The syllabus for discipline
« MODERN ANALYTICAL LABORATORY PRACTICE»

1. General information	
Name of the faculty	pharmaceutical faculty
Educational program	22 Health, 226 Pharmacy, Industrial Pharmacy, Second (master's) educational level, full-time course
Academic year	2021-2022
Course title, code	Modern Analytical Laboratory Practice; VB1.20,
Department (*address, phone, e-mail*)	Department of toxicological and analytical chemistry 79010, Lviv, Pekarska str., 69 +38 (032) 368437 kaf_toxchemistry@meduniv.lviv.ua
Head of department *(e-mail)*	Halkevych Irine, PhD, Associated professor, galkirin@meduniv.lviv.ua
Year of study	2rd year
Semester	III - IV semesters
Type of discipline	Optional
Lecturers	1. Halkevych I.Y., PhD, Associated professor, galkirin@meduniv.lviv.ua 2. Bidnychenko Yu.I., PhD, Associated professor, bidnyuri@i.ua 3. Davydovych S.I., PhD, Assistant professor, ihlitska.sophia@gmail.com
Erasmus yes/no	no
Author	1. Halkevych I.Y., PhD, Associated professor, galkirin@meduniv.lviv.ua 2. Assist. prof. Davydovych Sofiia ihlitska.sophia@gmail.com
Total credits ECTS	2.0 credits
Total number of hours	90 h (Lectures –10/ Seminar classes – 10 / ISW – 40)
Language	English
Information about consultations	Consultations at the department take place in accordance with the approved schedule of consultations
2. Course description (abstract)	
The elective course "Modern Analytical Laboratory Practice" is designed for students of higher educational institutions of the pharmaceutical profile of Ukraine and is an integral part of the state standard of education. Analytical laboratory practice is a training course that includes mastering a set of criteria that provide a basis for proper evaluation of results and conclusions, obtained during laboratory research and management of laboratory research.	

The subject of study of the discipline are:
- organizational structure and staff of analytical control laboratories;
- system of receipt of samples for research and analysis;
- test system;
- evaluation of test results;
- rules of storage of samples;
- requirements for reagents and standard samples;
- tools and their calibration;
- safety issues in laboratories.

3. Goals and objectives of the course

3.1. The purpose of the discipline "Modern analytical laboratory practice" is to provide students with the necessary theoretical knowledge and practical skills to apply national and international standards relating to the organization of chemical analytical laboratories for quality control of medicines; assessing the suitability of analysis methods, their reproducibility and establishing the limits of uncertainty of the obtained measurement results.

3.2. The main tasks of studying the discipline "Modern analytical laboratory practice" are to teach students the features of the system of production laboratory, knowledge of state and international standards, assessment of the suitability of methods of analysis; the ability to use national and international standards, conducting the necessary chemical and analytical studies, selecting the most appropriate methods of analysis, effectively determining the accuracy of the measurement results.

3.3. **Competences and learning outcomes**, the formation of which is facilitated by the discipline (relationship with the normative content of training of higher education, formulated in terms of learning outcomes in the Standard).

In accordance with the requirements of the standard, the discipline "**Modern analytical laboratory practice**" provides students with the acquisition of competencies:
integral:
- ability to solve typical and complex specialized problems and practical problems in the learning process, which involves research, innovation and is characterized by complexity and uncertainty of conditions and requirements;

general:
- ability to apply knowledge in practical situations;
- knowledge and understanding of the subject area and understanding of the profession;
- the ability to self-regulate and lead a healthy lifestyle, the ability to adapt and act in a new situation;
- ability to choose communication strategy, ability to work in a team, interpersonal skills;
- ability to communicate in the native language both orally and in writing, ability to communicate in a second language;
- skills of using information and communication technologies;
- ability to abstract thinking, analysis and synthesis, ability to learn and be modernly trained;
- ability to evaluate and ensure the quality of work performed;
- determination and persistence in terms of tasks and responsibilities;
- ability to act socially responsibly and socially consciously;
- the desire to preserve the environment;

special (professional, subject):
- ability to test, pharmaceutical research and control methods of medicines;
- ability to organize, provide and control the quality of medicines in a pharmacy and a pharmaceutical company;
- ability to determine the list of equipment and reagents for the organization of quality control of medicines in accordance with the requirements of the SPU and other regulations;
- ability to interpret and evaluate the results of drug analysis.

