COURSE SYLLABUS AND COURSE REQUIREMENTS
ACADEMIC YEAR ... SEMESTER ...

Course title	*Quality Assurance and Device Certification*
Course Code	***MSM610AN-EA-00***
Hours/Week: le/pr/lab	2hrs l/1hr p
Credits	4
Degree Programme	**Biomedical Engineering MSc**
Study Mode	**full time**
Requirements	
Teaching Period	**Spring / 4th**
Prerequisites	
Department(s)	**Department of Technical Informatics**
Course Director	
Teaching Staff	*Dr. habil Turcsán Judit*

COURSE DESCRIPTION

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

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SYLLABUS

Neptun: Instruction/Subjects/Subject Details/Syllabus

1. GOALS AND OBJECTIVES

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

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2. COURSE CONTENT

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

	TOPICS
LECTURE	1. *History of Quality Assurance* 2. *Quality assurance and quality control* 3. *ISO 13485* 4. *EU regulations for MDs*
PRACTICE	1. *Target group of MDs and the needs of costumers* 2. *Quality control of MD production* 3. *Quality assurance of MD; documentation* 4. *Audit of MD production*
LABORATORY PRACTICE	1. *topic* 2. *topic* 3. *topic* 4. *etc.*

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.	Introduction to quality assurance. Quality control and quality assurance in historical ages.		…	…
2.	Quality management system. Importance and meaning of PDCA – Plan, do, check, act. Differences among quality control, quality assurance and total quality management			
3.	Quality standards. Lean quality standards, six sigma, lean six sigma in health care.	Improta et al (2017): Improving performances of the knee replacement surgery process by applying DMAIC principles. Journal of Evaluation in Clinical Practice · September 2017 DOI: 10.1111/jep.12810		
4.	ISO 13485 – 1. Scope, 2. Normative references, 3. Terms and definitaions, 4. Quality management system (general and documentational requirements)	ISO 13485:2016 https://www.iso.org/obp/ui#iso:std:iso:13485:ed-3:v1:en		
5.	ISO 14385 5 Management responsibility 5.1 Management commitment 5.2 Customer focus 5.3 Quality policy 5.4 Planning 5.5 Responsibility, authority and communication 5.6 Management review			
6.	6 Resource management 6.1 Provision of resources 6.2 Human resources 6.3 Infrastructure 6.4 Work environment and contamination contrtol			
7.	ISO 13485 7 Product realization 7.1 Planning of product realization 7.2 Customer-related processes 7.3 Design and development 7.4 Purchasing 7.5 Production and service provision 7.6 Control of monitoring and meas			
8.	ISO 13485 8 Measurement, analysis and improvement 8.1 General 8.2 Monitoring and measuremen t8.3 Control of nonconforming product 8.4 Analysis of data 8.5 Improvement			
9.	Medical Device regulation in the USA.	www.fda.gov		
10.				

11.	Validation of medical devices			
12.	Measurements			
13.	Audits – internal audit			

PRACTICE, LABORATORY PRACTICE

week	**Topic**	**Compulsory reading; page number (from … to …)**	**Required tasks (assignments, tests, etc.)**	**Completion date, due date**
1.	Target group of Medical devices – measurements of demands and needs			
2.	Quality assurance of MD production – Quality policy; chapters of the manual			
3.	Planning the design of MD according to consumers demand			
4.	Teams and workers – division of labor and responsibilities			
5.	Planning the production of MD – raw materials – suppliers; production – equipments			
6.	Planning the production of MD – transport of MD to consumers			
7.	Quality control of production of MD – flow charts			
8.	Quality control of production – hazard analysis; critical points			
9.	Documentations of suppliers			
10.	Documentations of production			
11.	Documentations of transport			
12.	Consumer complaints – root cause analysis (backward and forward)			
13.	Validation of medical device			

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.)*

TEAMS online

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))*

Mid-term assessments, performance evaluation and their ratio in the final grade *(The samples in the table to be deleted.)*

Type	Assessment	Ratio in the final grade
Preparation of practical material based on the lecture material	*140 points*	*100 %*

Opportunity and procedure for re-takes (PTE TVSz 47§(4))

The specific regulations for improving grades and resitting tests must be read and applied according to the general Code of Studies and Examinations. E.g.: all tests and assessment tasks can be repeated/improved 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.

Preparing the documentation worked out on practices

Grade calculation as a percentage

based on the aggregate performance according to the following table

Course grade	Performance in %
excellent (5)	85 % …
good (4)	70 % ... 85 %
satisfactory (3)	55 % ... 70 %
pass (2)	40 % ... 55 %
fail (1)	below 40 %

The lower limit given at each grade belongs to that grade.

Course-unit with final examination

Mid-term assessments, performance evaluation and their weighting as a pre-requisite for taking the final exam

(The samples in the table to be deleted.)

Type	Assessment	*Weighting as a proportion of the pre-requisite for taking the exam*
1.		
2.		
3.		
4.		

Requirements for the end-of-semester signature

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

…

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.

…

Type of examination *(written, oral):* ……..

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

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

The mid-term performance accounts for … %, the performance at the exam accounts for … % in the calculation of the final grade.

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

Course grade	Performance in %
excellent (5)	85 % …
good (4)	70 % ... 85 %
satisfactory (3)	55 % ... 70 %

pass (2)	40 % ... 55 %
fail (1)	below 40 %

The lower limit given at each grade belongs to that grade.

4. SPECIFIED LITERATURE

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

COMPULSORY READING AND AVAILABILITY

[1.] **Regulation (EU) 2017/745 on medical devices** (MDR), fully applicable from 26 May 2021; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20200424

[2.] **Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices** (IVDR), fully applicable from 26 May 2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0746-20170505

https://www.iso.org/

[3.] **ISO 13485** https://www.iso.org/obp/ui#iso:std:iso:13485:ed-3:v1:en

[4.] PETER D. MAUCH: Quality Management Theory and Application. https://pqm-online.com/assets/files/lib/books/mouch.pdf

RECOMMENDED LITERATURE AND AVAILABILITY

[5.] Juran's Quality Handbook. https://gmpua.com/QM/Book/quality%20handbook.pdf

[6.] Mohamed Zairi (2002) Beyond TQM implementation: the new paradigm of TQM sustainability, Total Quality Management, 13:8, 1161-1172, DOI:10.1080/09544120200000011

[7.] O. M. Ikumapayi, E. T. Akinlabi, F. M. Mwema et al., Six sigma versus lean manufacturing – An overview, Materials Today: Proceedings,

https://doi.org/10.1016/j.matpr.2020.02.986

[8.] Improta, G, Balato, G, Romano, M, et al. Improving performances of the knee replacement surgery process by applying DMAIC principles. *J Eval Clin Pract*. 2017; 23: 1401– 1407. https://doi.org/10.1111/jep.12810