

Course title Metody walidacji/Validation methods		ECTS code 13.3.0393	
Name of unit administrating study Faculty of Chemistry			
Studies			
Field of study	Type	Form	
Chemistry	Master	Full-time studies	
Dr hab. Marek Gołębiowski, prof. UG			
Forms of classes, the realization and number of hours		ECTS credits classes 30 h Tutorial classes 5 h Student's own work 15 h TOTAL: 50 h - 2 ECTS	
A. Forms of classes, in accordance with the UG Rector's regulations lecture, auditorium classes			
B. The realization of activities In-class learning			
Number of hours lecture 15 h, auditorium classes 15 h			
The academic cycle First year, winter semester			
Type of course obligatory		Language of instruction Polish	
Teaching methods <ul style="list-style-type: none">• work in groups• Case studies<ul style="list-style-type: none">• Lectures including multimodal praesentations		Form and method of assessment and basic criteria for evaluation or examination requirements	
		A. Final evaluation, in accordance with the UG study regulations Course completion (with a grade)	
		B. Assessment methods Written test exam Project or presentation The final evaluation: Based on the evaluation of the partial test and final test from the material covering the entire range of exercises and presentation.	
		C. The basic criteria for evaluation or exam requirements 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.	

- Negative valuation can be improved on the basis of an additional test from the material covering the entire range of exercises (min 51% of points possible).

Required courses and introductory requirements

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, ruggedness, 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 ruggedness). 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, ruggedness, 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 ruggedness). 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

A. 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

B. Extracurricular readings

Czermański 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. Wydawnictwo Zofii Dobkowskiej, Warszawa 1998.

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