COURSE SYLLABUS AND COURSE REQUIREMENTS
ACADEMIC YEAR 2025/26 SEMESTER FALL

Course title	***Quality Assurance of Medical Devices***
Course Code	
Hours/Week: le/pr/lab	
Credits	
Degree Programme	MSc
Study Mode	
Requirements	
Teaching Period	
Prerequisites	
Department(s)	*Institute of Physiology*
Course Director	*Dr László Péczely*
Teaching Staff	*Dr. Attila Tóth, Zsolt Kisander, Dr. Ákos Odry, Dr. László Péczely*

COURSE DESCRIPTION

A short description of the course (max. 10 sentences).
Neptun: Instruction/Subjects/Subject Details/Basic data/Subject description

This course provides an in-depth overview of **quality assurance (QA) principles, regulations, and practices in the field of medical devices**. Students will learn the fundamentals of quality management systems, regulatory requirements (EU MDR 2017/745, IVDR 2017/746, ISO 13485, ISO 14971), and practical tools used throughout the medical device lifecycle.
Special emphasis is placed on **risk management, product development, design control, biocompatibility, sterilization, validation, clinical evaluation, post-market surveillance, and audits**. Students will engage in case studies, group assignments, and online workshops to develop practical problem-solving skills.
By the end of the course, students will be able to:

- Explain the regulatory framework for medical devices
- Apply risk management and quality management tools
- Evaluate processes for compliance with international standards
- Analyze ethical and legal issues related to device safety and patient protection

The course is delivered **online** (lectures + interactive practice sessions), encouraging active student participation and collaborative learning.

SYLLABUS

Neptun: Instruction/Subjects/Subject Details/Syllabus

1. GOALS AND OBJECTIVES

Goals, student learning outcome.
Neptun: Instruction/Subjects/Subject Details/Syllabus/Goal of Instruction

- To provide students with a comprehensive understanding of **quality assurance systems and regulatory frameworks** for medical devices.
- To familiarize students with the **international standards and guidelines** (ISO 13485, ISO 14971, MDR, IVDR) governing medical device development and lifecycle management.
- To develop the ability to critically analyze **QA processes, risk management approaches, and compliance requirements** in the medical device industry.
- To encourage **ethical awareness and responsibility** regarding patient safety, product liability, and healthcare outcomes.

Course Objectives

By the end of the course, students should be able to:

1. Define and classify medical devices, and describe their regulatory environment.
2. Explain the structure and function of a Quality Management System (QMS).
3. Apply **risk management tools** (e.g., FMEA) to identify and mitigate potential hazards.
4. Describe the processes of **design control, validation, and clinical evaluation**.

5. Evaluate requirements for **biocompatibility, sterilization, and process validation**.
6. Develop and assess **audit programs and post-market surveillance systems**.
7. Interpret and apply relevant **legal and ethical principles** in QA practice.
8. Integrate QA processes across the entire medical device lifecycle.

2. COURSE CONTENT

Neptun: Instruction/Subjects/Subject Details/Syllabus/Subject content

	TOPICS
LECTURE	WEEK 1 – INTRODUCTION TO MEDICAL DEVICES AND QA • Learning outcomes: Define medical devices, understand QA role, regulatory basics. • Methods: Online lecture + interactive Q&A. • Practice: Online case study discussion (failure analysis). WEEK 2 – QUALITY MANAGEMENT SYSTEMS (QMS) • Learning outcomes: Apply ISO 13485; differentiate from ISO 9001. • Methods: Lecture + breakout group activity. • Practice: Draft a QMS documentation structure. WEEK 3 – RISK MANAGEMENT • Learning outcomes: Apply ISO 14971; perform risk evaluation. • Methods: Lecture + online workshop (Miro/whiteboard). • Practice: FMEA exercise. WEEK 4 – PRODUCT DEVELOPMENT & DESIGN CONTROL • Learning outcomes: Understand design control, V&V. • Methods: Lecture + guided discussion. • Practice: Mini design project (glucose meter). WEEK 5 – MATERIALS AND BIOCOMPATIBILITY • Learning outcomes: Know ISO 10993; explain importance of biocompatibility. • Methods: Lecture + short video example. • Practice: Material evaluation exercise. WEEK 6 – STERILIZATION AND CLEANLINESS • Learning outcomes: Compare sterilization methods; understand validation. • Methods: Lecture + case study. • Practice: Analyze packaging failures. WEEK 7 – CLINICAL EVALUATION • Learning outcomes: Apply MDR requirements; understand PMCF. • Methods: Lecture + online workshop. • Practice: Build clinical evaluation matrix. WEEK 8 – MANUFACTURING AND PROCESS CONTROL • Learning outcomes: Understand GMP; apply SPC. • Methods: Lecture + problem-solving activity. • Practice: Fishbone analysis of defect. WEEK 9 – VALIDATIONS

- Learning outcomes: Describe IQ, OQ, PQ; understand software validation.
- Methods: Lecture + interactive quiz.
- Practice: Validation matrix creation.

WEEK 10 – POST-MARKET SURVEILLANCE
- Learning outcomes: Explain PMS/PMCF, vigilance reporting.
- Methods: Lecture + online case analysis.
- Practice: Prepare CAPA plan from complaint report.

WEEK 11 – AUDITS AND REGULATORY INSPECTIONS
- Learning outcomes: Plan internal audit; explain NB role.
- Methods: Lecture + role-play simulation.
- Practice: Online audit simulation with checklist.

WEEK 12 – ETHICAL AND LEGAL ASPECTS
- Learning outcomes: Analyze legal and ethical responsibility in QA.
- Methods: Lecture + structured debate.
- Practice: Debate on liability in implant failure.

