TO: The Engineering Faculty

FROM: The Davidson of Chemical Engineering

RE: New Concentration in Healthcare Technology for the Online Interdisciplinary Engineering Master's Program

The Faculty of the Charles D. Davidson School of Chemical Engineering have approved the following addition of the new Healthcare Technology Concentration for the Online Interdisciplinary Engineering Master's Program. This action is now submitted to the Engineering Faculty with recommendation for approval.

Description:
The Chemical Engineering Graduate Concentration in Healthcare Technology ("concentration") is being proposed to meet the educational needs of engineers working in the healthcare field while also strengthening the workforce pipeline of the field in general. The healthcare industry is an essential component of the local and national economies and continued improvement in healthcare delivery is highly dependent on technology advances. Engineers, including many Purdue graduates, comprise a significant proportion of technical positions in both the biopharmaceutical and medical device sectors, especially in the areas of research and development, manufacturing, and supply chain. These functions require a well-educated engineering workforce to support new product development and manage existing product portfolios. By helping to address this requirement, this concentration allows Purdue University to support an economically critical industry through its educational mission. Moreover, this concentration offers individual students, whether already employed in or aspiring to the healthcare industry, advancement opportunities within this field.

Reason:
Based on feedback from healthcare companies employing Purdue graduates and the lengthy experience of the concentration's proposer (Dr. William Clark) in the medical device industry, some engineers and scientists may lack a broad understanding of the healthcare sector in which they work. Moreover, the insights that these individuals have into the operational and commercial aspects of their own companies may be somewhat limited. Specifically, they may not fully understand and appreciate the broader clinical implications of the product they are helping to develop or manufacture, such as the relevant patient population, regulatory pathway, and reimbursement structure. Thus, the concentration is needed to help students align better with their organizational structure and goals - in this regard, there are three specific learning priorities:

1. Developing a better understanding for engineers of the manner in which healthcare is delivered, especially with respect to the use of medical technology.
2. Recognizing that unmet clinical needs are the primary driving force for medical technology development.
3. Appreciating the impact of COVID-19-related changes on the healthcare landscape, especially with respect to medical technology development.

Please see attached document for more information about the concentration specifics, including information about target audiences and a detailed plan of study.

Dr. Sangtae Kim
Distinguished Professor and Head
Davidson School of Chemical Engineering

CC: William Clark, Professor of Engineering Practice, CHE

PURDUE UNIVERSITY | Davidson School of Chemical Engineering

Proposal to Establish a New Graduate Concentration

1. **Graduate Program:** Interdisciplinary Engineering

2. **Title of Concentration:** Healthcare Technology

3. **Effective Session:** Fall

4. **Academic Year:** 2021-2022

5. **Degrees to which this concentration applies:**
   - ☐ Master of Science (choose other for named masters)
   - ☐ Master of Arts
   - ☐ Doctor of Philosophy
   - ☒ Other.
     a. **If other, explain:** Master of Science (MS); Master of Science in Engineering (MSE)

6. **Mode of Delivery:**
   ☒ Residential ☒ Digital (Online) ☐ Digital (Hybrid)

7. **State who will administer the program via Purdue Online** (Purdue program or outside vendor): Purdue Online College of Engineering

8. **Justification** (Statement of the mission of the proposed concentration including, but not limited to, the need for the concentration, the target audience, the relationship to the major under which the concentration will be listed, and the relationship to other concentrations in the degree program.):

   Purdue University is proposing the Healthcare Technology Concentration ("concentration") for the Online Interdisciplinary Master of Science in Engineering to meet the educational needs of engineers working in the healthcare field while also strengthening the workforce pipeline of the field in general. The healthcare industry is an essential component of the local and national economies and continued improvement in healthcare delivery is highly dependent on technology advances. Engineers, including many Purdue graduates, comprise a significant proportion of technical positions in both the biopharmaceutical and medical device sectors, especially in the areas of research and development, manufacturing, and supply chain. These functions require a well-educated engineering workforce to support new product development and manage existing product portfolios. By helping to address this requirement, this concentration allows Purdue University to support an economically critical industry through its educational mission. Moreover, this concentration offers individual students, whether already employed in or aspiring to the healthcare industry, advancement opportunities within this field.

