Texas A&M University
New Certificate, Bachelors, Masters, or Doctoral Program
• Proposal Checklist •

Requested by the Department or Unit of: BMEN

Program Type, Level, Designation, Title, Description, Hours
Program Type Certificate Program ☒ Degree Program ☐
Program Level Undergrad Certificate ☒ Grad Certificate ☒ Bachelor ☐ Master ☐ Doctoral ☐
Degree Designation (i.e., BS, BA, MA, MS, MAg, Med, PhD, EdD, etc.)
Title of proposed program: Certificate of Quality Engineering for Regulated Medical Technologies
Proposed CIP Code (if known):

Brief program description (provide a catalog description for undergraduate and graduate certificates):
Quality engineering principles are mandated by federal and state regulations for clinical facilities and for the design, testing, and manufacture of medical technologies (such as pharmaceuticals and imaging, diagnostic, and therapeutic devices). Completion of this certificate requires specific instruction in quality engineering and regulation of medical technologies; moreover, candidates must go beyond understanding concepts and demonstrate appropriate usage of quality engineering principles in a medically related internship. Given the challenging demands for both better outcomes and lower costs in medical care, candidates for this certificate are expected to be entering a high-growth job market for engineers.

Minimum program semester credit hours (SCH) Certificates - 12 hours* Bachelors - 120 hours Masters - 30 hours
Proposed program hours: 12
*12 hours minimum to appear on transcript

Off-Campus or Distance Delivery
% of Program a student can take off-campus or through
Distance Education
Program Start Date SACS Approval** When Provost needs to inform SACS
☒ 25% Fall 2013 Notification Only 6 months before first day of program
☐ 50% Approval Required 6 months before first day of program
☐ 80% Approval Required 6 months before first day of program
☐ 100% Approval Required 6 months before first day of program

**Notification letter arranged through the Vice Provost for Academic Affairs and sent by TAMU President.

Program Delivery Mode
☒ On-campus College Station
☐ Broadcast / TTVN
☐ Specific off-campus location***
☐ Distance Education / Internet In-State ☐ Out-of-State ☐ Start Date ☐
☐ Out-of-Country

Will this program be offered with another institution? Yes ☐ No ☐
If yes, contact the Vice Provost for Academic Affairs for additional reporting requirements.

***Is this an approved SACS location? Yes ☐ No ☐ If no, a program prospectus must be sent to SACS.
Approved locations as of September 2009: TAMU-Galveston, TAMU-Qatar, University Center-The Woodlands, Dubai (EMBA)

Program Funding
Has program funding been finalized at the department or college level? Yes ☒ No ☐
If no, explain or attach budget:
Will new costs for the first five years of the program be under $2 million? Yes ☒ No ☐
If new costs exceed $2 million, coordinating board approval is required.

Page 1 01/11/2012
Submitted by (Contact Person):

John C. Criscione, MD, PhD

Name

Associate Professor of Biomedical Engineering

Title

JCCriscione@tamu.edu

Email

979-845-5428

Phone

Certification Statement

By signing below, the Dean of the College certifies the proposed program complies with coordinating board standards. If the program is delivered through Distance Education, the Dean of the College certifies that they are following the Principles of Good Practice for Academic Degree and Certificate Programs and Credit Courses Offered Electronically.

Use additional signature lines if program is between three or more departments or colleges.

Signature, Department Head or Interdisciplinary Program Chair
Gerald Cote

Typed or Printed Name

Chair, College Review Committee

Date

Dean of College

Date

Chair, University Curriculum Committee or Graduate Council

Date

Additional Approvals Required: Faculty Senate and President.
New Program Request Form for Certificate Programs, Bachelor’s and Master’s Degrees

Directions: An institution shall use this form to propose a new bachelor’s or master’s degree program. In completing the form, the institution should refer to the document Standards for Bachelor’s and Master’s Programs, which prescribes specific requirements for new degree programs. Note: This form requires signatures of (1) the Chief Executive Officer, certifying adequacy of funding for the new program; (2) a member of the Board of Regents (or designee), certifying Board approval; and (3) if applicable, a member of the Board of Regents or (designee), certifying that criteria have been met for staff-level approval. NOTE: Preliminary authority is required for all engineering programs. An institution that does not have preliminary authority for a proposed engineering program shall submit a separate request for preliminary authority prior to submitting the degree program request form. That request shall address criteria set in Coordinating Board rules Section 5.24(a).

Administrative Information

1. Institution: Texas A&M University

2. Program Name – Show how the program would appear on the Coordinating Board’s program inventory (e.g., Bachelor of Business Administration degree with a major in Accounting):

   Certificate of Quality Engineering for Regulated Medical Technologies

3. Proposed CIP Code: 14.0501.0006

4. Brief Program Description – Describe the program and the educational objectives:

   Quality engineering principles are mandated by federal and state regulations for clinical facilities and for the design, testing, and manufacture of medical technologies (such as pharmaceuticals and imaging, diagnostic, and therapeutic devices). Completion of this certificate requires completion of the following educational outcomes: 1) to know and apply principles of quality engineering, 2) to know and understand the governmental regulation of medical technologies, and 3) be able to go beyond understanding concepts and demonstrate appropriate usage of quality engineering principles in a medically related internship. Given the challenging demands for both better outcomes and lower costs in medical care, candidates for this certificate are expected to be entering a high-growth job market for engineers.

   Number of Semester Credit Hours Required: 12 hrs

5. Administrative Unit – Identify where the program would fit within the organizational structure of the university (e.g., The Department of Electrical Engineering within the College of Engineering):

   College of Engineering

6. Proposed Implementation Date – Report the first semester and year that students would enter the program:

   Fall of 2013

Updated 06.07.2010
7. **Contact Person** – Provide contact information for the person who can answer specific questions about the program:

   Name: John C. Criscione, MD, PhD  
   Title: Associate Professor of Biomedical Engineering  
   E-mail: JCCriscione@tamu.edu  
   Phone: 979-845-5428

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**Program Information**

<p>| | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
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<td>2</td>
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<td>5</td>
</tr>
<tr>
<td>Headcount</td>
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<tr>
<td>FTSE</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

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**Note:** Complete IA and IB only if preliminary authority for the program was granted more than four years ago. This includes programs for which the institution was granted broad preliminary authority for the discipline.

A. **Job Market Need** – Provide short- and long-term evidence of the need for graduates in the job market.

   The industry advisory board for Biomedical Engineering identified a need for more thorough training in the engineering specific, quality requirements that arise from the regulation of medical technologies. This deficiency is a national problem in biomedical engineering programs, and the advisory board recommended with highest priority that we launch a certificate program to give our graduates an opportunity to be highly visible and employable to the medical industry.

