# *Course Syllabus: BMEN 6V87.501, Special Topics in Biomedical Engineering: Medical Device Regulations & Regulatory Strategies*

**Course Information**

**BMEN 6V87.002,** Special Topics in Biomedical Engineering: Medical Device Regulations & Regulatory Strategies

**Term:** Spring 2016

**Days & Times:** Mondays, 7-945pm, SLC 2.304

**Instructor Information**

**Name:** Professor Baduel

**Email:** arb151830@utdallas.edu

**Office Hours:** By appointment only, please schedule an appointment via email.

**Course Pre-requisites, Co-requisites, and/or Other Restrictions**

Graduate student status. No other pre-requisites are required.

**Course Description**

The ever-growing medical device industry has brought with it an onslaught of regulations which continue to increase as the industry itself develops. The main challenge for industry is no longer to merely identify the applicable regulations but to identify the means by which to apply the applicable regulatory framework in order to successfully gain market entry and remain in market.

This course will offer students exposure to the core concepts of the global medical device regulatory framework and provide a foundation for the practical application of the "least burdensome approach". The focus of the course is to aid students in the actual application of the regulations so that students are equipped to not only understand the core concepts embedded within the regulations but also apply them in real world scenarios.

The course will include all elements of the device product lifecycle; from idea to initial market entry, sustaining activities, post-market activities and the subsequent obsolescence of the device. Special focus will be placed upon the Medical Device Regulatory landscapes found in the US, Canada, European Union, Brazil, South Korea, Mexican, Australia, & Japan.

**Student Learning Objectives/Outcomes**

**1.** Identify the Medical Device Regulatory Framework for any given country based upon device type and create potential regulatory pathway strategies to gain market entry.

**2.** Identify and incorporate basic risk management concepts into the Quality Management System and medical device design throughout the medical device product lifecycle.

**3.** Be familiar with the use of harmonized approaches and standards leveraged in device design and Quality Management Systems.

**4.** Understand the post-marketing requirements associated with medical devices and how to communicate with competent authorities when post-market issues arise.

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**Required Reading Materials**

- There are no required books for this course.
- All required reading materials are referenced within the course outline provided below.

**All required materials will be made available to the student during the course at no additional cost to the student.*

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**Assignments & Academic Calendar**

**Homework Assignments:** All homework assignments are indicated in the schedule included below. It is expected that homework assignments are completed prior to the next class session. All materials required for homework assignments are included in the session folders within the e-learning system.

**In-Class Assignment:** There will an in-class assignment completed during a majority of the class sessions. On average there will be one (1) in-class activity per a session. These activities are designed to aid students in understanding real world application of the concepts presented. It is highly encouraged you participate as this is not only a key component of this course but also a part of your class participation grade which is 15% of your grade.

**Quizzes:** There will be a total of two (2) quizzes throughout the semester.

**Exams:** There will be two (2) online exams in total during the semester. The exams are open book and open notes as Regulatory is not a matter of knowing everything but knowing where to look to find the information and understanding how to apply the information. Students must complete the exams on their own. Cheating (i.e. working together to complete an exam or providing one another with the answers to the exam) **will not** be tolerated.

**Projects:** There will be a Group Project. Project teams will be identified and assigned on the first day of class. An outline of the expected deliverables for each project team can be found within the e-learning system in the "Group Project Outline" tab located in the e-learning homepage for this course.

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**Grading Policy:**
**Exams**-Mid-term-25%, Final-25%
**Quizzes**-10% (2 in total, 5% each)
**Group Project**- 25%
**Class Participation**- 15%

| % | 90.0%-100% | 80.0%-89.9% | 70.0%-79.9% | 60.0%-69.9% | ≤59.9 |
|---|---|---|---|---|---|
| **Letter Grade** | **A** | **B** | **C** | **D** | **F** |

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**Course & Instructor Policies**

**Attendance, Absence, Tardiness:** This course will employ expectations similar to those found in the traditional work place.

**Class Attendance:** Class attendance is mandatory since the classroom component of this course is critical. However, you are allowed one (1) absence without penalty. For any additional absences, advance notice for any non-emergency absence to the instructor is expected. Students will lose credit for the day of non-participation in the class activity.

**Quizzes:** No make-up quizzes or exams will be offered if a student is absent for reasons other than an emergency situation.

**Make up exams:** All students are expected to take the exams on the dates posted in the class schedule and as announced by the instructor. Unavoidable conflicts must be communicated to the instructor ahead of time. Missed exams without e-mail notification in advance of the absence will result in a grade of zero (0) for the assignment or test. Exceptions may be made for emergency situations, at the discretion of the instructor.

**Group Presentations**: Group members absent on the day of their group presentation will not be awarded credit for the group presentation. Each team member will be expected to present during the course of the classroom presentation. Team assignments will occur during Session 1 of the course.

**Cell Phones:** The use of cell phones during class while class is in session is prohibited. If you must take a call for an emergency situation or work related issues please step out of the classroom in order to be courteous to your fellow students. Laptops may be used during class sessions if in-class activities dictate the use of one to complete the assignment.

