From:	Smith, Randy
To:	Altgold, Tahlia; Fisher, Ashlynn
Cc:	Sutherland, Sue; Smith, Randy; Griffiths, Rob; Reed, Katie; Miriti, Maria; Duffy, Lisa; Hunt, Ryan; Ghadiali, Samir; Matyas, Cory; Tomasko, David
Subject:	Proposal to add a Medical Product Development specialization to the Master of Science in Biomedical Engineering
Date:	Friday, June 12, 2026 2:46:11 PM
Attachments:	image001.png

Ashlynn and Tahlia:

The proposal from the Department of Biomedical Engineering to add a Medical Product Development specialization to the Master of Science in Biomedical Engineering was approved by the Council on Academic Affairs at its meeting on June 11, 2026. Thank you for attending the meeting to respond to questions/comments.

No additional level of internal review/approval is necessary. This action will be included in the Council's next Annual Activities Report to the University Senate (July 2026).

The Office of the University Registrar will work with you on any implementation issues.

Please keep a copy of this message for your file on the proposal and I will do the same for the file in the Office of Academic Affairs.

If you have any questions please contact the Chair of the Council, Professor Sue Sutherland (.43), or me.

I wish you success with this important program development.

Randy

THE OHIO STATE UNIVERSITY

W. Randy Smith, Ph.D.
Vice Provost for Academic Programs
Office of Academic Affairs
University Square South, 15 E. 15th Avenue, Columbus, OH 43201
614-292-5881 Office
smith.70@osu.edu
Assisted by:
Katie Reed
Executive Assistant
(614) 292-5672

TO: Randy Smith, Vice Provost for Academic Programs

FROM: Graduate School Curriculum Services

DATE: **4/9/2026**

RE: Proposal to **Establish a Medical Product Development Specialization** in **The College of Engineering**

The **Department of Biomedical Engineering** in the **College of Engineering** is proposing a **Medical Product Development Specialization within the Master of Science in Biomedical Engineering**.

The proposal was received by the Graduate School on **2/25/2026**. The combined GS/CAA subcommittee first reviewed the proposal on **3/11/2026** via an E-Vote and support its review by the Council on Academic Affairs.

THE OHIO STATE UNIVERSITY

College of Engineering

Undergraduate Education & Student Services

122 Hitchcock Hall
2070 Neil Avenue
Columbus, OH 43210-1278

614-292-2651 Phone
614-292-9379 Fax

engineering.osu.edu

Memo

To: Randy Smith, Vice Provost for Academic Programs, Office of Academic Affairs
From: Cory Matyas, Assistant Dean for Curriculum and Assessment
Date: February 25, 2026
Re: Proposal to Establish Medical Product Development Specialization

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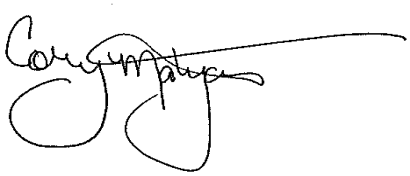
Please find enclosed the proposal to establish a Medical Product Development (MPD) Specialization within the Master of Science in Biomedical Engineering program. This specialization formalizes the long-standing MPD pathway and provides students with an official transcript designation recognizing their advanced training in medical product design, regulatory considerations, professionalism, and industry-aligned project work.

The Engineering College Committee on Academic Affairs reviewed the proposal on February 25, 2026, a vote was taken, and it was unanimously approved. The committee recognized that the specialization strengthens the existing curriculum, enhances student preparation for the medical device industry, and reflects the department's continued commitment to high-quality, practice-focused graduate education.

Thank you for your consideration.



Kowalsky, Lisa

From: Matyas, Cory
Sent: Thursday, April 9, 2026 2:07 PM
To: Kowalsky, Lisa
Cc: Miriti, Maria
Subject: Re: GS/CAA Review Meeting Feedback

Hi Lisa,
The MPD proposal authors would like to address some of your concerns and also do request that you forward their proposal, as it was shared with you, along to CAA if you're comfortable doing so. Here is their response below:

Can you clarify if this is a unique program? In other words, do other BME programs have similar designations?

