

**UMBC UGC Change in Existing Course: ENME489 Special Topics In Mechanical Engineering: Medical Device Development**

Date Submitted:

Proposed Effective Date: 8/1/2016

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**COURSE INFORMATION:** (please provide all information in the “current” column, and only the information changing in the “proposed” column)

change		current	proposed
<input checked="" type="checkbox"/>	Course Number(s)	ENME489	ENME414
<input checked="" type="checkbox"/>	Formal Title	Special Topics in Mechanical Engineering: Medical Device Development	Medical Device Development
<input type="checkbox"/>	Transcript Title (≤30c)	Medical Device Development	
<input type="checkbox"/>	Recommended Course Preparation	Senior standing	
<input type="checkbox"/>	Prerequisite <b>NOTE:</b> Unless otherwise indicated, a prerequisite is assumed to be passed with a “D” or better.	ENME301, ENME304, ENME320	
<input type="checkbox"/>	Credits	3	
<input type="checkbox"/>	Repeatable?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/>	Max. Total Credits	3	<b>Max. Total Credits:</b> This should be equal to the number of credits for courses that cannot be repeated for credit. For courses that may be repeated for credit, enter the maximum total number of credits a student can receive from this course. E.g., enter 6 credits for a 3 credit course that may be taken a second time for credit, but not for a third time. Please note that this does NOT refer to how many times a class may be retaken for a higher grade.
<input type="checkbox"/>	Grading Method(s)	<input checked="" type="checkbox"/> Reg (A-F) <input type="checkbox"/> Audit <input type="checkbox"/> Pass-Fail	<input type="checkbox"/> Reg (A-F) <input type="checkbox"/> Audit <input type="checkbox"/> Pass-Fail

**CURRENT CATALOG DESCRIPTION:**

This course will examine the multidimensional aspects of medical device development and manufacturing and provide students with the entrepreneurship skills necessary to understand how devices are developed and brought to market. Students will specifically learn how to assess a device’s clinical effectiveness, to evaluate its core function/technology, and to identify the appropriate path and requirements to obtain regulatory clearance/approval. The course will use a combination of lectures and case studies to explore the complex environment and challenges associated with medical device development and provide students with a foundation to work in that industry. Selected devices will be analyzed from technical, regulatory, and medical perspectives, including the evaluation of alternative technologies.

**PROPOSED CATALOG DESCRIPTION** (no longer than 75 words): leave blank if no changes are being proposed to the catalog description. NOTE: information about prerequisites should NOT appear in the catalog description.)

**RATIONALE FOR CHANGE:**

The course has been offered twice as a special topics course. We plan to now include it in the regular rotation of elective courses in Mechanical Engineering.