B. **Student Demand** – Provide short- and long-term evidence of demand for the program.

   The regulatory affairs classes for the BMEN department are elective and yet full every year (40+ students), and similarly for the quality courses in ISEN. Employers are in need of engineers with training in quality systems and in regulatory affairs, and hence students are also seeking these skills.

C. **Enrollment Projections** – Use this table to show the estimated cumulative headcount and full-time student equivalent (FTSE) enrollment for the first five years of the program. *(Include majors only and consider attrition and graduation.)*
II. Quality

A. **Certificate and Degree Requirements** – Use this table to show the certificate and degree requirements of the program. (*Modify the table as needed; if necessary, replicate the table for more than one option.*)

<table>
<thead>
<tr>
<th>Category</th>
<th>Semester Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Education Core Curriculum (bachelor’s degree only)</td>
<td></td>
</tr>
<tr>
<td>Required Courses</td>
<td>9</td>
</tr>
<tr>
<td>Prescribed Electives</td>
<td>3</td>
</tr>
<tr>
<td>Free Electives</td>
<td></td>
</tr>
<tr>
<td>Other (Specify, e.g., internships, clinical work)</td>
<td>(if not included above)</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>12</td>
</tr>
</tbody>
</table>

B. **Curriculum** – these tables to identify required courses and prescribed electives of program, and curriculum as it will appear in the undergraduate and graduate catalog. Note with an asterisk (*) courses that would be added if the program is approved. (*Add and delete rows as needed. If applicable, replicate the tables for different tracks/options as shown in the undergraduate catalog.*)

<table>
<thead>
<tr>
<th>Prefix and Number</th>
<th>Required Course in Regulatory Affairs</th>
<th>SCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMEN 440</td>
<td>Design and Manufacture of Medical Devices</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>BMEN 604</td>
<td>Design and Manufacture of Medical Devices</td>
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<td></td>
<td>OR</td>
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<td>BMEN 404</td>
<td>Medical Device Testing</td>
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<td>BMEN 430</td>
<td>Medical Device Regulation</td>
<td>3</td>
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<td></td>
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*Updated 06.07.2010*
Texas A&M University
New Certificate, Bachelors, Masters, or Doctoral Program
* Proposal Checklist *

Requested by the Department or Unit of: BMEN

Program Type, Level, Designation, Title, Description, Hours

<table>
<thead>
<tr>
<th>Program Type</th>
<th>Certificate Program</th>
<th>Degree Program</th>
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<tr>
<td>Program Level</td>
<td>Undergrad Certificate</td>
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Title of proposed program: Certificate of Quality Engineering for Regulated Medical Technologies

Proposed CIP Code (if known): ___

Brief program description (provide a catalog description for undergraduate and graduate certificates):
Quality engineering principles are mandated by federal and state regulations for clinical facilities and for the design, testing, and manufacture of medical technologies (such as pharmaceuticals and imaging, diagnostic, and therapeutic devices). Completion of this certificate requires specific instruction in quality engineering and regulation of medical technologies; moreover, candidates must go beyond understanding concepts and demonstrate appropriate usage of quality engineering principles in a medically related internship. Given the challenging demands for both better outcomes and lower costs in medical care, candidates for this certificate are expected to be entering a high-growth job market for engineers.

Minimum program semester credit hours (SCH) Certificates - 12 hours* Bachelors - 120 hours Masters - 30 hours

Proposed program hours: 12 ___ ___

*12 hours minimum to appear on transcript

Off-Campus or Distance Delivery

<table>
<thead>
<tr>
<th>% of Program a student can take off-campus or through Distance Education</th>
<th>Program Start Date</th>
<th>SACS Approval**</th>
<th>When Provost needs to inform SACS</th>
</tr>
</thead>
<tbody>
<tr>
<td>☒ 25%</td>
<td>Fall 2013</td>
<td>Approval Required</td>
<td>6 months before first day of program</td>
</tr>
<tr>
<td>☐ 50%</td>
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**Notification letter arranged through the Vice Provost for Academic Affairs and sent by TAMU President.

Program Delivery Mode

<table>
<thead>
<tr>
<th>Location</th>
<th>Specific off-campus location***</th>
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<tbody>
<tr>
<td>On-campus</td>
<td>College Station</td>
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<td>Will this program be offered with another institution? Yes ☐ No ☐ If yes, contact the Vice Provost for Academic Affairs for additional reporting requirements.</td>
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Program Funding

Has program funding been finalized at the department or college level? Yes ☒ No ☐

If no, explain or attach budget: ___

Will new costs for the first five years of the program be under $2 million? Yes ☒ No ☐

If new costs exceed $2 million, coordinating board approval is required.

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01/11/2012
Certification Statement

By signing below, the Dean of the College certifies the proposed program complies with coordinating board standards. If the program is delivered through Distance Education, the Dean of the College certifies that they are following the Principles of Good Practice for Academic Degree and Certificate Programs and Credit Courses Offered Electronically.

Use additional signature lines if program is between three or more departments or colleges.

Signature, Department Head or Interdisciplinary Chair
Date

Program Chair
Date

Cesar Malave

Typed or Printed Name

Chair, College Review Committee
Date

Dean of College
Date

Chair, University Curriculum Committee or Graduate Council
Date

Additional Approvals Required: Faculty Senate and President.
New Program Request Form for Certificate Programs, Bachelor's and Master's Degrees

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**Administrative Information**

1. **Institution:** Texas A&M University

2. **Program Name** – Show how the program would appear on the Coordinating Board’s program inventory (e.g., *Bachelor of Business Administration degree with a major in Accounting*):

   **Certificate of Quality Engineering for Regulated Medical Technologies**

3. **Proposed CIP Code:** 14.0501.0006

4. **Brief Program Description** – Describe the program and the educational objectives:

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   College of Engineering

6. **Proposed Implementation Date** – Report the first semester and year that students would enter the program:

   Fall of 2013

*Updated 06.07.2010*
7. **Contact Person** — Provide contact information for the person who can answer specific questions about the program:

- **Name**: John C. Criscione, MD, PhD
- **Title**: Associate Professor of Biomedical Engineering
- **E-mail**: JCCriscione@tamu.edu
- **Phone**: 979-845-5428

---

**Program Information**

I. **Need**

*Note: Complete LA and LB only if preliminary authority for the program was granted more than four years ago. This includes programs for which the institution was granted broad preliminary authority for the discipline.*

A. **Job Market Need** — Provide short- and long-term evidence of the need for graduates in the job market.

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*Updated 06.07.2010*


II. Quality

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B. Use the Curriculum – these tables to identify required courses and prescribed electives of program, and curriculum as it will appear in the undergraduate and graduate catalog. Note with an asterisk (*) courses that would be added if the program is approved. (Add and delete rows as needed. If applicable, replicate the tables for different tracks/options as shown in the undergraduate catalog.)

