

UD 8/11/11

Office of the Registrar  
FORM 40 REV. 11/09

**PURDUE UNIVERSITY**  
REQUEST FOR ADDITION, EXPIRATION,  
OR REVISION OF AN UNDERGRADUATE COURSE  
(10000-40000 LEVEL)

Print Form

EFD 81-10

DEPARTMENT Biomedical Engineering

EFFECTIVE SESSION Fall 2011

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

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> 1. New course with supporting documents | <input type="checkbox"/> 7. Change in course attributes (department head signature only)  |
| <input type="checkbox"/> 2. Add existing course offered at another campus   | <input type="checkbox"/> 8. Change in instructional hours                                 |
| <input type="checkbox"/> 3. Expiration of a course                          | <input type="checkbox"/> 9. Change in course description                                  |
| <input type="checkbox"/> 4. Change in course number                         | <input type="checkbox"/> 10. Change in course requisites                                  |
| <input type="checkbox"/> 5. Change in course title                          | <input type="checkbox"/> 11. Change in semesters offered (department head signature only) |
| <input type="checkbox"/> 6. Change in course credit/type                    | <input type="checkbox"/> 12. Transfer from one department to another                      |

PROPOSED:

EXISTING:

Subject Abbreviation BME

Subject Abbreviation \_\_\_\_\_

Course Number 49000

Course Number \_\_\_\_\_

Long Title Professional Elements of Design

Short Title Professional Elements Design

Abbreviated title will be entered by the Office of the Registrar if omitted. (30 CHARACTERS ONLY)

TERMS OFFERED  
Check All That Apply:

- Summer  Fall  Spring

CAMPUS(ES) INVOLVED

- Calumet  N. Central  
 Cont Ed  Tech Statewide  
 Ft. Wayne  W. Lafayette  
 Indianapolis

CREDIT TYPE

1. Fixed Credit: Cr. Hrs.   
 2. Variable Credit Range: Minimum Cr. Hrs.  To  Or  Maximum Cr. Hrs.   
 3. Equivalent Credit: Yes  No

COURSE ATTRIBUTES: Check All That Apply

1. Pass/Not Pass Only   
 2. Satisfactory/Unsatisfactory Only   
 3. Repeatable   
 4. Credit by Examination   
 5. Special Fees   
 6. Registration Approval Type Department  Instructor   
 7. Variable Title   
 8. Honors   
 9. Full Time Privilege   
 10. Off Campus Experience

ScheduleType	Minutes Per Mtg	Meetings Per Week	Weeks Offered	% of Credit Allocated
Lecture				
Recitation				
Presentation				
Laboratory				
Lab Prep				
Studio	100	1	16	100
Distance				
Clinic				
Experiential				
Research				
Ind. Study				
Pract/Observ				

Cross-Listed Courses  
 OFFICE OF THE REGISTRAR  
 RECEIVED  
 2011 AUG -9 AM 9:43

COURSE DESCRIPTION (INCLUDE REQUISITES/RESTRICTIONS):

Prerequisite: BME 39000. Co-requisite: BME 48800. This course advances and enhances engineering design tools, concepts, and knowledge relevant to biomedical engineering design. Students work individually and in small teams to investigate the topic within the context of their specific senior design project in preparation for their lab. Topics include project management, human and animal subjects, ethics, regulatory affairs, literature and patent searching, and entrepreneurship.

\*COURSE LEARNING OUTCOMES:

Students will have demonstrated the ability to: Effectively communicate skills in oral and written form, both individually and as part of a team. Explain/discuss realistic design constraints, including regulatory issues, societal influences, and ethical and professional responsibilities of biomedical engineers, as related to the engineering design process. Generate and justify solutions to a medical and/or biological problems that addresses customer needs and realistic constraints.

Calumet Department Head _____ Date _____	Calumet School Dean _____ Date _____
Fort Wayne Department Head _____ Date _____	Fort Wayne School Dean _____ Date _____
Indianapolis Department Head _____ Date _____	Indianapolis School Dean _____ Date _____
North Central Department Head _____ Date _____	North Central Chancellor _____ Date _____
West Lafayette Department Head <u>George R. Woodicka</u> <u>5/2/11</u>	West Lafayette College School Dean <u>Michael P. Hawn</u> <u>7/25/11</u>
	West Lafayette Registrar <u>[Signature]</u> <u>8/11/11</u>



BME 49000

Engineering Faculty Document No. 81-10

February 4, 2011

**TO:** The Faculty of the College of Engineering  
**FROM:** The Faculty of the School of Biomedical Engineering  
**RE:** New Undergraduate Course, BME 49000, Professional Elements of Design

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 49000 Professional Elements of Design**

Term offered: Fall, Studio 2, Cr. 1

Prerequisite: BME 39000

Co-requisite: BME 48800

**Description:** This course advances and enhances engineering design tools, concepts, and knowledge relevant to biomedical engineering design. Students work individually and in small teams to investigate the topic within the context of their specific senior design project in preparation for their lab. Topics include project management, human and animal subjects, ethics, regulatory affairs, literature and patent searching, and entrepreneurship.

