BME 595: Quality Systems for Regulatory Compliance
(3 credits, Summer)

Course Description:
Medical devices are developed and manufactured in a highly regulated environment. This course will provide an 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 regulatory science and quality compliance from a design control perspective. Instruction and mentoring in regulatory science skills is provided by academics and industry representatives with expertise in their fields. This course is part of a three-course series.

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
- Introduction of CAPAs and data collection for a CAPA
- Risk management as a foundation for decision making

Time/Location: This course, although separated into on-campus and distance sections, will meet completely online. This means that the students in the on-campus section should not be attending in the classroom in the prescribed times of M-W-F, 3:30 pm - 5:20 pm, Wang Hall. Instructors will not be in the class at that time as the lecture content is being pre-recorded. 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 Summer Session starting June 12, 2017

Prerequisites: none
Course Coordinator:
Andrew Brightman, Assistant Head, Weldon School of BME
Contact info: (765) 496-3537, aob@purdue.edu

Office Hours: Optional online chat sessions in Blackboard Learn or other digital platforms; office hours via phone or email by appointment

Required Texts:
"The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices" by A. Daniel and E. Kimmelman, Second Edition. ASQC Quality Press Milwaukee, WI. If you’d prefer to access this book online, you can use your Purdue career account and password to access the book in Knovel. (Additional class reading documents to be provided via Blackboard Learn.)

“21 CFR Part 820 Quality System Regulation | Good Manufacturing Practice for Medical Devices” by Food & Drug Administration, Revised as of April 1, 2016 – A copy of this reference booklet is online and a link is provided in the schedule of topics and assignments.

Recommended Text for Reference (now out of print but used copies available):
“Quality Planning and Analysis” by Frank M. Gryna, Fourth edition.

Learning Outcomes: A student who successfully fulfills the course requirements will be able to ...

- Demonstrate a functional understanding of regulatory compliance for biomedical devices.
- Use the main tools within the quality craft (Ex: confidence interval, control chart, difference between a T-test and F-test)
- Demonstrate understanding of how the FDA approaches control.

Learning Strategies: The course employs the learning strategies of reading, writing and discussing.

Assessment: Grading is based on submission of a video bio (10%); discussion question submission (15%), online quizzes (15%); mid-term exams (20%); reflection paper (20%); and exam (20%).

Video Bio: Create your 1-2 minute bio on video and upload to the online learning environment in Blackboard Learn. See instructions in online environment.

Writing a Test Question and Submitting a Webinar Question:
You will have opportunity to select a section of the course content during first week and then write and submit a multiple choice test question about that section of the content. You will also be asked to submit a question to be addressed during one of the webinars. A dropbox in the online learning environment will be provided for this purpose. You may see some of the student-written questions in one or more of the assessments (quizzes or exams).
**Quizzes, Mid-term and Final Exam:**
Quizzes, taken online in Blackboard Learn (no need for a proctor) cover, 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.

**Reflection Paper:**
The format for the 3 to 4-page paper will be described in more detail in the course content. You can also find notes about it at the end of the Schedule/Assignments document.

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.