NX-451

Regulatory, quality and clinical affairs

Rochat Kim Julien

Cursus	Sem.	Type
Biomedical technologies minor	E	Opt.
Life Sciences Engineering	MA2, MA4	Opt.
Neuro-X minor	E	Opt.
Neuro-X	MA2, MA4	Opt.

Language of teaching	English
Credits	2
Withdrawal	Unauthorized
Session	Summer
Semester	Spring
Exam	During the semester
Workload	60h
Weeks	14
Hours	**2 weekly**
Courses	1 weekly
Exercises	1 weekly
Number of positions	

It is not allowed to withdraw from this subject after the registration deadline.

Summary

This regulatory, quality and clinical module aims at providing with the necessary tools and competences to apprehend the European regulatory framework for developing, validating and placing a medical device on the market, it defines the activities to be undertaken to comply with the applicable rules

Content

Regulatory approval (European & Swiss Medical Devices Regulation)

• Context of the European regulatory framework, introduction on the Medical Device Regulation (MDR), the In-Vitro Diagnostic Device regulation (IVDR), and the Swiss Law on Therapeutical Products. Concept of harmonized and technical standards, key operators on the market.

Medical Device Regulation: Introduction and Classification

• Keys regulatory expectations with medical devices, qualification and classification of a medical device.

Medical Device Development - Validation & Verification

• Development stages of a medical device, key activities and optimal sequence from the development to the marketing of a medical device. Introduction to verifications and validations

Risk Management of Medical Devices

• Presentation of Risk Management principles applied to medical devices, application of ISO 14971

Quality Management System ISO 13485:2016

• Presentation of Quality Management System, key activities and processes to consider, application of ISO 13485 requirements

Clinical Activities - Good Clinical Practices

• Key principles when designing and conducting a clinical investigation for a medical device, introduction to Good Clinical Practices

Introduction to Digital Health

• Particularities of Medical Devices Software, qualification of software as medical devices

Learning Outcomes

By the end of the course, the student must be able to:

- Interpret the regulatory context associated with medical devices in Europe
- Decide when medical device regulations are involved in a project
- Anticipate the constraints associated with the development and validation of medical devices
- Assess / Evaluate risks associated with medical devices
- Describe key process of a Quality Management System
- Plan key steps of a clinical trial
- Discuss opportunity and challenges of digital health

Transversal skills

- Use a work methodology appropriate to the task.
- Respect relevant legal guidelines and ethical codes for the profession.
- Access and evaluate appropriate sources of information.

Teaching methods

Presentation, lectures and use cases, individual and group study

Assessment methods

Use case evaluation, Multiple choices evaluation

Resources

Moodle Link

- https://go.epfl.ch/NX-451