The purpose of the program

The purpose of the concentration is to prepare students for positions across a broad spectrum of engineering and technical positions in the healthcare industry. The knowledge gained by these learners will serve several purposes, including solidifying and refreshing existing knowledge for some while introducing entirely new concepts to others. Irrespective of the motivation for a specific student, those enrolled in the concentration will be prepared to support their healthcare organizations more effectively from both a strategy and implementation perspective. Moreover, the concentration will provide a point of differentiation for graduates within the organizations into which they are hired, positioning them for more rapid career advancement.

Why the program is needed

Based on feedback from healthcare companies employing Purdue graduates and the lengthy experience of the concentration's proposer (Dr. William Clark) in the medical device industry, engineers and scientists may not have a broad understanding of the healthcare sector in which they work. Moreover, the insights that these individuals have into the operational and commercial aspects of their own companies may not be deep. For example, engineers and scientists may become "siloed" in the relatively isolated roles that they play in the expansive process of developing a new medical technology. In this scenario, they may not fully understand and appreciate the broader clinical implications of the product they are helping to develop or manufacture, such as the relevant patient population, regulatory pathway, and reimbursement structure. Thus, the concentration is needed to help students align better with their organizational structure and goals - in this regard, there are three specific learning priorities.

One priority is development of a better understanding for engineers of the manner in which healthcare is delivered, especially with respect to the use of medical technology. As suggested, an engineer's understanding of medical technology development and manufacturing processes should be expansive, including insights about downstream application of a technology in the clinical environment. This need is highlighted by two themes currently prioritized in medical technology development. One is the emphasis on using a "patient-centric" approach involving a comprehensive understanding of all the potential effects that a technology may have on a particular patient. In turn, this requires a development or manufacturing engineer to take a holistic approach based on a deep understanding of the patient population that will be using the product (e.g., the special needs of a blind diabetic patient using the product).

The other theme being emphasized in the healthcare product industry is the need to incorporate "real world evidence" (RWE) in development and manufacturing processes. Underlying the RWE concept is the disparity in the results of product testing and evaluations done by a company before widespread clinical use and those generated after the product is more extensively utilized in the "real world". Contemporary product development, sustaining engineering, and manufacturing require engineers to be facile in the interpretation of RWE so that a company's product portfolio can be maintained efficiently. One of the courses comprising the concentration (*Analytical Approach to Healthcare Delivery*) is designed to provide students foundational knowledge about clinical medicine, particularly from the perspectives of patient centricity and RWE.

Another learning priority for the concentration is to allow students to gain an understanding that unmet clinical needs are the primary driving force for medical technology development. For a

variety of reasons, biomedical companies increasingly are expected to deliver truly innovative (rather than "me too") products that provide new options for the management of diseases that are frequently resistant to other treatments. To achieve this goal, engineers and scientists must first collaborate with others in their organizations to understand how the current limitations in managing a particular disorder define the innovation pathway. The second course comprising the concentration (*Medical Devices: Development and Clinical Application*) focuses on this aspect. In this course, the development of life-saving treatment for end-stage renal disease (i.e., dialysis) is used as a representative example of technology development in response to an urgent unmet clinical need. While the engineering aspects are emphasized, students also gain an appreciation of the market forces and health economic factors driving technology innovation.

The nature of this concentration requires the content to be dynamic and reflective of the rapidly changing healthcare environment. In this regard, both for engineers already working in the healthcare industry and aspirants, the impact of the COVID-19 pandemic on medical technology development has already been profound and will be long-lasting. ***The final learning priority of the concentration is to educate students about COVID-19-related changes in the healthcare landscape and their impact on medical technology development and manufacturing.*** In particular, the pandemic's effect on manufacturing and supply chains for biopharmaceutical and medical device companies is assessed. The third course comprising the concentration (*Medical Technology Development in the COVID-19 Era*) is specifically devoted to this topic.

In addition to the specific rationales provided above, the concentration fulfills the educational mission of the state of Indiana in several ways. The state, along with its robust commercial life sciences sector, is strongly motivated to educate and retain students with life science expertise for economic development. By providing the opportunity for students either to acquire *de novo* knowledge or recalibrate existing knowledge, this concentration supports the mission of Indiana (along with that of Purdue University) to be a world leader in the life sciences field.

From a higher education perspective, the concentration also addresses priorities and objectives of both the state of Indiana and Purdue University. Most engineers and scientists, including those in the healthcare industry, are lifelong learners and many would be interested in earning an advanced degree. The Online Interdisciplinary Master of Science in Engineering affords students this opportunity and the comprehensive educational content of this certificate allows for expansion and refinement of technical knowledge specifically in the healthcare field. Thus, the concentration is part of a cost-effective and efficient program for students interested in healthcare-related career advancements, many of whom may work for Indiana-based life sciences companies.

