Uniwersytet Gdański

KAPITAŁ LUDZKI
NARODOWA STRATEGIA SPÓJNOŚCI

Projekt współfinansowany przez
Unię Europejską w ramach
Europejskiego Funduszu
Społecznego

UNIA EUROPEJSKA
EUROPEJSKI
FUNDUSZ SPOŁECZNY

Course title	ECTS code
Validation methods	13.3.0393

Name of unit administrating study

null

Studies

faculty	field of study	type	drugiego stopnia
Wydział Chemii	Chemia	form	stacjonarne
		specialty	chemia biomedyczna, analityka i diagnostyka chemiczna, chemia obliczeniowa
		specialization	wszystkie

Teaching staff

dr hab. Marek Gołębiowski, profesor uczelni; prof. dr hab. Tomasz Puzyn; dr Agnieszka Gajewicz-Skrętna

Forms of classes, the realization and number of hours	ECTS credits
Forms of classes	2
Auditorium classes, Lecture	classes 30 h
The realization of activities	Tutorial classes 5 h
classroom instruction	Student's own work 15 h
Number of hours	TOTAL: 50 h - 2 ECTS
Lecture: 15 hours, Auditorium classes: 15 hours	

The academic cycle

2022/2023 winter semester

Type of course	Language of instruction
obligatory	polish

Teaching methods	Form and method of assessment and basic criteria for eveluation or examination requirements
- group work	**Final evaluation**
- multimedia-based lecture	Graded credit
- problem solving	**Assessment methods**
	- Based on the evaluation of the partial test and final test from the material covering the entire range of exercises and presentation.
	- (mid-term / end-term) test
	- assignment work – project or presentation
	The basic criteria for evaluation
	Lecture:
	Evaluation of final work - assessment criteria in accordance with Study regulations UG
	Tutorial classes:
	• Positive valuation: min. 51% of points possible to obtain from the partial test, final test (whole range of topics) and from the presentation. 100% of points you can get, 25% points obtained from the partial test, 60% points from the final test and 15% from the presentation.

Method of verifying required learning outcomes

Required courses and introductory requirements

A. Formal requirements

Statistics

B. Prerequisites

Statistics

Aims of education

• Familiarize the students with the parameters subjected to validation,
• Acquiring the knowledge about calculations necessary for the validation of analytical methods,
• Acquiring the knowledge for choosing the right analytical technique,
• Acquiring the skill of designing of experiments regarding the validation of analytical methods for analysis of selected analytes
• Acquiring the skill to prepare a validation report for an analytical method

Course contents

A. Lecture: Stages of the validation procedure, validation parameters of the analytical methodology: (precision, accuracy, linearity, measuring range, sensitivity, detection limit, quantification limit, specificity, selectivity, robustness, ruggednes, precision vs. accuracy, precision measures, repeatability, intermediate precision and reproducibility, comparison of the precision of two methods, comparison of the precision of several analytical methods, accuracy vs. trueness, accuracy measures, statistical conclusions on the basis of selected statistical tests, determination of the linearity, range and sensitivity methods on the basis of linear regression, determination of the linearity on the basis of detector response to concentration of analyte ratio, methods of determining the detection and quantification limit, verification of the specificity, selectivity, robustness and ruggednes), Determination of characteristic parameters of the test methods, the characteristics of the analytical procedure, the order of determining the validation parameters, the choice of analytical methods: standardized methods, methods developed in the laboratory, non-standardized methods, alternative methods, the scope of validation, initial validation, re-validation, criteria for validation of microbiological methods, validation methods of analysis of selected analytes (description of the selected analytes, description of the analytical methods, choice of the analytical methods, comparison of the analytical techniques). Inter-laboratory tests, proficiency tests, standardization tests, certification of materials, inter-laboratory comparisons. Stages in the analysis of data from inter-laboratory comparisons. Reference materials in the validation process: types of reference materials (certified and non-certified materials, reference materials with or without matrices), properties of reference materials (representativeness, homogeneity, stability), examples of reference materials.

B. Tutorial classes:

Validation methods of the analytical procedure, validation parameters of the analytical methodology (precision, accuracy, linearity, measuring range, sensitivity, detection limit, quantification limit, specificity, selectivity, robustness, ruggednes, precision vs. accuracy, precision measures, repeatability, intermediate precision and reproducibility, comparison of the precision of two methods, comparison of the precision of several analytical methods, accuracy vs. trueness, accuracy measures, statistical conclusions on the basis of selected statistical tests, determination of the linearity, range and sensitivity methods on the basis of linear regression, determination of the linearity on the basis of detector response to concentration of analyte ratio, methods of determining the detection and quantification limit, verification of the specificity, selectivity, robustness and ruggednes). Preparation of the validation report in the analysis of selected analytes: a description of the analytes, comparison and selection of analytical methods, selection of analysis parameters of selected methods, calculation of the validation parameters, preparation and presentation of the validation report.

Bibliography of literature

Literature required to pass the course

A.1. Literature used during classes:

Konieczka P., J. Namieśnik i in.: Ocena i kontrola jakości wyników analitycznych. Centrum Doskonałości Analityki i Moni-toringu Środowiskowego, Gdańsk 2004.

Łomnicki A.: Wprowadzenie do statystyki dla przyrodników. Wydawnictwo Naukowe PWN, Warszawa 2003

A.2. Literature for individual studies

Konieczka P., J. Namieśnik i in.: Ocena i kontrola jakości wyników analitycznych. Centrum Doskonałości Analityki i Moni-toringu Środowiskowego, Gdańsk 2004.

Łomnicki A.: Wprowadzenie do statystyki dla przyrodników. Wydawnictwo Naukowe PWN, Warszawa 2003

 Extracurricular readings

Czermiński J. B., A. Iwasiewicz i in.: Metody statystyczne dla chemików. Wydawnictwo Naukowe PWN, Warszawa 1992.

Kabata-Pendias A., B. Szteke (red.): Problemy jakości analizy śladowej w badaniach środowiska przyrodniczego. Wydaw-nictwo Zofii Dobkowskiej, Warszawa 1998.

The learning outcomes (for the field of study and specialization)	Knowledge
	1. knows and describes the parameters of the method subject to validation,
	2. knows and describes selected techniques and methods of analysis,
	3. knows and describes the stages of the analysis in the interlaboratory comparisons,
	4. knows and describes the reference materials used in the validation process,
	5. is able to calculate validation parameters of analytical methods,
	6. draws conclusions from the calculated validation parameters,
	Skills
	1. Demonstrates the skills to assess the parameters used to validation of analytical methods
	2. Demonstrates the skills to determine the parameters used to validation of analytical methods

	3. Evaluates the parameters used to validation of analytical methods
	4. Formulates opinions about validation parameters
	Social competence
	1. Understands the need for further education
	2. Discusses the problems of method validation
	3. Explains how to perform validation
	4. Promotes the importance of validation
	5. Consciously evaluates the values of calculated validation parameters

Contact

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