4. Course prerequisites		
Modern analytical laboratory practice as a discipline: a) is based on knowledge of mathematics, physics and inorganic chemistry; b) lays the foundations for the study of analytical, pharmaceutical and toxicological chemistry and provides for the formation of skills to apply the acquired knowledge for the study of special disciplines and in professional activities.		
5. Program learning outcomes		
List of learning outcomes		
Code of learning outcomes	**Content of learning outcomes** *Knowledge – Kn., Skill – Sk., Communication – C., Autonomy and responsibility – AR,* Learning outcomes – *LO.*	**Link to the code in the Competence Matrix**
General competencies		
Kn-1	Have specialized conceptual knowledge acquired in the learning process	*LO-1, 4, 13*
Kn-2	Have deep knowledge of the structure of professional activity	*LO-2, 14, 15*
Kn-3	Know ways to self-regulate, lead a healthy life	*LO-25*
Kn-4	Know the tactics and strategies of communication, laws and ways of communicative behavior	*LO-6, 10, 22*
Kn-5	Have a perfect knowledge of the native language and basic knowledge of a foreign language	*LO-8*
Kn-6	Have in-depth knowledge in the field of information and communication technologies used in professional activities	*LO- 9, 12, 29*
Kn-7	Know the methods of analysis, synthesis and further modern learning	*LO-7*
Kn-8	Know the methods of evaluating performance indicators	*LO-11, 16, 29*
Kn-9	Know the responsibilities and ways to accomplish the tasks	*LO-5*
Kn-10	Know your social and community rights and responsibilities	*LO-24*
Kn-11	Know the problems of environmental protection and ways to preserve it	*LO-3*
Kn-12	Know chemical and instrumental methods of analysis	*LO-17, 26*
Kn-13	Know the modern requirements for the organization and quality control of medicines in a pharmacy and a pharmaceutical company	*LO-19, 30*
Kn-14	Know the requirements of SPU and other regulations	*LO-27, 31*
Kn-15	Know the standard procedures of statistical analysis	*LO- 32*
Sk-1	Be able to solve complex problems and problems that arise in professional activities	*LO-1, 4, 13*
Sk-2	Be able to carry out professional activities that require updating and integration of knowledge	*LO-2, 14, 15*
Sk-3	To be able to apply means of self-regulation, to be able to lead a healthy way of life and to adapt to new situations of life and activity	*LO-25*
Sk-4	Be able to choose ways and strategies of communication to ensure effective teamwork	*LO-6, 10, 22*
Sk-5	Be able to apply knowledge of the native language, both orally and in writing, be able to communicate in a foreign language	*LO-8*
Sk-6	Be able to use information and communication technologies in the professional field, which requires updating and integration of knowledge	*LO- 9, 12, 29*
Sk-7	Be able to analyze information, make informed decisions, be able to acquire modern knowledge	*LO-7*

