Engineering Faculty Document No. 23-18
October 26, 2017

TO: The Faculty of the College of Engineering

FROM: The Faculty of the Weldon School of Biomedical Engineering

RE: New Graduate Course, BME 56200, Regulatory Issues Surrounding Approval of Biomedical Devices

The faculty of the School of Biomedical Engineering has approved the following new course. This action is now submitted to the Engineering Faculty with a recommendation for approval.

BME 56200 Regulatory Issues Surrounding Approval of Biomedical Devices
Terms offered: Spring, Lecture 3, Cr. 3
Prerequisite: N/A

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.

Reason: This course is part of a three-course series and includes both an overview and the specifics of regulatory science with respect to marketing medical devices

This course will fulfill requirements for our professional master's degree and will be listed as recommended courses for our grad tracks for students interested in careers in industry and global health.

George R. Wodicka

George R. Wodicka
Dane A. Miller Head and Professor
Weldon School of Biomedical Engineering

Office of the Registrar
FORM 40G REV. 1/17

PURDUE UNIVERSITY
REQUEST FOR ADDITION, EXPIRATION, OR REVISION OF A GRADUATE COURSE (50000-60000 LEVEL)

PRINT

DEPARTMENT: Biomedical Engineering EFFECTIVE SESSION: Summer 2018

INSTRUCTIONS: Please check the items below which describe the purpose of this request.

- [x] 1. New course with supporting documents (complete proposal form)
- [ ] 2. Add existing course offered at another campus
- [ ] 3. Expiration of a course
- [ ] 4. Change in course number
- [ ] 5. Change in course title
- [ ] 6. Change in course credit/type
- [ ] 7. Change in course attributes
- [ ] 8. Change in instructional hours
- [ ] 9. Change in course description
- [ ] 10. Change in course requisites
- [ ] 11. Change in semesters offered
- [ ] 12. Transfer from one department to another

PROPOSED:		EXISTING:	
Subject Abbreviation	BME	Subject Abbreviation	
Course Number	56200	Course Number	

Long Title: Regulatory Issues Surrounding Approval of Biomedical Devices

Short Title: Regulatory Approval
Abbreviated title will be entered by the Office of the Registrar if omitted. (30 CHARACTERS ONLY)

TERMS OFFERED (Check All That Apply)
- [ ] Fall
- [x] Spring
- [ ] Summer

CAMPUS(ES) INVOLVED
- [ ] Calumet
- [x] Cont Ed
- [ ] Ft. Wayne
- [ ] Indianapolis
- [ ] N. Central
- [ ] Tech Statewide
- [x] W. Lafayette

CREDIT TYPE
1. Fixed Credit: Cr. Hrs. 3
2. Variable Credit Range:
   Minimum Cr. Hrs
   (Check One) To [ ] Or [ ]
   Maximum Cr. Hrs
3. Equivalent Credit: Yes [ ] No [ ]
4. Thesis Credit: Yes [ ] No [ ]

COURSE ATTRIBUTES: Check All That Apply
1. Pass/Not Pass Only [ ]
2. Satisfactory/Unsatisfactory Only [ ]
3. Repeatable [x]
   Maximum Repeatable Credit: [ ]
4. Credit by Examination [ ]
5. Fees [ ] Coop [ ] Lab [ ] Rate Request [ ]
   Include comment to explain fee
6. Registration Approval Type
   Department [ ] Instructor [ ]
7. Variable Title [ ]
8. Honors [ ]
9. Full Time Privilege [ ]
10. Off Campus Experience [ ]

Schedule Type	Minutes Per Mtg	Meetings Per Week	Weeks Offered	% of Credit Allocated
Lecture	150	1	16	
Recitation				
Presentation				
Laboratory				
Lab Prep				
Studio				
Distance				
Clinic				
Experiential				
Research				
Ind. Study				
Pract/Observ				

Cross-Listed Courses

COURSE DESCRIPTION (INCLUDE REQUISITES/RESTRICTIONS): (Note: If description will not fit in space provided, please create a separate document and attach to this form.)

Attached

*COURSE LEARNING OUTCOMES: (Note: If course learning outcomes will not fit in space provided, please create a separate document and attach it to this form.)

