National Technical University of Ukraine
"Igor Sikorsky Kyiv Polytechnic Institute"

Department of
Biomedical Engineering

QUALITY MANAGEMENT SYSTEM IN MEDICINE

Working program of basic discipline (Syllabus)

Requisites for basic discipline	
Level of higher education	***First (bachelor's)***
Branch of knowledge	*16 Chemical engineering and bioengineering*
Specialty	*163 Biomedical Engineering*
Educational program	*Medical Engineering*
Discipline status	*Elective discipline*
Form of study	*full-time*
Year of preparation, semester	*4th course, spring semester*
The scope of discipline	*4 ECTS credits / 120 hours* *(Lectures – 20 hours, Practical classes – 40 hours, Independent study – 60 hours)*
Semester control / Control measures	*Pass/fail test, term paper, modular test*
Lessons schedule	*https://schedule.kpi.ua/*
Language of instruction	*Ukrainian*
Information about course leader / teachers	*PhD in Engineering, Associate Professor, Associate Professor of the Department of Biomedical Engineering Oksana K. Biloshytska, e-mail: biloshytska.oksana@lll.kpi.ua*
Course placement	*Sikorsky Distance Learning Platform – Course: Quality Management System in Medicine (Course code: zy05dw)*

Curriculum of the discipline

1. Course Description, Purpose, Subject Area, and Learning Outcomes

*The primary purpose of the academic discipline **"Quality Management System in Medicine"** is to develop students' understanding of the principles, competencies, and practical skills required for managing the quality of medical care and healthcare institutions.*

The objective of teaching the discipline is to provide students with theoretical knowledge and to develop practical skills and competencies related to the organization of audit activities in the field of quality management of systems, products, and services, as well as to define the principles and procedures for conducting internal and external audits of quality management systems and the requirements for auditors.

The objectives of studying the discipline include:

- *mastering general principles, methodologies, and approaches to auditing;*
- *acquiring knowledge of the procedures and processes for conducting audits of management systems (quality or environmental management systems);*
- *acquiring knowledge of the procedures and processes for conducting audits of product or process quality;*
- *gaining knowledge of the functioning and accreditation of certification bodies and testing laboratories;*

- *acquiring knowledge related to the certification and qualification of quality management system auditors.*

General Competencies

As a result of studying the academic discipline (educational component) ***"Quality Management System in Medicine"****, students should acquire the following general competencies:*

GC1. *Ability to think abstractly, analyze, and synthesize information, and to develop a systemic understanding of quality management processes in medical and biomedical fields.*

GC2. *Ability to apply knowledge in practical situations and make well-founded decisions taking into account standards, regulatory requirements, and ethical principles in healthcare.*

GC3. *Ability to communicate effectively with specialists from various fields, stakeholders, and representatives of certification bodies on issues related to the quality and safety of products and services.*

GC4. *Ability to engage in lifelong learning and independently master modern approaches, standards, and methods of quality management in medicine.*

Professional (Specialized) Competencies

Upon completion of the academic discipline (educational component) ***"Quality Management System in Medicine"****, students should possess the following professional (specialized) competencies:*

PC1. *Ability to apply principles, methods, and tools of quality management to ensure the quality of medical devices, processes, and services in accordance with international and national standards.*

PC2. *Ability to analyze, design, and improve quality management systems in medical and biomedical organizations based on process-oriented and system-based approaches.*

PC3. *Ability to apply statistical methods of quality control and quality management to assess process stability and the effectiveness of quality management systems.*

PC4. *Ability to participate in the preparation, implementation, and support of audits and certification of quality management systems in accordance with the requirements of ISO 9000 and ISO 9001 series standards.*

Program Learning Outcomes

The learning outcomes of studying the academic discipline (educational component) ***"Quality Management System in Medicine"*** *are as follows:*

PLO1. *Explain the essence, principles, and modern concepts of quality management, including Total Quality Management (TQM), and their application in medicine and biomedical engineering.*

PLO2. *Apply the requirements of ISO 9000 and ISO 9001 series standards in the development, implementation, and documentation of quality management systems in healthcare organizations.*

PLO3. *Use statistical methods and tools of quality control and quality management to analyze the quality of products (services), processes, and quality-related costs.*

PLO4. *Analyze the results of internal and external audits and formulate proposals for corrective and preventive actions aimed at continuous improvement of the quality management system.*

Contribution to the Educational Program Competencies

This course also contributes to the development of competencies and learning outcomes defined in the educational program approved by Rector's Order No. NON/434/24 dated June 10, 2024.

Integral Competency: *The ability to solve complex, specialized problems and practical problems in biomedical engineering and in the process, which provides the use of specific theories and methods of chemical, biological and medical engineering, and is characterized by the complexity and non-strict terms..*

General Competencies

GC01 – Ability to apply knowledge in practical situations.

GC02 – Knowledge and understanding of the subject area and professional activity.

GC06 – Ability to search for, process, and analyze information from various sources.

GC07 – Ability to generate new ideas (creativity).

GC09 – Ability to communicate with representatives of other professional groups at different levels (experts from other fields of knowledge/types of economic activity).

Professional Competencies

PC02 – Ability to provide engineering and technical expertise in the planning, development, evaluation, and specification of medical equipment.

PC06 – Ability to effectively use tools and methods for analysis, design, calculation, and testing in the development of biomedical products and services.

PC12 – Ability to ensure and monitor compliance with safety and biomedical ethics when working with medical equipment.

Program Learning Outcomes

PLO 03 - Manage complex actions or projects, take responsibility for making engineering decisions in unforeseen conditions, conduct technicaleconomic and safety assessments of projects.

PLO 04 - Apply the provisions of regulatory and technical documents governing the procedure for product certification, production certification.

PLO 10 - Be able to plan, organize, direct, and control medical-technical and bioengineering systems and processes

Teaching Methods

Lectures are conducted using explanatory-illustrative methods, problem-based teaching, and interactive methods aimed at establishing dialogue with students.