Sk-8	Be able to ensure quality work	*LO-11, 16, 29*
Sk-9	Be able to set goals and objectives to be persistent and conscientious in the performance of duties	*LO-5*
Sk-10	To form one's civic consciousness, to be able to act in accordance with it	*LO-24*
Sk-11	Be able to form requirements for themselves and others to preserve the environment	*LO-3*
Sk-12	Be able to apply chemical and instrumental methods of analysis, conduct biopharmaceutical research to control drugs	*LO-17, 26*
Sk-13	Be able to choose chemical and physico-chemical methods of drug quality analysis	*LO-19, 30*
Sk-14	Be able to prepare the necessary reagents and work with modern equipment of chemical laboratories	*LO-27, 31*
Sk-15	Be able to justify the sample size, apply methods of statistical analysis, provide the results of statistical data processing	*LO- 32*
C-1	Ability to apply knowledge in practical situations. results of drug analysis in accordance with the requirements of SPU	*LO-1, 4, 13*
C-2	Knowledge and understanding of the subject area and understanding of the profession	*LO-2, 14, 15*
C-3	Ability to self-regulate, lead a healthy lifestyle, ability to adapt and act in a new situation	*LO-25*
C-4	Ability to choose a communication strategy; ability to work in a team; interpersonal skills.	*LO-6, 10, 22*
C-5	Ability to communicate in the native language both orally and in writing; ability to communicate in a second language	*LO-8*
C-6	Skills in the use of information and communication technologies	*LO- 9, 12, 29*
C-7	Ability to abstract thinking, analysis and synthesis, the ability to learn and be modernly trained	*LO-7*
C-8	Ability to evaluate and ensure the quality of work performed	*LO-11, 16, 29*
C-9	Definiteness and perseverance in terms of tasks and responsibilities.	*LO-5*
C-10	Ability to act socially responsible and public consciousness.	*LO-24*
C-11	The desire to preserve the environment.	*LO-3*
C-12	Ability to test, biopharmaceutical research and drug control methods	*LO-17, 26*
C-13	Ability to organize, provide and control the quality of medicines in a pharmacy and a pharmaceutical company	*LO-19, 30*
C-14	Ability to determine the list of equipment and reagents for the organization of quality control of medicines in accordance with the requirements of the SPU and other regulations	*LO-27, 31*
C-15	Ability to interpret and evaluate the results of drug analysis in accordance with the requirements of SPU	*LO- 32*
AR-1	Responsible for making decisions in difficult conditions	*LO-1, 4, 13*
AR-2	Be responsible for professional development, ability to further professional training with a high level of autonomy	*LO-2, 14, 15*

AR-3	Be responsible for a healthy lifestyle and timely use of self-regulation methods	*LO-25*
AR-4	Be responsible for the choice and tactics of communication	*LO-6, 10, 22*
AR-5	To be responsible for fluency in the native language, for the development of professional knowledge	*LO-8*
AR-6	Be responsible for the development of professional knowledge and skills	*LO- 9, 12, 29*
AR-7	Be responsible for the timely acquisition of modern knowledge.	*LO-7*
AR-8	Be responsible for the quality of work	*LO-11, 16, 29*
AR-9	Responsible for the quality of the tasks	*LO-5*
AR-10	Be responsible for your civic position and activities	*LO-24*
AR-11	Be responsible for the implementation of environmental protection measures within its competence	*LO-3*
AR-12	Be responsible for deciding on the evaluation of the results of chemical, physicochemical and biopharmaceutical methods of drug control	*LO-17, 26*
AR-13	Be responsible for the organization, provision and quality control of medicines in a pharmacy and a pharmaceutical company	*LO-19, 30*
AR-14	Responsible for the organization of quality control of medicines in accordance with the requirements of the SPU and other regulations	*LO-27, 31*
AR-15	Be responsible for conducting analysis and obtaining reliable and reproducible results	*LO- 32*

6. The course format

The format of the course	Full-time course
Type of classes	The total number of hours
Lectures	10
Seminars	10
Self-study	40

