Paper ID #45472

Innovative Approaches to Medical Device Design Education: A Collaborative Industry-Academia Model

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Abstract

This paper describes a collaborative industry-academia model for teaching medical device design, which combines active learning with input from industry experts. The course covers interdisciplinary topics such as biological testing, human factors, usability engineering, risk management, and regulations, areas that go beyond the expertise of a single instructor. Industry professionals contribute through guest lectures, mentorship, and real-world case studies, ensuring that students gain practical, industry-relevant knowledge. Students work on hands-on projects that simulate real-world scenarios, helping them develop critical thinking, teamwork, and problem-solving skills. Active learning activities like sensor-based labs and prototype development further engage students and prepare them for careers in the medical device field. Drawing on two years of course implementation, this paper discusses the challenges, successes, and key outcomes of this approach, offering practical advice for educators interested in creating similar industry-collaborative courses.

Introduction

The Twin Cities region is a global leader in the medical device industry, home to a thriving ecosystem of established companies, innovative startups, and renowned healthcare institutions. This dynamic environment drives both economic growth and advancements in medical technologies, creating a high demand for engineering graduates who possess not only technical expertise but also practical, industry-relevant skills. Recognizing this demand, we sought to develop a course in medical device design aimed at improving the employability of our students interested in pursuing careers in this field. The course was designed to provide students with a comprehensive understanding of the medical device design process, including concept development, prototyping, regulatory compliance, and risk management, ensuring they graduate with the skills and knowledge needed to succeed in the medical device industry.

This paper outlines the creation and evolution of the course, emphasizing the critical role of industry collaboration in shaping a curriculum that addresses the practical needs of the medical device sector. Medical device development is inherently interdisciplinary, requiring knowledge across diverse areas such as biological testing, human factors, usability engineering, risk management, and regulatory frameworks. Recognizing that no single academic instructor can provide expertise in all these areas, we designed the course to leverage contributions from industry professionals. These experts bring real-world insights to the classroom through guest lectures, project guidance, and case studies, ensuring that students gain practical knowledge that aligns with current industry practices.

The course takes an active learning approach, incorporating hands-on projects that simulate realworld applications. Students engage in designing simple medical devices, such as weight scales, pedometers, shake detectors, and water tank level meters, which develop their problemsolving, teamwork, and technical skills. These projects help bridge the gap between theoretical learning and practical application, better preparing students for careers in the medical device industry.

A key feature of the course is its interdisciplinary makeup. Students come from diverse backgrounds, including mechanical engineering, electrical and computer engineering, computer science, industrial design, operations, and biology, with many pursuing a minor in medical product design. This diversity fosters collaboration across disciplines, mimicking the real-world challenges of medical device development, where solutions require input from multiple fields. The collaborative environment also helps students build essential communication and teamwork skills, which are critical for success in industry settings.

By reflecting on two years of course implementation, this paper provides practical insights into how strategic partnerships with industry experts can enhance student learning and ensure the relevance of course content. The findings demonstrate that meaningful courses that extend beyond the expertise of a single instructor can be created through collaboration with industry professionals. This paper aims to serve as a guide for educators interested in developing similar collaborative courses, offering a model for bridging the gap between academic theory and industry practice. Through dedication and strategic partnerships, even educators without prior medical device expertise can build innovative and impactful educational programs that better prepare students for careers in this evolving sector.

Literature Review

The integration of industry expertise into engineering education, especially in medical device design, is essential for bridging the gap between academic theory and practical applications. When combined with active learning, industry collaboration becomes even more impactful, enabling students to address real-world challenges [3]. Active learning, endorsed by organizations like SEFI and ABET, enhances student engagement and performance by connecting theoretical concepts to practical experiences [1][2]. It also improves understanding, retention, and problem-solving skills [3], and when combined with laboratory-based learning, is particularly effective in teaching technical and professional competencies [4].

The role of industry experts in academia, especially through guest lectures and project-based assessments, is widely recognized as beneficial for both students and the industry. The challenges of providing specialized knowledge in fields such as medical device design, where faculty may lack domain-specific expertise, are well-documented [5]. These experts provide students with valuable insights into current industry practices, trends, and innovations. Industryled assessments, such as real-world design projects, help students develop vocationally relevant skills [6][7]. Developing university-industry partnerships aligns well with current U.S. workforce development goals, which advocate for broadening participation in Science, Technology, Engineering, and Mathematics (STEM) [6][7]. These activities are particularly effective in preparing students for the complexities of the job market while ensuring that their education meets the needs of the industry.

Guest lectures not only enhance students' learning but also contribute to their professional development. Programs featuring guest speakers significantly boost student engagement and skill acquisition, especially when the speakers are industry experts. Alumni speakers, in particular, can have a profound impact, as they share a common educational background with the students. Their relatability and personal insights enhance students' perceived learning outcomes and communication skills [8]. Furthermore, guest speakers provide valuable networking opportunities, enabling students to build connections that can support their career advancement [9].