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<td>OR</td>
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<td>BMEN 630</td>
<td>Medical Device Regulation</td>
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Updated 08.07.2010
<table>
<thead>
<tr>
<th>Prefix and Number</th>
<th>Required Course in Quality</th>
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<tr>
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<td>Statistical Quality Control</td>
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<td>OR</td>
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<tr>
<td>ISEN 614</td>
<td>Advanced Quality Control</td>
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<table>
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<tr>
<td>XXEN 485</td>
<td>Internship (position must be approved by certificate faculty to meet experience needs)</td>
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<tr>
<td>XXEN 685</td>
<td>Internship (position must be approved by certificate faculty to meet experience needs)</td>
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<table>
<thead>
<tr>
<th>Prefix and Number</th>
<th>Required Courses, Choose 1 (Choice cannot be a course used to satisfy the required courses, and both the undergrad and grad versions of the same course cannot be used, e.g. BMEN 404 and 604 cannot both count towards fulfilling requirements)</th>
<th>SCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMEN 440</td>
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<td>ISEN 414</td>
<td>Total Quality Engineering</td>
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</tr>
<tr>
<td>ISEN 614</td>
<td>Advanced Quality Control</td>
<td>3</td>
</tr>
<tr>
<td>ISEN 616</td>
<td>Design and Analysis of Industrial Experiments</td>
<td>3</td>
</tr>
</tbody>
</table>

*Updated 06.07.2010*
C. **Faculty** – Use these tables to provide information about Core and Support faculty. Add an asterisk (*) before the name of the individual who will have direct administrative responsibilities for the program. *(Add and delete rows as needed.)*

<table>
<thead>
<tr>
<th>Name of Core Faculty and Faculty Rank</th>
<th>Highest Degree and Awarding Institution</th>
<th>Courses Assigned in Program</th>
<th>% Time Assigned To Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criscione, John Assistant Professor</td>
<td>MD, PhD in Biomedical Engineering, Johns Hopkins</td>
<td>BMEN Courses</td>
<td>15%</td>
</tr>
<tr>
<td>Pishko, Michael Professor</td>
<td>PhD in Chemical Engineering, University of Texas-Austin</td>
<td>BMEN Courses</td>
<td>10%</td>
</tr>
<tr>
<td>Ding, Yu Professor</td>
<td>PhD in Mechanical Engineering, University of Michigan</td>
<td>ISEN Courses</td>
<td>10%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of Support Faculty and Faculty Rank</th>
<th>Highest Degree and Awarding Institution</th>
<th>Courses Assigned in Program</th>
<th>% Time Assigned To Program</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

D. **Students** – Describe general recruitment efforts and admission requirements. In accordance with the institution’s Uniform Recruitment and Retention Strategy, describe plans to recruit, retain, and graduate students from underrepresented groups for the program.

This program is open to students enrolled in graduate or undergraduate programs at TAMU. However, the courses are upper level engineering courses, and hence, students outside of engineering may have difficulty enrolling in certificate courses—approval of instructor is often needed for non engineering majors to take upper level engineering courses. This certificate program will be used by engineering departments to better recruit students who, during their careers, plan to make an impact in healthcare through technological innovation.
E. **Library** – Provide the library director’s assessment of library resources necessary for the program. Describe plans to build the library holdings to support the program.

Current holdings are sufficient.

F. **Facilities and Equipment** – Describe the availability and adequacy of facilities and equipment to support the program. Describe plans for facility and equipment improvements/additions.

No new facilities or equipment required.

G. **Accreditation** – If the discipline has a national accrediting body, describe plans to obtain accreditation or provide a rationale for not pursuing accreditation.

Certificate courses are already part of established engineering programs that are accredited by ABET.

H. **Evaluation** – Describe the evaluation process that will be used to assess the quality and effectiveness of the new degree program.

The primary objective of this certificate program is to provide students with exceptional, marketable training in quality engineering as needed for development of regulated medical technologies. The best measures for effectiveness in meeting this objective is placement rates of graduates in the biomedical industry and employer surveys 1 year after placement.

### III. Costs and Funding

**Five-Year Costs and Funding Sources** – Use this table to show five-year costs and sources of funding for the program.

<table>
<thead>
<tr>
<th>Five-Year Costs</th>
<th>Five-Year Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel¹</td>
<td>$0</td>
</tr>
<tr>
<td>Facilities and Equipment</td>
<td>$0</td>
</tr>
<tr>
<td>Library, Supplies,</td>
<td>$0</td>
</tr>
<tr>
<td>and Materials</td>
<td></td>
</tr>
<tr>
<td>Other²</td>
<td>$0</td>
</tr>
<tr>
<td><strong>Total Costs</strong></td>
<td><strong>$0</strong></td>
</tr>
</tbody>
</table>

1. Report costs for new faculty hires, graduate assistants, and technical support personnel. For new faculty, provide individual salaries as a percentage of the time assigned to the program. If existing faculty will contribute to program, include costs necessary to maintain existing programs (e.g., cost of adjunct to cover courses previously taught by faculty who would teach in new program).
2. Specify other costs here (e.g., administrative costs, travel).
3. Indicate formula funding for students new to the institution because of the program; formula funding should be included only for years three through five of the program and should reflect enrollment projections for years three through five.
4. Report other sources of funding here. In-kind grants, “likely” future grants, and designated tuition and fees can be included.

*Updated 06.07.2010*
Signature Page

1. Adequacy of Funding – The chief executive officer shall sign the following statement:

   I certify that the institution has adequate funds to cover the costs of the new program. Furthermore, the new program will not reduce the effectiveness or quality of existing programs at the institution.

   __________________________________________  ____________________________
   Chief Executive Officer                      Date

2. Board of Regents or Designee Approval – A member of the Board of Regents or designee shall sign the following statement:

   On behalf of the Board of Regents, I approve the program.

   __________________________________________  ____________________________
   Board of Regents (Designee)                   Date of Approval

3. Board of Regents Certification of Criteria for Commissioner of Assistant Commissioner Approval – For a program to be approved by the Commissioner or the Assistant Commissioner for Academic Affairs and Research, the Board of Regents or designee must certify that the new program meets the eight criteria under TAC Section 5.50 (b): The criteria stipulate that the program shall:

   (1) be within the institution’s current Table of Programs;
   (2) have a curriculum, faculty, resources, support services, and other components of a degree program that are comparable to those of high quality programs in the same or similar disciplines at other institutions;
   (3) have sufficient clinical or in-service sites, if applicable, to support the program;
   (4) be consistent with the standards of the Commission of Colleges of the Southern Association of Colleges and Schools and, if applicable, with the standards or discipline-specific accrediting agencies and licensing agencies;
   (5) attract students on a long-term basis and produce graduates who would have opportunities for employment; or the program is appropriate for the development of a well-rounded array of basic baccalaureate degree programs at the institution;
   (6) not unnecessarily duplicate existing programs at other institutions;
   (7) not be dependent on future Special Item funding
   (8) have new five-year costs that would not exceed $2 million.