7. Topics and content of the course			
Type of classes	**Theme**	**Content**	**Code of learning outcomes**
L-1	Basic principles of quality management system in laboratories: importance of quality management system; characteristics of the main elements of the quality management system; history of development of quality principles; the relationship of the quality management model with the requirements of international standards. Laboratory environment: factors that affect quality; laboratory planning; equipment placement; change monitoring.	The importance of the quality management system; characteristics of the main elements of the quality management system; history of development of quality principles; the relationship of the quality management model with the requirements of international standards. Standards for laboratories, general provisions on standards (ISO 9001, ISO / IEC17025, ISO 15189, GLP). Provisions of the standard.	Kn-1 – Kn-15; Sk-1 – Sk-15; C-1 – C-15; AR-1 – AR-15.
L-2	Sampling. The importance of sampling. Identification of sample types. The essence and significance of sampling plans. Regulatory and legal requirements. Types of sampling: probable sampling, non-random sampling, sampling of bulk materials, sampling of acceptance control.	Sampling. The importance of sampling. Regulatory and legal requirements. Types of sampling. Good laboratory practice: pre-analytical stage; analysis; after analysis. The importance of calibration in chemical analysis.	Kn-1 – Kn-15; Sk-1 – Sk-15; C-1 – C-15; AR-1 – AR-15.
L-3	Preparation for analysis. Factors to consider when choosing a method of analysis. Obtaining information about the acceptability of the method. Determining the cause of unsatisfactory results. Rules of quality control: blank samples; control samples; re-execution of tests; blind samples; chemical standards and additives.	Factors to consider when choosing a method of analysis. Obtaining information about the acceptability of the method. Determining the cause of unsatisfactory results. Single samples; control samples; re-execution of tests; blind samples; chemical standards and additives. Laboratory environment: factors that affect quality; laboratory planning; equipment placement; change monitoring.	Kn-1 – Kn-15; Sk-1 – Sk-15; C-1 – C-15; AR-1 – AR-15.
L-4	Validation of analytical methods: scheme of validation process; determination of the appropriate level of validation; selectivity; precision; displacement (correctness); measurement range, detection limit (LOD) and limit of quantification (LOC). Validation report and documentation.	Scheme of the validation process; determining the appropriate level of validation; selectivity; precision; offset (correctness); measurement range, detection limit (LOD) and limit of quantification (LQ). Validation report and documentation.	Kn-1 – Kn-15; Sk-1 – Sk-15; C-1 – C-15; AR-1 – AR-15.
L-5	Data Processing. The values of the basic statistical parameters used to describe the set in the data. The terms "uncertainty", "error", "precision", "offset", "accuracy". Application of a systematic approach in estimating uncertainty.	Values of the main statistical parameters used to describe the data set. The terms "uncertainty", "error", "precision", "offset", "accuracy". Application of a systematic approach in	Kn-1 – Kn-15; Sk-1 – Sk-15; C-1 – C-15; AR-1 – AR-15.

		estimating uncertainty. Measurement process; the concept of uncertainty; errors (random, systematic). Precision, offset and accuracy. Use of uncertainty.	
S-1	Organization of the quality management system in the laboratory: the role of personnel in the quality management system; development of a plan for checking the competence of staff; sequence of actions for assessment and maintenance of staff competence; analysis of potential problems with customers; methods of measuring satisfaction. Responsibility of laboratory staff for quality: responsibility of management for quality; responsibilities of a quality manager; responsibilities of individual employees.	Organization of the quality management system in the laboratory: the role of staff in the quality management system; development of a plan for checking the competence of staff; sequence of actions to assess and maintain staff competence; analysis of potential problems with customers; methods of measuring satisfaction. Standards for laboratories, general provisions on standards (ISO 9001, ISO / IEC17025, ISO 15189, GLP). Provisions of the standard.	Kn-1 – Kn-15; Sk-1 – Sk-15; C-1 – C-15; AR-1 – AR-15.
S-2	Number of samples and sample size: uncertainty of sampling, number of primary samples. Sub-sample selection: sub-sample selection technique. The importance of proper sample preparation and storage of samples	Number of samples and sample size: uncertainty of sampling, number of primary samples. Sub-sample selection: sub-sample selection technique. The importance of proper sample preparation and storage of samples. Good laboratory practice: pre-analytical stage; analysis; after analysis. The importance of calibration in chemical analysis.	Kn-1 – Kn-15; Sk-1 – Sk-15; C-1 – C-15; AR-1 – AR-15.
S-3	Performance characteristics of the methods used for analysis. Performance characteristics of selected methods for determination of analytes: separation by thin layer chromatography; separation by gas or liquid chromatography. Causes of incorrect analytical results. Choice of devices, glassware and equipment: suitability; equipment qualification; contamination cleaning and drying.	Factors to consider when choosing a method of analysis. Obtaining information about the acceptability of the method. Determining the cause of unsatisfactory results. Single samples; control samples; repeated tests; blind samples; chemical standards and additions. Laboratory environment: factors that affect quality; laboratory planning; equipment placement; change monitoring.	Kn-1 – Kn-15; Sk-1 – Sk-15; C-1 – C-15; AR-1 – AR-15.
S-4	Conducting metrological simplicity: comparison samples; chemical standards	Values of the main statistical parameters used to describe the data set. The terms "uncertainty", "error", "precision", "offset", "accuracy". Application of a	Kn-1 – Kn-15; Sk-1 – Sk-15; C-1 – C-15; AR-1 – AR-15.

