Co-funded by the Erasmus+ Programme of the European Union

TECHNICAL UNIVERSITY OF KOŠICE

UNIVERSIDAD DE GRANADA

University of Hradec Králové

SYLLABUS STRUCTURE

1 Number and Name of Module

M10 – Product Design

2 Description of Module

The goal of every medical device manufacturer is to maintain consistent quality and to guarantee certain levels of safety and effectiveness. In order to achieve this, manufacturers must comply with a number of laws, standards, and regulations. The purpose of demonstrating compliance with all of these rules is to ensure product safety for patients, users, and third parties. Proof of compliance of technical documentation with all necessary requirements is the key to successful product registration in a particular market. The aim of this material is to support your ideas that can improve someone's quality of life.

3 Course Goals and Outcomes

In this module, the main summary of product design is described from the current EU regulatory point of view applicable since 26May2021. Creation of products that are meant to become a prototype of future medical device can be more attractive of investors, if standards applicable all over the word are involved. The European Medical Device Regulation (EU) 2017/745 has now become a new standard.

4 Time Allocation per Module

Topic Name	Topic Duration (minutes)
1. Device Description and Specification 1.1. The Rationale for the Qualification of the Product as a MD1 1.2. MD classification	15 min
2. Information to be Supplied by the Manufacturer 2.1. Label of the MD 2.2. The instructions for Use	10 min
3. Design and Manufacturing Information	10 min
4. General Safety and Performance Requirements (SPRs)	10 min
5. **Benefit-Risk Analysis and Risk Management** 5.1. Benefit Risk Analysis 5.2. Risk Analysis and Risk Management	15 min

Topic Name	Topic Duration (minutes)
6. MD Product Data, Verification and Validation 6.1 Pre-clinical and Clinical Data 6.2 Pre-clinical Safety of the MD 6.3 Software Verification and Validation 6.4 Stability, Including Shelf life 6.4 The Clinical EVALUATION Plan 6.5 Summary of Safety and Clinical Performance (SSCP)	30 min
7. EU Declaration of Conformity	10 min
8. Quality Management Documentation	10 min
9. Technical Documentation on Post-Market Surveillance	10 min

5 Target Group

- Researcher
- University management
- Ph.D. students
- Master students

6 Teaching Methods

A combination of more teaching methods will be used

- Lecture 30%
- Reading 5%
- Visual methods 10%
- Demonstration 15%
- Group discussions 40%

7 Teaching Forms

- On-site
- Online

8 Teaching/Training Competences and Experience for Lector

- Since 2011 has been working on clinical evaluation of pre-clinical and clinical research,
- Has actively participated in clinical trials and their management
- EUDAMED Actor of biomedical manufacturer

9 Knowledge and Skills Obtaining by this Module

As a results of this module, participants will be able:

- To have an overview of current requirements applicable for the EU market
- To find relevant information for their product design and development

10 Required Text and Study Materials

- Study Material
- Trainer Presentation

11 Recommended Literature

- Global Medical Devices Nomenclature System (GMDN) Agency home page https://www.gmdnagency.org/
- Universal Medical Devices Nomenclature System (UMDNS)ii by the Emergency Care Research Institute (ECRI) http://www.ecri.org.uk/umdns/index.htm
- Unique Device Identification (UDI) iv by the U.S. Food and Drug Administration (FDA) page http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/
- United Nations Standard Products and Services Code (UNSPSC)v page http://www.unspsc.org
- https://www.gmdnagency.org/
- http://www.ecri.org.uk/umdns/index.htm
- http://www.who.int/classifications/icd
- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/
- https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device
- http://www.unspsc.org/ vi. IMDRF Guidance document on the UDI of medical devices, IMDRF UDI Working Group, release 9 December 2013 (http:// www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf)
- https://decomplix.com/intended-purpose-medical-device/presentation on why design inputs go wrong at MD&M East in New York City on June 14, 2017.
- https://go.reedtech.com/medical-devices-and-eudamed-udi-and-device-registration?utm_campaign=LS-EUDAMED%20EU%20UDI&utm_source=MedTechDive
- MDCG 2021-24 Guidance on classification of medical devices
- https://www.medtechdive.com/spons/what-is-eudamed-and-basic-udi-di/598310/
- MDCG 2021-24 Guidance on classification of medical devices
- MDR Annex VIII
- https://ec.europa.eu/health/system/files/2020-09/md_mdcg_2019_13_sampling_mdr_ivdr_en_0.pdf
- https://eumdr.com/design-and-manufacturing-processes/
- https://www.tuvsud.com/en/industries/healthcare-and-medical-devices/medical-devices-and-ivd/clinical-services/clinical-data-for-medical-devices

- https://capgemini-engineering.com/us/en/insight/the-future-of-medical-care-is-software-part-2/#:~:text=In%20the%20medical%20world%2C%20there,device%20meets%20the%20intended%20purpose
- https://www.complianceonline.com/resources/software-verification-and-validation-requirements-for-medical-device-and-implementation-strategies.html
- https://j-pacmedical.com/Establishing-Shelf-Life-of-Medical-Devices.php
- https://www.i3cglobal.com/stability-studies/>

12 Testing Set - Evaluation/Grading Criteria

Testing Set - Evaluation/Grading Criteria

There are 10 questions asked with one correct answer. Every correct question is evaluated by 1 point.

10 points represent the maximum of 100%.