   On behalf of the Board of Regents, I certify that the new program meets the criteria specified under TAC Section 5.50 (b).

   __________________________________________  ____________________________
   Board of Regents (Designee)                   Date

Updated 06/07/2010
Subject: Certificate of Quality Engineering for Regulated Medical Technologies
(Proposal)

Contact: John C. Criscione, MD, PhD
Associate Professor
Department of Biomedical Engineering
TAMU MS:3120
College Station, TX 77843-3120
979-845-5428
JCCriscione@tamu.edu

Introduction/Reason for being: With the tremendous growth of the healthcare sector of the economy, nationally and globally, there has been a concerted effort within most engineering disciplines to harness technology and engineering principles to solve problems in medicine and medical care delivery. Biomedical engineering has grown in to its own discipline and is specifically focused on the medical industry. However, disciplines such as aerospace, mechanical, chemical, electrical, civil, industrial, nuclear, petroleum, engineering technology, and computer engineering have developed research programs, technologies, and engineering principles that contribute directly and indirectly to biomedical applications. Toward providing Dwight Look College of Engineering students with valuable and exceptional skills in the engineering of medical technologies that are subject to regulation, a "Certificate of Quality Engineering for Regulated Medical Technologies" is proposed. The industry advisory board for Biomedical Engineering identified a need for more thorough training in the engineering specific, quality requirements that arise from the regulation of medical technologies. This deficiency is a national problem in biomedical engineering programs, and the advisory board recommended with highest priority that we launch a certificate program to give our graduates an opportunity to be highly visible and valuable to the medical industry. Our industry advisors, in fact, will serve on a committee to review and validate the proposed certificate program to make sure it meets the needs of the medical technology industry with regard to engineering employment. For students in all engineering disciplines, this certificate program will allow them to compete effectively for jobs in the medical industry. Such a certificate on the transcript and/or resume of an applicant will be noticed by medical technology companies. Moreover, this certificate program will encourage motivated students to go beyond basic degree requirements—along a path with industry advisory board oversight. Students that complete this certificate are likely to be valuable ambassadors for the college of engineering within the medical industry, a growing industry with critical implications for society and for the strategic plan of the college.
What and who is the program designed for: The proposed certificate is designed for undergraduate and graduate students in the college of engineering who are highly motivated to pursue engineering careers in the medical industry. Students outside of the college of engineering are eligible to earn this certificate; however, enrollment in upper level engineering courses is not guaranteed—approval from individual instructors is required and appropriate prerequisites must be accepted by instructor. The program itself is designed for healthcare entities that require quality engineering (i.e., medical product design and manufacturing, clinical facility design and operation, and regulatory bodies that inspect and license such entities.)

Benefits: The proposed certificate is expected to benefit students and the college of engineering. For students pursuing careers in the medical industry, the training involved in obtaining the certificate is critical to job performance. Industry employers on the BMEN advisory board have stated that achievement of the certificate would be a very favorable factor in their hiring decisions because quality systems are required in clinical and manufacturing facilities that deliver medical products or services. For the college of engineering, the certificate program would further establish TAMU as a leader in the preparation of engineers for careers in technologically advanced industries. The national lack of training in regulatory affairs within engineering education is an opportunity for TAMU to provide leadership. The proposed certificate program is, in essence, an extension of efforts already underway. The Texas A&M Institute for Preclinical Studies, a large animal facility that can do studies under Good Laboratory Practices (GLP), and the National Center for Therapeutics Manufacturing a drug and vaccine facility that can do studies under Good Manufacturing Practices (GMP) are unique TAMU facilities that offer ample opportunity for students to learn quality engineering principals and regulatory requirements by direct experience.

Description and Courses: The requirements for the proposed certificate program are composed of three components.

1) Quality Systems Engineering (QSE) and Regulatory Affairs coursework (9 hrs): In the medical industry, quality systems are required by regulations for product development and medical care delivery. The US FDA specifies these systems via a set of requirements that are referred to as good manufacturing practices (GMP) for product development, good laboratory practices (GLP) for non-clinical laboratory studies, and good clinical practices (GCP) for human clinical studies. European governments have adopted similar guidelines that are specified in ISO publications. QSE as appropriate for medical device development, design and testing are contained in the courses below. Three
courses are required with one from group A, one from group B, and one from group A, B, or C.

A) Regulatory Affairs of Medical Technologies (1 Required)
   - BMEN 440/640 (Design and Manufacture of Medical Devices - GMP)
   - BMEN 404/604 (Medical Device Testing - GLP and GCP)
   - BMEN 430/630 (Medical Device Regulation)

B) Quality Engineering (1 Required)
   - ISEN 314 (Statistical Quality Control)
   - ISEN 414 (Total Quality Engineering)
   - ISEN 614 (Advanced Quality Control)

C) Pertinent Electives
   - ISEN 616 (Design and Analysis of Industrial Experiments)

2) Professional Experiential Learning (3hrs): An internship in medical technology company, regulatory body, academic entity, or testing facility is required with a project that involves the design, manufacturing, regulation, or testing of a regulated medical technology.

Expected Number of Students: In the next few years, we expect 5-10 undergraduate students and 1-5 Masters of Engineering students to earn the proposed certificate. As we advertise the certificate program to engineering graduates who are interested in starting careers in healthcare related fields, we expect the number of ME students to expand substantially to about 10-15 per year.

Faculty: John C. Criscione, MD, PhD and Michael V. Pishko, PhD from Biomedical Engineering and Yu Ding, PhD from Industrial and Systems Engineering.

Course Syllabi (on following pages):
   - Syllabus BMEN 430 Medical Device Regulation
   - Syllabus BMEN 440 Design and Manufacture of Medical Devices – GMP
   - Syllabus BMEN 404 Medical Device Testing – GLP and GCP
   - Syllabus ISEN 314 Statistical Control of Quality
   - Syllabus ISEN 414 Total Quality Engineering
   - Syllabus ISEN 614 Advanced Quality Control
BMEN 430
Medical Device Regulation
Term: TBA

Instructor: Professor John C. Criscione
Office: Zachary 335R
Phone: 845-5428, e-mail: JCCriscione@tamu.edu
Office Hours: XXXXXXXXXXXXXXXXXXXX

Lecture: INSERT Time/Location

Required Text: TBA

Course Description:
The medical device industry operates within a highly regulated, global environment. This course is focused on the regulations—i.e., regulatory laws and associated regulatory agencies. US, Canada, and European regulations are of primary interest. Regulations of medical devices worldwide will be considered at the introductory level.

Prerequisites: Admitted to major degree sequence and BMEN 430, U3 & U4 Classification

Learning Outcomes:

1. Learn the basics of animal testing requirements (GLP) in the development of medical devices that are subject to US FDA regulations.