Industry collaborations in academic settings are not one-sided; they also offer substantial benefits to the professionals involved. Through collaborations, companies can identify and engage talented students, which can lead to internships, co-op placements, or even future employment opportunities. These partnerships allow industry professionals to shape the next generation of engineers and ensure that the workforce is well-equipped to meet the challenges of an evolving field. Furthermore, the collaboration helps industry professionals stay connected with academic trends, fostering a mutual exchange of knowledge between academia and industry [10].

The integration of industry expertise into medical device design education through active learning strategies, guest lectures, and project-based assessments creates a dynamic and engaging learning environment. These collaborations bridge the gap between theoretical knowledge and real-world application, equipping students with the skills and understanding necessary to navigate the complexities of the medical device industry. By fostering strong partnerships between academia and industry, educational institutions can prepare students to address the challenges and innovations they will encounter in their professional careers. The involvement of industry experts not only enhances students' learning outcomes but also benefits industry professionals by allowing them to identify and mentor future talent, ultimately contributing to the development of a skilled, adaptable workforce in the medical device sector.

Methodology

The development of the medical device design course began with an extensive web search to identify and analyze existing courses offered by renowned universities, particularly those in the Twin Cities region. This research was crucial for understanding the current educational landscape and ensuring our course would be competitive and relevant. The findings were synthesized into a draft syllabus, which was then refined through collaboration with industry experts. Notably, one collaborator emphasized the need for hands-on sensor based labs tailored to our Mechanical Engineering and Technology students to improve their ability to collaborate with Electrical Engineers. This recommendation was based on their prior experience hiring and working with our students, highlighting a gap in practical skills that could be addressed through targeted lab activities.

Early meetings with industry collaborators focused on familiarizing them with our students' academic strengths and weaknesses, including their math proficiency, learning styles, and strong preference for applied, hands-on learning. Emphasis was also placed on the importance of inclass group exercises to reinforce learned concepts. Each expert provided an outline of their proposed lecture, including topics and hands-on activities, which the instructor reviewed and refined to align with course objectives and student needs. This collaborative process finalized the syllabus and ensured the inclusion of key topics that met academic standards while offering practical insights into medical device design. Subsequent meetings focused on finalizing lecture content, with contributors responsible for preparing their slides, lab activities, and assessments. My role involved reviewing and refining their materials, providing feedback, and offering guidance to ensure coherence and relevance across the course.

I collaborated with an industry partner experienced in drug delivery systems to design sensorbased labs and assessments, including a simulated insulin pump shown in Figure 1 to demonstrate real-world applications. We built eight lab setups, allowing three students per station in a class of 24. Python was selected as the programming language to align with the prior coursework of many mechanical engineering students.

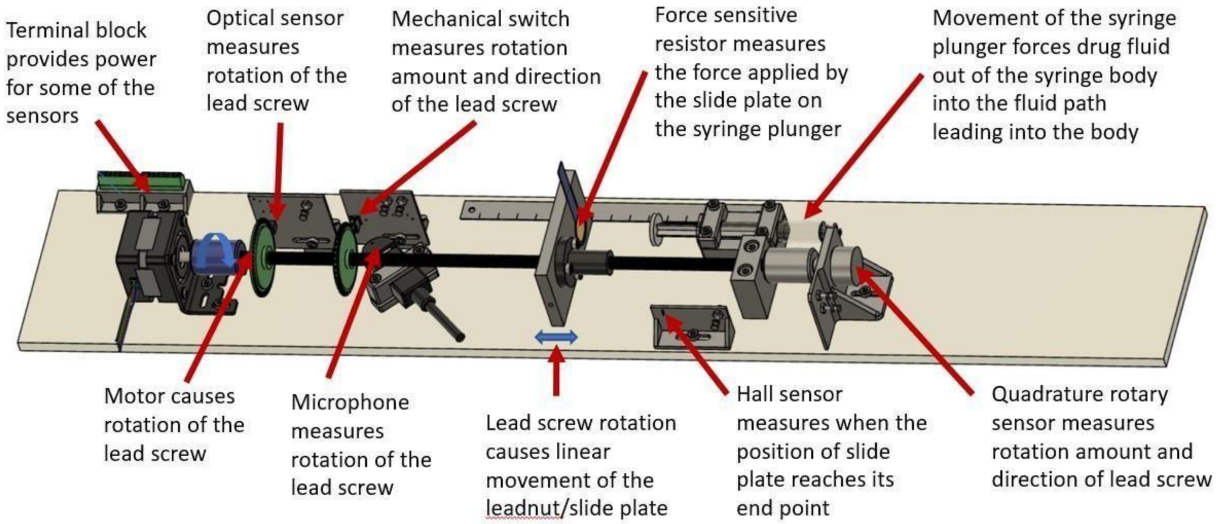

Figure 1: Schematic of Simulated Insulin Pump

Table 1 included in the appendix offers a comprehensive overview of the course structure by detailing weekly topics. The first nine weeks are predominantly composed of instructor-led lectures, while weeks 10 through 16 are centered around sensor labs and project work, culminating in student project presentations