Attached

Calumet Department Head	Date	Calumet School Dean	Date	Calumet Director of Graduate Studies	Date
Fort Wayne Department Head	Date	Fort Wayne School Dean	Date	Fort Wayne Director of Graduate Studies	Date
Indianapolis Department Head	Date	Indianapolis School Dean	Date	IUPUI Associate Dean for Graduate Education	Date
North Central Department Head	Date	North Central School Dean	Date	North Central Director of Graduate Studies	Date
George R. Wodicka 11/17/17					
West Lafayette Department Head	Date	West Lafayette College/School Dean	Date	Date Approved by Graduate Council	Date
Graduate Area Committee Convener	Date	Graduate Dean	Date	Graduate Council Secretary	Date
				West Lafayette Registrar	Date

OFFICE OF THE REGISTRAR

Form 40G Course Description and Learning Outcomes for BME 56200

Course Description:

Prerequisite: Not Applicable

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.

Course Learning Outcomes:

1) Students will be able to choose the appropriate regulatory classification and pathway for any medical device in the U.S.
2) Students will be able to describe the significance of each major component of a 510(k) submission.
3) Students will be able to describe the significance of each major component of a PMA submission.
4) Students will develop awareness for the need to seek country-specific expertise to prepare submissions for countries outside the U.S.
5) Students will be able to select the appropriate messages and clearly present, in both oral and written communication, at an FDA meeting.
6) Students will be able to identify contents of a CER and know the strategy for writing a CER.

Detailed Graduate Course Proposal for Academic Review

To: Purdue University Graduate Council

From: Faculty Member: Andrew Brightman
Department: BME
Campus: PWL

Date: **6/8/2017**

Subject: Proposal for New Graduate Course

Contact for information if questions arise:
Name: Tammy Siemers
Phone: 60294
Email: tsiemers@purdue.edu
Address: MJIS 1021

Course Number: BME 56200
Course Title: Regulatory Issues Surrounding Approval of Biomedical Devices
Short Title: Regulatory Approval

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.

A. Justification for the Course

Justification of the need for the course

This course is part of a three-course series and includes both an overview and the specifics of regulatory science with respect to marketing medical devices, including:

- 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

This course will fulfill requirements for our professional masters, MSE concentration and industry and global health grad tracks.

Justification that course will be taught at a graduate level

Students will be asked to investigate a product and submit a proposal for FDA approval in front of a mock panel. Students will need to keep up with current rules and regulation as well as research gold standards and current research being done in their area. This will all be assessed by the Mock FDA panel which will be made up of industrial professionals currently working in regulatory affairs.

Justification of the demand for the course

- Anticipated enrollment
  - Undergraduate 10
  - Graduate 15

Justification for online delivery

This course will also be offered online as it fulfills requirements for the Biomedical Concentration for the MSE degree offered through Engineering Professional Education and the Biomedical Device Design professional master's available through the Weldon School of Biomedical Engineering. The EPE degree is for working professionals and needs to be taught online where the professional master's degree requires students to take courses while on internship.

B. Learning Outcomes and Methods of Assessment

1) Choose the appropriate regulatory classification and pathway for any medical device in the U.S.
2) Describe the significance of each major component of a 510(k) submission.
3) Describe the significance of each major component of a PMA submission.
4) Develop awareness for the need to seek country-specific expertise to prepare submissions for countries outside the U.S.
5) Select the appropriate messages and clearly present, in both oral and written communication, in a mock FDA meeting.
6) Identify contents of a CER and know the strategy for writing a CER.

Learning Outcomes	Assessment Methods
1) Choose the appropriate regulatory classification and pathway for any medical device in the U.S. 2) Describe the significance of each major component of a 510(k) submission. 3) Describe the significance of each major component of a PMA submission. 4) Develop awareness for the need to seek country-specific expertise to prepare submissions for countries outside the U.S. 5) Identify contents of a CER and know the strategy for writing a CER.	• Quizzes

1) Choose the appropriate regulatory classification and pathway for any medical device in the U.S. 2) Describe the significance of each major component of a 510(k) submission. 3) Describe the significance of each major component of a PMA submission. 4) Develop awareness for the need to seek country-specific expertise to prepare submissions for countries outside the U.S. 5) Select the appropriate messages and clearly present, in both oral and written communication, in a mock FDA meeting. 6) Identify contents of a CER and know the strategy for writing a CER.	• Papers and Projects
1) Choose the appropriate regulatory classification and pathway for any medical device in the U.S. 2) Describe the significance of each major component of a 510(k) submission. 3) Describe the significance of each major component of a PMA submission. 4) Develop awareness for the need to seek country-specific expertise to prepare submissions for countries outside the U.S.	• Class Participation

- *Quizzes-*
  - Quizzes are in an online format.