Practical classes employ:

1. *Reproductive method for consolidating theoretical knowledge and applying it to practical tasks.*
2. *Partially exploratory (heuristic) method to develop problem-solving strategies.*
3. *Interactive method to engage students in solving tasks and discussing theoretical foundations.*
4. *Presentation and discussion of results using problem-based and interactive approaches.*
5. *Mathematical modeling during practical sessions.*

Students independently study literature and software tools for analysis and forecasting of medical data. In some cases, coursework may evolve into research activities.

2. Prerequisites and Course Position in the Curriculum

*The academic discipline **"Quality Management System in Medicine"** belongs to the cycle of **elective educational components**. Its study requires the following prerequisites:*

- ***Knowledge:** Basic knowledge of higher mathematics and mathematical statistics necessary for understanding quantitative methods of quality analysis and control. Fundamentals of engineering and biomedical technologies, including the principles of operation of medical devices, systems, and processes in healthcare. General knowledge of standardization, metrology, and certification in technical and medical fields. Fundamentals of management and organization of production and service processes, including elements of process-oriented and system-based approaches. Basic knowledge of occupational health and safety, safety regulations, and ethics in medicine and biomedical engineering.*
- ***Skills (Abilities):** Ability to analyze technical, regulatory, and educational documentation. Ability to work with quantitative data, perform basic statistical calculations, and interpret their results. Ability to apply theoretical knowledge from engineering and management disciplines to solve applied problems. Ability to logically structure information, formulate conclusions, and substantiate decision-making. Ability to use information technologies for data processing and preparation of educational and analytical materials.*

- ***Practical Skills:*** *Skills of independent learning and cognitive activity. Skills in working with computers, office software, and basic data analysis tools. Skills of teamwork and professional communication within an interdisciplinary environment. Skills of compliance with regulatory requirements, instructions, and standards in academic and professional activities. Skills of critical thinking and responsible attitude toward the quality of one's own work results.*

3. Course Content

Main Sections and Topics Covered in the Course

Section 1. Standardization of Terminology in the Field of Quality Management
Topic 1.1. Definition of quality. Quality requirements.
Topic 1.2. Aspects of product quality management. Product (service) quality indicators and methods for assessing their level.
Topic 1.3. Quality and stakeholders.

Section 2. Key Issues in Quality Management
Topic 2.1. Factors that shape and ensure quality.
Topic 2.2. Relationship between product (service) quality and competitiveness.
Topic 2.3. Interrelation between product (service) quality and quality of life.

Section 3. International and National Experience in Quality Management
Topic 3.1. Quality management experience in different countries worldwide.
Topic 3.2. Development of national quality management systems for products (services).

Section 4. Basic Concept of Total Quality Management (TQM)
Topic 4.1. Characteristics of the Total Quality Management (TQM) concept. Core TQM strategies.
Topic 4.2. Management cycle within the TQM system.
Topic 4.3. New approaches to human resource management under TQM conditions.

Section 5. Quality Management Systems
Topic 5.1. Principles of quality management.
Topic 5.2. System-based and process-oriented approaches to quality management of products (services).
Topic 5.3. Functions of the quality management system.

Section 6. Quality Management System in ISO 9000 and ISO 9001 Standards
Topic 6.1. Evolution of quality management systems and quality standards.
Topic 6.2. General characteristics of the ISO 9000 and ISO 9001 standards.
Topic 6.3. Development of a quality management system in accordance with the requirements of ISO 9000 and ISO 9001 international standards.
Topic 6.4. Quality policy and quality objectives.
Topic 6.5. Quality manual.
Topic 6.6. Fundamental principles of business process modeling in quality management systems.

Section 7. Statistical Methods and Tools for Quality Control and Management
Topic 7.1. Statistical methods and tools for quality control: principles of development and application.
Topic 7.2. Statistical methods and tools for quality management: principles of development and application.
Topic 7.3. Statistical methods for the development, implementation, maintenance, and improvement of quality management systems.

Section 8. Quality Costs and Their Classification
Topic 8.1. Theoretical approaches to managing the costs of product (service) quality.
Topic 8.2. Classification of quality-related costs.
Topic 8.3. Key approaches to accounting and analysis of quality costs.
Topic 8.4. The role of ISO 9000 and ISO 9001 standards in the economic aspects of product (service)

quality management.
Topic 8.5. Methods of managing quality-related costs.

Section 9. Certification and Audit of Quality Management Systems
Topic 9.1. General principles of auditing and certification of quality management systems.
Topic 9.2. Principles and general foundations for conducting audits of quality management systems.
Topic 9.3. Core principles of certification of quality management systems.
Topic 9.4. Procedure for conducting quality management system audits by certification bodies.
Topic 9.5. Requirements for personnel of bodies conducting audits and certification of quality management systems.
Topic 9.6. Register of certificates of conformity for quality management systems: structure and functions.

4. Training materials and resources

Basic literature:

1. *Білошицька, О. К. Система управління якістю в медицині. Практичні роботи [Електронний ресурс] : навч. посіб. для здобувачів першого (бакалаврського) рівня вищої освіти за освітньою програмою «Медична інженерія» спеціальності 163 «Біомедична інженерія» / О. К. Білошицька ; КПІ ім. Ігоря Сікорського. – Електронні текстові дані (1 файл: 1,46 Мбайт). – Київ : КПІ ім. Ігоря Сікорського, 2021. – 63 с. – Режим доступу: https://ela.kpi.ua/handle/123456789/47977*
2. *Управління якістю охорони здоров'я: методичні вказівки для самостійної роботи здобувачів вищої освіти/ Автори: Панчишин Н.Я., Смірнова В.Л., Петрашик Ю.М. Тернопіль: Тернопільський національний медичний університет імені І.Я. Горбачевського Міністерства охорони здоров'я України, 2025. 66 с. Режим доступу: https://repository.tdmu.edu.ua/bitstream/handle/123456789/18209/%D0%9F%D0%BE%D1%81%D1%96%D0%B1%D0%BD%D0%B8%D0%BA%20%D0%A3%D0%BF%D1%80%D0%B0%D0%B2%D0%BB%D1%96%D0%BD%D0%BD%D1%8F%20%D1%8F%D0%BA%D1%96%D1%81%D1%82%D1%8E%20%D0%9E%D0%97.pdf?sequence=1*
3. *В.Г. Алькема, О.М. Сумець, О.С. Кириченко. Менеджмент закладу охорони здоров'я: навчлаьний посібник. – К.: ВНЗ «Університет економіки і права «КРОК», 2023 – 254 с. Режим доступу: https://library.krok.edu.ua/media/library/category/navchalni-posibniki/alkema_0038.pdf*
4. *Должанський, А. М. Управління якістю: навч. посіб./ А.М. Должанський, О.А. Бондаренко; за ред. д-ра техн. наук, проф. А.М. Должанського; Укр. держ. ун-т науки і технологій.– Електрон. вид. –Дніпро:УДУНТ,2024.–282с. Режим доступу: https://e-book.ust.edu.ua/catalog/view/588/919/6648*