Finally, this concentration aligns with Purdue University's mission to expand educational opportunities beyond the traditional residential experience for students. Purdue is recognized as a leader in online education, especially in the field of engineering, and a substantial infrastructure already exists to support the development and rollout of the program described in this proposal.

Target audience

Although not limited to such individuals, the target audience is students interested in applying their learnings in the biopharmaceutical and medical device sectors. More specifically, the primary target student population consists of students enrolled in the Online Interdisciplinary Master of

Science in Engineering with a career interest in healthcare technology and a particular interest in achieving a competitive advantage upon graduation.

Relationship to the major under which the concentration is listed

While students in the Online Interdisciplinary Master of Science in Engineering program have diverse career interests, a significant proportion work in the healthcare industry or aspire to do so. In this regard, this concentration addresses a student population that stands to benefits from a comprehensive curriculum encompassing medical technology development across a broad spectrum, including both biopharmaceutical compounds and medical devices. At present, no existing concentration within the Online Interdisciplinary Master of Science in Engineering program addresses this need.

9. **Focus of the research or professional program:**

The Interdisciplinary Master of Science in Engineering program allows students to tailor their educational experience to their individual or company goals and current marketplace demands. This concentration is very consistent with the overall theme of the program and specifically focuses on students interested in the healthcare industry.

10. **Participating faculty, including name, academic rank, and departmental affiliation:**

William Clark, M.D.; Professor of Engineering Practice, Davidson School of Chemical Engineering

Michelle Chutka, M.S.; Continuing Lecturer, Davidson School of Chemical Engineering

11. **Currently enrolled or expected number of students:**

While it is difficult to predict the number of students who will participate in the concentration program, one piece of information may be useful. Of the concentration's three component courses, *Analytical Approach to Healthcare Delivery* has already been taught as a Purdue Online course in the Summer 2020 term. The course generated substantial interest among students in the Purdue Online Interdisciplinary Engineering M.S. degree program, with 26 students ultimately enrolling for this first online offering. While the data are limited, this suggests strong demand for this course and the concentration program overall, especially since no similar program currently exists. A greater frequency of courses in the future will facilitate completing the program in one academic year.

12. **List of Core Courses** (Minimum of 9 credits of unique courses for this concentration):
    a. CHE 59700 Analytical Approaches to Healthcare Delivery
    b. CHE 59700 Medical Devices: Development & Clinical Application
    c. CHE 59700 Medical Technology Development in the COVID-19 Era

13. **A description of how they fit into and support the degree program:**

The three courses required for concentration are described below:

CHE 59700 (Analytical Approach to Healthcare Delivery): This course provides a "real world" overview of healthcare delivery in the United States (US). The major medical technology segments (pharmaceutical compounds and medical devices) are a significant focus, including their research and development processes, regulatory framework, and market approaches. Another highlight of the course is an assessment of a series of critical medical conditions having the highest impact on the US healthcare system. Clinical cases illustrating these conditions along with case studies designed to provide practical examples of healthcare developments and challenges are included. A number of emerging healthcare developments, including precision medicine, artificial intelligence, digital health, and value-based care, are addressed. In addition, the numerous ways in which the COVID-19 pandemic has affected patients and the manner in which they receive healthcare are discussed.

While the above information will be presented didactically in online lecture format, deeper assessments of key aspects will be assigned on a regular basis for applied learning. In this regard, oral and written reports on a topic of each student's choosing (in lieu of examinations) are an important component of the class. An additional way in which students will gain practical knowledge is through a series of case studies over the course of the semester.

CHE 59700 (Medical Devices: Development and Clinical Application): This course is an introduction to the medical device field, with emphasis on the ways in which chemical engineering processes provide the foundation for many device-related therapies. The course involves the application of several fundamental chemical engineering principles, including those related to mass transfer, separations, and fluid flow, to devices used for extracorporeal therapies and other treatments. The first part of the course addresses the relevant physiology and pathophysiology serving as a foundation for subsequent clinical material. With the focus on extracorporeal devices, the interactions between blood and biomaterials in a general sense are also explored in this section. The second part of the course assesses the extracorporeal treatment of kidney failure by dialysis, which is highlighted as the only long-term, device-based replacement therapy for terminal organ failure (end-stage renal disease). This analysis will not only consider the evolution of dialysis therapy from a technology perspective but also the forces that have shaped its development into a market generating annual revenue of nearly $100 billion on a global basis. In addition, extracorporeal support therapies used clinically not only for failure of other organs (namely the heart, liver, and lungs) but also systemic inflammation secondary to severe infection (sepsis) will be presented. The third segment of the course addresses industry-focused concepts pertaining to medical device development, including verification/validation, lean manufacturing, project management, and regulatory issues.

