Engineering Faculty Document No. 24-18
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 56300, Quality Systems for Regulatory Compliance

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 56300 Quality Systems for Regulatory Compliance
Semester Offered: Summer, Lecture 3, Cr. 3
Prerequisite: N/A

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 academic and industry representatives with expertise in their fields.

Reason: This course is part of a three-course series and 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. This advanced education prepares students for rapid integration into regulatory affairs teams in critical areas of the industry.

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 2019

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	56300	Course Number	
Long Title	Quality Systems for Regulatory Compliance		
Short Title	Regulatory Compliance (Abbreviated title will be entered by the Office of the Registrar if omitted. (30 CHARACTERS ONLY))		

TERMS OFFERED (Check All That Apply): [ ] Fall [ ] Spring [x] 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	100	3	8	
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

Form 40G Course Description and Learning Outcomes for BME 56300

Course Description:

Prerequisite: Not applicable

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 academic and industry representatives with expertise in their fields. This course is part of a three-course series.

Course Learning Outcomes:

- Students will be able to demonstrate a functional understanding of regulatory compliance for biomedical devices.
- Students will be able to use the main tools within the quality craft (Ex: confidence interval, control chart, difference between a T-test and F-test).
- Students will demonstrate understanding of how the FDA approaches control.

Detailed Graduate Course Proposal for Academic Review

To: Purdue University Graduate Council

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

Date: **6/9/2017**

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 56300
Course Title: Quality Systems for Regulatory Compliance
Short Title: Regulatory Compliance

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.

A. Justification for the Course

Justification of the need for the course

This course is part of a three-course series and will provide and 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.

This advanced education prepares students for rapid integration into regulatory affairs teams in critical areas of the industry.

Justification that course will be taught at a graduate level

The course employs the learning strategies of reading, writing and discussing the critical elements of regulatory science and quality compliance from a design control perspective.

Justification of the demand for the course

- Anticipated enrollment
  - Undergraduate N/A
  - Graduate 25

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

- 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 Outcomes	Assessment Methods
• 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.	• Quizzes and Exams
• 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.	• Papers and Projects
• 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.	• Class Participation

- *Quizzes* and Exams
    - Quizzes, taken online in Blackboard Learn (no need for a proctor) cover the reading assignment, and will be in a 30-minute format. Mid-terms, also taken online in Blackboard Learn, will include review questions from previous quizzes plus additional questions covering content from lectures.

- *Papers and Projects—*
    - *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.

    - *Paper:* The format for the paper will be described in the first class session. The topic of the paper is, "The Value of an Integrated Quality System." Rubric and instructions will be provided.

- *Class Participation—*

    - *Discussion Questions:* You will have opportunity to submit discussion questions following the reading assignments and lectures. A dropbox in the online learning environment will be provided for this purpose.

Final Grading Criteria

Assessment Methods (should match method types in the previous table)	**Weight Toward Final Course Grade**
Exams and Quizzes	50%
Papers and Projects	25%
Class Participation	25%

Methods of Instruction

Class Hrs/Week	**Method of Instruction**	**Contribution to Outcomes**
3	Lecture	Instruction and mentoring in regulatory science skills is provided by academics and industry representatives with expertise in their fields.

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

E. Course Schedule or Outline

Option 1: Schedule Format

Week	Topic(s)
1	General overview of regulation history and how it has been enforced and CAPAS identification
2	Gathering data, problem solving and identification of hazards
3	Clinical Evidence Reports, quantification and decision drivers
4	Process validation and ethics
5	Quality of data, design reviews and design verification and validation
6	EU Requirements, Lean Six Sigma and systems engineering
7	Quality and human tissue
8	Class Wrap-up

F. Reading List (including course text)

Primary Reading List

- "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 will be provided to each student in the class via the instructor.

Secondary Reading List

- "Quality Planning and Analysis" by Frank M. Gryna, Fourth edition

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 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.

Time/Location: M-W-F, 3:30 pm - 5:20 pm, Wang Hall
Dates: Mod 2 & 3 of Purdue Summer Session; June 13 – Aug. 5
Prerequisites: none

Course Coordinators:
Andrew Brightman, Assistant Head, Weldon School of BME
Contact info: (765) 494-2982, aob@purdue.edu
Perry W. Guinn, Vice President, Quality Assurance and Regulatory Affairs, Cook Biotech
Contact info: (765) 497-3355, guinn@cookbiotech.com

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 will be provided to each student in the class via the instructor.

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 (5%); discussion question submission (25%), online *quizzes* (20%); mid-term exams (30%) and final paper of 5-8 pages (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.

Discussion Questions:
You will have opportunity to submit discussion questions following the reading assignments and lectures. A dropbox in the online learning environment will be provided for this purpose.

Quizzes and Mid-terms:
Quizzes, taken online in Blackboard Learn (no need for a proctor) cover the reading assignment, and will be in a 30-minute format. Mid-terms, also taken online in Blackboard Learn, will include review questions from previous quizzes plus additional questions covering content from lectures.

Paper:
The format for the paper will be described in the first class session. The topic of the paper is, "The Value of an Integrated Quality System." Rubric and instructions will be provided. 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