Additional literature:

1. *Впровадження системи управління якістю у лікувально-профілактичних організаціях ISO 9001:2015 : навчальний посібник / В. В. Касянчук, О. М. Бергілевич, О. І. Сміянова ; за ред. проф. В. А. Сміянова. – Суми : Сумський державний університет, 2019. – 246 с. Режим доступу: https://essuir.sumdu.edu.ua/server/api/core/bitstreams/dd73dc5b-5c42-4621-803d-e428fb1c916a/content*
2. *Управління якістю [Текст]: підручник / П. П. Воробієнко, І. В. Станкевич, Є. М. Стрельчук [та ін.]. – Одеса: ОНАЗ ім. О. С. Попова, 2014. – 376 с*
3. *Кириченко Л.С., Мережко Н.В. Основи стандартизації, метрології та управління якістю. - К.: КНТЕУ , 2011.*
4. *Шаповал М.І. Менеджмент якості: Підручник. – 3 вид., випр. і доп. -К.: Тов-во "Знання", КОО, 2007. - 471с.*
5. *ДСТУ ISO 9000-2007. Системи управління якістю. Основні положення і словник.*
6. *ДСТУ ISO 9001-2015. Системи управління якістю. Вимоги.*

Educational content

5. Methods of mastering the discipline (educational component)

No.	Lecture Title and Key Topics (teaching and learning methods, independent study tasks)	General, Professional Competencies and Program Learning Outcomes
Lecture 1	**Basic Concepts of the Quality Management System** **Key issues:** Concept of quality and quality management. Object and subject of the quality management system. Evolution of quality assurance approaches. Role of quality in medicine and biomedical engineering. Stakeholders and their expectations. **Didactic tools:** multimedia presentation; quality management system diagrams; examples from medical practice. **Independent study:** study basic terminology in quality management; prepare a brief summary of key concepts.	GC1, GC2, GC3, GC4 PC1 LO1
Lecture 2	**Quality Management System in Accordance with ISO 9000 Series Standards** **Key issues:** Purpose and structure of the ISO 9000 series standards. Terms and definitions in quality management. Principles of quality management. Importance of ISO standards for medical and biomedical organizations. **Didactic tools:** multimedia presentation; extracts from ISO standards; structural diagrams of the QMS. **Independent study:** study quality management principles; prepare a comparative table of ISO principles.	GC1, GC2, GC3, GC4 PC1, PC2 PLO1, PLO2
Lecture 3	**ISO 9001:2015 Standard. PDCA Cycle** **Key issues:** General characteristics of ISO 9001:2015. Process approach in the QMS. PDCA (Plan–Do–Check–Act) cycle and its application. Continuous improvement as the basis of quality management. **Didactic tools:** multimedia presentation; PDCA cycle diagram; examples of medical processes. **Independent study:** study the PDCA model; provide examples of its application in medical processes.	GC1, GC2, GC3, GC4 PC1, PC2 PLO1, PLO2
Lecture 4	**Requirements of ISO 9001:2015 for the Quality Management System** **Key issues:** Structure of ISO 9001:2015. Organizational context. Leadership and management responsibility. Planning, support, operation, performance evaluation, and improvement of the QMS. **Didactic tools:** multimedia presentation; tables of standard requirements; examples of QMS documentation. **Independent study:** study the sections of ISO 9001:2015; prepare a concise overview of the requirements.	GC1, GC2, GC3, GC4 PC1, PC2 PLO1, PLO2
Lecture 5	**Tools and Methods of Quality Management**	GC1, GC2, GC3, GC4

No.	Lecture Title and Key Topics (teaching and learning methods, independent study tasks)	General, Professional Competencies and Program Learning Outcomes
	Key issues: *Classical quality control tools. Analytical and managerial quality management methods. Process improvement methods. Application of quality tools in medicine.* ***Didactic tools:*** *multimedia presentation; examples of diagrams and charts; practical case studies.* ***Independent study:*** *study key quality management tools; prepare examples of their application.*	*PC3* *PLO3*
Lecture 6	***Risk Management in the Quality Management System*** ***Key issues:*** *Concept of risk and risk management. Risk identification, analysis, and assessment. Risk-based thinking in ISO 9001:2015. Risk management in medical activities.* ***Didactic tools:*** *multimedia presentation; risk matrices; examples of medical risks.* ***Independent study:*** *study the concept of risk-based thinking; develop an example of a risk matrix.*	*GC1, GC2, GC3, GC4* *PC1, PC2* *PLO1*
Lecture 7	***Total Quality Management (TQM) System*** ***Key issues:*** *Essence and principles of TQM. Core elements and strategies of TQM. Role of personnel in the TQM system. Application of TQM in healthcare.* ***Didactic tools:*** *multimedia presentation; TQM diagrams; implementation examples.* ***Independent study:*** *study TQM principles; prepare a brief overview of advantages and disadvantages of the concept.*	*GC1, GC2, GC3, GC4* *PC1, PC2* *PLO1, PLO2*
Lecture 8	***Strategic Quality Planning Based on SWOT Analysis*** ***Key issues:*** *Concept of strategic planning in quality management. Essence and stages of SWOT analysis. Application of SWOT analysis to improve the quality of medical services.* ***Didactic tools:*** *multimedia presentation; SWOT matrices; examples of strategic analysis.* ***Independent study:*** *conduct a SWOT analysis of a hypothetical medical organization; formulate conclusions.*	*GC1, GC2, GC3, GC4* *PC1, PC2* *PLO1, PLO2*
Lecture 9	***Quality of Medical Care*** ***Key issues:*** *Concept and criteria of medical care quality. Quality and patient safety indicators. Impact of medical service quality on quality of life. Role of biomedical engineering in ensuring medical care quality.* ***Didactic tools:*** *multimedia presentation; examples of quality indicators; analytical materials.* ***Independent study:*** *study medical care quality criteria; prepare a short report.*	*GC1, GC2, GC3, GC4* *PC4* *PLO4*
Lecture	***Licensing, Accreditation, and Internal Audit of Quality Management***	*GC1, GC2, GC3,*

