BME 59500 Regulatory Approval for Biomedical Devices (Spring 2015)

SYLLABUS
BME 59500 – Regulatory Issues Surrounding Approval of Biomedical Devices

Course Description:
Medical devices are developed, manufactured, and distributed in a highly regulated environment. This course primarily concerns the processes for obtaining FDA marketing approval or clearance for biomedical devices. Prior to marketing a medical device in the US, a specific governmental approval or clearance is required depending on the type of device and the risk associated with the device. This course is part of a three-course series dealing with various aspects of regulatory science.

Regulatory processes for class I, II, and III devices, including combination devices, are covered with specific focus on 510(k) and PMA requirements. Approval requirements in the EU, Japan and other countries will also be briefly considered. Throughout the course, emphasis will be placed on regulatory science, regulatory strategy and principles of interacting with regulatory agencies.

Time / On-Campus Location: Tuesdays, 3:00 pm – 5:50 pm, MJIS 1083 (Short break at 4:15 pm for on-campus students)

Time / Distance Course Availability: Course is asynchronous for the students enrolled at a distance. Lecture recordings are typically available to the distance students about 24 hours after being delivered live in the classroom. Course includes weekly assignments and a schedule that needs to be adhered to closely. The recorded lectures and the course materials in the online learning environment, Blackboard Learn, remain available until the end of the semester.

Learning Management System: Course materials, links and discussion forum will be in the online LMS, Blackboard Learn. The LMS is accessible by on-campus and distance students.

Prerequisites: None

Course Coordinators:

- **Vickie Maris, MS Ed,** Graduate Programs Director, Weldon School of BME
  Contact info: (765) 494-2982 (office line); vjmaris@purdue.edu
- **Daniel Dillon**, **MS, RAC,** Regulatory Scientist, MED Institute, Inc.
  Contact info: ddillon@medinst.com
- TA/Quizzes, Group Assignments, Deadlines - **Carolina Vivas-Valencia, Graduate Student,** Weldon School of BME
  Contact Info: cvivas@purdue.edu
  Office Hours: By email/appointment – MJIS 1086
- TA/Assignment Grading, Blackboard Learn Questions – **Ryan Dorton, Graduate Assistant,** Krannert School of Management
  Contact Info: rdorton@purdue.edu
  Office Hours: By email/appointment – MJIS office location TBD

Required Texts: No required text. Informational class handouts, links to assigned reading and in some cases, prerecorded lectures will be provided.

Course Topics: This course introduces students to both an overview and the specifics of regulatory science with respect to marketing medical devices, including:

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- FDA regulatory classification
- 510(k) and PMA regulations, content, strategies, and processes
- Labeling and claim language;
- Regulation of combination devices and pediatric devices;
- HDE and HUD approvals;
- Standard Technical Documents (STeDs) and Clinical Evidence Reports (CERs);
- Product approval regulations outside the US; and
- Post-approval requirements (e.g., filing decisions, annual reports)

Learning Outcomes: A student who successfully fulfills the course requirements will have demonstrated a functional understanding of regulatory approval and clearance processes for biomedical devices. The following specific learning outcomes will direct the course:

1) Students will have knowledge of, and be able to differentiate between, the regulatory pathways for medical devices;
2) Students will understand the significance of the specific format and contents of both 510(k) and PMA submissions, and be able to identify major discrepancies in poorly written documents.
3) Students will have an awareness of the relationship between a medical device company and the various regulatory bodies (e.g. FDA in US), and be able to select appropriate methods and messages for a variety of situations requiring clear yet sensitive communication during the regulatory process.
4) Students will have knowledge of how regulatory science forms the basis for effective decision-making by manufacturers and regulators.

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

Assessments: Grading is based on a biography assignment and participation (5%); online quizzes (25%) covering reading assignments, lectures, and previous class discussions; several writing assignments (32.5%), and team projects (37.5%). Each assessment is worth a point value and total accumulated points will determine the course grade.

Quizzes: Quizzes are in an online format. In the week a quiz occurs, it will be accessible by noon (EST) on Thursday and is to be completed by noon (EST) on the following Monday. Once the quiz attempt is started, a student has 30 minutes to complete it.

Class Participation/Online Threaded Discussion: This course has on-campus and at-a-distance (online) sections which have been merged into one online course environment in Blackboard Learn. The participation grade has two components. The first component is the completion and submission of the class biography assignment, which is valued at 5 points. The second component involves each student submitting one quiz question in the appropriate weeks of the course – complete with a question and the possible responses/answers.

Writing Assignments: The writing assignments in the course are part of the team project. The individual point values for the writing assignments can be found in the course calendar and grading scheme within this syllabus.

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Team Project: The project deliverables of each team are worth pre-determined point values, and are due at specific milestone points during the semester (see course calendar). Each team project will be presented on one of two dates that will be announced early in the semester. Teams can request the date that works best for the team members. If neither of the two dates work for a team, a special accommodation would need to be requested early in the semester for a different arrangement for the presentation.