While the above information will be presented didactically in online lecture format, deeper assessments of key aspects will be assigned on a regular basis for applied learning. In this regard, oral and written reports on a topic of each student's choosing (in lieu of examinations) are an important component of the class. An additional way in which students will gain practical knowledge is through a series of case studies over the course of the semester.

CHE 59700 (Medical Technology Development in the COVID-19 Era): This course is designed to provide students with an understanding of how the COVID-19 pandemic is shaping medical technology development. Although curriculum development for this course is ongoing as the pandemic continues to evolve, topics to be covered include:

- Clinical overview of COVID-19 (including therapeutic approaches, such as vaccines and monoclonal antibodies)

- Regulatory considerations (especially emergency use applications)
- Effect of COVID-19 on the operational aspects of biopharmaceutical and medical device companies
- Critical role of diagnostics in COVID-19
- Supply chain considerations related to COVID-19
- Specific COVID-19 case studies from industry
- Lasting effects of the COVID-19 pandemic (both on healthcare delivery and product development

While the above information will be presented didactically in online lecture format, deeper assessments of key aspects will be assigned on a regular basis for applied learning. In this regard, oral and written reports on a topic of each student's choosing (in lieu of examinations) are an important component of the class. An additional way in which students will gain practical knowledge is through a series of case studies over the course of the semester.

With respect to the manner in which the concentration fits into and supports the Online Interdisciplinary Master of Science in Engineering, the most important consideration is that the concentration offers a curriculum which is distinct from all other concentrations. As such, the proposed concentration not only provides greater educational options for students currently enrolled in the program but also increases the program's attractiveness to prospective students.

Of note, the first two courses have also been taught as on-campus offerings several times. While the third course has not been taught on-campus, the plan is to offer this also to residential students in the future (see next section).

14. **Will new courses be created for this concentration?**

☒ Yes ☐ No

a. **If yes, list new courses and if proposals have been submitted:**

CHE 59700 Medical Technology Development in the COVID-19 Era: the course proposal has been submitted.

15. **Learning outcomes** (e.g., unique knowledge or abilities, capacity to identify and conduct original research, ability to communicate to peer audiences, critical thinking and problem-solving skills, etc.):

After completion of the three courses comprising the certificate, students will be expected to have gained a better understanding of the healthcare industry, especially from a medical technology perspective. The learning outcomes for the entire certificate program are:

- Characterize several major clinical conditions having a significant public health burden, especially from the perspective of medical technology use and health economics.
- Analyze the major segments of medical products (pharmaceutical/biotechnology compounds and medical devices) along with the development processes and regulatory framework applying to each of these segments.
- Understand the interactions between different organ systems and extracorporeal medical devices.

- Apply fundamental chemical engineering principles in the analysis of treatments for specific clinical disorders, including end-stage renal disease, acute kidney injury, sepsis, cardiac failure, liver failure, and respiratory failure.
- Develop an understanding of the regulatory expectations for objective evidence in support of medical device approval, including concepts as part of the quality system, risk management, and design controls.
- Recognize engineering roles in manufacturing considerations of a medical device, including concepts in lean manufacturing and process validation.

- Describe the important clinical features of COVID-19 disease and the major preventive or therapeutic interventions.
- Characterize the effect of the COVID-19 pandemic on the operational aspects of biopharmaceutical and medical device companies, especially from the development, manufacturing, and supply chain perspectives.

16. **Is this a Professional concentration?**

☐ Yes ☒ No

a. If this is a "Professional" concentration the Graduate School will need to sign the Rate Request. Please forward the rate request for signature and it will be returned to your business office for the remaining approvals. The Graduate School will need a copy of the final approval for our records and it will be attached to this proposal at a later date. The rate request approvals will not hold up the concentration approval. We will continue to move the concentration proposal through the review/approval steps.