No.	Lecture Title and Key Topics (teaching and learning methods, independent study tasks)	General, Professional Competencies and Program Learning Outcomes
10	**Systems** **Key issues:** *Concepts of licensing and accreditation in healthcare. Quality management system audits. Types of audits and their stages. Requirements for personnel and documentation.* **Didactic tools:** *multimedia presentation; audit process diagrams; examples of audit reports.* **Independent study:** *study internal audit stages; prepare a list of typical nonconformities.*	*GC4* *PC4* *LO4*

No.	Title of the class and list of key issues (teaching aids, independent study tasks)	GC, PC and PLO according to the Educational Program
Practical class 1	**Introduction to Practical Classes in Quality Management.** **Key issues:** *purpose and objectives of practical classes; role of practical training in quality management competencies; overview of practical works and assessment criteria.* **Didactic tools:** *methodological guidelines; multimedia presentation; sample tasks.* **Independent study:** *familiarize with the requirements for completing practical works.*	*GC1, GC2, GC3, GC4; PC1; PLO1*
Practical class 2	**Basic Concepts and Terminology of the Quality Management System.** **Key issues:** *analysis of key ISO 9000 terms; quality, process, system, stakeholders; application examples in medicine.* **Didactic tools:** *glossaries; presentation; regulatory documents.* **Independent study:** *study quality management terminology.*	*GC1, GC2, GC3, GC4; PC1; PLO1, PLO2*
Practical class 3	**Process Approach in the Quality Management System.** **Key issues:** *process identification; inputs and outputs; process owner; interaction of processes in a medical organization.* **Didactic tools:** *process diagrams; examples of medical processes.* **Independent study:** *prepare an example of a process description.*	*GC1, GC2, GC3, GC4; PC1, PC2; PLO1, PLO2*
Practical class 4	**Practical Work No. 1. Development of the Deming Cycle for Improving the Quality of Medical Care.** **Key issues:** *application of the PDCA cycle; planning, implementation, checking, and corrective actions.* **Didactic tools:** *PDCA diagrams; medical case studies.* **Independent study:** *prepare a report on Practical Work No. 1.*	*GC1, GC2, GC3, GC4; PC1, PC2; PLO1, PLO2*
Practical	**Defense of Practical Work No. 1.**	*GC1, GC2, GC3,*

class 5	***Analysis of ISO Quality Management Principles.*** ***Key issues:*** *customer focus; leadership; engagement of people; evidence-based decision making.* ***Didactic tools:*** *principle tables; implementation examples.* ***Independent study:*** *study quality management principles.*	*GC4; PC1, PC2; PLO1, PLO2*
Practical class 6	***Practical Work No. 2. Development of the Quality Loop.*** ***Key issues:*** *concept of the quality loop; stages of product and service life cycle; quality loop for a medical service.* ***Didactic tools:*** *life-cycle diagrams; quality loop templates.* ***Independent study:*** *prepare a report on Practical Work No. 2.*	*GC1, GC2, GC3, GC4; PC1, PC2; PLO1, PLO2*
Practical class 7	***Defense of Practical Work No. 2.*** ***Quality Indicators of Medical Services.*** ***Key issues:*** *quantitative and qualitative indicators; quality assessment criteria; data sources.* ***Didactic tools:*** *indicator examples; analytical tables.* ***Independent study:*** *select indicators for a chosen medical service.*	*GC1, GC2, GC3, GC4; PC1, PC2; PLO1, PLO2*
Practical class 8	***Statistical Methods of Quality Control.*** ***Key issues:*** *purpose of statistical methods; control charts; analysis of process variation.* ***Didactic tools:*** *charts; statistical data examples.* ***Independent study:*** *study statistical quality control methods.*	*GC1, GC2, GC3, GC4; PC3; PLO3*
Practical class 9	***Practical Work No. 3. Ishikawa Cause-and-Effect Diagram.*** ***Key issues:*** *construction of the Ishikawa diagram; identification of causes of quality problems; factor analysis.* ***Didactic tools:*** *diagram templates; case studies.* ***Independent study:*** *prepare a report on Practical Work No. 3.*	*GC1, GC2, GC3, GC4; PC3; PLO3*
Practical class 10	***Defense of Practical Work No. 3.*** ***Risk-Based Thinking in the Quality Management System.*** ***Key issues:*** *types of risks in medicine; risk identification and assessment.* ***Didactic tools:*** *risk matrices; examples of risks.* ***Independent study:*** *prepare a list of risks for a process.*	*GC1, GC2, GC3, GC4; PC1, PC2; PLO1, PLO2*
Practical class 11	***Practical Work No. 4. Risk Management in a Healthcare Institution.*** ***Key issues:*** *development of a risk matrix; risk response measures.* ***Didactic tools:*** *matrix templates; practical examples.* ***Independent study:*** *prepare a report on Practical Work No. 4.*	*GC1, GC2, GC3, GC4; PC1, PC2; PLO1, PLO2*
Practical class 12	***Defense of Practical Work No. 4.*** ***Strategic Quality Management.*** ***Key issues:*** *strategic quality objectives; relationship between strategy and the QMS.* ***Didactic tools:*** *strategic diagrams; examples.* ***Independent study:*** *study materials on strategic management.*	*GC1, GC2, GC3, GC4; PC1, PC2; PLO1, PLO2*
Practical	***Practical Work No. 5. Strategic Planning Based on SWOT Analysis.***	*GC1, GC2, GC3,*

