Texas A&M University  
Departmental Request for a New Course  
Undergraduate • Graduate • Professional  
* Submit original form and attach a course syllabus.*  

1. This request is submitted by the Department of  
   Biomedical Engineering  
   
2. Course prefix, number and complete title of course:  
   BMEN 604, FDA Good Laboratory and Clinical Practices  
   
3. Catalog course description (not to exceed 50 words):  
   Implementation of Good Laboratory Practices (GLP) for the submission of preclinical studies and use of Good Clinical Practices (GCP) in clinical trials in accordance with Food and Drug Administration (FDA) regulations; includes similarities and differences in GLP and GCP critical for the introduction of new drugs and medical devices.  
   
4. Prerequisite(s):  
   BMEN 430 or 630 and Graduate Classification, or instructor approval  
   Cross-listed with:  
   Cross-listed courses require the signature of both department heads.  
   
5. Is this a variable credit course?  
   ☐ Yes  
   ☑ No  
   If yes, from ________ to ________  
   
6. Is this a repeatable course?  
   ☐ Yes  
   ☑ No  
   If yes, this course may be taken ________ times.  
   Will this course be repeated within the same semester?  
   ☐ Yes  
   ☑ No  
   
7. This course will be:  
   a. required for students enrolled in the following degree program(s) (e.g., B.A. in history)  
   b. an elective for students enrolled in the following degree program(s) (e.g., M.S., Ph.D. in Biomedical Engineering)  
   MS, MEng, and Ph.D. in Biomedical Engineering  
   
8. If other departments are teaching or are responsible for related subject matter, the course must be coordinated with these departments.  
   Attach approval letters.  
   
9. Prefix | Course # | Title (excluding punctuation)  
BMEN 604FDA GOOD LAB/CLINIC PRAC  

<table>
<thead>
<tr>
<th>Lect.</th>
<th>Lab</th>
<th>SCI</th>
<th>GCP and Fund Code</th>
<th>Admin. Unit</th>
<th>Acad. Year</th>
<th>FICE Code</th>
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Approval recommended by:  

Department Head - Gerard L. Cote  
June 16, 2009  

Chair, College Review Committee  
Date  

Dean of College  
Date  

Dean of College  
Date  

Submitted to Coordinating Board by:  

Associate Director, Curricular Services  

Questions regarding this form should be directed to Sandra Williams at 845-8201 or sandra.williams@tamu.edu.  
Curricular Services - 3/09  

1 of 2 B4
Course: BMEN 604

Course Title: FDA Good Laboratory and Clinical Practices

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

Textbook: TBA

Description: Implementation of Good Laboratory Practices (GLP) for the submission of preclinical studies and use of Good Clinical Practices (GCP) in clinical trials in accordance with Food and Drug Administration (FDA) regulations; includes similarities and differences in GLP and GCP critical for the introduction of new drugs and medical devices.

Prerequisites: BMEN 430 or 630 & Graduate Classification, or instructor approval

Outline of Subject Matter

<table>
<thead>
<tr>
<th>Subject</th>
<th>Hours</th>
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<tbody>
<tr>
<td>GLP Regulations</td>
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<tr>
<td>GCP Regulations</td>
<td>18</td>
</tr>
<tr>
<td>GLP/GCP in practice</td>
<td>6</td>
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<td>Total</td>
<td>42</td>
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Evaluation:
- Exams: 60% 100-90%........A
- Assignments: 40% 80-89%........B
- 100% 70-79%........C
- 60-69%........D
- <60%........F

• 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/rule7.htm.

• Note: It is the student’s responsibility to make arrangements to reschedule exams/ quizzes. Exams and quizzes must be completed in accordance with University policies which can be found online at http://student-rules.tamu.edu/rule7.htm.

Americans with Disabilities Act

The American with Disabilities Act (ADA) is a federal antidiscrimination 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 the Department of Student Life, Services for Students with Disabilities in Room B118 of Cain Hall, or call 845-1637.

Academic Integrity

Aggie Code of Honor: "Aggies do not lie, cheat, or steal, nor do they tolerate those who do."

“It is the responsibility of students to help maintain scholastic integrity at the university by refusing to participate in or tolerate scholastic dishonesty,” which can be found online at http://student-rules.tamu.edu/rule20.htm.