PURDUE ENGINEERING

WELDON SCHOOL OF
BIOMEDICAL ENGINEERING

BME 595: Quality Systems for Regulatory Compliance

(3 credits, Summer, 2019)

Course Description:
Medical devices are developed and manufactured in a highly regulated environment. This course will provide a basic introduction, overview, and systematic study of the intent and impact of the major federal laws and regulations governing the development, manufacturing, distribution, and marketing of medical devices. Focus is on understanding the critical elements of quality systems and quality compliance from a risk analysis perspective. Instruction in regulatory science of quality systems and compliance is provided by academics, FDA, and industry representatives with expertise in their fields. This course is part of a three-course series which will be introduced in class.
This course will be delivered entirely on-line through learning modules and video conferenced Q&A.

Key topics covered:

- Intent and impact of the major federal laws and regulations governing the development, manufacturing, distribution, and marketing of medical devices
- 21 CFR Part 820 Quality Systems Regulation of the FDA
- Critical elements of regulatory science and use of quality systems for compliance from a design control perspective
- Important roles of a quality systems manager and members of the team
- Benefit / risk analysis and management as a foundation for decision making

Time/Location: This course will meet completely online. All of the lecture content is pre-recorded. Instructors will be available weekly for an online discussion session on Wednesdays at a time that is determined when the most students might be able to join by video conferencing, however these sessions will be recorded and posted for those who cannot participate live. Learning activities are asynchronous, so you will be able to read, watch videos, or post in the online learning environment during times that are convenient to your schedule and that meet the deadlines set in the course. The course is facilitated by Professor Andrew Brightman.

Dates: Mod 2 & 3 of Purdue 2019 Summer Session starting June 10 and ending August 2.

Prerequisites: No prerequisite courses required. Students enrolling in this course should be either Engineering undergraduates or have graduate student classification.

Course Instructor(s):
Andrew O. Brightman, Associate Professor of Engineering Practice, Assistant Head**,** Weldon School of BME. Contact info: aob@purdue.edu

Additional Guest Instructors from multiple industries and roles will contribute content expertise.

Office Hours: Optional online open discussions (see course schedule); additional individual meetings can be scheduled by email or phone by appointment.

Required Texts: None.
However, the book: "The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices" (2008) by A. Daniel and E. Kimmelman, Second Edition ASQC Quality Press Milwaukee, WI, has been used previously and will likely be referenced during the course. The book is now over ten years old and thus some aspects are out of date. We will be using primarily the most current FDA materials accessible online at the FDA website. If you'd like to refer to this book you can access it online using your Purdue career account and password in Knovel. https://app-knovel-com.ezproxy.lib.purdue.edu/web/ Additional class reading documents to be provided via Blackboard Learn.

We will also make use of the current code of federal regulations: "21 CFR Part 820 Quality System Regulation | Good Manufacturing Practice for Medical Devices" which can be accessed on line here. – A copy of this reference booklet is online and a link is provided in the schedule of topics and assignments.

We will also make use of references to the ISO 13485 standard. More about this can be found at: https://www.iso.org/iso-13485-medical-devices.html

Learning Outcomes: At the end of the course, a student who has mastered the course material should be able to:

- Demonstrate understanding of how the FDA approaches quality systems and controls
- Demonstrate a functional understanding of the components of an integrated quality system for regulatory compliance for biomedical devices
- Demonstrate practical understanding of the main tools within the quality craft (Ex: Control documents, CAPA, quality systems records, benefit-risk assessments, statistical techniques)
- Demonstrate practical understanding of ethics and compliance issues related to medical device development and manufacturing.

Assessment: Grading is based on submission of a video bio (5%); discussion/quiz question submission (20%), online *quizzes* (20%); mid-term exam (20%); reflection paper (15%); and final exam (20%).

Video Bio: Create your 1-2 minute bio on video and upload to the online learning environment in Blackboard Learn. Instructions for creating and posting your video will be in BBL.

Writing Test Questions:
You will have several opportunities to submit a multiple choice test question about sections of the course content. A dropbox in the online learning environment will be provided for this purpose. These student-written questions will be used for discussion sessions and included along with instructor questions and questions from previous class offerings in the online assessments (quizzes or exams). Written questions will be due on Tuesdays.

Quizzes, Mid-term and Final Exam:
Quizzes assessing understanding of content from all previous course materials will be held online in Blackboard Learn (no need for a proctor), and will be in a 30-minute format. Mid-term and final exam, also taken online in Blackboard Learn, will include review questions from previous quizzes plus additional questions on integration of knowledge, in a 60-minute format. Quizzes will become available on Thursdays (typically noon) and should be completed within 48 hours.

Reflection Paper:
The format for the 3-page paper will be described in more detail in the course content on BlackBoard Learn.

Each assignment is worth a point value and total accumulated points will determine the course grade.

Grading scale:
90-100% A
80-89% B
70-79% C
60-69% D
0-59% F

Policy on academic honesty:
The commitment of the acts of cheating, lying, stealing, and deceit in any of their diverse forms (such as the use of ghostwritten papers, the use of substitutes for taking examinations, the use of illegal cribs, plagiarism, and copying during examinations) is dishonest and not tolerated. Moreover, knowingly to aid and abet, directly or indirectly, other parties in committing dishonest acts is in itself dishonest.

Emergency statement:
In the event of a major campus emergency, course requirements, deadlines and grading percentages are subject to changes that may be necessitated by a revised semester calendar or other circumstances.

Adaptive programs statement:
Students with disabilities must be registered with Adaptive Programs in the Office of the Dean of Students before classroom accommodations can be provided. If you are eligible for academic accommodations because you have a documented disability that will impact your work in this class, please schedule an appointment with the instructor as soon as possible to discuss your needs.