		systematic approach in estimating uncertainty. Measurement process; the concept of uncertainty; errors (random, systematic). Precision, offset and accuracy. Use of uncertainty.	
S-5	Application of statistical methods in laboratory proficiency testing programs. Target value: certified CRM value; set value; agreed value from expert laboratories; agreed value from the laboratories of the participants.	Organization of laboratory qualification assessment programs. Combination of z-indices. Interpretation of numerical estimates. Robust statistics. Benefits of participating in RT programs.	Kn-1 – Kn-15; Sk-1 – Sk-15; C-1 – C-15; AR-1 – AR-15.
ISW-1	Responsibility of laboratory staff and management for the quality of experimental research		Kn-1 – Kn-15; Sk-1 – Sk-15; C-1 – C-15; AR-1 – AR-15.
ISW-2	Laboratory equipment, its selection and qualification.		
ISW-3	Control of the purity class of chemical reagents and labeling in the analytical laboratory. Chemical standards, their choice.		
ISW-4	Good laboratory practice. The value of the pre-analytical stage of laboratory work.		
ISW-5	The importance of sampling. What are the types of sample identification		
ISW-6	Stages and stages of analytical laboratory work.		
ISW-7	Rules for checking the linearity of quantitative methods. Research of stability of a technique of the analysis.		
ISW-8	Application of statistical methods in laboratory proficiency testing programs (target range: set value; predicted value; results joint research).		
ISW-9	Rules for checking the reproducibility of quantitative methods.		
ISW-10	Validation of methods and determination of the required level of validation characteristics.		

Learning methods

In the process of studying the discipline "Modern analytical laboratory practice" the following teaching methods are used:

- explanatory-illustrative - (verbal and visual - lectures, theoretical part of the seminar);
- partial search method - preparation for a seminar, testing, monitoring the performance of independent work;
- research method - performing experimental work.

Preference is given to active and interactive methods and multimedia learning (multimedia lectures, educational films).

8. Verification of learning outcomes

Current control

Assimilation of the topic is controlled in seminars in accordance with specific objectives, assimilation of the content module (intermediate control) - in the final lesson. The following means of control of level of preparation of students are applied:

- oral examination and written assignments,
- solving situational problems,
- checking the ability to interpret and evaluate the results of various methods of quantitative determination of medicinal substances, control of practical skills.

Forms of current control:

1. Theoretical knowledge - individual surveys, interviews;
2. Practical skills and abilities - solving typical and situational problems and control of practical actions.

Final control is carried out on the basis of control of theoretical knowledge, practical skills and abilities. At each lesson, the level of students' knowledge is assessed on a 4-point scale ("5", "4", "3", "2") in accordance with the criteria for assessing the current activities of the student. The obtained scores are converted into appropriate points.

Distribution of points received by students

Current control is carried out at each seminar. In each lesson, the student answers 10 tests and 5 questions on the topic of the seminar, the knowledge of which is necessary to understand the current topic, the issues of the lecture course and independent work related to the current lesson; demonstrates knowledge and skills of practical skills in accordance with the topic of practical training.

Excellent ("5"). The student correctly, clearly, logically and fully answers the standardized questions of the current topic, including questions of independent work. Closely connects theory with practice. Freely solves situational problems of increased complexity, is able to summarize the material.

Good ("4"). The student correctly and essentially answers the standardized questions of the current topic, independent work. Is able to solve easy and medium situational problems. Has the necessary practical skills and techniques to perform them in excess of the required minimum.

Satisfactory ("3"). The student incompletely, with the help of additional questions, answers the standardized questions of the current topic, lecture course and independent work. Cannot build a clear, logical answer on their own. The student solves only the easiest problems, has only a mandatory minimum of research methods.

Unsatisfactory ("2"). The student does not know the material of the current topic, can not build a logical answer, does not answer additional questions, does not understand the content of the material. Makes significant, gross mistakes when answering and demonstrating practical skills.

