Work in Progress: Bridging Research and Entrepreneurship - Master's Certificate in Translational Biomedical Research at Northwestern University

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Casey J. Ankeny, PhD is an Assistant Professor of Instruction at Northwestern University. Casey received her bachelor's degree in Biomedical Engineering from the University of Virginia in 2006 and her doctorate degree in Biomedical Engineering from Georgia Institute of Technology and Emory University in 2012 where she studied the role of shear stress in aortic valve disease. Currently, she is investigating cyber-based student engagement strategies in flipped and traditional biomedical engineering courses. She aspires to understand and improve student attitude, achievement, and persistence in student-centered courses.

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Mark teaches product development and entrepreneurial classes at Northwestern University in addition to consulting to a variety of medical device companies and global health non-profits in the US and internationally. He has thirty plus years of product development experience in industry and in consulting. Mark has a particular interest in developing curricula focussed on providing students with both the engineering and non-engineering skills required to be successful in careers in industry and in applied research.

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introduction

The National Institutes of Health (NIH) has made a major push to fund translational medicine, especially within biomedical research. The demand for biomedical engineers with an understanding about the science of translation and practical experience is expected to grow. Recognizing this need and curricular gaps in bridging research and commercialization of medical innovations, universities across the country, including ours, have implemented degree-granting translational graduate programs. Structures and attributes of the programs vary. However, most do not require candidates have experience in graduate-level engineering research.

Northwestern University's Master's Certificate in Translational Biomedical Research distinguishes itself from existing programs within Northwestern University and translational Master's (MS) programs offered at other peer institutions in the background of the participating students and its focus. Participants are recruited from the MS student pool within the school of engineering. The curricular focus is on the integration of engineering in the translational pathway.

The interdisciplinary program is designed to immerse the students in the integrative approach and experience needed to take their engineering background to the clinical space and industry. The certificate program capitalizes on the existing extensive research collaborations of the Department of Biomedical Engineering (BME) with the schools of medicine, arts and sciences, and Shirley Ryan AbilityLab, as well as industry relationships formed through faculty, the Farley Center for Entrepreneurship and Innovation, alumni and advisory board members.

Currently, Northwestern University's coursework-based MS students in the BME Department can participate in research through BME 499: Independent Research. NUvention courses offer them the opportunity to partake in product and customer development by working in a four-member interdisciplinary student team with a focus on entrepreneurship. The certificate program provides the missing link between these domains.

curriculum

The certificate curriculum is offered in a two-quarter sequence spanning Summer and Fall. It consists of one (1) core course, two (2) elective courses, and a paid 6-month Summer internship. These requirements for the certificate program are in addition to the MS degree program requirements the students are enrolled in.

Learning outcomes of the program are for the students to:

- Gain an understanding about the science of translation
- Generate and critically evaluate clinical data
- Identify the regulatory issues related to new medical innovations
- Communicate and function effectively in a multi-disciplinary team environment

The core course, “Introduction to Translational Research,” is offered in Summer. This foundational course, scheduled in the evening, is intended to introduce graduate students to the thought processes involved in human disease research and its translation into therapy by providing an overview of disease processes, how they are treated, how basic biological science is used to develop those treatments, and the role of various stakeholders in the translational research pipeline. At the end of this course, the student should understand the medical rationale for studying basic pathomechanisms and how to utilize that rationale to design studies and grant proposals. For the final project of the course, students are provided with examples of recent discoveries based on a basic science article published within the past three years and asked to describe how to take that discovery to clinical application.

Elective courses are chosen from each of the two areas: research design and methods, and regulatory science. Depending on the student’s plan of study, electives can be taken while they are fulfilling their MS degree requirements or thereafter.

Summer internship positions are secured by the Certificate Program Director, leveraging existing and new industry relationships formed through Northwestern University faculty, the Center for Entrepreneurship and Innovation, alumni and advisory board members of the BME Department. Geographically, all of the companies are located in the metropolitan CL area. Company sizes range from startups to major corporations. Firms assign a designated mentor for the intern. The mentor’s responsibilities include conducting progress meetings with the student and communicating with the Certificate Program Director to offer feedback.

admission

The program is marketed to prospective and incumbent BME MS students. Priority is given to coursework-based BME MS students with research experience. BME MS students in the thesis program are considered on a case-by-case basis. Internship job descriptions are made available to the students in advance. As part of their application package, students submit their CV and transcripts from their undergraduate and graduate courses. The admission committee consists of the Certificate Program Director, BME MS Program Director, and representatives of the company offering internships. The screening process involves matching the interest and goals of each student through interviews with company representatives and mentors.

enrollment

The program has undergone a pilot phase in 2017. Three (3) BME MS students applied, from whom two (2) were selected. They completed their internships at EOM in Summer 2017 and coursework at the end of Fall 2017. The 2018 cohort is projected to be larger, judging by the number of people who attended the informational sessions on the program.

pilot assessment and results

For the pilot cohort of two, qualitative assessment was used. The students were interviewed by the Certificate Program Director and the BME MS Program Director after the final exam period of the Fall 2017 quarter. Interview questions included the following:

- Which classes did you take?

- What influenced your choice of the two electives?
- What knowledge did you gain in class?
- How applicable were skills and knowledge acquired in the classroom with respect to the Summer internship?
- How well did the Summer internship match your expectations and interests?
- How is the certificate received by prospective employers in your current job search?
- Do you have any feedback for the certificate program administration?
- Do you have any advice for prospective participants?

Students in the pilot program expressed overall high satisfaction with the curriculum. They were as excited at the conclusion of the program as they were at the beginning of the program. Drawbacks they pointed out were the limited specialties the internship positions represented and narrow choices in elective courses. For the courses they were able to enroll, however, they agreed what they learned in the classroom were immediately applicable to their work at Edge One Medical. The students came with different undergraduate backgrounds, but as observed by their Edge One Medical mentor, there was no marked difference in the students' progress and performance.

coursework revision, assessment, and future plans

The program will be offering a wider variety of internship positions for the 2018 cohort. The BME MS Program is small – about 30 students enroll every year, and only 40% of these students pursue the non-thesis track, which is eligible for this Certificate – we do not expect more than 10 students to enroll.

Based on the feedback from the pilot students, BME advisory board members, and faculty, the coursework for 2018 has been revised to give students more flexibility. The Certificate Director has worked across departments to make more electives available to the certificate students. The classes for the certificate will be selected from four categories; students must take one class from three of the four categories described below.

I. REGULATORY
- Healthcare regulatory environment
- Medical Device Regulations
- Regulatory Sciences in Biotechnology
- Drug and Biologics Regulations

II. BIOSTATISTICS AND CLINICAL TRIALS
- Intro to biostatistics
- Biostatistics for Clinical Investigators
- Clinical Research Design
- Clinical Research Design, Methods, and Grant Writing
- Experimental Design and Measurement
- Clinical Trials
- Data Science for Clinical, Translational, and Population Researchers

III. PROJECT MANAGEMENT AND PRODUCT DEVELOPMENT PROCESS
- NUvention Therapeutics

- Project Management
- Applied Project Management
- Drug Development Process
- Introduction to Translational Research

IV. QUALITY SYSTEMS

- Quality Systems for Regulatory compliance
- Quality Assurance Quality Management
- Practical Quality Management

A curriculum matrix to evaluate adherence to the program objectives and associated learning outcomes is under development for use in Summer 2018. To evaluate the program for the 2018 cohort and beyond, we will use both quantitative and qualitative methods. The quantitative method will involve assessing student performance and perception. Entrance surveys, exit surveys, and course evaluations will be used to collect data. The qualitative method will comprise interviews with students, course instructors, and internship mentors. Surveys and interview questions have been developed by working with Northwestern University's Center for Advancing Learning & Teaching. The results of the analysis will be then used to reflect on the curriculum and form a basis for possible future revisions. As the alumni of the program builds, we will conduct follow-up surveys to assess impact of the program on the participants' careers. In the long term, we intend to expand the applicant pool to other engineering majors with BME-related research experience.