2. Learn the basics of clinical trial requirements (GCP) in the development of medical devices that are subject to US FDA regulations.

3. Develop a better understanding of GLP and GCP by comparing and contrasting them.

4. Verify knowledge transferred through examinations, homework, and group work assignments.

Grading Policies:

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Assessment</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>30%</td>
<td>Midterm Exam</td>
<td>100-90% ..........A</td>
</tr>
<tr>
<td>30%</td>
<td>Final Exam</td>
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</tr>
<tr>
<td>20%</td>
<td>Homework Assignments</td>
<td>70-79% ..........C</td>
</tr>
<tr>
<td>20%</td>
<td>Develop Regulatory Proposal to include SOP, AUP, GCP</td>
<td>60-69% ..........D</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;60% ..........F</td>
</tr>
</tbody>
</table>

100%

- Attendance: Only University excused absences will be accepted for makeup exams/quizzes to be given. In accordance with University policies which can be found online at http://student-rules.tamu.edu/rule07.htm.
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## Course Topics

### Overview

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<thead>
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<th>Week</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Device Development Process &amp; Regulations</td>
</tr>
<tr>
<td>2 &amp; 3</td>
<td>Quality Systems Engineering</td>
</tr>
</tbody>
</table>

### GLP Regulations

<table>
<thead>
<tr>
<th>Week</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Organizational, Personnel, &amp; Facilities Responsibilities</td>
</tr>
<tr>
<td>5</td>
<td>Operations and SOPs</td>
</tr>
<tr>
<td>6</td>
<td>Study Protocol and Implementation</td>
</tr>
<tr>
<td>7</td>
<td>Reporting</td>
</tr>
<tr>
<td>8</td>
<td>GLP in Practice</td>
</tr>
<tr>
<td>8</td>
<td>Mid-Term</td>
</tr>
</tbody>
</table>

### GCP Regulations

<table>
<thead>
<tr>
<th>Week</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>Overview of Clinical Trials</td>
</tr>
<tr>
<td>10</td>
<td>Clinical Investigation Plan</td>
</tr>
<tr>
<td>11</td>
<td>Organizational, Personnel, and Facilities Responsibilities</td>
</tr>
<tr>
<td>12</td>
<td>Records &amp; Reporting</td>
</tr>
<tr>
<td>13</td>
<td>Pre-IDE and IDE</td>
</tr>
<tr>
<td>14</td>
<td>Post-Market Clinical and Device Evaluation</td>
</tr>
<tr>
<td>14</td>
<td>GCP in Practice</td>
</tr>
<tr>
<td>15</td>
<td>Final Exam</td>
</tr>
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</table>

### Americans with Disabilities Act (ADA) Policy Statement

The American with Disabilities Act (ADA) is a federal anti-discrimination statute that provides comprehensive civil rights protection for persons with disabilities. Among other things, this legislation requires that all students with disabilities be guaranteed a learning environment that provides for reasonable accommodation of their disabilities. If you believe you have a disability requiring an accommodation, please contact Disability Services, in Cain Hall, Room B118, or call 845-1637. For additional information visit [http://disability.tamu.edu](http://disability.tamu.edu)

### Academic Integrity Statement and Policy

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"An Aggie does not lie, cheat, or steal, or tolerate those who do."
Design and Manufacture of Medical Devices (GMP)
EMEN 440/640
Term: Summer 2010, Session II

Instructor:  John C. Criscione, MD, PhD
Office: Zachry Engineering Center Rm. 335R
Phone: 845-5428
Email (preferred method of contact): JCCriscione@tamu.edu
Office Hours: TBD

Lectures: MTWRF 10-11:35am

Text: Medical Device Quality Systems Manual: A Small Entity Compliance
Guide First Edition. Published by the FDA. Hard copies available from
FDA, yet the manual is available for free online at the website of FDA.
(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Post
marketRequirements/QualitySystemsRegulations/MedicalDeviceQualityS
ystemsManual/default.htm)

Course Description: Overview of multiple issues that must be addressed in designing a
marketable medical device, including the design process from clinical
problem definition through prototype and clinical testing to market readiness.
FDA regulation, human factors, failure and safety, and medical product
liability may be considered.

This course is not about designing anything in particular, meaning no circuit
design, stress analysis, materials, etc. It is about the design process and the
design process management and regulation. By the end of the course you
should be able to:

- Define a medical device and identify medical devices currently in the
  market,
- Identify and analyze the major issues in designing a medical device,
- Construct an approach to navigate and address major issues confronting a
  medical device through its life cycle.

Prerequisites: Introduction to FDA and/or instructor approval

Grading: Final Exam (100% of grade)

Schedule: Subject to change, however, topics of each week are expected to be as
follows in table.

<table>
<thead>
<tr>
<th>Week</th>
<th>Topics</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Device Development Process from R&amp;D to Market Approval, Quality</td>
</tr>
<tr>
<td></td>
<td>Systems, ISO Standards, GMP, QSR</td>
</tr>
<tr>
<td>---</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>2</td>
<td>Design Process and Design Controls</td>
</tr>
<tr>
<td>3</td>
<td>Process Validation, Personnel, Buildings and Environment, Equipment and Calibration</td>
</tr>
<tr>
<td>4</td>
<td>Device Master Record, Document and Change Control, Purchasing and Acceptance Activities, Labeling, Product Evaluation</td>
</tr>
<tr>
<td>5</td>
<td>Packaging, Storage Distribution and Installation, Complaints, Servicing, Quality Systems Audits, Factory Inspections</td>
</tr>
</tbody>
</table>

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**Copyrights**

The handouts used in this course are copyrighted. By "handouts" we mean all materials generated for this class, which include but are not limited to syllabi, lab problems, in-class materials, review sheets, and additional problem sets. Because these materials are copyrighted, you do not have the right to copy the handouts, unless the author expressly grants permission.

**Scholastic Dishonesty**

"An Aggie does not lie, cheat or steal, or tolerate those who do."

For more information on Honor Council Rules and Procedures, go to: [http://www.tamu.edu/aggiehonor](http://www.tamu.edu/aggiehonor)
BMEN 404
Medical Device Testing (GLP/GCP)
Term: TBA

Instructor: Professor John C. Criscione
Office: Zachary 335R
Phone: 845-5428, e-mail: JCCriscione@tamu.edu
Office Hours: XXXXXXXXXXXXXXXXXXX

Lecture: INSERT Time/Location

Required Text: TBA

Course Description:
Following Food and Drug Administration (FDA) regulations for the submission of preclinical studies by implementing methods of Good Laboratory Practices (GLP), and the use of Good Clinical Practices (GCP) in clinical trials, including similarities and differences in GLP and GCP critical for the introduction of medical devices.

