

COURSE DESCRIPTION

Academic year: 2023/2024	
University: Comenius University Bratislava	
Faculty: Faculty of Pharmacy	
Course ID: FaF.KGF/10-Mgr-A/22	Course title: Medical Devices
Educational activities: Type of activities: lecture Number of hours: per week: 2 per level/semester: 28 Form of the course: on-site learning	
Number of credits: 2	
Recommended semester: 5.	
Educational level: I.II.	
Prerequisites:	
Course requirements: Attendance of the lectures is obligatory. There can be excused two absences on the basis of a medical certificate as maximum, and student replaces her/his absence by drawing up the specified topic according to the teacher's instruction. The semester ends with a comprehensive semester written exam. The minimal level for passing this test is 60%. Assessment scale: A 93,00–100,00%, B 85,00–92,99%, C 77,00–84,99%, D 69,00–76,99%, E 60,00–68,99%, FX 59,99% and less.	
Learning outcomes: The student acquires basic knowledge of medical devices and handling with them. Emphasis is placed on medical devices (MDs) that are available in pharmacy and medical supplies dispensaries. The student's knowledge also includes the process of the MDs' market access. The course focuses on important attributes of MDs, these are quality and safety. The student acquires knowledge on those MDs, which are the most frequently indicated in medical and preventive health care. Student learns the MD properties, material used, and can specify a proper handling, including storage, renovation options, disposal, including.	
Class syllabus: Definition of medical devices (MDs) and an interface with drugs, MDs classification, Regulatory aspects of placing MD on the market, declaration of conformity, registration, distribution of MDs, MDs for wound healing (dry wound healing, wet wound healing, burns), MDs in outpatient health care, MDs for self-monitoring, Medical devices in mother and child care, MDs for compression therapy, MDs for diabetics, MDs for incontinent patients and for patients with stoma, MDs for patients with hearing and vision disorders, MDs made of metal, MDs in vitro diagnostic purposes,	

Rehabilitation and compensation of the MDs.

Recommended literature:

European legislation

European Pharmacopoeia, 10th Edition. Strasbourg: EDQM, 2022.

Central Library, Faculty of Pharmacy Comenius University Bratislava

Aulton, M. E.: Aulton's Pharmaceutics: the design and manufacture of medicines. Edinburgh: Churchill Livingstone.

<https://uniba.sk/en/about/faculties-and-units/comenius-university-academic-library/external-electronic-information-resources/>

Scientific Literature

Ecker, W. 2019. Medical Devices and IVDs. Market Access under the new EU-Regulations.

National Library of Germany. Edition by Dr. Wolfgang Ecker, 2nd. edition, Feb 2019. 239 p.

ISBN 978-3-7481-3746-7

Ecker, W., Labek, G., Mittermayr, T. et al. 2020. Clinical Evaluation and Investigation of Medical Devices under the new EU-regulation. National Library of Germany. Edition by Michael Ring, 2020. 260 p. ISBN 978-3-7519-3766-5

Languages necessary to complete the course:

English

Notes:

The course is available only in summer term, if minimal 5 students are enrolled. Total capacity of the course is limited to 40 students.

Past grade distribution

Total number of evaluated students: 0

A	ABS	B	C	D	E	FX
0,0	0,0	0,0	0,0	0,0	0,0	0,0

Lecturers: PharmDr. Veronika Šimunková, PhD., PharmDr. ThLic. Mária Raučinová, PhD., PharmDr. Jarmila Ferková, PharmDr. Milica Molitorisová, PhD., Ing. Silvia Molnárová

Last change: 29.08.2022

Approved by: doc. Mgr. Martina Hrčka Dubníčková, PhD.