class 13	***Key issues:*** *conducting SWOT analysis; development of strategic decisions.* ***Didactic tools:*** *SWOT matrices; case studies.* ***Independent study:*** *prepare a report on Practical Work No. 5.*	*GC4; PC1, PC2; PLO1, PLO2*
Practical class 14	***Defense of Practical Work No. 5.*** ***Quality Costs of Medical Services.*** ***Key issues:*** *classification of quality costs; preventive and corrective costs.* ***Didactic tools:*** *tables; calculation examples.* ***Independent study:*** *study the classification of quality costs.*	*GC1, GC2, GC3, GC4; PC1, PC2; PLO1, PLO2*
Practical class 15	***Practical Work No. 6. Calculation of the Efficiency of Medical Services.*** ***Key issues:*** *economic efficiency indicators; cost–result analysis.* ***Didactic tools:*** *calculation tables; examples.* ***Independent study:*** *prepare a report on Practical Work No. 6.*	*GC1, GC2, GC3, GC4; PC1, PC2; PLO1, PLO2*
Practical class 16	***Defense of Practical Work No. 6.*** ***Certification of Quality Management Systems.*** ***Key issues:*** *objectives and stages of certification; role of certification bodies.* ***Didactic tools:*** *regulatory documents; certification schemes.* ***Independent study:*** *study the certification procedure.*	*GC1, GC2, GC3, GC4; PC4; PLO4*
Practical class 17	***Submission of a Term Paper. Analysis of Certification Stages.*** ***Key issues:*** *preparation for certification; compliance analysis with ISO 9001 requirements.* ***Didactic tools:*** *audit material examples.* ***Independent study:*** *prepare a list of required certification documents.*	*GC1, GC2, GC3, GC4; PC4; PLO4*
Practical class 18	***Internal Audit of the Quality Management System.*** ***Key issues:*** *types of audits; planning and conducting internal audits; nonconformities and corrective actions.* ***Didactic tools:*** *checklists; report examples.* ***Independent study:*** *study internal audit stages.*	*GC1, GC2, GC3, GC4; PC4; PLO4*
Practical class 19	***Modular Control Work (MCW).*** ***Key issues:*** *assessment of theoretical and practical learning outcomes.* ***Didactic tools:*** *control tasks; test and situational problems.* ***Independent study:*** *review course materials.*	*GC1, GC2, GC3, GC4; PC1, PC2, PC3, PC4; PLO1, PLO2, PLO3, PLO4*
Practical class 20	***Generalization and Systematization of Educational Material.*** ***Key issues:*** *generalization of key concepts, methods, and tools of quality management; preparation for final assessment.* ***Didactic tools:*** *summary diagrams; discussion.* ***Independent study:*** *systematize notes and prepare for the final assessment.*	*GC1, GC2, GC3, GC4; PC1, PC2, PC3, PC4; PLO1, PLO2, PLO3, PLO4*

6. Student Independent Study

Preparation for classroom activities – 40 hours
Preparation for the modular control test – 4 hours
Completion of the individual semester assignment – 10 hours
Preparation for the pass/fail test – 6 hours

Types of Student Activities and Estimated Time Allocation

Type of student activity	***Estimated time (hours)***
Preparation for 1 hour of lectures	*0.4*
Preparation for 1 hour of practical classes	*0.8*
Preparation for the modular control test	*4*
Preparation for the pass/fail test	*6*
Individual semester assignment (term paper / report)	*10*

*One of the main forms of semester assessment during the study of the course **"Quality Management System in Medicine"** is the preparation of a **term paper (report)**. The term paper is completed during the semester, formatted according to the established requirements, and submitted for assessment during the **17th practical class**.*

*A term paper is a **scientific and technical document** that contains comprehensive and systematized information on a selected topic. It involves the presentation of material based on specially selected literature and independently conducted research. A student may prepare a term paper **only on a topic approved by the instructor**.*

General requirements for the term paper:

- *clarity and logical consistency of the presentation;*
- *persuasiveness of arguments;*
- *conciseness and precision of formulations that exclude ambiguous interpretation;*
- *specificity in presenting research results;*
- *justification of recommendations and proposals.*

The term paper must address:

- *the relevance of the topic and its correspondence to the current state of science, technology, and production-related issues;*
- *justification of the chosen research direction and problem-solving methods, including their comparative evaluation;*
- *analysis and generalization of existing research results;*
- *development of a general research methodology;*
- *the nature and content of performed theoretical studies and calculations, research methods applied;*
- *justification of the need for experimental studies, principles of operation of developed software tools, their characteristics, evaluation of calculation errors, and obtained experimental data;*
- *assessment of the completeness of solving the stated problem;*
- *evaluation of the reliability of obtained results and their comparison with analogous results;*
- *scientific and practical value of the completed work.*

Structure of the term paper:

title page; table of contents; list of symbols, abbreviations, and terms (if necessary); introduction; main body; conclusions; list of references; appendices (if necessary).