It is recommended to evaluate the test control according to the following criteria:

Proportion of correct answers (minimum)	Score on a four-point scale
90% - 100%	5
70%	4
55%	3
Less than 55%	2

Code of learning outcomes	Type of classes	Verification of learning outcomes	Enrollment criteria
Kn-1 – Kn-15; Sk-1 – Sk-15; C-1 – C-15; AR-1 – AR-15.	L 1-5; S 1–5;	Current control: • oral control over the topic of the lesson, standardized questions, knowledge of which is necessary to understand the current topic, questions of the lecture course that relate to the current lesson; • written test control, • solving situational problems,	Assessment according to established criteria (see above) with 4-point (national) scale. To enroll in the discipline, it is necessary to confirm

		• conducting laboratory tests, • interpretation and evaluation of laboratory test results, • report on the performed laboratory work.	the achievement of each learning outcome.
Kn-1 – Kn-15; Sk-1 – Sk-15; C-1 – C-15; AR-1 – AR-15.	ISW-1– ISW-8	• Oral control in the form of a survey in accordance with the subject of independent work. • Test control on the subject of independent work.	Enrolled / not enrolled

The maximum number of points that a student can receive for the current activity is 200 points. **The minimum number of points** that a student can score for the current activity for the test is 120 points.

The calculation of the number of points is based on the grades obtained by the student on the traditional scale during the study of the discipline, by calculating the arithmetic mean (CA), rounded to two decimal places. The value obtained is converted into points on a multi-point scale as follows:

$$x = \text{CA} \times 120 / 5.$$

Recalculation of the average score for current activities in a multi-point scale is based on the table:

Recalculation of the average score on "Modern analytical laboratory practice" for the current activity into a multi-scale scale:

4-point rate	**5**	**4.97**	**4.95**	**4.92**	**4.9**	**4.87**	**4.85**	**4.82**	**4.8**	**4.77**	**4.75**	**4.72**	**4.7**
200-point rate	200	199	198	197	196	195	194	193	192	191	190	189	188
4-point rate	**4.67**	**4.65**	**4.62**	**4.6**	**4.57**	**4.52**	**4.47**	**4.45**	**4.42**	**4.4**	**4.37**	**4.35**	**4.32**
200-point rate	187	186	185	184	183	181	180	178	177	176	175	174	173
4-point rate	**4.3**	**4.27**	**4.24**	**4.22**	**4.19**	**4.17**	**4.14**	**4.12**	**4.09**	**4.07**	**4.04**	**4.02**	**3.99**
200-point rate	172	171	170	169	168	167	166	165	164	163	162	161	160
4-point rate	**3.97**	**3.94**	**3.92**	**3.89**	**3.87**	**3.84**	**3.82**	**3.79**	**3.77**	**3.74**	3.**72**	3.**7**	3.**67**
200-point rate	159	158	157	156	155	154	153	152	151	150	149	148	147
4-point rate	**3.65**	**3.62**	**3.57**	**3.55**	**3.52**	**3.5**	**3.47**	**3.45**	**3.42**	**3.4**	3.**37**	3.**35**	3.**32**
200-point rate	146	145	143	142	141	140	139	138	137	136	135	134	133
4-point rate	**3.3**	**3.27**	**3.25**	**3.22**	**3.2**	**3.17**	**3.15**	**3.12**	**3.1**	**3.07**	3.**02**	3	**Less than 3**
200-point rate	132	131	130	129	128	127	126	125	124	123	121	120	Not enough

The Final control

The form of final control of study in the course "Modern Analytical Laboratory Practice" - is a test that is given to a student who has completed all types of work provided by the curriculum, completed all classes and scored no less than the minimum.

Discipline scores for students who have successfully completed the program are converted into a traditional 4-point scale according to the absolute criteria, which are given in the table below:

The final grade for the lesson is determined by the sum of the results of test control and laboratory work as follows:

The sum of points	Score on a four-point scale
170 - 200	5
140 - 169	4
From 139 points to the minimum number of points that a student must score	3
Below the minimum number of points that a student must score	2

The student's independent work is assessed during the current control of the topic in the relevant classroom. Assessment of topics that are submitted for independent study and are not included in the topics of classroom training, are controlled during the final tests and tests.

9. Course policies

In the process of studying the discipline "Modern analytical laboratory practice" the following teaching methods are used:

- explanatory-illustrative - (verbal and visual - lectures, theoretical part of the seminar);
- partial search method - preparation for a seminar, testing, monitoring the performance of independent work;
- research method - performing experimental work.

Preference is given to active and interactive methods and multimedia learning (multimedia lectures, educational films).

