The University Senate of Michigan Technological University Proposal 12-21 (Voting Units: Academic)

Establishment of a New Graduate Certificate in Medical Devices and Technologies Submitted by: Department of Biomedical Engineering

- 1. Proposal Date: Fall 2020
- 2. Proposing Contacts and Department: Dr. Sean J. Kirkpatrick, Department of Biomedical Engineering sjkirkpa@mtu.edu
- 3. Sponsor Department Approvals At the end of the document

4. General Description and Characteristics of Program:

4.1 General Description of Certificate

The Biomedical Engineering program at Michigan Technological University proposes a ten credit Certificate in Medical Devices and Technologies. The Graduate Certificate in Medical Devices and Technologies has the following three objectives: i) to attract students from various disciplines who wish to learn the basics of medical imaging as related to devices, regulatory aspects of medical devices and packaging and miniaturization of medical devices; ii) to teach students basic skills in design, development and testing; and, iii) to provide students the opportunity to gain fundamental knowledge to participate in research and development.

4.2 Catalog Description

The Certificate in Medical Devices and Technologies is designed to develop skills and competencies in biomedical devices and technologies including principle of operation, design, manufacturing, and packaging. In addition, the curriculum integrates application of these skills in real-world problems and implementation of application specific solutions.

5. Rationale for Certificate:

The fields of Medical devices, medical imaging, device packaging have all seen tremendous growth in recent years. The current drive for miniaturization of medical devices (diagnostics and wearables) has led to renewed interest and need for continued education in this field. New graduates and experienced industry professionals can benefit from

- Greater understanding of principles and applications of medical imaging systems, and microelectromechanical system fabrication techniques
- Assess and interpret regulatory requirements of devices
- Design, develop and implement diagnostic and/or therapeutic devices for biomedical applications

Completion of the requirements for this certification indicates specialization in medical devices and technologies.

6. Related Programs:

- Stanford Online: <u>Biomedical Engineering: Imaging, Devices and Systems</u> Includes Medical imaging, Technology Assessment and Regulation of Medical Devices and Introduction to Micro and Nano electromechanical systems.
- Purdue Online: <u>Biomedical Engineering Concentration</u> Includes Tissue Engineering, Medical Imaging and Diagnostics Technologies and Fundamental of MEMS & Micro-Integrated Systems.
- UMass Lowell: <u>List of Certificates</u> Three separate certifications required to cover Medical imaging, Microelectromechanical systems and Medical devices.

7. Projected Enrollments:

Based on discussions with industry advisors, we have arrived at the following projections:

Academic Year	On-campus	On-line
	Enrollment	Enrollment
2020 -2021	1	3
2021-2022	3	5
2022-2023	3	5
2023-2024	5	10
2024-2025	5	10

8. Scheduling Plans:

No change in the regular scheduling of the existing courses is anticipated. BME will deliver the online courses in our regular scheduling plans. Classes scheduled to be offered in the Fall 2020 will be online ready in the Fall of 2020. Classes scheduled to be offered in the Spring 2021, will be online ready for the Spring 2021 term. Courses will be offered in an asynchronous online format.

9. Curriculum Design:

Required Coursework: 10 credits

BE5410: Medical Imaging (3)
BE5670: Micro & Nano Technologies (3)
BE5755: Medical Devices (3)
BE5900: Biomedical Engineering Masters Topics (with prior approval of the dept.) (1)*

Course Descriptions:

BE5410: Medical Imaging This course covers the physical nature of the interactions between the waves and matter, especially the biological tissues, principle imaging modalities used in modern medicine and the common techniques used for processing of the resulting images. Offered every Spring.

BE5670: Micro & Nano Technologies This course will introduce students to micro- and nanotechnologies and the processes involved in their manufacturing. Particular emphasis will be on their use in biomedical applications. Goal is to provide information beneficial in research and development, and the industry. Offered every Fall.

BE5755: Medical Devices An introduction to medical devices used for diagnosis, monitoring, and treatment in clinical medicine. Topics covered include product planning, reliability, clinical trial design, regulatory as well as technical aspects of common medical devices. Offered every Fall. **BE5900: Biomedical Engineering Masters Topics:** Biomedical engineering courses will be offered as professional electives dependent upon the interest of the student & faculty. In the context of this

certificate this will be a 1 credit project. (Requires approval of Department).

*The 1 credit project may take on various forms depending upon the needs and interests of the student. This is not a thesis. Examples of projects may include literature reviews, participation in a research project, or a work-related project that the student needs to complete at their place of employment.

10. Model Schedule Demonstrating Completion Time

The certificate is designed to be completed in 2 semesters.

Fall Semester

BE5670: Micro & Nano Technologies BE5755: Medical Devices

Spring Semester

BE5410: Medical Imaging BE5900: Biomedical Engineering Masters Topics

11. Library and other Learning Resources

No library or other learning resources are required at this time.

12. Faculty Resumes

The following faculty will be supporting the program. Dr. Sean J. Kirkpatrick, Professor, Biomedical Engineering <u>https://www.mtu.edu/biomedical/people/faculty/kirkpatrick/</u> Dr. Orhan Soykan, Professor of Practice, Biomedical Engineering <u>https://www.mtu.edu/biomedical/people/faculty/soykan/</u> Dr. Smitha Rao, Assistant Professor, Biomedical Engineering <u>https://www.mtu.edu/biomedical/people/faculty/rao/</u>

13. Equipment

No additional equipment will be required.

14. Program Costs

Initial costs for offering the certificate will not incur additional costs, but as enrollment grows additional instructional resources will be needed.

15. Space

There are no new space requirements.

16. Policies, Regulations, and Rules

Not applicable

17. Accreditation Requirements

Michigan Tech is accredited by the <u>Higher Learning Commission</u> (HLC). The proposed certificate will meet HLC criteria 3 and 4. The proposed certificate will not seek additional accreditation.

18. Planned Implementation Date

Spring 2021.

19. Assessment

Upon completion of this certificate, students will be able to:

1. Create device requirements for medical product design and development using fundamental knowledge of engineering, biomedicine, and biotechnology

2. Integrate high-level engineering principles to solve specific biomedical problems related to medical devices and technologies.

3. Apply knowledge of device development, manufacturing and regulatory requirements to reallife medical device design and development scenarios.

Assessment Points	Graduate Learning Objectives	
Grades in Certificate Courses	GLO 1, GLO 2	
(BE5410, BE5670, BE5755)		
Class Professional Skill	GLO 3	
Evaluation- form instructor		
completes		

Approval Process

Departmental Graduate Committee: June1, 2020 Department: May 29, 2020 College of Engineering: June 2, 2020 Graduate School Provost's Office and Deans' Council Approved by the Senate: Approved by the President: