SYLLABUS – A COURSE DESCRIPTION

I. General informaion

1. Course name: **Legal and ethical dimensions in medical biotechnology**
2. Course code: **01-W-BTA-LEGETH**
3. Course type (compulsory or optional): **compulsory**
4. Study programme name: **Biotechnology**
5. Cycle of studies (1st or 2nd cycle of studies or full master's programme): **2nd cycle of studies**
6. Educational profile (general academic profile or practical profile): **general academic profile**
7. Year of studies (if relevant): **I**
8. Type of classes and number of contact hours (e.g. lectures: 15 hours; practical classes: 30 hours):

   conversatorium: 15 hours
9. Number of ECTS credits: **2**
10. Name, surname, academic degree/title of the course lecturer/other teaching staff:

Prof. Tomasz Twardowski, Instytut Chemii Bioorganicznej

Prof. UAM Ewa Nowak , ewa.nowak@amu.edu.pl, Zakład Etyki, Wydział Filozofii UAM

11. Language of classes: **English**
12. Online learning – yes (partly – online / fully – online) / no: **-**

II. Detailed information

1. Course aim (aims)

   The aim of the course is to present ethical, social and economic issues of biotechnology. Modern biotechnology, particularly technologies stemming from genetic engineering are at the core of the scientific and innovative foundation of most of the different bioeconomy policies developed around the world. The challenges and perspectives of bioeconomies are immense, but most of them are focused to guarantee food security and quality, new biomaterials and bioenergy, as well as new drugs and diagnosis techniques in a sustainable and economics way for 9 billion people for the year 2050. In the discussions about bioeconomies, it must be acknowledged that irrespective of the fact that several different technologies might be available, just a few may be considered useful and socially desirable and acceptable. Europeans are consumers of GM products as well as the inventors of novel technologies towards drugs, diagnosis, biomaterials, food and feed but not the producers. It is important to remind that biotechnology is a very wide field, deeply anchored in human history since ancient times and not limited to GMO or genetic engineering. Even much broader in both scope and impact than biotechnology and encompassing holistically further aspects beyond science and technology is the concept of bioeconomy. The future development depends on legislation friendly for innovations, public perception and acceptance of novel product on the market and investment towards science by states and by private industry. Based on holistic interpretation of science bioeconomy is a new paradigm whose aim is to develop a new economic system based on a sustainable use of renewable biological resources. Ethical issues that arise from modern biotechnologies include the availability and use of privileged information, potential for ecological harm, access to new drugs and treatments, and the idea of interfering with nature. Applications include agriculture and health care.

   From bioengineering to biofsafety and ethical safety. Risk management and a safe & responsible research project. Basic documents, procedures and best practices
2. Pre-requisites in terms of knowledge, skills and social competences (if relevant)

   No prerequisite
3. Course learning outcomes (EU) in terms of knowledge, skills and social competences and their reference to study programme learning outcomes (EK)

Course learning outcome symbol (EU)	On successful completion of this course, a student will be able to:	Reference to study programme learning outcomes (EK)
EU_01	Understand the fundamental aspects of legislation concerning biotechnology in Poland within European Union	BT_W08, BT_U05, BT_W09
EU_02	Recognize ethical aspects of innovative bio-technologies	BT_W08, BT_U05

EU_03	Describe basic principles of different dimensions of bioeconomy	BT_U04, BT_K04
EU_04	Recognize the significance of public perception, public acceptance and education of the society	BT_U04, BT_U03, BT_K04
EU_05	Gain the knowledge how to find information concerning legislation, including intellectual property rights	BT_K05, BT_U07
EU_06	Use the scientific English terminology in social aspects of biotechnology	BT_U05, BT_W09
EU_07	Developing and applying biotechnologies in terms of biosafety and bioethics (academic, experimental, medical contexts)	BT_W02, BT_W08, BT_K05
EU_08	Conduct a risk management analysis for responsible experimentation	BT_W08, BT_U04
EU_09	Develop expertise in basic procedural ethics & best practices and provide an ethical statement for a sample research project	BT_W08, BT_W07, BT_U04, BT_K05

4. Learning content with reference to course learning outcomes (EU)

Course learning content	Course learning outcome symbol (EU)
Overview of legislation, public perception and ethical aspects of innovative bio-technologies	EU_01, EU_02, EU_06
Background information how legislation is formulated in confrontation with scientific data, public opinion and political situation	EU_03, EU_06, EU_05
Overview of three religions on biotechnology: islam, judaizm and chrystianism	EU_03, EU_04
Introduction to public perception surveys and interpretation of data	EU_04, EU_06
The concept of basic factors for further development of bioeconomy, e.g. education, cooperation, perception	EU_05
From biotechnologies to biosafety and bioethics (academic, experimental, medical contexts)	EU_07
Risk management analysis and responsible experimentation	EU_08
Basic procedural ethics, best practices vs. malpractices, ethical statement.	EU_09

5. Reading list (fragments indicated by the teachers)

1. Torgersen, H., Hampel, J., Von Bergmann-Winberg, M-L., Bridgman, E., Durant, J., Einsiedel, E., Fjæstad, B., Gaskell, G., Grabner, P., Hieber, P., Jelsøe, E., Lassen, J., Marouda-Chatjoulis, A., Nielsen, T.H., Rusanen, T., Sakellaris, G., Seifert, F., SmiBT, C., Twardowski T., Kamara, M.W. : Promise, problems and proxies: twenty-five years of debate and regulation in Europe, [in:] Biotechnology – the Making of a Global Controversy, (eds) M. W. Bauer, G. Gaskell, 21-94, Cambridge University Press with the Science Museum, London, 2002

Kenneth D. Pimple (Ed.), Research Ethics, Ashgate 2008; Andrew Lakoff, Pharmaceutical reason, Cambridge Univ. Press 2005; J. Różyńska, Marcin Waligóra, Badania naukowe z udziałem ludzi w biomedycynie. Standardy międzynarodowe, Warszawa 2012; CIOMS http://www.cioms.ch/ ; Belmont Report, http://www.wma.net/; research integrity principles NCN https://www.ncn.gov.pl/sites/default/files/pliki/Code-of-the-National-Science-Centre-on-Research-Integrity.pdf

Articles:

1. (2018): Special issue “bioeconomy”, New Biotechnology, 40
2. Grunert, K.G., Bredahl, L. and Scholderer, J. (2003): Four questions on European consumers’ attitudes toward the use of genetic modification in food production, Innov. Food Sci. Emerg. Technol., I 4, 435–445
3. Hess, S., Lagerkvist, C.-J., Redekop, W. and Pakseresht, A. (2013): Consumers´ evaluation of biotechnology in food products: new evidence from a meta-survey., Proceedings of the Agricultural & Applied Economics Association´s 2013 AAEA & CAES joint annual meeting, Washington, DC.,
4. Lucht, J.M. (2015): Public acceptance of plant biotechnology and GM crops, Viruses, 7: 4254-4281
5. Marris, C. (2001): Public views on GMOs – deconstructing the myths. , EMBO Reports, 21(7): 545-548
6. Eriksson, D., de Andrade, E.,Bohanec, B., Chatzopolou, S., Defez, R., Eriksson, N.L., van der Meer, P., van der Meulen, B., Ritala, A., Sági, L., Schiemann, J., Twardowski, T., Vaněk T. (2018): Why the European Union needs a national GMO opt-in mechanism, Nature Biotechnology, 36: 18-19
7. Aguilar, A., Wohlgemuth, R., Twardowski, T. (2018): Preface to the special issue bioeconomy, New Biotechnology, 40, Part A: 1-4
8. Woźniak, E., Twardowski, T. (2018): The bioeconomy in Poland within the context of the European Union, New Biotechnology, 40, Part A: 96-102
9. Aguilar, A., Wohlgemuth, R., Twardowski, T. (2018): Perspectives on bioeconomy , New Biotechnology, 40, Part A: 181-184
10. Małyska, A., Bolla, R., Twardowski, T. (2018): Communicating Biotech Advances: Fiction versus Reality, Trends in Biotechnology, 36(2), 121-123
11. Tyczewska, A., Wozniak, E., Gracz, J., Kuczynski, J., Twardowski, T. (2018): Towards Food Security: Current State and Future Prospects of Agrobiotechnology, Trends in Biotechnology, 36(12), 1219-1229
12. Gaskell, G., Allum, N., Bauer, M., Durant, J., Allansdottir, A., Bonfadelli, H., Boy, D., de Cheveigné, S., Fjaestad, B., Gutteling, J.M., Hampel, J., Jelsoe, E., Jesuino, J.C., Kohring, M., Kronberger, N., Midden, C., Nielsen, T.H., Przestalski, A., Rusanen, T., Sakellaris, G., Torgersen, H., Twardowski, T., Wagner, W. (2000): Biotechnology and the European public, Nature Biotechnology, 18, 935-938

III. Additional information

1. Teaching and learning methods and activities to enable students to achieve the intended course learning outcomes (please indicate the appropriate methods and activities with a tick or/and suggest different methods)

Teaching and learning methods and activities	
Lecture with a multimedia presentation	X
Interactive lecture	X
Problem – based lecture	X
Discussions	X
Text-based work	X
Case study work	X
Problem-based learning	
Educational simulation/game	
Task – solving learning (eg. calculation, artistic, practical tasks)	
Experiential work	
Laboratory work	
Scientific inquiry method	
Workshop method	X
Project work	
Demonstration and observation	
Sound and/or video demonstration	

Creative methods (eg. brainstorming, SWOT analysis, decision tree method, snowball technique, concept maps)	
Group work	

2. Assessment methods to test if learning outcomes have been achieved (please indicate with a tick the appropriate methods for each LO or/and suggest different methods)

Assessment methods	Course learning outcome symbol					
	EU_1	EU_2	EU_3	EU_4	EU_5	EU_6
Written exam						
Oral exam						
Open book exam						
Written test						
Oral test						
Multiple choice test						
Project						
Essay						
Report	X	X	X	X	X	X
Individual presentation						
Practical exam (performance observation)						
Portfolio						

3. Student workload and ECTS credits

Activity types	Mean number of hours spent on each activity type
Contact hours with the teacher as specified in the study programme	15
Preparation for classes	10
Reading for classes	15
Essay / report / presentation / demonstration preparation, etc.	20
Project preparation	
Term paper preparation	
Exam preparation	
Total hours	60
Total ECTS credits for the course	2

4. Assessment criteria according to AMU in Poznan grade system

Very good (bdb; 5,0): outstanding performance without errors
Good plus (+db; 4,5): above the average standard but with minor errors
Good (db; 4,0): generally sound work with some errors
Satisfactory plus (+dst; 3,5): fair but with significant shortcomings
Satisfactory (dst; 3,0): performance meets the minimum criteria
Unsatisfactory (ndst; 2,0): fail – considerable further work is required before the credit can be awarded