Adherence to academic integrity by students provides:

1. Independent performance of educational tasks, tasks of current and final control of learning outcomes (for persons with special educational needs this requirement is applied taking into account their individual needs and opportunities);
2. References to sources of information in the case of the use of ideas, developments, statements, information; Compliance with copyright and related rights legislation;
3. Providing reliable information about the results of their own (scientific, creative) activities, used research methods and sources of information.

Violations of academic integrity are: academic plagiarism, self-plagiarism, fabrication, falsification, write-off, deception, bribery, biased evaluation.

For violation of academic integrity, students may be involved in re-assessment.

10. Recommended Literature

Compulsory course literature

1. General requirements for the competence of testing and calibration laboratories: DSTU ISO17025: 2006 - DSTU ISO17025: 2006 - [effective from 2007-07-01]. K .: Derzhspozhyvstandart Ukrainy, 2007. – 24p. - (National standards of Ukraine).
2. Taylor J. K., Cihon C. Statistical Techniques for Data Analysis, 2nd Edition, ISBN 1-58488-385-5, Chapman & Hall/CRC Press, Boca Raton, FL, USA, 2004.
3. Chan C.C., Lee Y.C., Lam H. and Zhang, X.-M. (Eds), Analytical Method Validation and Instrument Performance Verification, ISBN 0-471-25953-5, John Wiley & Sons, Inc., Hoboken, NJ, USA, 2004.
4. Prichard E., Barwick V. Quality assurance in analytical chemistry (Vol. 25). John Wiley & Sons. 2007. 318 p.
5. Mullins E., Statistics for the Quality Control Chemistry Laboratory, ISBN 0-85404-671-2, The Royal Society of Chemistry, Cambridge, UK, 2003
6. International Organization for Standardization, (2015). ISO Survey 2015. Available at: http://www.iso.org.

7. Fonseca L., Domingues J.P. ISO 9001: 2015 edition-management, quality and value. *International Journal of Quality Research*, *1*(11). 2017. P. 149-158.
8. Valdivieso-Gómez V., Aguilar-Quesada R.. Quality Management Systems for Laboratories and External Quality Assurance Programs, Quality Control in Laboratory, Gaffar Sarwar Zaman, IntechOpen. 2008. DOI: 10.5772/intechopen.73052. Available from: https://www.intechopen.com/chapters/58966

Auxiliary

9. LGC, In-House Method Validation. A Guide for Chemical Laboratories, ISBN 0-94892-618-X, LGC, Teddington, UK, 2003.
10. Baiulescu, G., Stefan, R.-I. and Aboul-Enein, H. Y., Quality and Reliability in Analytical Chemistry (Analytical Chemistry Series), ISBN 0-84932-3762, Interpharm Press/CRC Press, Boca Raton, FL, USA, 2000.
11. Management to achieve sustainable success of the organization. Quality management approach: DSTU ISO9004: 2012 - DSTU ISO9004: 2012 - [effective from 2012-01-01]. K .: Derzhspozhyvstandart Ukrainy, 2012. –40p. - (National standards of Ukraine).
12. Watson, G. H., Conti, T., & Kondō, Y. (Eds.). (2003). Quality into the 21st century: perspectives on quality and competitiveness for sustained performance. Asq Press. 2003. 280 p.
13. COMMISSION REGULATION (EC) No 401/2006of 23 February 2006 layingdown the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs

Information resources

14. http://www.twirpx.com/file/945198/
15. http://chemscience.pu.if.ua/documents/Predmetu/XA_B/Lab_Anal_B_1.pdf
16. http://www.oecd.org/env/ehs/testing/glp-frequently-asked-questions.htm
17. http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:31995L0046
18. www.moz.gov.ua/ua/portal/Pro_20090514_0.html
19. https://newiso9001.files.wordpress.com/2016/12/clause_by_clause_explanation_of_iso_9001_2015_en.pdf

11. Equipment, logistics and software of the discipline / course

Multimedia texts of lectures, computers, a set of situational tasks for classes, recommended literature.

12. Additional information

The time and place (specialized, classroom, laboratory, studio, etc.) of the discipline is determined in accordance with the approved schedule. All compulsory and auxiliary literature are available as an e-books.

Syllabus author
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