**Product Design Laboratory** (EN.520.427 and EN.520.657)

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Location: Barton Hall – Biophotonics laboratory.

Designing a biomedical system is a complex process that requires application of engineering methodologies and additional inputs and conditions that are unique to a product which is to be used in a clinical setting.

The course will expose students to those additional requirements. During the course, the students will acquire tools that will enable them to cope with the complexity of designing a biomedical system.

The course format is a combination of lectures and laboratory throughout the whole semester. It will include the following subjects: market research, identification of an unmet need, product proposal, patents search and patent writing, regulatory issues (in the US and across the world), safety, ethical consideration, payment reimbursement codes, Communication between the system and the medical environment and business models.

The Students in the course will be grouped (2 people on their own discretion). Each group is considered a “start-up” company. It will develop a complete product portfolio during the semester. The portfolio includes the proposed product, conceptual initial planning, detailed planning, software writing, product drawings, components list, Envelope design, User-Machine interface, Patent writing, expected regulation submission plan and business model and budget for 2 years of operation and milestones to be achieved. There is a functional working prototype at the end of the course with “blueprint” of the device that include all the above tasks. The students will pitch their “company” to a panel which will include investors, Corporate lawyer, patent lawyer, regulatory experts and marketing professionals. They will need to convince the panel why it makes sense to invest in their group.

This will be an interactive course. The different groups will interact with each other and with the teaching staff. Any decision before the next stage will be presented to the entire class for comments, corrections and improvements.

Every task in the class is graded. The course final grade is the sum of all grades together with the panel combined evaluation and grade.

The course is suitable for senior year and grad students. It is open to all students within the Whiting school of engineering.

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