

**SOUTH DAKOTA BOARD OF REGENTS**

**Academic and Student Affairs**

**AGENDA ITEM: 4 – K (6)**

**DATE: March 30 – April 1, 2016**

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**SUBJECT: New Certificate: USD Certificate in Regulatory Affairs**

The University of South Dakota (USD) requests authorization to offer a certificate in Regulatory Affairs. The certificate is intended to address the growing medical device and pharmaceutical industries in South Dakota. The certificate will benefit students by providing knowledge and skills related to regulations required to get drugs and devices from trial procedures to the market place. Students with the certificate will also find employment in quality assurance and quality control aspects of such businesses. The certificate consists of 11 credit hours.

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**RECOMMENDED ACTION OF THE EXECUTIVE DIRECTOR**

I move to approve USD's new certificate request for a Regulatory Affairs Certificate as described in Attachment I.

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**Certificate Request**

This form is to be used to request approval for a new certificate program that includes currently offered courses. A certificate program is not a major or minor. Refer to BOR policy 2:23 Certificate Programs.

<u>USD</u>	<u>Arts &amp; Sciences / Biomedical Engineering</u>	<u>Elizabeth M. Freeburg</u>	<u>11/22/15</u>
<b>Institution</b>	<b>Division/Department</b>	<b>Institutional Approval Signature</b>	<b>Date</b>

1. **Name of Program:** Certificate in Regulatory Affairs

2. **Provide a justification for the program.**

The University of South Dakota seeks permission to offer a certificate in regulatory affairs. Sioux Falls and the surrounding region has rapidly growing medical device and pharmaceutical product industries. This growth was spurred by T. Denny Sanford's investment in then Sioux Valley Hospital and continues to be a focus of economic development efforts by both Sioux Falls and South Dakota. Recently, USD has partnered with the City and Forward Sioux Falls to establish the Discovery District at the University Center site. The proposed certificate in regulatory affairs will benefit the existing companies and support the emergence and recruitment of new companies. Graduates with a certificate in regulatory affairs will understand the different pathways set forth by the FDA to take a drug/device/test from pre-clinical trials to products in the market place. These students will likely end up in the "quality assurance/quality control" side of a business.

3. **Who is the audience for the program?**

The audience for this certificate includes those working in or looking to work in companies in pharmaceutical products and medical devices. Completion of the certificate program can be the first step in a student's educational pathway. All the credits from the certificate program can be applied to an existing Associate's Degree in General Studies. Additionally, USD has proposed an A.A. degree in Integrated Science and is preparing an Intent to Plan for a B.S. degree in Biomedical Engineering; all of the credits earned in the Laboratory Science Certificate can be applied to these degrees. Students that are already seeking (or have already received) B.S. degrees in STEM fields can earn the certificate and better prepare themselves for jobs in the rapidly expanding bioscience field, which the Governor's Office of Economic Development has identified as one of the key industries for growth<sup>1</sup>.

4. **List the courses to be completed, the credit hours of each course, and the total number of credit hours required for the program.**

Prefix & #	Title	Credit Hrs
ISCI 151	Integrated Science I	3
ISCI 151L	Integrated Science I Laboratory	1
ISCI 215	Good Laboratory Practices	3
ISCI 215L	Good Laboratory Practices Laboratory	1
ISCI 353	Regulatory Affairs	3
<b>Total Credit Hours Required</b>		<b>11</b>

5. **Proposed CIP code** 41.0301

6. **Effective Date of Certificate Program** Fall 2016

<sup>1</sup> <http://www.sdreadytowork.com/Key-Industries/Bioscience.aspx>