Prerequisites: Admitted to major degree sequence and BMEN 430, U3 & U4 Classification

Learning Outcomes:

1. Learn the basics of animal testing requirements (GLP) in the development of medical devices that are subject to US FDA regulations.

2. Learn the basics of clinical trial requirements (GCP) in the development of medical devices that are subject to US FDA regulations.

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ISEN 314 Statistical Control of Quality
G.K. Bennett

Course Description:
Quality control with statistical principles applied to quality problems, including statistical
analysis, density and distribution functions, parameter estimation, confidence intervals,
hypothesis testing and control chart concepts, process capability analysis; laboratory exercises
for exposure to basic metrology and applied statistics for quality control applications in discrete-
item manufacturing systems; introduction to six-sigma principles including DMAIC and variance
reduction strategies.

Course Objectives:
That students (1) learn formulations, models, and analytical procedures for the study of quality
control, (2) learn fundamental principles of statistical quality control techniques, (3) be able to
implement the quality engineering tools in industrial applications; and (4) improve team working
skills and data-collecting capability.

Learning Outcomes:
• Understand the importance of quality control, and its role in six-sigma program;
• Understand and appreciate the statistical concepts and methods and how they help
achieve the quality control objective;
• Comprehend the tools in quality control and be able to use them to solve quality
engineering problems.

Pre-requisite: Basic statistics (STAT 211 and STAT 212 or equivalent).

Instructor Information
Instructor: Dr. G. Kemble Bennett, 4007 ETB, Phone: 458-2364
Email: kem-bennett@tamu.edu

Lab Instructor: Rhett Goodman
Email: Rhett_Goodman@tamu.edu

Classroom and Schedule
Lecture: 1013 ETB, 10:20-11:10 pm MW
Lab: 1013 ETB, 4:10-6:40 pm W

Office Hours
4007 ETB MW 1:30 – 3:30 or by appointment. Walk-in is welcome. Please call to be sure I
am available.

Course Materials
Course Materials: On G drive in folder: ISEN_314_Spring_2012_Bennett

Grade Distribution

<p>| | |</p>
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Exams 1 - 3</td>
<td>45% total (100 points each. Lowest exam grade dropped)</td>
</tr>
<tr>
<td>Final Examination</td>
<td>30% (comprehensive, 100 points)</td>
</tr>
<tr>
<td>Lab</td>
<td>20%</td>
</tr>
<tr>
<td>Quizzes</td>
<td>5% (5 unannounced pop quizzes, 1 point each)</td>
</tr>
</tbody>
</table>

There will be approximately 10-12 laboratory exercises. Each lab exercise will be worth 20-100 points apiece. The total points which can be accumulated (TP) will be used to normalize total points earned (TPE) as follows:

\[
\text{Lab Grade} = \frac{\text{TPE}}{\text{TP}} \times 100
\]

The best two exam grades, final exam grade, homework grade and the normalized lab grade will all be averaged as follows:

\[
0.225(T_1 + T_2) + 0.30(\text{Final}) + 0.2(\text{Lab}) + \text{Quiz Total} = \text{final grade}
\]

Course grade will be assigned as follows:

<table>
<thead>
<tr>
<th>Average Grade</th>
<th>Course Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 &gt; AG &gt;= 90</td>
<td>A</td>
</tr>
<tr>
<td>90 &gt; AG &gt;= 80</td>
<td>B</td>
</tr>
<tr>
<td>80 &gt; AG &gt;= 70</td>
<td>C</td>
</tr>
<tr>
<td>70 &gt; AG &gt;= 50</td>
<td>D</td>
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Examination Schedule

Exam 1: Feb 15, 2012, Wednesday, in-lab;
Exam 2: March 21, 2012, Wednesday, in-lab;
Exam 3: April 18, 2012, Wednesday, in-lab;
Final: May 4, 2012, Friday, 3:00 - 5:00pm.

Final is cumulative.

Make up

No make-up labs, exams or quizzes except for university allowed excuses. Case will be assessed and approved on an individual basis by the instructor.

Lab Report

Class and lab attendance and participation will be noted and could influence grades in borderline cases. Lab attendance and participation in labs are mandatory.

Students will be allowed one week after each lab exercise is returned to the student to discuss
assigned grades. After one week, there will be no discussion.

It is likely that due to the lack of proper computer resources in the lab, teams of 2-3 may be necessary to work together on each lab exercise. If teams are formed it is expected that all members of the team will equally share in the problem solving exercise. No copying between teams is allowed, each team must do its own work. Each team will only turn in one report. Lab report is due in a week. Late report will be docked by 25% per calendar day it is late. If plagiarism is detected, BOTH teams will be given a zero on that lab exercise with no debate or recourse. Those who miss a lab will NOT be allowed to be on any team.

Lab exercises and homework will be monitored and graded by the assigned Graduate Assistant. Each exam, class quiz and the final examination will be graded by the course instructor. These individuals are your first points of contact to discuss lab exercises and grades.

Re-grading Policy
If you would like to have your homework/exam/report re-graded, you have to do so within one week from the time when the work is returned to you.

Course Overview

Chapter 2. The DMAIC Process: Overview of the DMAIC process. The Design, Measure, Analyze, Improve and Control steps.


Chapter 4: Inference About Process Quality: Point estimate. Confidence interval. Hypothesis test. Type-I error (α-error) and Type II error (β-error). A summary of different tests on mean and variance.


Chapter 7. Control Chart for Attributes: p-chart, np-chart, c-chart and u-chart. α-error and β-error for attribute control chart.
Students With Disabilities:
The Americans with Disabilities Act (ADA) is a federal anti-discrimination statute that provides comprehensive civil rights protection for persons with disabilities. Among other things, this legislation requires that all students with disabilities be guaranteed a learning environment that provides for reasonable accommodation of their disabilities. If you believe you have a disability requiring an accommodation, please contact Disability Services, visit http://disability.tamu.edu, call 845-1637, or go to Cain Hall, Room B118.

Academic Integrity
Aggie Honor Code: “An Aggie does not lie, cheat, or steal or tolerate those who do.”
Upon accepting admission to Texas A&M University, a student immediately assumes a commitment to uphold the Honor Code, to accept responsibility for learning and to follow the philosophy and rules of the Honor System. Ignorance of the rules does not exclude any member of the Texas A&M University community from the requirements or the processes of the Honor System. For additional information please visit: www.tamu.edu/aggiehonor/

Handling of Academic Misconducts
The complete information of university regulations regarding the handling of academic misconducts (including the appeal process) can be found at http://aggiehonor.tamu.edu/.
Basically speaking, there are two approaches: (1) faculty deals with the misconduct autonomously but needs to report any incidents (for first offenses only) to the Aggie Honor Council; (2) faculty reports the incidents directly to the Aggie Honor Council, and the Council will investigate and impose sanctions if a violation is found. In ISEN 314, I will take Approach 2, namely to let the Aggie Honor Council handle any suspected violation of academic integrity.
ISEN 414 Total Quality Engineering

Course Description:
Introduction to the principles of total quality engineering; total quality management philosophy, engineering approaches for designing quality into products and processes; off-line experimentation methods for robust design; emphasis on teamwork and continuous quality improvement.

