

## Course Outline BMDE-654 Biomed Reg Affairs–Med Devices

### General Information

**Course #:** 654

**Section #:** 001

**Term:** Fall

**Year:** 2017

**Course Schedule:** Monday  
4:05 – 6:55 pm

**Number of credits:** 3

**Location:** Room 321, Duff Medical Building  
3775 University Street  
Montreal, Quebec, H3A 2B4

### Instructor Information

**Name and Title:** Danny Kroo, Quality Management and Regulatory Affairs Consultant

**Email** info@docusys.ca

**Telephone number:** 514-574-9733

**Office Location:** Room 304, Duff Medical Building  
3775 University Street  
Montreal, Quebec, H3A 2B4

### 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.

**Reference Text:**

**Course Content/Outline**

**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 Medical Device Regulations
  - Medical device classification in US and Canada
  - Discussion about projects
- **Week 2 and Week 3:- video**
  - 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 4: video**
  - Health Canada Medical Device Licence and MDEL
  - CE Marking requirements
- **Week 5: video**
  - Post marketing requirements for Canada, US and Europe
    - Complaint reporting, SAE reporting, post approval studies, and annual reports

## Part 2: Quality Assurance

- **Week 6: video**
  - Overview of recognized consensus standards and QMS
  - Requirements for quality systems in different jurisdictions- CMDCAS, MDSAP, FDA, EU
  - UDI
  - ISO 13485:2016 Medical devices requirements-
- **Week 7 and week 8: video**
  - ISO 13485:2016– Medical Devices – Quality risk management systems – Requirements for regulatory purposes- detailed review
- **Week 9: video**
  - ISO 14971:2007 – Medical Devices – Application of risk management to medical devices
- **Week 10: video**
  - IEC 62304:2006 – Medical device software – Software life cycle processes
- **Week 11: not yet defined**
  - IEC60601 series, IEC60601-1 Electrical Safety, and IEC60601-1-2 EMC
  - Design Controls
- **Week 12: video**
  - FDA Quality System Regulations
- **Week 13:**
  - Labelling
  - Process validation
  - Corrective and Preventive Actions (CAPA) process

### Assessment/Evaluation:

Class Quizzes: 30%

Project: 40%

There will be a selection of projects that can be selected that have been submitted by medical device companies.

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. Additionally he is a lead assessor for medical devices for a leading certification body and notified body and is qualified to audit Health Canada and CE Marking requirements.

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