Each team presents once. Teams work together on previously submitted written assignments, on the preparation and delivery of the presentation, and on the document that is submitted as a team.

Options for the various media available for making the presentations will be presented early in the semester. It is up to each individual team to select the option that works best for their team presentation and to notify the instructor of their selection by the due date.

Formation of the Teams: Specifics will be outlined at the beginning of the course and groups that include both on-campus and distance students will be formed by the instructors. A tentative list of team members will be posted in the online course environment and students will be given a couple of days to request a change to a different team.

A team will be formed in a way so that research lab mates (among the in-classroom students) or coworkers (among the distance students) will not be on the same teams if at all possible.

Grading Scheme:

Assignment	Points
Biography assignment and class participation (Week of Jan. 12)	5
Writing Assignment – Test Report Summary (Week of Jan. 19)	10
Writing Assignment – Device Description (Week of Jan. 26)	20
Submit Quiz Question – Labeling	5
Quiz 1 – Labeling (Week of Feb. 2)	5
Writing Assignment – 510(k) Testing Assessment (Week of Feb. 9)	30
Writing Assignment – 510(k) Substantial Equivalence Rationale (Week of Feb. 16)	30
Submit Quiz Question – PMA Regulations	5
Quiz – PMA Regulations	25
Writing Assignment – 510(k) Submission – complete (Week of March 2)	30*
Submit Quiz Question – Guidances	5

Quiz – Guidances (Week of March 9)	10
PMA Panel Document (Week of March 23)	50*
PMA Panel Presentation (Week of March 23; Class Session on March 24)	70*
PMA Response to Panel Requests (Week of April 6)	20
Writing Assignment – CER (Clinical Evidence Report; Week of April 13)	20
Quiz – Combination Product (Week of April 20)	20
Quiz – Classification of Devices Outside US (Week of April 27)	20
Quiz – Submit or Not Submit - regulatory decision process (Week of April 27)	20
Total	400

Grading

Total Points Available: 400 points

Scale:

A+ = (>96%)
A = (>92%)
A- = (>89%)
B+ = (>86%)
B = (>82%)
B - = (>79%)
C+ = (>76%)
C = (>72%)
C- = (>69%)
D = (>60%)
F = (below 59%)

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Class Lecture Date	**Class**	**Main Topic**	**Instructors** *(Guest instructors subject to change in any given semester)*	**Assignment(s) Due***	**Point Value of Assessment**
Jan. 13	1	**Overview of Approval Processes; Regulatory Science**	**Bill Voorhees / Dan Dillon**	Bio Assignment – a short survey in Qualtrics (link in Blackboard Learn); Assignment due by Monday, Jan. 19 at midnight EST.	**5**
Jan. 20	2	**510(k) Session I**	**Dan Dillon**	Test Report Summary –	10
Jan. 27	3	**Labeling and Claims Language**	**Video**	Device Description Submit Quiz Question – Labeling	20 5
Feb. 3	4	**510(k) Session II**	**Dan Dillon**	Labeling Quiz	5
Feb. 10	5	**PMA Preparation / Submission I** Regulations / Content	**Neal Fearnot**	510(k) Testing Assessment	30
Feb. 17	6	**510(k) Session III**	**Dan Dillon**	510(k) Substantial Equivalence Rationale Submit Quiz Question – PMA Regulations	30 5
Feb. 24	7	**PMA Preparation / Submission II** Review of Specific Guidances	**Scott Williams**	PMA Regulations Quiz	25
Mar. 3	8	**PMA Preparation / Submission III** Strategies and Process	**Neal Fearnot**	510(k) Submission Submit Quiz Question – Guidances (PMA Panel Document assigned)	30 5
Mar. 10	9	**PMA Preparation / Submission IV** Preparations for Panel Meeting	**Neal Fearnot**	Guidances Quiz	10
Mar. 17		**NO Class – Spring Break Week**			
Mar. 24	10	**Panel Meeting, Team Project Presentations****	**All Instructors as Evaluators**	Submit PMA Panel Document Team Presentation	50 70
Mar. 31	11	**Panel Meeting, Team Project Presentations****	**All Instructors as Evaluators**		See above
Apr. 7	12	**Regulations in Japan/ STED & CERs**	**Lori Nolte, Miki Ishida, and Jennifer Brown**	PMA response to panel requests	20
Apr. 14	13	**Combination Devices / HDE / HUD / Pediatrics**	**Bill Voorhees**	Submit CER (Clinical Evidence Report)	20
Apr. 21	14	**Regulations in EU,**	**Amanda**	Combination Product Quiz	20

		Canada, and Other Regions	**Schoolcraft**		
Apr. 28	15	**PMA Supplements / Annual Reports; 510(k) Letters to File; Review and Final Discussion**	**Dan Dillon / Neal Fearnot**	None	
Final Exam Week				Classification of Devices Outside U.S. Quiz Submit or not submit Quiz (Both due last day of Finals; May 2)	20 20

Assignments are always due 7:00 pm EST, on the Monday before the scheduled class lecture, unless otherwise noted above.

***** Team project presentation times are in EST time zone.***