

SOUTH DAKOTA BOARD OF REGENTS

Academic and Student Affairs
Consent

AGENDA ITEM: 4 – A (2)

DATE: August 10, 2017

SUBJECT: New Specialization: USD Medical Product Development and Manufacturing Specialization in the M.S. Biomedical Engineering Program

University of South Dakota (USD) requests authorization to offer a Medical Product Development and Manufacturing Specialization with the Masters of Science (M.S.) in Biomedical Engineering program. Specializations within a degree program appear on a transcript and require Board approval.

The proposed specialization will focus upon providing masters students with training to design next-generation medical products, including course knowledge on regulatory pathways and commercial marketing for biomedical products. A total of 21 credit hours will be required to complete this specialization, with a total of 33 required to complete a degree. Four new courses are being proposed to compliment the specialization.

USD is requesting authorization to offer the specialization through the University Center in Sioux Falls.

DRAFT MOTION 20170810_4-A(2): I move to approve USD’s Medical Product Development and Manufacturing Specialization within the Masters of Science (M.S.) in Biomedical Engineering program as described in Attachment I.



SOUTH DAKOTA BOARD OF REGENTS ACADEMIC AFFAIRS FORMS

New Specialization

UNIVERSITY:	USD
TITLE OF PROPOSED SPECIALIZATION:	Medical Product Development and Manufacturing
NAME OF DEGREE PROGRAM IN WHICH SPECIALIZATION IS OFFERED:	Biomedical Engineering, M.S. (BMDE)
INTENDED DATE OF IMPLEMENTATION:	7/22/2017
PROPOSED CIP CODE:	14.0501
UNIVERSITY DEPARTMENT:	Biomedical Engineering (UBME)
UNIVERSITY DIVISION:	College of Arts & Sciences

University Approval

To the Board of Regents and the Executive Director: I certify that I have read this proposal, that I believe it to be accurate, and that it has been evaluated and approved as provided by university policy.

Institutional Approval Signature <i>President or Chief Academic Officer of the University</i>	Date
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1. Level of the Specialization:

Baccalaureate Master's Doctoral

2. What is the nature/purpose of the proposed specialization?

South Dakota has a small, but rapidly growing medical device and pharmaceutical products industry. These are highly regulated industries and the route that a technology takes from discovery to market is often complex. The proposed specialization in Medical Product Development and Manufacturing will provide master's students in Biomedical Engineering with a strong foundation in biomedical engineering that will enable them to design next-generation medical products and complement that foundation with a firm understanding of both regulatory pathways and commercial markets so their discoveries can move rapidly into the marketplace.

3. Provide a justification for the specialization, including the potential benefits to students and potential workforce demand for those who graduate with the credential.¹

Several companies in the region, including SAb Biotherapeutics, Alumend, Immutrix, and Sanford Vascular Innovations are developing products that have entered or will soon enter clinical trials; as these companies grow they will need workers that are familiar with the complex regulatory pathways that must be followed. Additionally, the South Dakota Governor's Office of Economic Development (GOED) and the Sioux Falls Chamber of Commerce are actively

¹ For workforce related information, please provide data and examples; data sources may include but are not limited to the South Dakota Department of Labor, the US Bureau of Labor Statistics, Regental system dashboards, etc.

recruiting companies in the medical device and pharmaceutical products industries. Sioux Falls has identified biomedical business as a key industry for the city and GOED has identified bioscience as a key industry for the state.² Moreover, *2020 Vision: The South Dakota Science and Innovation Strategy* identifies Human Health (including medical technology and medical products) as target sectors to help drive the future of South Dakota's economy.³ The skilled workforce developed by this specialization will be a key recruitment tool in these economic development efforts and graduates with this specialization will gain a competitive advantage in securing these positions. Nationally, the Bureau of Labor Statistics projects 23% growth for Biomedical Engineers in general from 2014 to 2024.⁴

4. List the proposed curriculum for the specialization (including the requirements for completing the major – **highlight courses in the specialization**):

Prefix	Num.	Course Title <i>(add or delete rows as needed)</i>	Credit Hours	New (yes, no)
Core courses:				
BME	710	Experimental Design & Data Analysis in Biomedical Engineering	3	No
BME	790	Seminar (1 credit hour course taken 3 times)	3	No
Required courses subtotal:			6	
Plan B only				
BME	788	Master's Research Problems/Project	6	No
Master's research requirements subtotal:			6	
Medical Product Development and Manufacturing Specialization:				
BME	525	Medical Product Development	3	Yes
BME	550	Regulatory Pathways for Medical Product Development	3	Yes
BME	715	Science Communication	3	Yes
Electives (Select 1 course; 3 credit hours required)				
BME	601	Biomaterials	3	No
BME	721	Tissue Engineering		No
BME	723	Cellular Engineering		Yes
BME	751	Drug Delivery		No
Non-departmental requirements				
BADM	580	Foundations of Marketing and Organizational Behavior	3	No
BADM	771	Leadership Development	3	No
POLS	771	Public Policy Process and Evaluation	3	No
Total number of hours required for completion of specialization			21	
Total number of hours required for completion of major			33	
Total number of hours required for completion of degree			33	

² <http://siouxfallsdevelopment.com/biomedical.cfm> and <http://www.sdreadytowork.com/Key-Industries/Bioscience.aspx>.

³ <http://sdepescor.org/sdepescorHome/wp-content/uploads/2015/07/2020-Vision.pdf>

⁴ <https://www.bls.gov/ooh/architecture-and-engineering/biomedical-engineers.htm>.

5. Complete the following charts to indicate if the university intends to seek authorization to deliver the entire specialization at any off-campus location or intends to seek authorization to deliver the entire specialization through distance technology?⁵

	Yes/No	If Yes, list location(s), including the physical address	Intended Start Date
Off-campus	Yes	UC Sioux Falls	7/22/2017

	Yes/No	If Yes, identify delivery methods	Intended Start Date
Distance Delivery	No		

6. **Additional Information:** N/A

⁵ The accreditation requirements of the Higher Learning Commission (HLC) require Board approval for a university to offer programs off-campus and through distance delivery.