To our knowledge, this is a unique program. There are other medical product graduate programs/tracks available at other institutions but based more in clinical experience/exposure and do not appear to be project-based. Students in our MPD program are exposed to a two-year project experience, paired with companies from other MPD areas, not just clinical (although clinical experience/projects are sometimes included).

It may be worth explaining why MCR 7770 and/or BME 5639 aren't required (or at least strongly encouraged) given the importance of regulation/compliance.

Regulation/compliance is woven throughout the required MPD specialization courses, and students apply this knowledge/concepts to their capstone projects. Therefore, all MPD students are receiving a foundation in regulation/compliance. Students can choose to add depth on this topic by choosing a regulatory course as their elective, but we are not requiring it as they might wish to add depth in another MPD related topic.

Thank you!
Cory

THE OHIO STATE UNIVERSITY

Corinne Matyas
Assistant Dean of Curriculum and Assessment
College of Engineering
117 Hitchcock Hall | 2070 Neil Ave. | Columbus, OH 43210
614-292-2154 | matyas.3@osu.edu

From: Kowalsky, Lisa <kowalsky.10@osu.edu>
Date: Thursday, April 2, 2026 at 12:13 PM
To: Matyas, Cory <matyas.3@osu.edu>
Cc: Miriti, Maria <miriti.1@osu.edu>
Subject: GS/CAA Review Meeting Feedback

Dear **Cory,**

Good afternoon! We hope that you are doing well. We are reaching out to let you know that on **3-11-2026** the combined Graduate School – Council on Academic Affairs (GS/CAA) reviewed a proposal via E-VOTE from the **College of Engineering** to **Establish a Biomedical Engineering Specialization in Medical Product Development**. GS/CAA thought this was a thoughtful and well-written proposal and support the proposal advancing to Council of Academic Affairs (CAA). Congratulations!

The GS/CAA Committee had the following comments about the proposal for your consideration:

1. Can you clarify if this is a unique program? In other words, do other BME programs have similar designations?

In CBE, we have specializations in different areas such as polymers or biological science.

2. It may be worth explaining why MCR 7770 and/or BME 5639 aren't required (or at least strongly encouraged) given the importance of regulation/compliance.

3. In Table 3, the List of Approved Electives doesn't indicate how many credits should be taken in this section (List of Approved Electives). Is it the 9 credits as Graduate Electives indicated on page 6? Please clarify

Please note that it is not required to address these comments in a revised file. However, if you would like to do so and send an updated file, please let me know. Otherwise, if you would like the proposal to be forwarded to CAA for review without revisions please confirm and we will ensure it is sent up.

Best,
Lisa

THE OHIO STATE UNIVERSITY
GRADUATE SCHOOL

Lisa Clouser (Kowalsky)

The Ohio State University
Graduate School
247E University Hall
230 N. Oval Mall, Columbus, OH 43210
614-292-2267 Office
gradsch.osu.edu

Pronouns: she/her/hers

Department of Biomedical Engineering

GRADUATE SPECIALIZATION IN
MEDICAL PRODUCT DEVELOPMENT

DEPARTMENT OF BIOMEDICAL ENGINEERING

Contact:
Tanya Nocera, PhD
Professor of Practice, Department of Biomedical Engineering
Director of Medical Product Development Program, Department of Biomedical Engineering

Email: nocera.15@osu.edu
Phone: (614) 292-4753

Ashlynn Fisher, M.Ed.
Undergraduate Program Services Specialist, Department of Biomedical Engineering

Email: fisher.1399@osu.edu
Phone: (614) 292-3221

Proposal for Medical Product Development Specialization within Master of Science in Biomedical Engineering

Rationale

The Medical Product Development (MPD) Program is a pathway within Biomedical Engineering (BME) that was established in 2018 to provide master's students with a distinctive product design experience aimed at preparing graduates for roles in the medical product industry. The MPD Program has an embedded project-based capstone sequence (BME 5901, 5902) where teams of students are partnered with medical product industry sponsors and/or clinicians to develop a solution to an unmet clinical need. This pathway also includes a specialized supporting curriculum, including an MPD industry ethics course (BME 5983), an MPD industry and professionalism seminar course (BME 5810), and relevant elective options, which collectively facilitate professional MPD skillsets for those enrolled. Admission to the MPD program pathway is competitive, with most recent cohorts consisting of 8–10 students. To date, 37 students have graduated from this pathway, of which 32 have successfully entered careers in the medical product industry and 5 have pursued further education (medical and/or doctoral degrees) with goals of incorporating medical product development into their future careers.

Until now, all graduates on an MPD pathway have earned a Master of Science in Biomedical Engineering—the same degree awarded to all students in BME's master's programs (thesis and non-thesis). We are now proposing the creation of a formal Medical Product Development specialization within BME's existing MS programs. This will allow students who complete the MPD program pathway to receive an official designation on their transcripts, recognizing and communicating their specialized training to their employers and/or further education admissions committees.

The objectives of this proposal are to:

1. Define the requirements of the MPD specialization and their conjunction with the BIOMEDE Non-Thesis MS.
2. Establish procedures for monitoring the progress of the MPD students enrolled in this specialization.
3. Detail the MPD Program learning outcomes and corresponding assessment plan.
4. Describe the impact of this specialization on resources, faculty load, etc.
5. Specify a transition plan for current MPD students.

Specialization Courses/Requirement

The MPD curriculum is based on the framework of BME's non-thesis MS program, which requires a minimum of 31 credit hours for graduation. Below is a breakdown of the standard non-thesis MS curriculum, followed by the proposed MPD specialization curriculum.

Table 1: BME Non-Thesis MS Curriculum Requirements

BME Core Courses – Required for all non-thesis MS Students (10-11 credits)

Dept. Name & Course #	Course Title	Credit Hours
BIOMEDE 6000	Scientific Methods in BME	1
BIOMEDE 8810-8811	BME Seminar (2 semesters)	1
CBE 5779 or ISE 5110 or STAT 6410	Graduate Research Design	3-4
BIOMEDE 6983	Graduate Research Ethics	2
PHYSIO 6101 or 6102	Graduate Physiology	3

BME Fundamental Courses* – 4 Courses Required (12 credits)

Dept. Name & Course #	Course Title	Credit Hours
Fundamental 1	--	3
Fundamental 2	--	3
Fundamental 3	--	3
Fundamental 4	--	3

*Students must take at least 2 OSU BME fundamental courses and may take up to 2 non- BME, BME-type OSU courses (approved by BME Graduate Studies Committee), and no more than 1 non-OSU BME course, by petition.

Graduate Electives* – Minimum of 3 Courses (9 credits)

Dept. Name & Course #	Course Title	Credit Hours
Elective 1	--	3
Elective 2	--	3
Elective 3	--	3

*No more than 1 elective can be S/U graded. Electives can be in Engineering, Life Sciences, Teaching, Business/Technology Commercialization, etc.

To align with the unique objectives of the MPD program, several courses have been modified or pre-selected for participating students, differing from the standard non-thesis MS curriculum. These tailored course requirements form the foundation of the proposed MPD specialization. Table 2 outlines the specific courses required for the MPD specialization, Table 3 provides the approved elective options, while Table 4 demonstrates how these courses integrate into the

broader BME non-thesis MS curriculum—ultimately leading to a Master of Science in Biomedical Engineering with a Medical Product Development (MPD) Specialization.

Table 2: MPD Specialization Required Courses (13 credits)

Dept. Name & Course #	Course Title	Credit Hours
BIOMEDE 5810	Industry/Professionalism Seminar (2 semesters)	2
BIOMEDE 5983	Ethics in Medical Product Development	2
BIOMEDE 5901	MPD I	3
BIOMEDE 5902	MPD II	3
Elective (from Approved List)	--	3

Table 3: List of Approved Electives for MPD Specialization

Dept. Name & Course #	Course Title	Credit Hours
BIOMEDE 5639	Medical Device Development & Regulation	3
MECHENG 5682.01	Fundamentals of Product Design	3
MCR 7770 (DL)	Fundamentals of Medical Product Development & Regulation	3
PHR 7572 (DL)	Global Regulation of Medical Products	3

*Department elective approvals provided in Appendices

Table 4: BME Non-Thesis MS Curriculum Requirements with MPD Specialization

BME Core Courses – Required for all MPD Students (10-11 credits)

Dept. Name & Course #	Course Title	Credit Hours
BIOMEDE 5810	Industry/Professionalism Seminar (2 semesters)	2
CBE 5779 or ISE 5110 or STAT 6410	Graduate Research Design	3-4
BIOMEDE 5983	Ethics in Medical Product Development	2
PHYSIO 6101 or 6102	Graduate Physiology	3

BME Fundamental Courses – 4 Courses Required (12 credits)

Dept. Name & Course #	Course Title	Credit Hours
BIOMEDE 5901	MPD I	3
BIOMEDE 5902	MPD II	3
Fundamental 3	--	3
Fundamental 4	--	3

Graduate Electives – Minimum of 3 courses (9 credits)

Dept. Name & Course #	Course Title	Credit Hours
Elective 1	--	3
Elective 2	--	3
Elective 3	--	3

Evaluation of Requirements

To ensure successful completion of both the BME MS degree and the MPD specialization, each student will develop a formal Program of Study in collaboration with their faculty advisor and the MPD program administrator. This Program of Study must satisfy all course requirements outlined by the BME department for the non-thesis MS track, as well as the additional requirements specific to the MPD specialization.

Once finalized, the Program of Study must be reviewed and approved by the student's two MS committee members and subsequently by the BME Graduate Studies Committee (BMEGSC). Students are expected to revisit their approved Program of Study prior to each semester's course registration to confirm alignment with degree and specialization requirements. Any proposed changes must be re-approved by both the committee members and BMEGSC to ensure continued compliance.

To obtain the MPD specialization, the program administrator will initiate the specialization request for each student through GradForms, enabling the Graduate School to add the designation to the student's academic record. In the semester of graduation, students must submit their application to graduate via GradForms. At this time, the MPD program administrator will perform a comprehensive audit of the student's advising report to confirm completion of all required coursework for both the MPD specialization and the BME MS degree. Once verified, the administrator will approve the graduation application in the system and forward it to the Graduate School for final review and transcript designation.

Learning Outcomes & Assessment Plan

Students successfully completing the Medical Product Development (MPD) specialization will be able to demonstrate the 6 learning outcomes listed below. These learning outcomes are formally assessed within the core MPD specialization course(s) associated with each outcome (BME 5901/5902, 5810, or 5983).

1. Design, implement, and document testing plans to verify and validate a medical product or process with respect to user needs, design requirements, standards, and national and international regulatory pathways (assessed within BME 5901/5902)
2. Research, develop and pitch strategies for intellectual property protection, regulatory, business/marketing, and/or other key considerations for commercialization of a medical product (assessed within BME 5901/5902)
3. Collaborate and lead effective communications within multidisciplinary teams that include integration between clinical professionals, patients, and industry clients (assessed within BME 5901/5902)
4. Recommend solutions that balance both ethical and engineering ramifications of medical product design and processes (assessed within BME 5983).
5. Utilize engineering and management tools for medical product design, project management, progress reporting, and documentation (assessed in 5901/5902)
6. Create professional career documents, including a design portfolio and resume, tailored to a profession related to medical product development (assessed within BME 5810)

Impact

Since its inception (2018), the MPD program has operated with the goal of financial self-sustainability and minimal reliance on departmental, college, or university resources. Each academic year, industry partners sponsoring MPD student teams commit funding that supports key programmatic needs, including project materials, instructional support, and other programmatic costs. These funds are managed through MPD-designated project accounts within the Office of Sponsored Programs.

The MPD program currently employs three part-time lecturers with current or former (retired) full-time positions in the medical device industry, and one part-time graduate teaching associate, all funded through MPD-specific industry funding resources. These instructional staff members support the MPD curriculum by teaching or assisting with MPD-designated courses (BIOMEDE 5810, BIOMEDE 5983, BIOMEDE 5901, and BIOMEDE 5902), as well as the popular elective

BIOMEDE 5639. As a result, the MPD program has deliberately minimized additional instructional load on the department's tenure-track and professional practice faculty. MPD directorship is led by Dr. Tanya Nocera, a professional practice faculty who initially developed and maintains the program as her core teaching responsibility. Additionally, program administration, is shared by Dr. Nocera and BME Senior Academic Program Services Specialist, Ashlynn Fisher, whose position description formally incorporates MPD-related responsibilities.

In terms of course access and scheduling, the MPD program has not presented challenges for students completing their MS degree requirements. Although the program has increased the overall number of MS students in Biomedical Engineering by approximately 40% since 2022, the department has effectively managed enrollments in graduate-level courses to ensure availability and appropriate course sequencing. For electives offered outside BME (MECHENG 5682.01, MCR 7770, and PHR 7572), formal approval has been secured from the respective units to include these courses on the MPD elective list. MPD students follow existing enrollment procedures: MCR 7770 and PHR 7572 require instructor permission, while MECHENG 5682.01 admits students through standard enrollment controls without reserved seats for MPD participants. Should a student be unable to enroll in a selected elective due to capacity or lack of instructor approval, they may choose an alternative approved elective or consult with the MPD program administrator to adjust their academic plan.

Transition Plan

The MPD Program operates on a spring semester graduation timeline, with the next cohort expected to complete their Master of Science in Biomedical Engineering in Spring 2026 (SP26). The goal is to have the proposed MPD specialization formally approved and implemented in time for these students to receive the specialization designation on their transcripts upon graduation.

If the specialization is not approved by SP26, students in that cohort will graduate with the standard Master of Science in Biomedical Engineering degree, consistent with previous MPD cohorts. This contingency ensures that no student progress is disrupted during the transition.

Importantly, the current MPD students expected to graduate in SP26 are already enrolled in and completing all required coursework for the proposed specialization. This includes the core MPD courses as well as elective options. All SP26 MPD students have either completed or are scheduled to complete at least one course from the approved elective list, ensuring full alignment with the proposed specialization requirements.

No curricular changes or additional accommodations are necessary for current students, as the specialization formalizes an existing academic pathway. There should be no impact on student progression, advising, or graduation timelines.

Appendix A

MPD Program of Study Template

Name

	REQUIRED COURSES								
Category	**Course Name**	**Term/YR**	**Department**	**Number**	**Credits**	**Grade**	**Professor**	**Institution**	
Req Core	Industry and Professionalism Seminar (take 2x, 1cr each)	AU26/SP27	Biomedical Engineering	5810	2		Eichaker	OSU	
Req Core	Design and Analysis of Experiments		ChBE	5779	3			OSU	Or ISE 5110 or STAT 6410
Req Core	Ethics for Medical Product Development	AU26	Biomedical Engineering	5983	2		Higgins	OSU	
Req Core	Advanced Human Physio I		Physio CB	6101	3			OSU	Or PHYSIO 6102 (spring)

	Culminating Experience Area/Topic	Medical Devices						
Category	**Course Name**	**Term/YR**	**Department**	**Number**	**Credits**	**Grade**	**Professor**	**Institution**
Fund 1	Med Product Develop I	AU26	Biomedical Engineering	5901	3		Nocera	OSU
Fund 2	Med Product Develop II	SP27	Biomedical Engineering	5902	3		Nocera	OSU
Fund 3	Fundamental 3		Biomedical Engineering					
Fund 4	Fundamental 4		Biomedical Engineering					

	ELECTIVE COURSES:							
Category	**Course Name**	**Term/YR**	**Department**	**Number**	**Credits**	**Grade**	**Professor**	**Institution**
Elect 1	Elective 1							OSU
Elect 2	Elective 2							OSU
Elect 3	Elective 3							OSU

REQUIRED COURSES	*10-11 cr hours required*	10
4 FUND	*12 cr hours required*	6
3 ELECTIVES	*9 cr hours required*	0
COURSE TOTAL	***31 cr hours required***	16
BME RESEARCH HOURS (MS thesis program only)	***0 cr hours required***	0
GRAND TOTAL	*min 30 cr hours required*	16

