BIOE 598 RI – Regulatory and Safety Issues in Bioengineering

**Course description**: Overview of regulatory agencies involved in approval of medical products. Approaches to safety and risk analysis for medical products. Students will learn from case studies of medical product approvals and perform risk analysis for medical products.

This course provides an overview of regulatory agencies involved in approval of medical products. We explore approaches to safety and risk analysis for medical products. Students will engage in class discussions about regulatory and safety issues as well as learn from case studies of medical product approvals. In order to be successful in this class, you will need to

* Attend lecture and/or review lecture materials on your own
* Read assigned papers and regulatory documents to gain a deeper understanding of concepts explained in lecture
* Attend discussion sessions ready to engage and discuss with classmates

**Learning Objectives**:

Students will be able to

* Articulate the unique challenges of medical product approval versus other engineering products
* Read and understand medical regulation guidance and documentation from regulatory agencies
* Identify classification of medical devices in US and EU context
* Identify pathways for medical device approval in US and EU
* Perform risk analysis for medical products
* Apply Six Sigma Analysis to perform verification testing
* Combine knowledge into a project

**Detailed Learning Objectives**

Intro to Regulatory Agencies

* Articulate the unique challenges of medical product approval versus other engineering products
* Read and understand medical regulation guidance and documentation from regulatory agencies
* Identify classification of medical devices in US and EU context
* Identify pathways for medical device approval in US and EU

Intro to Safety for Medical Devices to

* Perform risk analysis for medical products
* Identify standards for use in testing protocols
* Describe the difference between verification and validation activities in medical product testing

Intro to Quality Control and Testing

* Define variables for a system and bounds for performance
* Read process diagrams to identify areas for improvement
* Apply Six Sigma Analysis to perform verification testing

**Course Schedule**

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| --- | --- | --- | --- | --- | --- | --- |
| Week | Date | Lecture Topic | Date | Discussion Topic | Assignment | Due |
| 1 | 1/16/24 | Overview of Course and Regulatory Agencies background | 1/18/24 | Discussion 1 | None |  |
| 2 | 1/23/24 | Classifications, documentation, and process to market | 1/25/24 | Discussion 2 | Classification & FDA Documentation Assignment | 1/29/24 |
| 3 | 1/30/24 | US and EU Regulatory Bodies for Devices and Drugs | 2/1/24 | Case Study I | Case Study I Report | 2/5/24 |
| 4 | 2/6/24 | PostProduction: Product Lifecycle, Packaging, Labeling, and Marketing | 2/8/24 | Discussion 3 | Labeling Assignment | 2/12/24 |
| 5 | 2/13/24 | Software as a Medical Device | 2/15/24 | Case Study II | Case Study II Report | 2/19/24 |
| 6 | 2/20/24 | Combination and Custom Products | 2/22/24 | Discussion 4 | Medical Mobile Apps | 2/26/24 |
| 7 | 2/27/24 | Risk Management and Safety Through Standards | 2/29/24 | Case Study III | Case Study III Report | 3/4/24 |
| 8 | 3/5/24 | Safety Using Failure Mode Effect Analysis | 3/7/24 | Discussion 5 | None | 3/11/24 |
| 9 | 3/12/24 | Spring Break | 3/14/24 | Spring Break | None |  |
| 10 | 3/19/24 | Good Manufacturing Practices and Testing Design Protocols | 3/21/24 | Discussion 6 | FMEA Assignment | 3/25/24 |
| 11 | 3/26/24 | Statistical Control Processes | 3/28/24 | Discussion 7 | Six Sigma Worksheet I | 4/1/24 |
| 12 | 4/2/24 | FDA Approval Process and Checks and Balances at the FDA | 4/4/24 | Mock Panel | None | 4/8/24 |
| 13 | 4/9/24 | Design of Experiments | 4/11/24 | Case Study IV | Case Study IV Report | 4/15/24 |
| 14 | 4/16/24 | Clinical Trials, Project Overview & Teaming | 4/18/24 | Project Work Day Consultations | Progress report, Six Sigma Worksheet II | 4/22/24 |
| 15 | 4/23/24 | Ethics in Medical Devices | 4/25/24 | Project Work Day Consultations | Progress report | 4/29/24 |
| 16 | 4/30/24 | Presentations - FDA Panel and Reading Day |  | Final report and presentation |  |

**Assessments**

Assignments – short answer and calculations related to course content: FDA and CE homework, FMEA Homework, and (2) Six Sigma Worksheets

Quizzes – (3) online quizzes related to course content: FDA quiz, Safety Quiz, Six Sigma Quiz

In-class Discussions (9) in-class discussions with deliverables

Case Study summary – individual case write-up with case summary and findings

Team Project – FDA Panel report and presentation summarizing product recommendations including Team Progress Reports, presentation, and report

**Grading**

Assignments and Quizzes (6) 450 pts

In-class Discussion Assignments (7) 208 pts

Case Study Summaries (4) 252 pts

Team Project (1) – Team Progress Reports (2) 20 pts, presentation 80 pts, and report (100 pts)

**Graduate Level Content**

Students in the 598 RI section will have additional assignments to fulfill graduate requirements and the extra hour of credit.

