Course Outline BMDE-654
Biomed Reg Affairs–Med Devices

General Information

Course #: 654

Section #: 001

Term: Fall

Year: 2023

Course Schedule: Thursdays
4:05 – 6:55 pm

Number of credits: 3

Location: Onsite

Instructor Information

Name and Title: Danny Kroo, Quality Management and Regulatory Affairs Consultant
Email danny.kroo@mcgill.ca

Calendar Course Description:

Regulatory strategies and quality management systems are critical for medical device development. This course provides an overview of regulatory requirements, and familiarize students with the important ISO and IEC standards pertaining to medical device development. This course will provide biomedical engineers with an understanding of the regulatory and quality requirements to translate a medical device idea into a commercial product, and will draw upon the expertise of invited speakers currently working in the medical devices industry.

Learning Outcomes By the end of this course, students will:

1. Understand the FDA's, European (CE Marking) and Health Canada's requirements for medical devices.
2. Gain insight into the best practices required for timely regulatory clearance and entry of medical devices into USA, European and Canadian markets.
3. Appreciate the critical role of quality systems and effective process management in the innovation process.
4. Understand quality management definitions, concepts, and guidelines.

5. Understand the requirements of the ISO 13485:2016, ISO 14971:2007, and IEC 62304:2006 standards, and FDA's Quality System Regulations (21CFR820).

Course Material: Course material, prepared by the Lecturers, will be available to registered students via MyCourses. The students will have to obtain a copy of ISO 13485:2016 standard.

Reference Text:

None.

Course Content/Outline (Subject to change)

Part I: Regulatory Affairs

- Week 1: In class
    - Overview of regulatory requirements for medical devices
        - US Regulatory Requirements under the US Food, Drug and Cosmetic Act
        - Health Canada Requirements under the Canadian Medical Device Regulations
    - Medical device classification in US and Canada
    - Discussion about projects

- **Week 2**
    - Medical device classification in Europe
    - Review of EU Medical Device Regulations
    - Videos-FDA Premarket Notification 510(k)
        - Exemptions from Premarket notification
    - FDA Premarket Approval PMA
        - PMA review process, application method, application content, quality system, clinical studies, and post-approval requirements
- **Week 3: in class**
    - FDA regulatory requirements- 510k changes, De Novo, IDE
    - MDR requirements
    - IVDR requirements
    - Videos for FDA and CE Marking requirements
- **Week 4:**
    - Overview of recognized consensus standards and QMS
    - Requirements for quality systems in different jurisdictions- MDSAP, FDA, EU MDR

- **Week 5:**
    - ISO 13485:2016– Medical Devices – Quality risk management systems – Requirements for regulatory purposes- detailed review

- **Week 6:** midterm exam

- **Week 7:**
    - Risk Management- ISO 14971 and IEC 60601

- IEC 62304-Medical Device Software

- **Week 8:**
  - Post marketing requirements for Canada, US and Europe
  - Complaints management

- **Week 9:**
  - 21CFR 820 requirements and Process Validation
  - ISO 14971– Medical Devices – Application of risk management to medical devices

- **Week 10:**
  - Internal audit and Corrective Action

- **Week 11:**
  - MDSAP review

- **Week 12:**

  Review

  Week 13:
  - Final exam

Assessment/Evaluation

Class Quizzes:	20%	
Project:	30%	(10-20 pages long-text)
Midterm exam	20%	
Final Exam:	30%	

McGill Policy Statements: McGill University values academic integrity. Therefore, all students must understand the meaning and consequences of cheating, plagiarism and other academic offences under the Code of Student Conduct and Disciplinary Procedures.

In accord with McGill University's Charter of Students' Rights, students in this course have the right to submit in English or in French any written work that is to be graded.

Biography of instructor.

Danny Kroo is the President of Docusys Corporation, a quality management and regulatory affairs consulting company. Since 1994, Mr. Kroo has provided consulting services to clients in Canada, USA, and Europe.

Danny Kroo graduated with degree in Mechanical Engineering, Industrial Engineering option from Concordia University and has a Diploma in Management from McGill University.