WEEK 13 – SUMMARY & EXAM PREPARATION
- Learning outcomes: Integrate QA processes; exam readiness.
- Methods: Lecture + revision workshop.
- Practice: Final case study – QA lifecycle of a surgical robot.

PRACTICE LABORATORY PRACTICE

WEEK 1 – INTRODUCTION TO MEDICAL DEVICES AND QA
- Practice: Online case study discussion (failure analysis).

WEEK 2 – QUALITY MANAGEMENT SYSTEMS (QMS)
- Practice: Draft a QMS documentation structure.

WEEK 3 – RISK MANAGEMENT
- Practice: FMEA exercise.

WEEK 4 – PRODUCT DEVELOPMENT & DESIGN CONTROL
- Practice: Mini design project (glucose meter).

WEEK 5 – MATERIALS AND BIOCOMPATIBILITY
- Practice: Material evaluation exercise.

WEEK 6 – STERILIZATION AND CLEANLINESS
- Practice: Analyze packaging failures.

WEEK 7 – CLINICAL EVALUATION
- Practice: Build clinical evaluation matrix.

WEEK 8 – MANUFACTURING AND PROCESS CONTROL
- Practice: Fishbone analysis of defect.

WEEK 9 – VALIDATIONS
- Practice: Validation matrix creation.

WEEK 10 – POST-MARKET SURVEILLANCE
- Practice: Prepare CAPA plan from complaint report.

WEEK 11 – AUDITS AND REGULATORY INSPECTIONS
- Practice: Online audit simulation with checklist.

WEEK 12 – ETHICAL AND LEGAL ASPECTS
- Practice: Debate on liability in implant failure.

WEEK 13 – SUMMARY & EXAM PREPARATION
- Practice: Final case study – QA lifecycle of a surgical robot.

DETAILED SYLLABUS AND COURSE SCHEDULE

ACADEMIC HOLIDAYS INCLUDED

LECTURE

week	**Topic**	**Compulsory reading; page number (from … to …)**	**Required tasks (assignments, tests, etc.)**	**Completion date, due date**
1.		1st lecture slides	-	-
2.		2nd lecture slides	-	-
3.		3rd lecture slides	-	-
4.		4th lecture slides	-	-
5.		5th lecture slides	-	-
6.		6th lecture slides	-	-
7.		7th lecture slides	-	-
8.		8th lecture slides	-	-
9.		9th lecture slides	-	-
10.		10thlecture slides	-	-
11.		11th lecture slides	-	-
12.		12th lecture slides	-	-
13.		13th lecture slides	-	-
14.		14th lecture slides	-	-
15.				

PRACTICE, LABORATORY PRACTICE

week	**Topic**	**Compulsory reading; page number (from … to …)**	**Required tasks (assignments, tests, etc.)**	**Completion date, due date**
1.		1st practice slides	-	-
2.		2nd practice slides	-	-
3.		3rd practice slides	-	-
4.		4th practice slides	-	-
5.		5th practice slides	-	-
6.		6th practice slides	-	-
7.		7th practice slides	-	-
8.		8th practice slides	-	-
9.		9th practice slides	-	-
10.		10th practice slides	-	-

11.		11th practice slides	-	-
12.		12th practice slides	-	-
13.		13th practice slides	-	-
14.	*Oral report (Grade offer for the practice)*	14th practice slides	-	-
15.				

3. ASSESSMENT AND EVALUATION

(Neptun: Instruction/Subjects/Subject Details/Syllabus/Examination and Evaluation System)

ATTENDANCE

In accordance with the Code of Studies and Examinations of the University of Pécs, Article 45 (2) and Annex 9. (Article 3) a student may be refused a grade or qualification in the given full-time course if the number of class absences exceeds 30% of the contact hours stipulated in the course description.

Method for monitoring attendance *(e.g.: attendance sheet / online test/ register, etc.*

attendance sheet

ASSESSMENT

Cells of the appropriate type of requirement is to be filled out (course-units resulting in mid-term grade or examination). Cells of the other type can be deleted.

Course resulting in mid-term grade *(PTE TVSz 40§(3))*

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Course-unit with final examination

Requirements for the end-of-semester signature

(Eg.: mid-term assessment of 40%)

Attendance of the lectures and practices is mandatory, more than 40% absences implies the refusal of the end-of-semester signature.

Re-takes for the end-of-semester signature (PTE TVSz 50§(2))

The specific regulations for grade betterment and re-take must be read and applied according to the general Code of Studies and Examinations. E.g.: all the tests and the records to be submitted can be repeated/improved each at least once every semester, and the tests and home assignments can be repeated/improved at least once in the first two weeks of the examination period.

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Type of examination *(written, oral):* ☒ ***Practical assignments****: Preparation of written materials based on lecture content (in English), case studies, and project work –* ***100%****.*

☐ *There will be* ***no final exam****.*

The exam is successful if the result is minimum - %. *(The minimum cannot exceed 40%.)*

Calculation of the grade *(TVSz 47§ (3))*

In the exam the students have to report 3 topics: 2 theoretical related to the lectures and 1 related to the practice.

Calculation of the final grade based on aggregate performance in percentage.

In each exam topic the grade should be minimally mark 2 (satisfactory). The final grade is calculated averaging the three subgrades.

4. SPECIFIED LITERATURE

In order of relevance. (In Neptun ES: Instruction/Subject/Subject details/Syllabus/Literature)

COMPULSORY READING AND AVAILABILITY

ISO 13485:2016 Medical devices – Quality management systems
ISO 14971:2019 Medical devices – Risk management
MDR 2017/745 and IVDR 2017/746 (EU Regulations)
AAMI Technical Information Reports
Pietzsch, J. B. (2016). Medical Device Quality Management Systems: Strategy and Techniques for Improving Efficiency and Effectiveness. Academic Press.