- *Papers and Projects—*
  - *Team Written Assignment:* Clinical Evidence Report
  - *Individual Written Assignments*
  - *Oral Presentation*—Present your product to a PMA Mock FDA Panel

- *Class Participation—*
  - *Biography and Pre-assessment knowledge*— The first component is the completion and submission of the class biography assignment
  - *Weekly Quiz Question:* submit-a-weekly-quiz-question with responses

Final Grading Criteria

Assessment Methods (should match method types in the previous table)	**Weight Toward Final Course Grade**
Exams and Quizzes	17.5%
Papers and Projects	62.5%
Class Participation	15%

Methods of Instruction

Class Hrs/Week	**Method of Instruction**	**Contribution to Outcomes**
3	Lecture	Throughout the course, emphasis will be placed on regulatory science, regulatory strategy and principles of interacting with regulatory agencies.

C. Prerequisite(s)

- Not Applicable

D. Course Instructor(s)

Name	Rank	School, dept., or center	Graduate Faculty or expected date
Andrew Brightman	Assistant Head, Associate Professor of Practice	BME	Yes
Perry Guinn	Vice President/ Quality Assurance and Regulatory Affairs	Cook Biotech	No
Dan Dillon	Regulatory Scientist	MED Institute, Inc.	No

E. Course Schedule or Outline

Option 1: Schedule Format

Week	Topic(s)
1	Introduction to Regulatory Affairs Profession
2	Differentiating the major regulatory pathways
3	510(k) Session
4	510(k) Session (cont'd)
5	510(k) Session (cont'd)
6	Other US regulatory pathways, combination products and pediatrics
7	PMA Preparation
8	PMA Preparation (cont'd)
9	PMA Preparation (cont'd)
10	PMA Preparation (cont'd) and in-class prep for team presentations
11	Team Presentations to mock FDA panel
12	Team Presentations to mock FDA panel (cont'd)
13	Regulations in Japan
14	Regulations in EU, Canada, Other Regions
15	PMA Supplements and annual reports
16	Not applicable

F. Reading List (including course text)

Primary Reading List

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

G. Library Resources

Name of journal, proceedings, book, video, or other acquisition	Already in Libraries?
Not Applicable	[type yes or no)]

H. Course Syllabus (now required)

BME 595: Regulatory Issues Surrounding Approval of Biomedical Devices

(3 credits, Spring)

Instructors:

Andrew Brightman
Assistant Head, Associate Professor of Practice

aob@purdue.edu

Perry Guinn, Vice President/Quality Assurance and Regulatory Affairs, Cook Biotech, Inc.

pguinn@cookbiotech.com

Dan Dillon, MS, RAC, Regulatory Scientist, MED Institute, Inc.

ddillon@medinst.com

TA:

Carolina Vivas-Valencia, Graduate Student, Weldon School of Biomedical Engineering

cvivas@purdue.edu

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

Class meeting time: Thursdays 3:00 – 5:50 p.m. EST

On-campus meeting place: MJIS 1083

Online meeting place: This course is designed for online as well as on-campus delivery. Please register in the appropriate section. Distance students can get more enrollment details from ProEd: https://engineering.purdue.edu/ProEd/

The course sections (on-campus and online) are combined into one section within the online learning management system, Blackboard Learn. Students will find lecture resources, online quizzes, assignment grades, and other class-related materials in the online environment.

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.

Course Topics:

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

- 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: Student will be able to ...

1) Choose the appropriate regulatory classification and pathway for any medical device in the U.S.
2) Describe the significance of each major component of a 510(k) submission.
3) Describe the significance of each major component of a PMA submission.
4) Develop awareness for the need to seek country-specific expertise to prepare submissions for countries outside the U.S.
5) Select the appropriate messages and clearly present, in both oral and written communication, in a mock FDA meeting.
6) Identify contents of a CER and know the strategy for writing a CER.

Prerequisites: None

Course Note: Undergraduate upperclassmen, please contact instructor ahead of course enrollment.

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

Required software and hardware: Access to the Internet and willingness to interact in the online learning management system (LMS), Blackboard Learn, hosted by Purdue. Access to and ability to use a standard office software suite of products such as MS Office or similar, and webcam/microphone for recording short video presentations to be shared by students in LMS for class discussion and assignments.