**Reason:** This course replaces the lecture component of the old BME 405. This course is required of all BME students completing their senior design laboratory courses. The content of the course ensures all relevant design tools and concepts are introduced to all students. This studio style design course involves professional skill development under the guidance of faculty and staff using in-class active learning strategies. This interactive format allows real-time mentoring and feedback to enhance the students' senior design experience. Circulation of faculty, staff, and teaching assistants during the studio period ensure questions are answered in a timely manner and the students understand the tools and concepts well enough to put them into practice in the senior design lab components (BME 48800 and 48900).

BME 48800 Preliminary Senior Project Design (1 credit lab)

BME 48900 Senior Design Project Lab (2 credit lab)

BME 49000 Professional Elements of Design (1 credit studio)

George R. Wodicka  
George R. Wodicka, Professor and Head  
Weldon School of Biomedical Engineering

APPROVED FOR THE FACULTY  
OF THE SCHOOLS OF ENGINEERING  
BY THE ENGINEERING  
CURRICULUM COMMITTEE

ECC Minutes #17

Date 4-20-11

Chairman ECC R Cipa



**BME 490 Professional Elements of Design****Course Staff**

---

**Course Instructor:**

Dr. Ann Rundell

Dr. Sherry Voytik-Harbin

**Lab Coordinators:**

Dr. Marcia Pool

Dr. Allison Sieving

**Teaching Assistant:**

Jamie Brugnano

**Course Operation**

---

**Course Description:** The biomedical engineering design process is completed starting from a preliminary Course description: This course introduces advanced engineering design tools & concepts relevant to biomedical engineering design. Each topic is briefly introduced and students work individually as well as in small teams to investigate the topic within the context of their specific senior design project during the class period. Topics include project management, human and animal subjects, ethics, regulatory affairs, literature and patent searching, and entrepreneurship.

**Course Format:** Class sessions are designed to be interactive with minimal formal lectures. Typically, class sessions will start with a 20 minute introduction to a topic followed by a charge to the students to investigate the topic within the context of their senior design project. To investigate topics students will use the first floor laboratories and computer room for internet access and electronic document support. Faculty and staff will circulate to address questions and encourage thought on the topic at hand. All assignments are to be completed in class and submitted through blackboard to the course instructors.

**Campus Emergency Response Procedures:**

- Fire Alarm – Evacuate the building using the exits on the east side of RM 1087 or 1083 MJIS. Only gather personal items if it does not jeopardize your safety. Assist those who need help, if possible. Proceed to the front lawn of the Burton Morgan Building. Report to a course instructor your name before leaving the emergency assembly area.



- All hazards warning (examples of hazards: tornado (severe weather)/hazardous materials release/civil unrest/directed by police personnel) – When you hear the all hazards alarm immediately seek shelter. Continue to a safe location (typically the lowest level of the building in an area without windows).

**Campus Emergency Policy:** In the event of a campus wide emergency the class outline and course requirements may be subject to change. The course instructor will provide information in regards to changes in the course requirements or course schedule as a result of a campus wide emergency.

### Course Assessment

#### Course Outcomes:

	Course outcome	Relationship to BME program outcomes
I	Effectively communicate skills in oral and written form, both individually and as part of a team.	6, 7
II	Explain/discuss realistic design constraints, including regulatory issues, societal influences, and ethical and professional responsibilities of biomedical engineers, as related to the engineering design process	8,9
III	Generate and justify solutions to a medical and/or biological problems that addresses customer needs and realistic constraints	1, 3

**Academic Conduct:** You are expected to behave in a professional and ethical manner in all aspects of this course. Plagiarism, cheating, or other acts of academic dishonesty will not be tolerated. Any infractions whatsoever will result in immediate expulsion from the course and a failing grade for the semester. Instances of plagiarism or cheating will also be reported to the Dean of Students Office to be recorded on your permanent academic record. If an individual behaves in any other manner that is unprofessional or unethical during the semester, the course instructor(s) reserves the right to fail the student for that as well. For more information, see the Purdue University Student Conduct Code at:

<http://www.purdue.edu/odos/administration/codeconduct.htm>.

**Grading Scale:** Assignments will be graded on a Pass/Fail basis. Mastery of assignments is required to pass the course. Grading will be based on attendance, class participation, and satisfactory performance on all in-class assignments. Students receiving an unsatisfactory assessment will be permitted to repeat the assignment.





**Grading Scheme:** Final grades for the course will be determined by 3 components: 1) student demonstration of skill mastery on in-class assignments, 2) attendance, and 3) class participation.

