

DESCRIPTION OF THE COURSE OF STUDY

Course code	0512.6.BIOT2.B/C.KJwLB	
Name of the course in	Polish	Kontrola jakości w laboratorium biotechnologicznym
	English	Quality control in a biotechnology laboratory

1. LOCATION OF THE COURSE OF STUDY WITHIN THE SYSTEM OF STUDIES

1.1. Field of study	Biotechnology
1.2. Mode of study	Full-time studies
1.3. Level of study	Second cycle
1.4. Profile of study*	General academic
1.5. Person/s preparing the course description	Sabina Dołęgowska, Artur Michalik
1.6. Contact	Sabina.Dolegowska@ujk.edu.pl; tel. 41-349-70-23

2. GENERAL CHARACTERISTICS OF THE COURSE OF STUDY

2.1. Language of instruction	Polish, English
2.2. Prerequisites*	Biostatistics

3. DETAILED CHARACTERISTICS OF THE COURSE OF STUDY

3.1. Form of classes	Lecture, laboratory classes (computer classes)	
3.2. Place of classes	Courses in the teaching rooms of UJK	
3.3. Form of assessment	Lecture: exam Laboratory classes: credit with grade	
3.4. Teaching methods	Lecture: informative lecture Laboratory classes: solving problems	
3.5. Bibliography	Required reading	Accreditation for Microbiological Laboratories. EURACHEM, 2013. EURACHEM/CITAC Guide. Quantifying uncertainty in analytical measurement. 2nd edition. 2000. Konieczko P., Namieśnik J. Ocena i kontrola jakości wyników pomiarów analitycznych. Wyd. Nauk.-Techn. Warszawa. 2014.
	Further reading	Validation of Analytical Procedures. Text and Methodology. ICH Topic Q 2 (R1), CPMP/ICH/381/95. European Medicines Agency. 1995. Wyznaczanie niepewności w pomiarach analitycznych. Biuletyn Informacyjny Klubu POLLAB. 2016

4. OBJECTIVES, SYLLABUS CONTENT AND INTENDED LEARNING OUTCOMES

<p>4.1. Course objectives (including form of classes)</p> <p>C1. Lecture – Standards and procedures in biotechnical laboratories. External and internal quality control requirements. Validation and verification of analytical procedures. Measurement uncertainty.</p> <p>C2. Laboratory classes – Assessment of analytical procedures. Estimation of validation parameters and measurement uncertainty.</p>
<p>4.2. Detailed syllabus (including form of classes)</p> <p>Lecture: Good laboratory practice. Quality control and quality assurance system. External and internal quality control requirements. Standards and procedures in laboratories. Method validation. Characterization of validation parameters. Revalidation. Measurement uncertainty (standard, combined and expanded uncertainty). Traceability. Reference materials, reference bacterial strains. Interlaboratory comparisons. Personnel requirements and working conditions. Laboratory equipment.</p> <p>Laboratory classes: Calculation of validation parameters. Assessment of analytical procedures based on validation parameters. Methods of estimating measurement uncertainty.</p>

4.3 Intended learning outcomes

Code	A student, who passed the course	Relation to learning outcomes
within the scope of KNOWLEDGE:		
W01	Knows the quality assurance and quality control system	BIOT2A_W08
W02	Knows the external and internal requirements of quality control	BIOT2A_W08

W03	Knows the parameters of validation procedure	BIOT2A_W07
W04	Knows statistical methods used for the estimation of measurement uncertainty	BIOT2A_W07
within the scope of ABILITIES:		
U01	Can calculate the parameters of validation procedure	BIOT2A_U03
U02	Can estimate the measurement uncertainty	BIOT2A_U03
U03	Can critically evaluate the results of measurements	BIOT2A_U06
within the scope of SOCIAL COMPETENCE:		
K01	Is aware of the requirements related to laboratory quality control and quality assurance system	BIOT2A_K03

4.4. Methods of assessment of the intended learning outcomes		
Teaching outcomes (code)	Method of assessment (+/-)	
	Exam oral*	Test*
	Form of classes	Form of classes
	L	C
W01	+	-
W02	+	-
W03	+	-
W04	+	-
U01	-	+
U02	-	+
U03	-	+
K01	+	-

*delete as appropriate

4.5. Criteria of assessment of the intended learning outcomes		
Form of classes	Grade	Criterion of assessment
lecture (L) (including e-learning)	3	51%-60% of the total number of available points
	3,5	61%-70% of the total number of available points
	4	71%-80% of the total number of available points
	4,5	81%-90% of the total number of available points
	5	91%-100% of the total number of available points
classes (C)* (including e-learning)	3	51%-60% of the total number of available points
	3,5	61%-70% of the total number of available points
	4	71%-80% of the total number of available points
	4,5	81%-90% of the total number of available points
	5	91%-100% of the total number of available points

5. BALANCE OF ECTS CREDITS – STUDENT'S WORK INPUT

Category	Student's workload	
	Full-time studies	Extramural studies
<i>NUMBER OF HOURS WITH THE DIRECT PARTICIPATION OF THE TEACHER /CONTACT HOURS/</i>	60	
<i>Participation in lectures*</i>	30	
<i>Participation in laboratory classes*</i>	30	
<i>INDEPENDENT WORK OF THE STUDENT/NON-CONTACT HOURS/</i>	40	
<i>Preparation for the lecture*</i>	10	
<i>Preparation for the laboratory classes*</i>	30	
<i>TOTAL NUMBER OF HOURS</i>	100	
ECTS credits for the course of study	4	

*delete as appropriate

Accepted for execution (date and legible signatures of the teachers running the course in the given academic year)

.....