2 MS Committee Members		**Area of Expertise**	**Signatures required before BMEGSC review**
Advisor	*Dr. Tanya Nocera*	*MPD*	
Member 2	*Dr. Alexis Ortiz-Rosario*	*MPD*	

Appendix B

Program Elective Department Approvals

College of Nursing

Heminger Hall
1577 Neil Ave
Columbus, OH 43210

Phone (614) 292-8900
Fax (614) 292-4535
E-mail nursing@osu.edu
Web nursing.osu.edu

THE OHIO STATE UNIVERSITY
COLLEGE OF NURSING

October 15, 2025

Department of Biomedical Engineering Graduate Studies,

I am writing to confirm my approval for the inclusion of **MCR 7770: Fundamentals of Medical Product Development and Regulation** and **MCR 7572: Global Regulations of Medical Products** as approved elective courses within the proposed **Medical Product Development (MPD)** specialization in the **Biomedical Engineering MS** programs.

Please feel free to contact me with any questions.

Sincerely,

Becky Lorenz, PhD, RN

Associate Professor
Senior Associate Dean for Academic Affairs and Educational Innovation
College of Nursing
346 Newton Hall
295 W. 10th Avenue
Columbus, Ohio 43210
Phone: 614-292-4320
Email: lorenz.182@osu.edu

Thursday, October 23, 2025 at 11:50:27 Eastern Daylight Time

Subject: Re: MECHENG 5682.01 - MPD Specialization
Date: Wednesday, October 22, 2025 at 10:41:42 PM Eastern Daylight Time
From: Corlew, Anna
To: Fisher, Ashlynn, Breckenridge, Nick
CC: Nocera, Tanya
Attachments: image001.png

Hi Ashlynn,

So sorry for the late email. I heard back about this, and it is fine to include this class as an elective for your program.

Thanks,

Anna

Get Outlook for iOS

From: Fisher, Ashlynn <fisher.1399@osu.edu>
Sent: Tuesday, October 21, 2025 4:39 PM
To: Corlew, Anna <corlew.3@osu.edu>; Breckenridge, Nick <breckenridge.17@osu.edu>
Cc: Nocera, Tanya <nocera.15@osu.edu>
Subject: Re: MECHENG 5682.01 - MPD Specialization

Hi Anna,

Just following up on my below email. I probably should have included Nick on my initial email in case it is better suited for him/MAE graduate program, so doing so now.

Thanks!
Ashlynn

From: Fisher, Ashlynn <fisher.1399@osu.edu>
Date: Thursday, October 9, 2025 at 7:05 PM
To: Corlew, Anna <corlew.3@osu.edu>
Cc: Nocera, Tanya <nocera.15@osu.edu>
Subject: MECHENG 5682.01 - MPD Specialization

Hello Anna,

I hope your semester is going well! I'm reaching out for your assistance—or guidance on who best to contact—regarding a request to include **MECHENG 5682.01** as an approved elective in a new

specialization within the Biomedical Engineering MS programs.

Dr. Tanya Nocera and I are developing a **Medical Product Development (MPD)** specialization for the BME MS programs. While the MPD MS program has existed for several years, this specialization will allow future graduates to have the MPD designation officially reflected on their transcripts.

As part of the proposed curriculum, students will complete one elective from an approved list. We'd like to request approval to include **MECHENG 5682.01** on that list.

We anticipate an impact of about 4-5 MPD students wishing to enroll in MECHENG 5682.01 each semester. MPD students meet the prerequisites for this course so will be able to self-enroll. If the course reaches capacity, we will advise MPD students to either enroll to the waitlist or select another elective.

If you're willing to approve this request, would you be able to provide a brief letter of approval for us to include in our formal submission? I have attached a draft approval letter if you would simply like to copy/paste it on official letter head.

A decision by Wednesday, October 22 would be much appreciated. Please let me know if you have any questions or if someone else would be more appropriate to contact.

Thank you!
Ashlynn

THE OHIO STATE UNIVERSITY

Ashlynn Fisher, M.Ed.
Undergraduate Program Services Specialist
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