The course's effectiveness was evaluated through pre and post-course assessments, feedback surveys, and project evaluations. Grading was divided into three main components: quizzes (30%), labs (40%), and projects (30%). Quizzes included pre-lecture and post-lecture assessments to reinforce learning. Labs offered hands-on experience with sensors, requiring detailed lab reports. Projects involved building two medical device prototypes, allowing students to apply theoretical knowledge to practical designs. Project evaluation focused on creativity, fabrication quality, device performance, user interface simulation, measurement accuracy, and demonstration clarity.

The course development process took 12 months, including one month of pre-planning, six months to secure expert commitments, and five months for content finalization.

Challenges and Future Work

The development process faced several challenges, particularly in selecting an appropriate standard development kit (SDK) for sensor data collection. It was essential to choose SDKs that balance ease of use for students, sensor compatibility, real-time processing, industry relevance, and cost. After evaluating several options, we opted for the STMicroelectronics SDK due to its robust real-time data processing capabilities and compatibility with a wide range of medical sensors, such as accelerometers and pressure transducers. The SDK's industry relevance was also a factor, given STMicroelectronics' leadership in microelectronics for medical devices.

Looking ahead, we plan to transition from the STMicroelectronics SDK to the NI myRIO platform. This change aims to improve the programming environment for students, especially those with limited or no programming experience. While the NI myRIO is more expensive, its user-friendly interface will make it more accessible to beginners. The current SDK's limitations in real-time data collection, signal processing, and control restrict complex tasks and advanced features. The migration to the NI myRIO platform will address these limitations, providing students with a more powerful toolset for real-time processing and signal manipulation.

Another challenge was developing a platform to demonstrate sensor applications. The complexity of real-world medical devices and the need for students to grasp sensor integration required a thoughtful approach. We created a simulated insulin pump to serve as the teaching platform, offering a relevant context for exploring sensor applications like glucose monitoring and delivery. This hands-on experience enhanced student understanding of sensor functionality in medical devices, increasing engagement. However, the conception, development, testing, and ongoing maintenance of the insulin pump required a significant time commitment, with annual checks to ensure its continued functionality.

Securing the participation of industry contributors was another challenge. Initial resources included our program's advisory board, which provided recommendations, and attending medical device conferences and using LinkedIn for outreach. Internal company referrals were the most significant source of connections, as they facilitated smoother collaboration by leveraging existing professional relationships. However, many sought-after experts were located 1.5 hours away, presenting logistical challenges for voluntary participation. To address this, we offered virtual guest lectures and adjusted teaching dates to accommodate contributors' schedules, ensuring continued involvement without disrupting their professional commitments. These efforts helped bridge the gap between academic theory and industry practice.

Despite careful planning, two initial contributors withdrew due to professional and personal changes. However, by leveraging our network, we quickly secured replacements. To mitigate future disruptions, we plan to continue expanding our network of backup contributors and build in-house expertise. Additionally, all lectures are recorded to provide students with accessible supplementary materials, ensuring the continuity of industry insights in case a contributor cannot attend in person. This proactive approach minimized course disruptions while maintaining high standards of expertise.

It remains vital to continue networking to create backup contributors and build in-house expertise to reduce reliance on external sources. Additionally, we have recorded all lectures to provide students with supplementary materials, ensuring that valuable content remains accessible even if a guest contributor is unable to attend in person. This proactive strategy minimized disruptions to the course schedule while maintaining high standards of expertise and industry insight throughout the curriculum.

Results and Conclusions

The medical device design course has successfully run for two semesters, with strong collaboration from 13 contributors, including university faculty and industry experts including alumni. Student feedback has been overwhelmingly positive, with measurable improvements in sensor integration and device prototyping skills. The course's combination of academic insights and real-world applications has increased student confidence and readiness for medical device careers. We are also continuing to build internal expertise by learning from industrial experts to reduce future reliance on external contributors. Looking ahead, the course will continue refining its approach based on student feedback. A planned transition to the NI myRIO platform will enhance the programming experience, particularly for students with limited programming skills. This change will improve real-time data processing and signal control, further aligning the course with industry standards and better preparing students for professional roles in the medical device sector.

