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
Dane A. Miller Head and Professor
Weldon School of Biomedical Engineering
### PURDUE UNIVERSITY
REQUEST FOR ADDITION, EXPIRATION, OR REVISION OF A GRADUATE COURSE (50000-60000 LEVEL)

**DEPARTMENT**: Biomedical Engineering  
**EFFECTIVE SESSION**: Summer 2019

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

- [ ] New course with supporting documents (complete proposal form)
- [ ] Add existing course offered at another campus
- [ ] Explanation of a course
- [ ] Change in course number
- [ ] Change in course title
- [ ] Change in course credit/attribute
- [ ] Change in course attributes
- [ ] Change in instructional hours
- [ ] Change in course description
- [ ] Change in course requisites
- [ ] Change in semesters offered
- [ ] Transfer from one department to another

**PROPOSED**:  
**Subject Abbreviation**: BME  
**Course Number**: 50000  
**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)**

**EXISTING**:  
**Subject Abbreviation**:  
**Course Number**:  
**Long Title**:  
**Short Title**:  
**Abbreviated title will be entered by the Office of the Registrar if omitted. (30 CHARACTERS ONLY)**

** TERMS OFFERED**: Check All That Apply  
- [ ] Fall  
- [ ] Spring  
- [ ] Summer

**CAMPUS(ES) INVOLVED**:  
- [ ] Calumet  
- [ ] Cent Ed  
- [ ] Ft. Wayne  
- [ ] Indianapolis  
- [ ] N. Central  
- [ ] Tech Slatevía  
- [ ] W. Lafayette

**CREDIT TYPE**

- 1. Fixed Credit or Hrs.: 5
- 2. Variable Credit Range:  
  - Minimum Cr. Hrs: (Check One)  
  - Maximum Cr. Hrs:  
- 3. Equivalent Credit: Yes [ ] No [ ]
- 4. Thesis Credit: Yes [ ] No [ ]

**COURSE ATTRIBUTES**: Check All That Apply
- [ ] Pass/Not Pass Only
- [ ] Satisfactory/Unsatisfactory Only
- [ ] Repeatable
- [ ] Maximum Repeatable Credit:
- [ ] Credit by Examination
- [ ] Fees: [ ] Coop: [ ] Lab: [ ] Rate Request
- [ ] 10. Off-Campus Experience
- [ ] Include comment to explain fee

**SCHEDULE TYPE**

- Lecture: 100 [ ] 3 [ ] 8[ ]
- Recitation: [ ]
- Presentation: [ ]
- Laboratory: [ ]
- Lab Prep: [ ]
- Studio: [ ]
- Distance: [ ]
- Clinic: [ ]
- Experiential: [ ]
- Research: [ ]
- Ind. Study: [ ]
- Pract/Observ: [ ]

**Weeks Offered**: [ ]

**% of Credit Allocated**: [ ]

**Cross-Listed Courses**:  

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**ATTACHED**

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

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**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.)

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**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**

**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**

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**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.
<table>
<thead>
<tr>
<th>Learning Outcomes</th>
<th>Assessment Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Demonstrate a functional understanding of regulatory compliance for biomedical devices.</td>
<td>• Quizzes and Exams</td>
</tr>
<tr>
<td>• Use the main tools within the quality craft (Ex: confidence interval, control chart, difference between a T-test and F-test)</td>
<td></td>
</tr>
<tr>
<td>• Demonstrate understanding of how the FDA approaches control.</td>
<td></td>
</tr>
<tr>
<td>• Demonstrate a functional understanding of regulatory compliance for biomedical devices.</td>
<td>• Papers and Projects</td>
</tr>
<tr>
<td>• Use the main tools within the quality craft (Ex: confidence interval, control chart, difference between a T-test and F-test)</td>
<td></td>
</tr>
<tr>
<td>• Demonstrate understanding of how the FDA approaches control.</td>
<td></td>
</tr>
<tr>
<td>• Demonstrate a functional understanding of regulatory compliance for biomedical devices.</td>
<td>• Class Participation</td>
</tr>
<tr>
<td>• Use the main tools within the quality craft (Ex: confidence interval, control chart, difference between a T-test and F-test)</td>
<td></td>
</tr>
<tr>
<td>• Demonstrate understanding of how the FDA approaches control.</td>
<td></td>
</tr>
</tbody>
</table>

- **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**—
  o *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.
  
  o *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**—
  
  o *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**

<table>
<thead>
<tr>
<th>Assessment Methods (should match method types in the previous table)</th>
<th>Weight Toward Final Course Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exams and Quizzes</td>
<td>50%</td>
</tr>
<tr>
<td>Papers and Projects</td>
<td>25%</td>
</tr>
<tr>
<td>Class Participation</td>
<td>25%</td>
</tr>
</tbody>
</table>

**Methods of Instruction**

<table>
<thead>
<tr>
<th>Class Hrs/Week</th>
<th>Method of Instruction</th>
<th>Contribution to Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Lecture</td>
<td>Instruction and mentoring in regulatory science skills is provided by academics and industry representatives with expertise in their fields.</td>
</tr>
</tbody>
</table>

**C. Prerequisite(s)**

• Not Applicable
D. Course Instructor(s)

<table>
<thead>
<tr>
<th>Name</th>
<th>Rank</th>
<th>School, dept., or center</th>
<th>Graduate Faculty or expected date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andrew Brightman</td>
<td>Assistant Head, Associate Professor of Practice</td>
<td>BME</td>
<td>Yes</td>
</tr>
<tr>
<td>Perry Guinn</td>
<td>Vice President, Quality Assurance and Regulatory Affairs</td>
<td>Cook Biotech</td>
<td>No</td>
</tr>
</tbody>
</table>

E. Course Schedule or Outline

*Option 1: Schedule Format*

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

<table>
<thead>
<tr>
<th>Name of journal, proceedings, book, video, or other acquisition</th>
<th>Already in Libraries?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>[type yes or no]</td>
</tr>
</tbody>
</table>
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