**General Course Outline:**

| Session # | Date | Session Topic | Session Activities | Supplemental Course Materials/ Homework Assignment(s): <u>To be completed prior to following session</u> |
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| **1** | 1/11 | **Intro to Medical Devices & US Medical Device Regulations** | *Review Materials Covered in Module 0 to be completed prior to 1st session*<br><br>**In-Class Activity:**<br>-Pre-assessment<br>-Group Project Team Assignments<br><br>**Topic 1:** Definition of a Medical Device in the US & Medical | 1. Watch the US FDA Introduction to the QSR (1hr, 45 mins)<br><br>(The video can be located here: http://fda.yorkcast.com/webcast/Play/dd2d4823b14a4e4ca6d60eae43c5ac9c)<br><br>2. Read the one (1) page article posted on Emergo's website titled, "Does your medical mobile app |

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| | | | Device Product Lifecycle<br><br>**Topic 2:** History of US FDA Medical Device Regulations & Overview of US Medical Device Regulatory Requirements<br>•History of US FDA Medical Device Regulations<br>•HHS & FDA Organizational Charts, FDA's Role & Authority<br>•Overview of US Medical Device Regulatory Requirements<br><br>**In-Class Activity:** Navigating the US FDA Public Databases | need FDA clearance?"<br><br>This webpage con be located here: http://www.emergogroup.com/resources/united-states/usfda-mobile-medical-app-appendix |
| **N/A** | 1/18 | **Holiday** | **University Closed: MLK Day** | **N/A** |
| **2** | 1/25 | **Intro to International Regulatory Requirements** | •Introduction to International Regulatory Requirements & Device Pathways (Canada, EU)<br>•Introduction to ISO 13485<br>•Integration of country specific regulations into the QMS (Canada, Europe)<br><br>**In-Class Activity:**<br>Identifying specific Regulatory Requirements for Brazil<br><br>**Quiz #1** | Read GHTF/SG3/N15R8, Implementation of risk management principles and activities within a Quality Management System |
| **3** | 2/1 | **Integration of Risk Management** | **Topic 1:** Application of Risk Management throughout product lifecycle<br><br>**Topic 2:** Integration of Risk Management into the supporting QMS | Read FDA Guidance Document Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices |
| **4** | 2/8 | **Intro to Standardized Approaches & Standards** | **Topic 1:** Standardization in the Application of Practices<br>•GHTF & IMDRF Working Groups & Documents<br>•NBOG Working Group & Documents<br>•Authorized Representative Documents<br>•Competent Authority Published Guidance Documents<br>•Use of Codes to Identify Medical Devices<br><br>**Topic 2:** The Use of Standards<br>•Common Product & Systems Standards<br>•FDA Consensus Database<br>•EU Harmonized Standards List | 1. Watch US FDA Standards Resources Video (15 mins): http://fda.yorkcast.com/webcast/Play/f00e6d6a7a0f43398828ac2a815e946d1d<br><br>2. Bring to class the information pulled out of the US FDA Consensus Standards Database as per homework outline provided in the Session 4 folder in the e-learning system<br><br>3.Review the content of US FDA Form 3654 used with 510k submissions |

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| | | | **In-Class Activity:** The search for 10993-1 | |
| **5** | 2/15 | **In-Depth Study: Regulatory Pathways to Market: US Specific** | •Exempt Devices<br>•510(k)<br>•Letter to File (K-97)<br>•513(g)<br>•De Novo<br>•Meetings with FDA<br><br>**In-Class Activity:** Determining the Pathway for a Medical Device | 1. Watch US FDA Third Party Review Program Video (15 mins): http://fda.yorkcast.com/webcast/Play/cace6e43f57d47639911944180eb17b3<br><br>2. Read FDA Guidance Document on Humanitarian Use Device (HUD) Designations (15 pages) |
| **6** | 2/22 | **In-Depth Study: Regulatory Pathways to Market: US Specific (Continued)** | •Custom devices<br>•HUD/HDE<br>•IVD's<br>•Combination products<br>•HCT/P's<br><br>**In-Class Activity (Part 1):** Determining US Market Pathway: Bone Marrow Needles & Bone Marrow Aspiration Needles<br><br>**Exam 1 Prep:** Q&A Session | Review slide presentation, "FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations" |
| **7** | 2/29 | **EXAM 1** | **Exam 1:** Available online from 11pm Monday February 22, 2016 until 11pm Monday, February 29, 2015.<br>(50 questions) | **N/A** |
| **8** | 3/7 | **In-Depth Study: Regulatory Pathways to Market: US Specific (Continued)** | •PMA's (not including HDE's)<br>•IDE's & HDE exemptions<br>•IRB's, Clinical Trials & HUD variances<br>•GCP<br>•GLP<br>•Introduction to FURLS<br><br>**In-class activity:** A walk through the FURLS registration system & public database | 1. Review FDA Slide Presentation, "FDA Device Establishment Registration & Listing"<br><br>2. Complete interactive FURLS Initial Registration Module<br><br>3. Read EU Guidance Document on Product Classification as per the MDD, "EU Guidance Doc 2_4_1_rev_9_classification_en" |
| **N/A** | 3/14 | **Holiday** | **No Class: Spring Break**<br>Monday 3/14-Sat 3/19 | **N/A** |