* Students will present snapshots of a product or drug
* Students will prepare a case study related to their in class snapshot presentation

Graduate Snapshots: Present 1 slide with regulatory information about a medical product of interest to you. Answer the following questions:

* Name, manufacturer, description of product
* What is the intended use of the product/drug?
* What classification is the product/drug?
* Any other fun facts or information to share?

I will assign these to start after week 2 and they will be presented in the first 5 minutes of class on the assigned day.

Graduate Case Study Reports: Submission should consist of a slide deck, a completed case study template, and any support documents needed for the case. Each case study should include

1. **Real-World Scenario.** Cases are generally based on real-world situations, although some facts may be changed to simplify the scenario, provide confidentiality, or maintain the learning environment.
2. **Supporting Data and Documents.** Effective case assignments typically provide real world situations for student to analyze. These can be simple data tables, links to URLs, quoted statements or testimony, supporting documents, images, video, audio, or any appropriate material.
3. **Open-Ended Problem.** Most case assignments require students to answer an open-ended question or develop a solution to an open-ended problem with multiple potential solutions. Requirements can range from a proposed action plan, discussion, calculation, or decision.

**Disability Statement and Resources**

To obtain disability-related academic adjustments and/or auxiliary aids, students with disabilities must contact the course instructor and the Disability Resources and Educational Services (DRES) as soon as possible. To contact DRES, you may visit 1207 S. Oak St., Champaign, call 333-4603, e-mail disability@illinois.edu or go to the DRES website. If you are concerned you have a disability-related condition that is impacting your academic progress, there are academic screening appointments available on campus that can help diagnosis a previously undiagnosed disability by visiting the DRES website and selecting “Sign-Up for an Academic Screening” at the bottom of the page.

If you are interested in obtaining information to improve writing, study skills, time management or organization, the following campus resources are available to all students:

Writer’s Workshop, http://www.cws.illinois.edu/workshop

https://www.disability.illinois.edu/strategies

http://www.counselingcenter.illinois.edu/self-help-brochures/

Also, most college offices and academic deans provide academic skills support and assistance for academically related and personal problems. Links to the appropriate college contact can be found by going to this website and selecting your college or school: http://illinois.edu/colleges/colleges.html

If you are experiencing symptoms of anxiety or depression or are feeling overwhelmed, stressed, or in crisis, you can seek help through the following campus resources:

Counseling Center, 206 Fred H. Turner Student Services Building, 7:50 a.m.-5:00 p.m., Monday through Friday Phone: 333-3704

McKinley Mental Health, 313 McKinley Health Center, 8:00 a.m.-5:00 p.m., Monday through Friday Phone: 333-2705

McKinley Health Education offers individual consultations for students interested in learning relaxation and other stress/time management skills, call 333-2714.

**Diversity, Equity, and Inclusion Statement**

It is my intent that students from all diverse backgrounds and perspectives be well-served by this course, that students' learning needs be addressed both in and out of class, and that the diversity that the students bring to this class be viewed as a resource, strength and benefit. It is my intent to present materials and activities that are respectful of diversity: gender identity, sexuality, disability, age, socioeconomic status, ethnicity, race, nationality, religion, and culture. Your suggestions are encouraged and appreciated. Please let me know ways to improve the effectiveness of the course for you personally, or for other students or student groups.

Important note: Given the sensitive and challenging nature of the material discussed in class, it is imperative that there be an atmosphere of trust and safety in the classroom. I will attempt to foster an environment in which each class member is able to hear and respect each other. It is critical that each class member show respect for all worldviews expressed in class. It is expected that some of the material in this course may evoke strong emotions, please be respectful of others' emotions and be mindful of your own. Please let me know if something said or done in the classroom, by either myself or other students, is particularly troubling or causes discomfort or offense. While our intention may not be to cause discomfort or offense, the impact of what happens throughout the course is not to be ignored and is something that I consider to be very important and deserving of attention. If and when this occurs, there are several ways to alleviate some of the discomfort or hurt you may experience:

Discuss the situation privately with me. I am always open to listening to students' experiences, and want to work with students to find acceptable ways to process and address the issue.

Discuss the situation with the class. Chances are there is at least one other student in the class who had a similar response to the material. Discussion enhances the ability for all class participants to have a fuller understanding of context and impact of course material and class discussions.

Notify me of the issue through another source such as your academic advisor, a trusted faculty member, or a peer. If for any reason you do not feel comfortable discussing the issue directly with me, I encourage you to seek out another, more comfortable avenue to address the issue.

**Academic Integrity**

The University of Illinois at Urbana-Champaign Student Code should also be considered as a part of this syllabus.

Academic dishonesty may result in a failing grade. Every student is expected to review and abide by the Academic Integrity Policy. Students should pay particular attention to Article 1, Part 4: Academic Integrity. Read the Code at the following URL: http://studentcode.illinois.edu/.

The Grainger College of Engineering uses the FAIR system to document and track academic integrity violations across courses. Multiple violations, even across multiple units, may be cause for dismissal. Ignorance is not an excuse for any academic dishonesty. It is your responsibility to read this policy to avoid any misunderstanding. Educate yourself on all policies here: https://provost.illinois.edu/policies/policies/academic-integrity/students-quick-reference-guide-to-academic-integrity/

Do not hesitate to ask the instructor(s) if you are ever in doubt about what constitutes plagiarism, cheating, or any other breach of academic integrity.