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Appendix A

Week	Day	Topic
1	M	**HeartLogic Product Design Case** • Detailed examination of HeartLogic, a sensor-rich heart failure diagnostic solution. • Insights into the complexities of developing advanced medical devices.
1	W	**A Clinician Perspective on Medical Devices** • Exploration of various types and classifications of medical devices and their realworld applications. • Focus on key design requirements: functionality, reliability, and usability.
2	M	**Medical Imaging Devices** • X-rays, ultrasound, CT scans and MRI
2	W	**Innovation in Medical Device Design** • Introduction to the bio design process: identify, invent, implement. • Case studies on successful and unsuccessful devices. • Overview of premarket submissions and regulatory requirements

3	M	**Statistical Data Analysis and Regulatory Considerations** ☐ Principles of diagnostic testing, experimental design, and key metrics. ☐ Use of 2x2 tables for sensitivity, specificity, and calculations of positive predictive value, and negative predictive value. ☐ Hypothesis testing, point estimates, and confidence intervals. ☐ The FDA's least burdensome approach to regulation and the role of endpoints in diagnostic tests.
3	W	**Hands-on Statistical Data Analysis Activity** ☐ Group activities to apply statistical methods. ☐ Real-world scenarios for calculating sensitivity, specificity, and other metrics.
4	M	**Human factors and Usability Engineering** ☐ Definitions, methodologies, and the general design process. ☐ Emphasis on task analysis and both formative and summative evaluations, with practical case studies.
4	W	**Biological Testing of Medical Devices** ☐ Methodologies for good laboratory practices (GLP) safety testing, biocompatibility assessments, and non-GLP discovery and pilot studies. ☐ Introduction to the biocompatibility testing matrix (ISO 10993) and the body's generic biomaterial healing response. ☐ Hands-on experience with various heart-related medical devices.
5	M	**Wound healing, Biocompatibility and Hands-on Tissues Lab** ☐ Examination of long-term effects of chronic implants in the heart and coronary arteries. ☐ Wet lab studies involving diseased and healthy tissues with and without devices. ☐ Real-world animal R&D study for mitral regurgitation, highlighting the role of animal models.

		☐ Chemical characterization testing, focusing on extractables and leachables.

5	W	**Regulatory Pathways and GLP Study Design/Conduct** - Overview of device approval processes and types of clinical trials. - Focus on early feasibility studies and customer complaint management. - Introduction to the European Union Medical Device Regulation.
6	M	**Risk Management** - Introduction to ISO 14971:2019 and essential risk management tools: hazard analysis, design failure mode and effects analysis (DFMEA), and fault tree analysis.
6	W	**Hands-On Hazard Analysis and DFMEA** - Group activity applying hazard analysis and DFMEA methodologies to a BandAid case study.
7	M	**Managing Device Development** - Overview of product lifecycle and project management methodologies. - Comparison of waterfall and agile approaches. - Tools for collaboration and project tracking, including Miro, Slack, fever charts, and the critical chain method. - Communication tools such as 4-panel updates, summary timelines, and issue escalation techniques.
7	W	**Hands On Mock Workshop on Project Planning** - Structured project planning exercise, including workstream formation and schedule optimization.
8	M	**Spring Break**
8	W	**Spring Break**
9	M	**Standards Management and Design Controls** - Overview of design controls: user needs, design inputs, outputs, verification, and validation. - Procedures for managing design changes and transfers, and the importance of maintaining design history.

		Introduction to the V-model, design traceability, and design assurance.
9	W	**Risk Management Standards** In-depth exploration of ISO 14971:2019 and ISO/TR 24971:2020. Detailed discussion of DFMEA and process failure ode effects analysis (PFMEA)
10	M	**IMU** Position estimation, drift compensation, and noise handling.
10	W	**Advisement Day (No Classes)**
11	M	**IMU** Step counter, shake detector, and free fall detector.
11	W	**Pressure Sensor/ Discuss Projects** Atmospheric pressure measurement, liquid height detector, elevation detector, inhalation event detector, and occlusion detector.
12	M	**Thermistor/Load Cell/Sound Sensor** Water and body temperature measurement, and weight detection using calibrated weights.
12	W	**Motor Control/ Project Update** Use Trinamic's stepper motor driver for position control, velocity control, linear movement, and rotary movement.
13	M	**Position Sensors (Hall Effect, Optical, Mechanical, Rotary)** Using the PicoScope oscilloscope. Measuring rotation using photo-interrupter sensor and encoder wheel.

13	W	**Position Sensors (Hall Effect, Optical, Mechanical, Rotary)** Measuring rotation using toothed wheel and mechanical switch. Measuring rotation using quadrature rotary encoder. Measuring limit position using the Hall Effect Sensor.
14	M	**Project work** Weight scale, pedometer, shake detector, medical thermometer, altimeter, water tank level meter, grip strength tester, and compass.
14	W	**Project work**
15	M	**Project work**
15	W	**Project Presentations**
16	M	**Project Presentations**

Table 1: Course Outline