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| **9** | 3/21 | **Emerging Topics in Regulatory & Device Classification and Regulatory Pathways to Market for EU & Canada** | **Topic 1:** Special/Emerging Topics<br>•Digital Health<br>•Home Use Medical Devices & Design Considerations<br>•Devices Reprocessed in a Healthcare Environments<br><br>**Topic 2:** Regulatory Pathways to Market (EU & Canada)<br>•Device Classification<br>•IVD's<br>•Navigation & Use of Health Canada Device License Database (MDALL)<br>•Notified Body<br>•Authorized Representative<br>•CMDCAS | Read the Emergo Group Whitepaper, "EUROPEAN TECHNICAL FILES FOR CE MARKING OF MEDICAL DEVICES An Overview of the Technical File Preparation Process" (7 pages) |
| **10** | 3/28 | **In-Depth Regulatory Pathways to Market EU & Canada (Continued)** | •Technical Documentation (Technical Files, Design Dossiers, STED Files)<br><br>•Clinical Literature Evaluations & Clinical Evaluation Reports<br><br>**In-Class Exercise (Part 2):** Determining EU & Canadian Market Pathways: Bone Marrow Needles & Bone Marrow Aspiration Needles<br><br>**In-Class Group** Presentation: 1st Team Project Presentation **(Australia)** | Read European Commission, MEDDEV 2.12-1 rev. 8, Guidelines on a Medical Devices Vigilance System |
| **11** | 4/4 | **Post-market Activities & Data Collection** | •The purpose of PM Activities<br>•Post- Market Surveillance<br>•Post-Market Surveillance Studies<br>•Post-Approval Studies<br>•European Vigilance System<br>•Clinical Evaluation Reports<br><br>**In-Class Activities:**<br>1.Review of Post-market data in FDA Databases for Assigned Product Codes<br>2.Clinical Literature (White Paper) Search for Device Assigned<br><br>**In-Class Group** Presentation: 2nd Team Project Presentation **(Mexico)** | Read IMDRF/NCAR WG/N14 FINAL:2015, Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form |

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| **12** | 4/11 | **Post-market Systems** | •Complaints<br>•Adverse Events (including eMDR reporting)<br>•Field Actions<br>•CAPA<br><br>**In-Class Activity:** Deciding when & how to report an adverse event -completing a MedWatch Form & MDV Form for an adverse event<br><br>**In-Class Group** Presentation: 3rd Team Project Presentation **(S. Korea)** | 1. Read European Commission (EC) Field Safety Notice Form<br><br>2. Read European Union (EU) Field Safety Corrective Action Filing Form<br><br>3. Read, US FDA Guidance Document, "Distinguishing Medical Device Recalls from Medical Device Enhancements" |
| **13** | 4/18 | **Post-market Systems (continued)** | •Types of Field Actions<br>•Classification of Field Actions<br>•US, EU, & Canadian Regulatory Requirements & Notification Process<br><br>**In-Class Group** Presentation: 4th Team Project Presentation **(Japan)**<br><br>**In-Class Activity:** Risk Evaluation, deciding when to initiate a field action, & creation of an 806 report | Review Case Study files to prepare for class working session on April 25, 2016, National Medical Device Curriculum Case Study, "Regulatory Pathways for Medical Devices, Choosing the Right One" |
| **14** | 4/25 | **In-Class Project** | •**In-class Case Study:** US National Medical Device Curriculum, "Regulatory Pathways for Medical Devices, Choosing the Right One".<br><br>•**In-class Case Study (Expanded):** "Regulatory Pathways for Medical Devices, Choosing the Right One", EU, Canada, & Australia<br><br>•**Post-Assessment**<br><br>•**Exam 2 Prep:** Q&A Session | Exam 2 Preparation |
| **15** | 5/3-5/9 | **EXAM 2** | **Exam 2:** Available online from 11pm Tuesday, May 3, 2016 until 11pm Monday, May 9, 2015.<br>(50 questions, non-cumulative) | **N/A** |
| **N/A** | 5/10 | **Grades Avail.** | **Final Grades Available Online** | **N/A** |

**Comet Creed**

*This creed was voted on by the UT Dallas student body in 2014. It is a standard that Comets choose to live by and encourage others to do the same:*

"As a Comet, I pledge honesty, integrity, and service in all that I do."

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**UT Dallas Syllabus Policies and Procedures**

The information contained in the following link constitutes the University's policies and procedures segment of the course syllabus.

Please go to http://go.utdallas.edu/syllabus-policies for these policies.

***The descriptions and timelines contained in this syllabus are subject to change at the discretion of the Professor.***