Approximate list of term paper topics:

1. *Concept and evolution of quality management in medicine.*
2. *The role of quality management systems in improving patient safety.*
3. *ISO quality management principles and their application in healthcare institutions.*
4. *Process approach in the quality management system of medical services.*

5. *The PDCA cycle as a tool for continuous quality improvement in medicine.*
6. *The concept of Total Quality Management (TQM) and possibilities for its implementation in healthcare.*
7. *Risk-based thinking in ISO 9001:2015 and its significance for medicine.*
8. *Statistical methods of quality control in medical and biomedical processes.*
9. *Cause-and-effect diagrams as a tool for analyzing quality problems in medical services.*
10. *Quality costs of medical services: classification and management methods.*
11. *Economic efficiency of quality management systems in healthcare institutions.*
12. *Strategic quality planning of medical services based on SWOT analysis.*
13. *Documentation of the quality management system in accordance with ISO 9001 requirements.*
14. *Internal audit of quality management systems: objectives, principles, and stages of implementation.*
15. *Certification of quality management systems in medicine: benefits and implementation challenges.*
16. *Quality of medical care as a component of population quality of life.*
17. *The role of biomedical engineering in ensuring the quality and safety of medical devices.*
18. *Human resource management under the implementation of a quality management system.*
19. *International experience in implementing quality management systems in healthcare.*
20. *Prospects for the development of quality management systems in medicine in the context of digitalization.*

Title page requirements:

The title page of the term paper must include: the name of the university; the name of the faculty; the name of the department; the name of the specialty; the name of the educational program; the name of the course; the title of the term paper; the student's first and last name; year of study; academic group number; and the year of completion.

Following the title page, a list of abbreviations (if necessary) and a detailed table of contents must be provided. The table of contents should clearly identify the introduction, sections of the main body (main topics to be considered), subsections (if necessary), conclusions, and the list of references. Page numbers indicating the beginning of each section must be aligned on the right. Each section must begin on a new page.

*The total length of the term paper, depending on the selected topic, may range from **25 to 40 pages of the main text** (subject to agreement with the instructor). The length is determined by the student's ability to concisely and comprehensively explain and analyze the obtained information.*

Mandatory requirements:

*All sources of information must be clearly referenced. All numerical data, facts, scientific opinions, quotations, and formulas must include references in the form **[2]**, where the number corresponds to the source in the reference list at the end of the paper. Tables, schemes, graphs, diagrams, and other visual materials must be used.*

*The list of references must contain **at least 10 sources** and be formatted according to the **APA citation style**. All sources must have been published within the **last 5 years**. Preference is given to **foreign (international) sources**. If information is obtained from the Internet, the author, title of the article, and the website address must be indicated, as for printed sources.*

Assessment criteria:

The term paper is evaluated based on the following criteria: logical structure of the outline; completeness and depth of topic coverage; reliability of obtained data; inclusion of practical materials; correctness of conclusions and final results; quality of formatting; justification of the student's own viewpoint in the conclusions.

Submission deadline:

*The final deadline for submitting the term paper for assessment is the **17th practical class**.*

*The term paper is **not checked for plagiarism**, but it must comply with the principles of **academic integrity**. In cases of academic misconduct, the paper is annulled and not assessed.*

Policy and Assessment

7. Course Policy (Educational Component)

Attendance

*Attendance at **practical classes is mandatory**, as these classes include short in-class assessments / test tasks, as well as the completion and defense of practical works. A student is required to be present for the **entire duration of the class**, from the beginning to the end, and to actively participate in the learning process.*

*Attendance at **lectures is not mandatory**.*

*In case of justified absence (illness, official circumstances), the student must inform the instructor in advance or as soon as possible and **make up for the missed class** in accordance with the established procedure.*

Rules of Conduct During Classes

*Students are required to adhere to the principles of **academic ethics** and mutual respect toward the instructor and other students.*

Active participation is encouraged during classes, including answering questions, participating in discussions, and completing learning tasks.

If necessary, students may prepare short oral or written presentations, reports, or analytical texts related to the course topics.

Mobile phones and other personal communication devices must be switched off or set to silent mode.

*The use of laptops, tablets, and mobile devices is permitted **exclusively for educational purposes**, such as completing practical tasks, searching for materials on relevant educational platforms, in open-access sources, or working with educational datasets.*

Missed Assessment Activities

Missed assessment activities (defense of practical works) must be completed during subsequent classes, provided that the task planned for the current class has been completed, or during scheduled consultations.

*Missing the **modular control test** or short in-class assessments / test tasks is **not permitted**. A term paper submitted **after the established deadline** is **not assessed**.*

Rules for the Defense of Practical Works

*A practical work is considered completed provided that the results are submitted on time and **successfully defended orally**.*

The defense of a practical work includes: explanation of problem-solving methods; interpretation of obtained results; and answering the instructor's questions.

*Works completed in violation of the principles of **academic integrity** (plagiarism, copying, use of others' results without proper referencing) are **not admitted for defense and are not assessed**.*

Deadline and Retake Policy

All types of academic work (practical works, term paper, modular control test) must be completed within the deadlines specified in the syllabus.

*Late submission of assignments without a valid reason may result in **refusal to assess the work**.*

*In the presence of justified reasons, a student has the right to **individually agree on a new submission deadline** with the instructor.*

Retaking assessment activities is carried out in accordance with the regulations, orders, and instructions of ***Igor Sikorsky Kyiv Polytechnic Institute****.*

Bonus Points

Bonus points may be awarded for creative academic activities related to the course (e.g., participation in academic competitions, conferences, scientific contests, preparation of reviews of scientific works or publications, etc.). These bonus points ***do not form part of the standard grading scale****.*

The total number of bonus points ***may not exceed 10 points****, and the overall student rating* ***may not exceed 100 points****.*

Academic Integrity

The policy and principles of academic integrity are defined in ***Section 3 of the Code of Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute"****. More details are available at: https://kpi.ua/code*

Ethical Standards of Conduct

The standards of ethical conduct for students and staff are defined in ***Section 2 of the Code of Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute"****. More details are available at: https://kpi.ua/code*

Procedure for Appealing Assessment Results

Students have the right to raise any issues related to assessment procedures and may expect them to be reviewed in accordance with predefined procedures.