Learning activities and assessments:

- Lectures plus overviews and recaps of content, in-class exercises and/or mini case studies, and class discussion
- In-class activities and lectures are captured via video for distance students registered through ProEd
- Online learning management system, Blackboard Learn, will be in use for on-campus and distance students – online quizzes, threaded discussion forum
- Reading, writing and presentation assignments

Grade composition (subject to change with advance notice):

- Class participation (such as video bio and submit-a-weekly-quiz-question with responses), 15%
- Online quizzes, 17.5%
- Team-written assignment graded as a team assignment, 10%
- Individual written assignments, 45%
- Oral presentation to a mock FDA panel (graded individually), 12.5%

Grading scale:

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

Online Course Environment: Course materials, online quizzes, links to pre-recorded video when applicable and discussion forum will be in the online learning management system (LMS), Blackboard Learn. The LMS is accessible by on-campus and distance students. Quizzes and other online assessments will be accessible within Blackboard Learn.

For the quiz questions and responses to questions done following the weekly lecture and learning activities: To earn full point value, you should submit your quiz question with appropriate responses (multiple choice format) about the previous week's lecture and learning activity by Wednesday, 8 AM EST prior to the next class period (no partial

points will be given on the student-submitted quiz questions/responses that are part of the Participation portion of the grade).

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.

I. Calendar for BME 595, Spring 2016

Date	Topic*
Jan. 14, 2016 *(Week 1)*	Introduction to Regulatory Affairs Profession Course Organization
Jan. 21, 2016 *(Week 2)*	Differentiating the major regulatory pathways and 510(k) Session 1
Jan. 28, 2015 *(Week 3)*	510(k) Session 2
Feb. 4, 2016 *(Week 4)*	510(k) Session 3
Feb. 11, 2016 *(Week 5)*	510(k) Session 4
Feb. 18, 2016 *(Week 6)*	Other U.S. Regulatory Pathways Combination Products Pediatrics
Feb. 25, 2016 *(Week 7)*	PMA Preparation / Submission / Session 1
March 3, 2016 *(Week 8)*	PMA Preparation / Submission / Session 2
March 10, 2016 *(Week 9)*	PMA Preparation / Submission / Session 3
March 17, 2016 *(Week 10)*	Spring Break Week
March 24, 2016 *(Week 11)*	PMA Preparation / Submission / Session 4 and In-Class Prep for Team Presentations
March 31, 2016 *(Week 12)*	Team Presentations to Mock FDA Panel – Set 1

April 7, 2016 *(Week 13)*	Team Presentations to Mock FDA Panel - Set 2 of Team Presentations might occur in this week but not during the Thursday class period. If team presentations are already concluded; this will be a lecture/learning activity class period on Thursday.
April 14, 2016 *(Week 14)*	Regulations in Japan / STED & CERs
April 21, 2016 *(Week 15)*	Regulations in EU, Canada, Other Regions
April 28, 2016 *(Week 16)*	PMA Supplements / Annual Reports; Course wrap-up / overview

Assignments	**Points**	**Indiv.**	**Team**
Biography assignment, weekly quiz questions, and class participation - Due weekly	60	15%	
510(k) Assignment 1 – Due Jan. 20	20	5%	
510(k) Assignment 2 - Due Jan. 27	20	5%	
510(k) Assignment 3 – Due Feb. 3	20	5%	
510(k) Assignment 4– Due Feb. 10	30	7.5%	
510(k) Assignment 5 - Due Feb. 24	40	10%	
Quiz 1 – Combination Products – Open Feb 19	10	2.5%	
Submit Quiz Question – PMA Regulations - Due Mar. 2			
Quiz 2 – PMA Regulations - Open March 4	20	5%	
Submit Quiz Question – PMA Guidances - Due March 9			
Quiz 3 – PMA Guidances - Open March 11	20	5%	
PMA Mock FDA Panel Document - Due March 29	40		10%
PMA Mock FDA Panel Presentation - Week of March 31	50	12.5%	
Response to PMA Panel Requests - Due April 13	20	5%	
Quiz 4 – OUS Regulations – Open April 15	10	2.5%	
Quiz 5 – Regulatory decision process; Open April 29	10	2.5%	
CER - Clinical Evidence Report - Due May 3	30	7.5%	
Total	**400**	**90%**	**10%**