CENTER FOR BIOENGINEERING INNOVATION & DESIGN

David E. Swirnow MSE in Bioengineering Innovation and Design Program Curriculum

580.601/602/603 Seminar - Special Topics in Bioengineering Innovation and Design
This year long seminar series features experts from the medical device industry, venture capital firms, FDA, patent attorneys, entrepreneurs, and many more. They will share their real-world insights into the medical device innovation and commercialization process. Some of the topics covered will include bioethics, regulatory and reimbursement planning, medical device recalls, good design practices, and entrepreneurial success stories. The overarching philosophy of this seminar series is to complement the theoretical and practical aspects of the program curriculum, by learning from the experiences and insights of professionals in the field. These seminars are taken in a sequence of summer, fall, and spring. They are required for CBID masters students and are open to those students only.
Summer, Fall, Spring
Faculty: Soumyadipta Acharya

660.604/605/606 The Business of Bioengineering Innovation and Design
This year-long course comprises two distinct but related components. The first is a broad introduction to the terms, concepts, and values of business and management. Particular emphasis will be placed on the economic, financial, and corporate contexts of our business culture, and how they impact the organization, strategy, and decision-making of business firms. The second component is an introduction to the sociological and economic forces that shape the development and diffusion of new technologies. This part is primarily designed to provide a framework for determining the commercial viability of new medical devices and the best path for realizing their value, including how to develop a compelling value proposition, analyze markets and competitors, and protect intellectual property. Throughout, the course utilizes individual exercises, case analyses, and team projects.
Summer, Fall, Spring
Faculty: Lawrence Aronhime

580.607 Regulation of Medical Devices
This summer course introduces CBID graduate students to the medical device regulatory framework, as it pertains to bringing a medical device from concept to market. Topics covered include; FDA Design Controls; Regulatory Approval mechanisms, including the 510k and PMA process; Investigational Device Exemption (IDE); planning clinical trials needed for bringing a medical device to market; and post-market surveillance. Students learn from a series of invited lecturers from the FDA as well as professionals from the medical device industry.
Fall
Faculty: FDA staff

580.608 Identification and Validation of Medical Device Needs - Clinical Rotations
This summer course teaches the art and skill of identifying medical device opportunities by experiencing real world scenarios in an immersive clinical environment. Students rotate through multiple clinical disciplines and become part of the team of senior clinicians, surgeons, residents, fellows, nurses and medical technologists. They learn to identify unmet medical device needs through direct observations in a variety of clinical settings including the hospital ward and operating room, interviews (with patients, doctors, nurses, hospital administration), literature survey, and more. Concurrently, they learn the process of filtering all observations to a few valid medical device opportunities by assessing the market size, intellectual property landscape, regulatory framework, and competitor dynamics in addition to the clinical impact that such a device could have. The ability to identify a relevant medical device need is an important first step in the medical device innovation cycle; this course aims to provide students with practical hands- on training in that process.
Summer
Faculty: Clifford Weiss, Soumyadipta Acharya, Hien Nguyen

580.611/612 Medical Device Innovation and Design (for US market)
The two-semester design project provides teams of students with hands-on design experience and takes them through a practical journey of the entire medical device innovation cycle for the US market. Student teams select a project after scrutiny of various factors such as clinical impact, commercial viability and potential, and technical feasibility. Next, they define the needs and requirements of such a device, in close consultation with the target user (clinician and patient, typically). This is followed by development of an engineering solution: invention, design and prototyping of the device. Concurrently, teams develop a commercialization strategy that includes planning for regulatory and reimbursement approval, generating and protecting intellectual property, going from prototype to manufacturing, and taking the final product to market either through the startup or licensing route.
Fall, Spring
Faculty: Soumyadipta Acharya

580.618 Identification and Validation of Global Health Needs
In this course, students are introduced to clinical needs in the low resource settings of the developing world which presents unique challenges. Working with partner Jhpiego, a Johns Hopkins affiliate that is a world leader in family health, students develop device projects that will have the greatest clinical impact in these settings. Students will travel in August to the field locations around the world to see first-hand the clinical environment for these projects and meet the health care workers who will be using the devices.
Summer
Faculty: Soumyadipta Acharya

580.619/620 Principles and Practice of Global Health Innovation and Design
In these courses, students develop device projects that will have the greatest clinical impact in resource-restrained settings around the world. Partnering with Jhpiego, a Johns Hopkins affiliate focusing on maternal and child health, students design, build and test devices that will be used in these setting by a semi-skilled health care workers. Students will work with staff and faculty from Jhpiego as well as other clinicians, engineers, and advisors to make sure the devices work as well as possible at the most affordable price.
Fall, Spring
Faculty: Soumyadipta Acharya

580.621/622 Insight Informed Innovation
These two courses aim to equip students with a repeatable/structured process and the tools required to:

1. Identify opportunities for new medical devices through unmet, unarticulated and underserved stakeholder needs
2. Link these insights to an exhaustive set of potential solutions
3. Synthesize solutions and features into validated product concepts

Particular emphasis will be placed upon the Front End of Innovation (FEI), Voice of the Customer (VoC) and ethnographic research in a clinical setting. The working assumption for this course is that the (rigorous) FEI/VoC background among incoming students is minimal. The objective, therefore, is to equip students with the process and tools that they will need to:

- Extract maximum benefit from their clinical rotations; building the research resource from which they will identify their team projects.
- Scout and/or ideate and prioritize an exhaustive set of potential technical solutions which meet prioritized stakeholder needs
- Advocate the Voice of the Customer during the concept development process in order to build appropriate stakeholder validated product concepts

A rigorous introduction to customer research and capture will be given during the summer as students begin to conduct their clinical rotations and gather customer (stakeholder) insight. These courses are a distillation of industry best-practices and are taught by industry practitioners.
Summer and Fall
Faculty: Paul Fearis, Brandon Craft