A student has the right to appeal the results of an assessment activity in accordance with the approved ***Regulation on Appeals at Igor Sikorsky Kyiv Polytechnic Institute*** *(approved by Order No. NON/128/2021 dated May 20, 2021): https://osvita.kpi.ua/index.php/node/182*

Inclusive Education

The course ***"Quality Management System in Medicine"*** *may be delivered to most students with special educational needs, except for students with severe visual impairments that prevent them from performing tasks using personal computers, laptops, and/or other technical devices.*

Distance Learning

Distance learning is conducted via the ***"Sikorsky" Distance Learning Platform****.*

Distance learning through additional online courses on specific topics is allowed subject to agreement with students. If only a small number of students express a desire to complete an online course on a particular topic, studying the material through such courses is permitted; however, students must complete ***all assignments предусмотрені by the course syllabus****.*

The list of available courses is proposed by the instructor after students express their interest, as the pool of available courses is updated almost monthly.

The student must provide a document confirming completion of the online course (in case of completing the full course) or submit completed practical tasks from the online course. Upon successful completion of an oral interview with the instructor on the studied topics, the student may receive grades for the assessment activities предусмотрені for the relevant topics (short assessments / test tasks, practical works).

Practical works and the term paper are completed during students' ***independent study in a distance-learning format****, with the possibility of consultations with the instructor via email or social networks.*

Instruction in a Foreign Language

*Instruction in English is provided **only for international students**.*

At the request of students, studying course materials through English-language online courses corresponding to the topics of specific classes is permitted.

8. Types of Assessment and the Rating-Based Grading System (RGS)

The assessment system is focused on awarding points for student engagement and for completing tasks aimed at developing practical skills and competencies.

Assessment System (Continuous Assessment)

No.	Assessment component	%	Weight (points)	Quantity	Total
1	Short in-class assessments / test tasks	20	2	10	20
2	Completion and defense of practical works	54	9	6	54
3	Modular control test	12	12	1	12
4	Term paper (report)	14	14	1	14
5	Pass/Fail assessment work[1]	86	86	1	86
	Total	**100**			**100**

[1] *The result is counted toward the overall rating together with the term paper grade if the student has earned fewer than 60 points during the semester or wishes to improve the final grade.*

*Failure to complete a continuous assessment activity **in synchronous mode without a valid reason** is graded **0 points**.*

Rules for Assessing the Completion and Defense of Practical Works

- *Each practical work is graded on a **9-point rating scale**.*
- *The **maximum score** for one practical work is 9 **points**.*
- *The **minimum passing threshold** is **at least 60%** of the maximum score, which corresponds to **6 points**.*
- *A result below the threshold (**less than 6 points**) is considered **unsatisfactory** and is graded **0 points**.*

Criteria for Assessing a Practical Work

Criterion	Maximum points
Correctness of calculations and modeling	4
Justification of selected methods and models	2
Analysis and interpretation of results	2
Oral defense and answers to questions	1
Total	9

Conditions for Passing a Practical Work

- *A practical work is considered passed if the student scores **6-9 points**.*
- *If **0 points** are awarded, the work **cannot be revised or re-defended** during the academic debt remediation period.*
- *Works completed in violation of **academic integrity principles** are **not accepted** and are graded **0 points**.*

Rules for Assessing the Term Paper

- *The term paper is graded on a **14-point rating scale**.*
- *The **maximum score** for the term paper is **14 points**.*
- *The **minimum passing threshold** is **at least 60%**, which corresponds to **9 points**.*
- *A term paper graded **below 9 points** is considered **not passed** and is graded **0 points**.*

Criteria for Assessing the Term Paper

Criterion	Maximum points
Relevance to the topic and completeness of coverage	4

Correct application of mathematical models and methods	*4*
Independence of analysis and soundness of conclusions	*5*
Quality of formatting and compliance with academic integrity	*1*
Total	***14***

Conditions for Passing the Term Paper

- *A term paper is considered passed if the student scores **9–14 points**.*
- *If **0 points** are awarded, the student must **revise the paper and resubmit it** before the start of the academic debt remediation period.*
- *Detection of plagiarism or other violations of **academic integrity** results in a grade of **0 points**.*

Pass/Fail Assessment and Application of the Rating System

*Students who have met all eligibility requirements for the pass/fail assessment and have accumulated **60 or more points** receive the corresponding rating grade **without completing an additional semester assessment**.*

*For students who have met all eligibility requirements but have a rating score **below 60 points**, as well as for those who wish to **improve their rating**, the instructor conducts a semester assessment during the examination week in the form of a **pass/fail test or an oral interview**.*

After completing the pass/fail assessment:

- *if the score obtained in the pass/fail assessment is **higher** than the accumulated rating, the student receives the **pass/fail assessment score**;*
- *if the score obtained is **lower** than the accumulated rating, a **"strict" Rating-Based Grading System** is applied: the student's previous rating (excluding points for the individual semester assignment) is annulled, and the final grade is determined **solely based on the pass/fail assessment result**.*

*This approach fosters a **responsible attitude** toward the decision to undertake the pass/fail assessment, encourages students to **critically evaluate their level of preparedness**, and motivates thorough preparation for the final assessment.*

Calendar control (CC) is not provided for this course.

*In case of detection of **academic misconduct** during the learning process, the corresponding assessment activity **is not credited**.*

Semester Assessment: Pass/Fail Test

Eligibility Requirements for Semester Assessment

*Admission to the semester assessment (pass/fail test) requires **no outstanding academic debts** in practical works and the individual semester assignment (term paper), as well as **completion of the modular control test**.*

Mandatory Eligibility Requirements

No.	***Requirement***	***Criterion***
1	*Current rating*	*RD ≥ 40*
2	*Positive grade for the term paper*	*More than 9 points*
3	*All practical works completed and defended*	*More than 36 points*
4	*Modular control test completed*	*More than 7 points*

Optional Eligibility Requirements

1. *Attendance of lecture classes.*

Conversion of Rating Points to Grades (University Grading Scale)

Number of points	***University grade***
95–100	*Excellent*
85–94	*Very good*
75–84	*Good*
65–74	*Satisfactory*
60–64	*Pass*

Less than 60	*Fail*

9. Additional Course Information (Educational Component)

*The list of questions for preparation for the **modular control test** as well as for preparation for the **pass/fail assessment** is provided in **Appendix 1**.*

*Distance learning through the completion of additional **online courses** on specific topics is permitted subject to agreement with students. In cases where only a limited number of students express a desire to complete an online course on a particular topic, studying the material through such courses is allowed; however, students are required to complete **all assignments by the course syllabus**.*

The list of recommended courses is proposed by the instructor after students express their interest, as the pool of available courses is updated almost monthly.

