17. New Course – *from November 13, 2009 meeting*

**BMEN 404. FDA Good Laboratory and Clinical Practices. (3-0). Credit 3.** 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: Admitted to major degree sequence and BMEN 430; junior or senior classification.
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 404, 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):
   Admitted to major degree sequence and BMEN 430; junior or senior classification

5. Is this a variable credit course? □ Yes ✓ No
   If yes, from _______ to _______

6. Is this a repeatable course? □ Yes ✓ No
   Will this course be repeated within the same semester? □ Yes ✓ No
   If yes, this course may be taken _______ times.

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 geography)

   BS 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 404 FDA GOOD LAB / CLINIC PRACT

   Lec. Lab SCH CIP and Fund Code Admin. Unit Acad. Year FICE Code
   0 3 0 0 0 3 1 4 0 5 0 1 0 0 0 6 0 4 5 0 1 0 - 1 1 0 3 6 3 2

   Approval recommended by:
   Gerad L. Cote
   Date

   Chair, College Review Committee
   Date

   Dean of College
   Date

   Submitted to Coordinating Board by:
   Effective Date

   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

June 17, 2009

2 of 6
Course: BMEN 404

Course Title: FDA Good Lab and Clinical Practices

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

Textbook: TBA

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 new drugs and medical devices.

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

Outline of Subject Matter

GLP Regulations

Overview ................................................................. 3
Quality Systems ...................................................... 3
Organizational, Personnel, and Facilities Responsibilities .......... 3
Operations and SOPs ................................................ 3
Study Protocol and Implementation ................................ 3
Reporting ............................................................ 3
Total GLP Regulations ............................................. 18

GCP Regulations

Overview of Clinical Trials ........................................ 3
Clinical Investigation Plan ........................................ 3
Organizational, Personnel, and Facilities Responsibilities .......... 3
Records and Reporting ............................................ 3
Pre-IDE and IDE .................................................. 3
Post-Market Clinical and Device Evaluation ....................... 3
Total GCP Regulations ............................................. 18

GLP/GCP in practice ................................................ 6
Total ............................................................... 42

Evaluation:

Midterm Exam 30% 100-90%.......A
Final Exam 30% 80-89%.......B
Homework Assignments 20% 70-79%.......C
Develop Regulator Proposal to include SOP, AUP, GCP 60-69%.......D
and IRB protocol 20% <60%.........F
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/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 Disabilities Services 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.
MEMORANDUM

September 28, 2009

FROM: Dr. Gerard L. Coté  
Charles H. & Bette Barclay Professor and Department Head

TO: Dr. Theresa W. Fossum  
Tom and Joan Reed Chair & Professor of Veterinary Small Animal Clinical Sciences

RE: Letter of Support Requested

The Department of Biomedical Engineering is planning to offer a new graduate course as part of the graduate curriculum: FDA Good Lab and Clinical Practices. To avoid delays in the approval process, we are requesting that you please review the attached syllabus and provide us with a brief letter of support for the course or simply check the appropriate box below, sign and return the form. Alternatively, if there is overlap with this course and courses in your department, please let us know so we can work to resolve the issue(s). Please send letter of support or return this memo to our graduate academic advisor, Dr. Fidel G. Fernandez, at MS 3120. Thank you for your assistance on this matter.

Approval Section:

___ Yes, please proceed with the course approval process since I see no problem with the Department of Biomedical Engineering offering this course.

___ No, do not proceed. I wish to discuss ASAP.

Theresa W. Fossum, DVM, Ph.D.  
Tom and Joan Reed Chair  
Professor of Veterinary Small Animal Clinical Sciences  
Director of T.I.P.S.  
Director of the Michael E. DeBakey Institute

Oct 5, 09

Date
Fidel Fernandez

From: Poppy Capehart [poppycapehart@ag.tamu.edu]
Sent: Tuesday, October 06, 2009 9:38 AM
To: Fidel Fernandez
Cc: Robert Knight; sjwilliams@dsmail.tamu.edu; j-keeton@tamu.edu
Subject: BMEN 404 - FDA Good Laboratory and Clinical Practices

Howdy, Fidel - I am in receipt of your memo related to BMEN 404 and its status as a new course proposal.

I didn’t block this course and prior to the UCC meeting in question, had no idea it existed. I do think it is prudent of all departments to vet new course proposals in virtually every direction to ensure the least conflict with that proposal's progress and given this course had FDA in its title and in the course description, it would have been appropriate to check.

Dr. Knight asked the body in general and you and me specifically if NFSC had reviewed it to which both of us said "No."

With that, the course was tabled.

Dr. Keeton, NFSC Dept. Head, reviewed the information provided and found no reason to object to the intentions of the course. As far as NFSC is concerned, there are no objections to BMEN 404.

Poppy

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Dr. Poppy Capehart, ’75
Undergraduate Program Coordinator
Department of Nutrition & Food Science
College of Agriculture and Life Sciences
Texas A&M University
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"Patience is not really the ability to wait, but the ability to keep a good attitude and stay peaceful while doing it."
MEMORANDUM

November 1, 2010

To: Dr. Gerald Cote  
Charles H. & Bette Barclay Professor and Department Head

From: Dr. Linda L. Logan  
Department of Veterinary Pathobiology

Subject: Support Initiation of Undergraduate Course FDA Good Lab and Clinical Practices

The Department of Veterinary Pathobiology has reviewed the course syllabus for the new course FDA Good Lab and Clinical Practices. We find very little overlap with the VTPB 489 course on Laboratory Biosafety and Biosecurity. We are very supportive of the Department of Biomedical Engineering going forward with listing their new course in the University catalog.

Thank you for your patience during our transition period between two acting Department Heads and the incumbent, me who is settling in. All the best.