Title:	**Pharmaceutical Biotechnology**
Lecture hours:	15 hours, conversatory classes
Study period: (summer/winter)	winter
Number of credits:	3
Assessment methods:	Test
Language of instruction:	English
Prerequisites:	Immunology, cell biology, biochemistry
Course content:	Lecture 1: Pharmaceutical biotechnology: introduction to the topic, basic concepts. Challenges and direction of development of pharmaceutical biotechnology. Lecture 2: First generation biopharmaceuticals. Overview of the basic groups of drugs, the production process, their use and administration routes. Lecture 3: Nex generation biopharmaceuticals, using of genetic engineering in the production of biopharmaceuticals. Lecture 4: Pharmacokinetic and pharmacodynamic models. Basic concepts, routes of administration of biotechnological drugs, Lecture 5: Research models in pharmacological research of biopharmaceuticals. In vitro, ex vivo and in vivo studies. Lecture 6: Vaccines as a specific biopharmaceutical, types of vaccines, methods of their production and application. Lecture 7: Clinical trials, phases of clinical trials, legal conditions of the way to introduce the drug to the market.
Learning outcomes:	The purpose of this course is to provide an advanced understanding of the meaning of pharmaceutical biotechnology and production of biopharmaceuticals. Students will get acquainted with the production process of biopharmaceuticals and their application in medicine. Furthermore, students will familiarize with the models applied in the biotechnological research focusing on the research in the area of pharmaceutical biotechnology.
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Literature:	• Shargel L, Yu AC. eds. Applied Biopharmaceutics & Pharmacokinetics, 7e. McGraw Hill; 2016. • Gary Walsh Biopharmaceuticals: Biochemistry and Biotechnology, Second Edition, Wiley-Blackwell, 2003