning of the lessons, the students must be acquainted with the evaluation standards, procedures for current control, and feedback options concerning their progress during the semester.

#### **14. Formation of the final evaluation mark**

The final evaluation mark determines the extent to which the student has achieved the aim of the tuition defined in the beginning. It is multicomponent and includes the evaluation mark of the written final examination, the evaluation of the oral final examination, and the current control evaluation mark.

For each component participating in the final evaluation, a significance ratio is assigned ranging in the interval 0 - 1, and the total of the ratios must always be 1. The final evaluation 6 mark is calculated as a sum of the evaluation marks according to the Bulgarian evaluation marks system of the individual components multiplied by the respective significance ratios.

**Q final evaluation mark =  $\kappa_1$  Q evaluation mark for current control +  $\kappa_2$  Q written examination mark +  $\kappa_3$  Q oral examination evaluation mark**

$$\kappa_1 = 0.20; \kappa_2 = 0.50; \kappa_3 = 0.30$$

When one of the components of the final exam is “Weak (2)”, the final evaluation mark is obligatorily “Weak (2)”.

The components participating in the formation of the evaluation mark and the significance ratios for each subject are determined by the Academic Council with the approval of the current academic standard of the discipline.

#### **15. Documenting, keeping the results and control of the evaluation activity**

- The students subjected to evaluation have the right and obligation to be informed about the evaluation rules, procedures, and results and to submit claims and complaints when the current rules are not observed.
- The student's right in the aspect of the above paragraph is enforced in case of established technical omissions or errors (e.g. at calculating or at entering the evaluation marks in the relevant files) as well as in case of serious grounds for biasing of the exhibited knowledge, skills and competence and the final evaluation mark assigned to the student.
- Evaluation marks revisions are admitted in cases within the above paragraph and are entered in the student's record book, examination protocol or in the lot in the Main Record Book only by the discipline holder.
- Any eventual arguments and claims on students' behalf are supplied in written form to the evaluating team that must provide a substantiated reply by the end of the next working day.
- Any established and proven cases of serious violation of students' rights in evaluating their knowledge, skills, and competencies are submitted in written form to the Vice Rector responsible for Quality Assurance and Accreditation.

The examination materials are stored and allowed for the students to get acquainted with them as well as with the grounds for evaluation in compliance with predefined order and procedure. The period for students' access to the test materials is no longer than 3 (three) working days after the examination date. The characteristic of the discipline is submitted to the students at the beginning of the training. This corresponds to Art. 56, par. 1 of the University Education Law, according to which the lecturers must elaborate and adequately announce the description of the course lectured by them, including headings and sequence of the topics, forming the educational content, recommendable reference materials, way of forming the evaluation mark and forms of checking the knowledge and skills.

**Approved by:**

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The academic standard for the discipline „Medical Devices” is adopted by Decision of the Chair Council, Protocol No 02/25.02.2026.