Course Objective:
(1) Learn formulations, concepts, and analytical procedures for designing quality into products and processes; (2) Learn the connection between ISEN 414 to six-sigma program; (3) Learn fundamental principles of robust design and off-line experimentation techniques; (4) Learn to implement robust design tools in industrial applications; (5) Improve team working skill, data-collecting, and experiment planning capability.

Learning Outcomes:
- Understand the importance of designing quality into products and processes, and its role in six-sigma program;
- Understand and appreciate the response surface methodology and its role in total quality engineering;
- Comprehend the concepts and tools in response surface methodology and be able to use them to solve the total quality engineering problems.

Pre-requisite: Basic statistics or quality control (ISEN 314 or equivalent)

Instructor Information
Instructor: Dr. Yu Ding, Room 4016 ETED, Phone: 458-2343
Email: yuding@iemail.tamu.edu (NOT yuding@tamu.edu)

TA: Arash Pourhabib, Room 3022 ETED, Phone: 402-9556
Email: arash.pourhabib@neo.tamu.edu

Classroom and Schedule
Lecture: 1013 ETED MW 1:50 pm - 2:40 pm
Lab: 1013 ETED, R 3:55 - 6:25 pm.

Office Hours
Instructor: 3 - 4 pm MW. Walk-in is welcome as long as I am not occupied, or by email appointment.

TA: 4-5 pm Tuesday and 2:30-3:30 pm Thursday, or appointment by emails.

Textbook and Course Materials
Course Website: http://ise.tamu.edu/isen414
Coursepack (required). Available for purchase at Copy Corner, 2307 Texas Avenue South, College Station, Texas 77840.


Software used in this course: MATLAB and Microsoft EXCEL

A note on class-related emails: The instructor and TA will send out email notifications, reminders, as well as answers to some common questions through a class email list generated by the registrar’s office. However, it is my understanding that the registrar’s office uses each person’s TAMU email address when generating the email list. If your TAMU email address is not the one for your regular use but you do not want to miss any class related email, you should take proper actions forwarding the emails that are sent to your TAMU address to your regularly used one.

Grade Distribution

<table>
<thead>
<tr>
<th>Component</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exam I</td>
<td>30%</td>
</tr>
<tr>
<td>Exam II</td>
<td>30%</td>
</tr>
<tr>
<td>Homework</td>
<td>20%</td>
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<tr>
<td>Design competition</td>
<td>15%</td>
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<tr>
<td>Lab</td>
<td>5% (Lab on-time)</td>
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Grade/minimum points required: A/90; B/78; C/60; D/45

Examination Schedule

Exam I: In-lab, 10/20/2011, Thursday.
Exam II: In-lab, 12/01/2011, Thursday.

Homework Policy

Homework is due in class on the designated date. You must turn in your homework before the end of the class. Late homework will be docked by 15% per every day it is late (the count of a day starts from 5pm on the due day). For homework before two exams (I will remind you which ones are those), no late homework will be accepted. You will share the data with your group members for homework problems related to experiments you did in lab. But you are required to work out the homework problems INDEPENDENTLY and you MUST turn in the solution of your own. A word-by-word duplicate of others’ solution is considered cheating. If you would like to have your homework or exam re-graded, you have to do so within 10 days from the time when the homework/exam is returned to you.
Course Topic Breakdown

Chapter 1. Introduction: Typical quality control methods; focus of this course; six-sigma program


Chapter 3. Data Analysis: Natural variable versus coded variable; How to estimate the unknown parameters; ANOVA.

Chapter 4. Full Factorial Design: Factorial design versus one-factor-at-a-time; $2^k$ full factorial design; Unreplicated experiments; Normal plot and half normal plot.

Chapter 5. Fractional Factorial Design: Principles enabling fractional factorial designs; Design generator and criteria; $2^{kp}$ design and use of the design table.

Chapter 6. Second Order Design: Check for curvature; Central composite design (CCD); Steepest ascent/descent; Canonical analysis.

Chapter 7. Robust Design: Concept of design robustness; Robust design via experimentation; Cross array strategy; Taguchi's signal-to-noise (SN) ratio.

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ISEN 614 Advanced Quality Control

General Information
Instructor: Dr. Yu Ding, Office: 4016 ETED
Phone: 458-2343
Email: yuding@email.tamu.edu (NOT yuding@tamu.edu)

Textbook: None. Class notes will be posted on the course website.

Reference Books


Useful software: MATLAB and R (freeware).

Description of Course: Fundamental methods about anomaly and change detection in a process or an environment. Methods covered include the univariate and multivariate analysis for continuous and discrete data, risk adjustments, data pre-analyses (such as dimension reduction), and scan statistics. Methods of anomaly and change detection find themselves in a broad spectrum of applications, including manufacturing quality control, health care delivery, as well as homeland security surveillances.

This course is designed for master's students in the engineering and statistics fields to learn about the basic concepts and practical tools for performing anomaly and change detections. It will help doctoral students in both fields broaden their knowledge base and get exposed to new applications. But theoretical analysis is NOT the focus of this course.

Topic breakdown
1. Basic mathematical setup
2. Univariate analysis: Shewhart control chart, CUSUM and EWMA
3. Univariate analysis: Risk adjustments
4. Multivariate analysis: $T^2$, multivariate EWMA and CUSUM
5. Multivariate analysis: Handling the high-dimension profile signals
6. Time-space cluster detection: spatial-temporal scan statistics
7. Handling discrete or categorical data
8. Applications (quality control, healthcare, security applications)

Preferred Background
1. Linear Algebra or Matrix Algebra
2. Knowledge on hypothesis test and linear regression (ISEN 414, STAT 608, or equivalent).
ISEN 616
Design and Analysis of Industrial Experiments

General Information
Instructor: Dr. Yu Ding, Office: 4016 ETED
Phone: 458-2343
Email: yuding@lemail.tamu.edu (NOT yuding@tamu.edu)

Textbook and Course Materials


Useful software: MATLAB, R (freeware)

Description: The main objective of this course is to develop and discuss the fundamental theory, principles, concepts, and procedures required in the efficient design and analysis of engineering experiments. Emphasis is placed on engineering formulations and applications.

Course Overview

Chapter 1. Basic principle and experiments with a single factor: Design principals, hypothesis test, least square estimation, one-way layout model, ANOVA, multiple comparison, residual analysis, relation of this course to six-sigma program

Chapter 2. Experiments with more than one factor: two-way layout model, multi-way layout model, paired comparison design, randomized block design, Latin square design, balanced incomplete block design.

