



SOUTH DAKOTA BOARD OF REGENTS
ACADEMIC AFFAIRS FORMS
New Course Request

USD	Biomedical Engineering	
Institution	Division/Department	
<i>Elizabeth M. Freeburg</i>		5/10/2017
Institutional Approval Signature		Date

Section 1. Existing Course Title and Description

Prefix & No.	Course Title	Credits
BME 450/550	Regulatory Pathways for Medical Product Development	3

Course Description
The Food and Drug Administration has developed several pathways such as Fast Track, Breakthrough Therapy, and Accelerated Approval that can be used to more efficiently move a drug or device through the approval process. This course will explore the different pathways and how the FDA determines which products can use these alternative regulatory pathways to move medical products from discovery to market.

Pre-requisites or Co-requisites (add lines as needed)

Prefix & No.	Course Title	Pre-Req/Co-Req?
ISCI 353	Regulatory Affairs	ISCI 215 (prereq. for this course is ISCI 151)

Registration Restrictions N/A

Section 2. Review of Course

2.1. Was the course first offered as an experimental course (place an "X" in the appropriate box)?
 Yes (if yes, provide the course information below) No

2.2. Will this be a unique or common course?

Unique Course

Prefix & No.	Course Title	Credits
ISCI 253	Regulatory Affairs	3

Provide explanation of differences between proposed course and existing system catalog courses below:

The proposed course is a higher level course for upper-division undergraduate and graduate students which explores a particular aspect of this topic in more detail.
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Section 3. Other Course Information

3.1. Are there instructional staffing impacts?

No. Schedule Management, explain below: The Department of Biomedical Engineering has added new faculty and will integrate this course into teaching schedules

3.2. Existing program(s) in which course will be offered: Biomedical Engineering

3.3. Proposed instructional method by university: R-Lecture

- 3.4. Proposed delivery method by university: 001 Face-to-Face
- 3.5. Term change will be effective: Fall 2017
- 3.6. Can students repeat the course for additional credit?
 Yes, total credit limit: _____ No
- 3.7. Will grade for this course be limited to S/U (pass/fail)?
 Yes No
- 3.8. Will section enrollment be capped?
 Yes, max per section: 25 No
- 3.9. Will this course equate with any other unique or common courses in the common course system database in Colleague and the [Course Inventory Report](#)?
 Yes No
- 3.10. Is this prefix approved for your university?
 Yes No

Section 4. Department and Course Codes (Completed by University Academic Affairs)

- 4.1. University Department Code: UBME
- 4.2. Proposed [CIP Code](#): 14.0501

Is this a new CIP code for the university? Yes No