Letter Grade	Skill Mastery		Attendance		Class Participation
A	Achievement of a P or BP on all in-class assignments	AND	No more than one time late to class	AND	Consistently participated
B	Achievement of a P or BP on all in-class assignments	AND	One unexcused absence OR late to class twice	AND	Consistently participated
C	Achievement of a P or BP on all in-class assignments	AND	Two unexcused absences OR late to class three times	OR	Occasionally participated OR failed to complete the end of course evaluation
D	Achievement of a P or BP on all in-class assignments	AND	Two unexcused absences OR late to class three times	AND	Occasionally participated OR failed to complete the end of course evaluation
F	Failed to achieve higher than a NP on any in-class assignment	OR	Three unexcused absences OR late to class four times	OR	Consistently did not contribute to class

**Class Attendance Policy:** On-time attendance is required in this course. Students that arrive after the start of class, but within the first 45 minutes of the class will be considered late. Students that arrive after the first 45 minutes of class will be considered absent. When a student is tardy to class they should immediately inform one of the course instructors of their arrival in order to prevent a late arrival being recorded as an absence. In cases of excused absences due to extenuating circumstances (e.g., death in family, illness, job interview), the course instructor should be contacted immediately (preferably prior to the class) and written documentation will be required.

**Class Participation Policy:** In order for team based assignments to be successful, all team members must play an active role in the assignment. Instructor observations and periodic peer reviews will be used to monitor student participation on team based assignments. To help students gauge if their class participation is at an appropriate level a course instructor will provide feedback after the 2<sup>nd</sup> week of class. Students that have been identified as having low class participation in the first 2 weeks of class still have the opportunity to improve their grade to "A" status by demonstrating consistent participation for the remainder of the semester. Students that demonstrate a pattern of low participation or suddenly stop participating after that initial 2 week window will be unable to make improvements to their class participation grade.



**Course Schedule:**

<b>Week (date)</b>	<b>Presentation Topic (15 min max)</b>	<b>Concepts to be understood</b>
1 Aug 23	Generating engineering specifications for designing a product	<p>What are technical specifications</p> <p>How the customer desires and the application determine the realistic constraints and technical specs?</p> <p>Realistic constraints include economic, regulatory, ethical, sustainability, manufacturability, environmental, societal, etc.</p>
2 Aug 30	Literature & patent searching	<p>Significance of a literature and Patent/Intellectual property searches to establish the current state of the art in the field.</p> <p>Documentation of literature and patents within notebooks</p>
3 Labor Day	No class	
4 Sept 13	Project management and scheduling	<p>Demonstrate how by breaking project into subsystems or sub-problems, can more effectively complete project on time and in budget.</p> <p>Understand that a Gantt Chart is a scheduling tool that can help link dependencies to predict timing ramifications of certain decisions and delays;</p> <p>Consider the multidisciplinary nature of the project and (to the extent possible) assign responsibilities along the lines of interests and strengths while still balancing contributions to the workload.</p>
5 Sept 20	Human and Animal Subject Trials	<p>Understand the responsibilities of the researcher to protect and ethically treat the subject</p> <p>Know the certification and training process to participate and conduct Human or Animal research</p> <p>Understand the need for a unbiased review process and what is involved in that process</p> <p>Justify the necessity of the trial and its design</p> <p>Respect the ongoing process for amendments with revisions to protocols and resulting time lags that may occur</p>
6 Sept 27	Hazard Assessment	<p>Consider all aspects of their product design and look for potential modes of failure and the risks that can emerge</p> <p>Failure Modes, Effects, and Criticality Analysis (FMECA)</p>
7 Oct 4	Regulatory Affairs I	<p>Learn about the regulatory process</p> <p>Understand the role of preclinical animal trials and clinical studies</p>
Fall Break	No class	



**Course Schedule Continued:**

Week (date)	Presentation Topic (15 min max)	Concepts to be understood
8 Oct 18	The review process	<p>What is constructive feedback?</p> <p>How should we respond to valid (and inappropriate) comments?</p> <p>How do we evaluate other work?</p> <p>Intent of document, Audience, Technical content and approach, Grammar, language, Organization, Use of tables and figures, referencing</p>
9 Oct 25	Testing plan	Consider technical specifications, realistic constraints, and customer needs and figure out how to test, demonstrate that the project meets all requirements
10 Nov 1	Career Planning	<p>Appropriate preparation for professional development and career placement</p> <p>What is expected of them?</p> <p>What should they be doing now and in the near future?</p> <p>How to differentiate themselves from a crowd?</p>
11 Nov 8	Final Report Options (5 minutes to explain 3 report options)	<p>What is appropriate for a journal article, provisional patent, or design competition entry?</p> <p>Authorship and Ownership;</p> <p>perspectives extracted from responsible conduct of research</p>
12 Nov 15	Ethics	<p>Emergence of potential ethical dilemmas</p> <p>Accommodation and implication of ethical dilemmas within the design process</p>
13 Nov 22	Evaluate oral presentations	(Note this is thanksgiving week)
14 Nov 29	Entrepreneurship/ commercialization/ tech transfer	From the perspective of a potential business opportunity, refine and delineate the significance of their contributions (or planned contributions)
15 Dec 6	Regulatory II	Recognize the time, money, and process required to get a prototype to market