Chapter 3. Full factorial experiments: Factorial experiments versus one-factor-at-a-time; main effects and interaction effects, ANOVA for factorial experiments; unreplicated design and half normal plot; regression for computing factorial effects.

Chapter 4. Fractional factorial experiments: Design principles for fractional factorial design, maximum resolution and minimum aberration criteria; construction of fractional factorial design; use of design tables.

Chapter 5. Response surface methodology: Concept of response surface methodology; check for curvature; central composite design; steepest descent/ascent method; canonical analysis.

Chapter 6. Robust parameter design: Concept of robust design; noise factor; cross array strategy; comparison of cross array and single array strategies; Taguchi’s signal-to-noise ratio and its limitations.

Preferred Background
1. Linear Algebra or Matrix Algebra
2. Knowledge on linear regression.
Statement on conferral of degree requirement: Conferral of degree is not required to earn the proposed certificate.

Statement on grade requirement: The proposed certificate is intended for students who are either in graduate school or who are excelling in their undergraduate studies, and hence a GPA minimum of 3.0 is required.

Letters of Support (on following pages):
- Texas A&M Department of Biomedical Engineering Industrial Advisory Board
- Texas A&M Institute for Preclinical Studies
- Texas A&M National Center for Therapeutics Manufacturing
October 31, 2011

John C. Criscione, MD PhD
Associate Professor of Biomedical Engineering
Texas A&M University
Mailstop 3120
College Station, TX 77843-3120

RE: Proposed “Certificate of Quality Engineering for Regulated Medical Technologies”

Dr. Criscione,

On behalf of the Industry Advisory Board of the Department of Biomedical Engineering at Texas A&M University, this letter is provided to detail our support for and efforts toward the launching of a certificate program in the area of regulatory affairs.

As a supplier of design and test hardware and software to the medical device industry, my experience is that the industry suffers substantial-training costs and loss of productivity when new hires lack the necessary knowledge about regulatory compliance. I see a preference from the companies National Instruments serves to hire graduates who, as proposed in the certificate program, have studied regulatory affairs and have participated in projects that are subject to regulatory oversight.

Approximately 3 years ago, we advised the Department of Biomedical Engineering to develop a certificate program in regulatory affairs and we offer our strongest support for the proposed program.

It is the opinion of the advisory board that the proposed certificate program will enhance the standing of Texas A&M within our industry, and more importantly, it will give students an opportunity to learn valuable skills for engineering careers in biomedicine.

Sincerely,

John Hanks  
National Instruments  
Vice President, Medical Life Science Segment  
Office: 1 512 683 6840  
Cell: 1 512 656 8279
September 25, 2012

Dear Dr. Criscione,

Texas A&M Institute for Preclinical Studies (TIPS) supports the development of a Certificate of Quality Engineering for Regulated Medical Technologies for students in The Dwight Look College of Engineering at Texas A&M University. The addition of this program will provide greater employment and advancement opportunities for engineering graduates in the highly competitive field of medical device development. There is a growing trend among academic institutions across the country to develop regulatory science degrees and certificate programs to address the need for new drugs and medical technologies to treat and prevent diseases. Texas A&M is uniquely positioned to develop such programs given the medical device expertise of faculty at the College of Engineering and the access to highly qualified research personnel and state-of-the-art GLP facilities at TIPS.

TIPS provides Good Laboratory Practices (GLP) compliant preclinical services in support of regulatory submissions to the Food and Drug Administration as well as pilot and feasibility studies on a wide array of medical devices. Large animal model development, imaging, and biomarker assessment are conducted at our 112,000 sq ft dedicated large animal facility, with a specialized staff of translational researchers. TIPS has unsurpassed facilities and equipment, including four operating rooms, intensive care unit and a 3T MRI with simultaneous fluoroscopy in addition to the 128 slice PET/CT, and a GLP clinical diagnostic lab. Internships through the TIPS facility will provide valuable educational opportunities in the practical setting for our students.

On behalf of TIPS, I support the development of the certificate program and look forward to participating through internships or other appropriate means. I am highly enthusiastic about the program and offer my support to participate.

Sincerely,

Theresa W. Fassum, DVM, PhD
Diplomate ACVS
Tom and Joan Read Chair in Veterinary Surgery
Director and Founder, Texas Inst. for Preclinical Studies
Director, Clinical Programs and Biomedical Devices, Michael E. DeBakey Institute
Professor of Surgery
College of Veterinary Medicine
Texas A&M University
tfassum@tamu.edu
Tel: (979) 845-3374
Fax: (979) 845-6522

Texas A&M Institute for Preclinical Studies
800 Raymond Stotzer Blvd
Suite 2060
College Station, Texas 77843-4478
800 Stotzer Parkway, Building 1904
4478 TAMU
College Station, TX 77843-4478
Tel. 979.847.8477 Fax. 979.845.6522
http://tips.tamu.edu
October 1, 2012

John C. Criscione, MD PhD
Associate Professor of Biomedical Engineering, Texas A&M University
Advisory Board Member of FDA Medical Device Industry Coalition

RE: Proposed “Certificate of Quality Engineering for Regulated Medical Technologies”

Dear Dr. Criscione:

Thank you for considering the needs of our National Center for Therapeutics Manufacturing (NCTM) when developing your proposed certificate program in quality engineering for medical technologies. We enthusiastically support the proposed certificate and agree that the medical industry is in need of engineering graduates with specific training in quality engineering.

The National Center for Therapeutics Manufacturing (NCTM) is both a provider of training and education for biopharmaceutical workforce development as well as an employer of this workforce. NCTM is a core biopharmaceutical manufacturing, research, and education facility nearing finally completion on the Texas A&M University campus under the management of the Texas Engineering Experiment Station, and supported by the Texas Emerging Technology Fund. Utilizing the revolutionary “flexible-by-design” platforms that allow for continuous operation and surge capacity, NCTM will be able to rapidly produce drugs in precisely targeted quantities. It will also provide an interactive learning environment for students, researchers, and industrial partners, a unique component of this program, compared to conventional training and curriculum.

With such a focus on related medical technologies, the NCTM has multiple opportunities for students to experience quality engineering in practice. Moreover, for our grant from the Texas Workforce Commission, we collaborate with multiple industry partners with potential internship and employment opportunities in quality systems engineering. This grant also involves curriculum development, and as quality courses are developed, I look forward to having them included as options toward meeting the proposed certificate requirements (i.e., 6 hrs in quality systems engineering).

Please feel free to contact me for further information or for further support of the proposed certificate program.

Sincerely,

Michael Pishko, PhD
Director, National Center for Therapeutics Manufacturing
Stewart & Stevenson Professor II

100 Discovery Drive
College Station, TX 77849-3122