

**Subject card**

|  |  |  |                         |                                     |  |            |     |
|--|--|--|-------------------------|-------------------------------------|--|------------|-----|
| <b>Subject name and code</b>                       | Monoclonal antibodies as drugs: from development to registration, PG_00153644  |  |                         |                                     |  |            |     |
| <b>Field of study</b>                              | Biotechnology  |  |                         |                                     |  |            |     |
| <b>Date of commencement of studies</b>             | October 2026   | <b>Academic year of realisation of subject</b>           |                         |                                     | 2027/2028  |            |     |
| <b>Education level</b>                             | Master's studies   | <b>Subject group</b>                                     |                         |                                     | Obligatory subject group in the field of study<br>Optional subject group<br>Subject group related to scientific research in the field of study |            |     |
| <b>Mode of study</b>                               | full-time studies  | <b>Mode of delivery</b>                                  |                         |                                     | at the university  |            |     |
| <b>Year of study</b>                               | 2  | <b>Language of instruction</b>                           |                         |                                     | Polish   |            |     |
| <b>Semester of study</b>                           | 3  | <b>ECTS credits</b>                                      |                         |                                     | 2.0  |            |     |
| <b>Learning profile</b>                            | academic   | <b>Assessment form</b>                                   |                         |                                     | credit   |            |     |
| <b>Conducting unit</b>                             | Intercollegiate Faculty of Biotechnology UG-MUG -> Rector  |  |                         |                                     |  |            |     |
| <b>Name and surname of lecturer (lecturers)</b>    | <b>Subject supervisor</b>  |  | dr hab. Andrea Lipińska |                                     |  |            |     |
|  | <b>Teachers</b>  |  |                         |                                     |  |            |     |
| <b>Lesson types</b>                                | <b>Lesson type</b>   | Lecture  | Tutorial                | Laboratory                          | Project  | Seminar    | SUM |
|  | <b>Number of study hours</b>   | 30.0   | 0.0                     | 0.0                                 | 0.0  | 0.0        | 30  |
|  | E-learning hours included: 0.0   |  |                         |                                     |  |            |     |
| <b>Learning activity and number of study hours</b> | <b>Learning activity</b>   | Participation in didactic classes included in study plan |                         | Participation in consultation hours |  | Self-study | SUM |
|  | <b>Number of study hours</b>   | 30   |                         | 5.0                                 |  | 15.0       | 50  |
| <b>Subject objectives</b>                          | The aim of this course is to familiarize students with the techniques and research tools used in biotechnology related to the production of biological drugs, particularly monoclonal antibodies. Students will also become familiar with methods for large-scale production of biological drugs, legal regulations related to drug registration, and methods for searching, selecting, verifying, and presenting information related to these topics. |  |                         |                                     |  |            |     |

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|--|---|--|-----------------------------------|
| Learning outcomes  | Course outcome  | Subject outcome  | Method of verification            |
|  | [BIOTECHMU2_W07] The graduate possesses knowledge in the social sciences and humanities that is helpful in entrepreneurship and effective functioning in society, and understands the principles of responsibility in conducting scientific research, is able to interpret scientific and organizational decisions in the light of ethical, social and economic values.   | The student understands the importance of knowledge from social sciences and humanities in the context of entrepreneurship in biotechnology and functioning in society, characterizes the principles of ethical, legal and social responsibility in conducting scientific research and biotechnology projects, with particular emphasis on research on biological drugs. | [SW4] test/exam - oral or written |
|  | [BIOTECHMU2_W03] The graduate has in-depth, specialized knowledge of therapy and diagnostic methods of human diseases, including the mechanisms of action of selected drugs, immunotherapy, cellular and gene therapy, understanding the ethical, legal and social dilemmas involved and being able to evaluate them from the perspective of the patient's well-being and the public interest.  | The student explains the complex concept and mechanisms of immunotherapy, including methods of production, validation and clinical trials of antibody-based drugs.   | [SW4] test/exam - oral or written |
|  | [BIOTECHMU2_K04] The graduate understands the ethical dilemmas and risks associated with conducting scientific research and introducing highly advanced technologies using biotechnology; appreciates the importance of intellectual property; and acts ethically, reflecting on one's own worldview, attitudes and professional responsibility.  | The student explains the ethical dilemmas and risks associated with the introduction of advanced antibody-based technologies and discusses the importance of intellectual property when developing immunotherapy.  | [SK4] test/exam - oral or written |
| Subject contents   | <p>Biological medicines, including biosimilars, and their impact on the healthcare system</p> <p>healthcare system</p> <p>Pharmacology of therapeutic monoclonal antibodies. Impact of critical quality parameters on PK/PD and clinical data</p> <p>clinical</p> <p>Development and validation of analytical methods</p> <p>Antibodies as therapeutic agents. A case study</p> <p>Generation of cell lines for biological production - general principles. Case study</p> <p>Laboratory scale process development and optimisation - general principles. Case study</p> <p>Finished product development - formulation development and selection of immediate packaging. Finished product process development</p> <p>Large scale manufacturing - scaling up</p> <p>Large scale manufacturing - upstream processes</p> <p>Large scale manufacturing - downstream processes</p> <p>Clinical trials - introduction and historical background. Clinical trials - methodology, strategies, design - including biosimilar medicines</p> <p>Clinical trials - from plan to report</p> <p>Registration - introduction. Health system regulators - guidelines and interactions</p> <p>Registration pathway for biologic medicines</p> <p>Technical development plan for a biological drug including biosimilar</p> |  |                                   |
| Prerequisites and co-requisites                                |   |  |                                   |
| Assessment methods and criteria                                | Subject passing criteria  | Passing threshold  | Percentage of the final grade     |
|  | Written test  | 51.0%  | 100.0%                            |
| Recommended reading  | Basic literature  | A. Literature required for final course credit (passing the exam):<br>A.1. used in class<br>A.2. studied independently by the student  |                                   |
|  | Supplementary literature  | Materials provided in class by the instructor<br>Supplementary literature will be provided during the class.   |                                   |
|  | eResources addresses  |  |                                   |
| Example issues/<br>example questions/<br>tasks being completed |   |  |                                   |
| Work placement   | Not applicable  |  |                                   |

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