*The student must provide a document confirming completion of the distance course (in the case of completing the full course) or submit completed practical assignments from the distance course. Upon successful completion of an **oral interview with the instructor** on the studied topics, the student may receive grades for the assessment activities provided for the relevant topics (short in-class assessments / test tasks, practical works).*

*In the event of the introduction of an **asynchronous learning mode**, the deadlines for completing assessment activities may be adjusted.*

Course Syllabus

The course syllabus was prepared by Associate Professor of the Department of Biomedical Engineering, PhD in Engineering, Associate Professor Oksana Biloshytska

***Approved by** the Department of Biomedical Engineering (protocol № 16 of June 21, 2024)*
***Approved by** the Methodical Commission of the Faculty of Biomedical Engineering (protocol № 9 of June 26, 2024)*

List of Questions for Preparation for the Modular Control Test

and for the Pass/Fail Assessment

1. *What is quality management? What is its essence?*
2. *Explain the eight principles of quality management.*
3. *Present the conceptual model of a quality management system and explain it.*
4. *What is the difference between the process approach and the system approach to management?*
5. *What is the principle of the Deming cycle?*
6. *What is the purpose of the continuous improvement process?*
7. *What requirements for continuous improvement do you know?*
8. *What methods of continuous improvement exist? Explain them.*
9. *Provide the key definitions of ISO 9001:2015 applicable to a healthcare institution.*
10. *Define the term "audit" and explain its essence. What are the objectives of an audit? Why are audits conducted?*
11. *Describe the reasons for conducting an audit.*
12. *What classifications of audits exist? How do they differ from one another?*
13. *What are the advantages of internal audits compared to external audits?*
14. *Explain the disadvantages of internal audits compared to external audits.*
15. *What types of quality audits do you know?*
16. *What requirements does ISO 9001:2015 specify for internal audits?*
17. *What types of certification audits exist?*
18. *What is the purpose of an audit program?*
19. *What should an organization consider when planning an audit program?*
20. *List the main stages of an audit.*
21. *What does "information collection" include as one of the audit stages?*
22. *What actions does the auditor perform during the "planning and preparation" stage of an audit?*
23. *What meetings should an auditor conduct during an audit? Explain the purpose of the opening meeting and the auditor's actions during it. What is the essence of the closing meeting? What responsibilities does the audit team leader bear during the audit?*
24. *What do "follow-up actions" include as one of the audit stages?*
25. *What are nonconformity reports? What are they used for? What general considerations should an auditor observe when preparing a nonconformity report?*
26. *What is the purpose of using matrix analysis of nonconformities?*
27. *What is a corrective action?*
28. *Explain the distribution of responsibilities between the auditor and the auditee.*
29. *What methods of information collection during an audit do you know?*
30. *What does document review include during an audit?*
31. *What is the purpose of observation during an audit?*
32. *What is an audit trail?*
33. *Explain what process audits and audits of process interactions are.*
34. *What should an auditor do when preparing to audit a specific process?*
35. *Explain the importance of record-keeping during an audit.*
36. *What is the importance of effective reporting of audit results?*
37. *What is meant by the quality of reports? Name the characteristics of report quality and explain which aspects they are related to.*
38. *Describe the characteristics of an audit report in terms of content and form.*
39. *What does the term "quality index" mean?*
40. *What style should an audit report have?*

41. *What requirements are imposed on auditors?*
42. *What functions are performed by auditors involved in product (service) certification?*
43. *What functions are performed by auditors involved in certification of quality management systems?*
44. *What are the duties of a quality management auditor? What responsibilities does the auditor bear?*

Appendix 2 to the Course Syllabus
"Quality Management System in Medicine"

Program Learning Outcomes (Extended Form)

*As a result of studying the course **"Quality Management System in Medicine"**, students will be able to achieve the following learning outcomes:*

Learning outcomes		***Alignment of learning outcomes with competencies according to the Educational Program***	
		General competencies (soft skills)	***Professional (specialized) competencies***
PLO1	*Explain the essence, principles, and modern concepts of quality management, including Total Quality Management (TQM), and their application in medicine and biomedical engineering.*	*GC1 – Ability for abstract thinking, analysis, and synthesis; GC4 – Ability for lifelong learning and mastering modern approaches and standards.*	*PC1 – Ability to apply quality management principles and tools; PC2 – Ability to analyze and improve quality management systems.*
PLO2	*Apply the requirements of ISO 9000 and ISO 9001 series standards in the development, implementation, and documentation of quality management systems in healthcare organizations.*	*GC2 – Ability to apply knowledge in practical situations and make well-founded decisions; GC4 – Ability to independently master modern standards.*	*PC1 – Ability to ensure the quality of products, processes, and services in accordance with standards; PC2 – Ability to design quality management systems.*
PLO3	*Use statistical methods and tools of quality control and quality management to analyze the quality of products (services), processes, and quality-related costs.*	*GC1 – Ability for analysis and synthesis; GC2 – Ability to apply knowledge in practical situations.*	*PC3 – Ability to use statistical methods of quality control and management; PC1 – Ability to apply quality management tools.*
PLO4	*Analyze the results of internal and external audits and formulate proposals for corrective and preventive actions aimed at continuous improvement of the quality management system.*	*GC3 – Ability for effective professional communication; GC2 – Ability to make well-founded managerial decisions.*	*PC4 – Ability to participate in audits and certification of quality management systems; PC2 – Ability to improve quality management systems.*