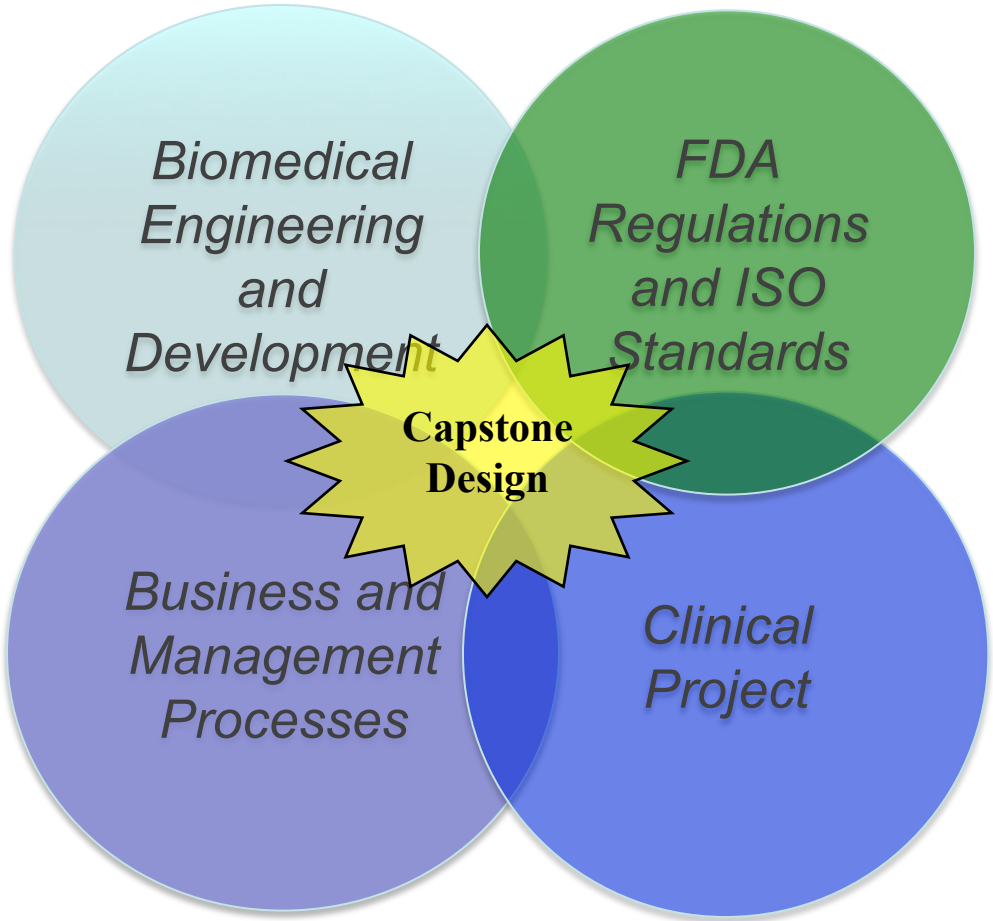
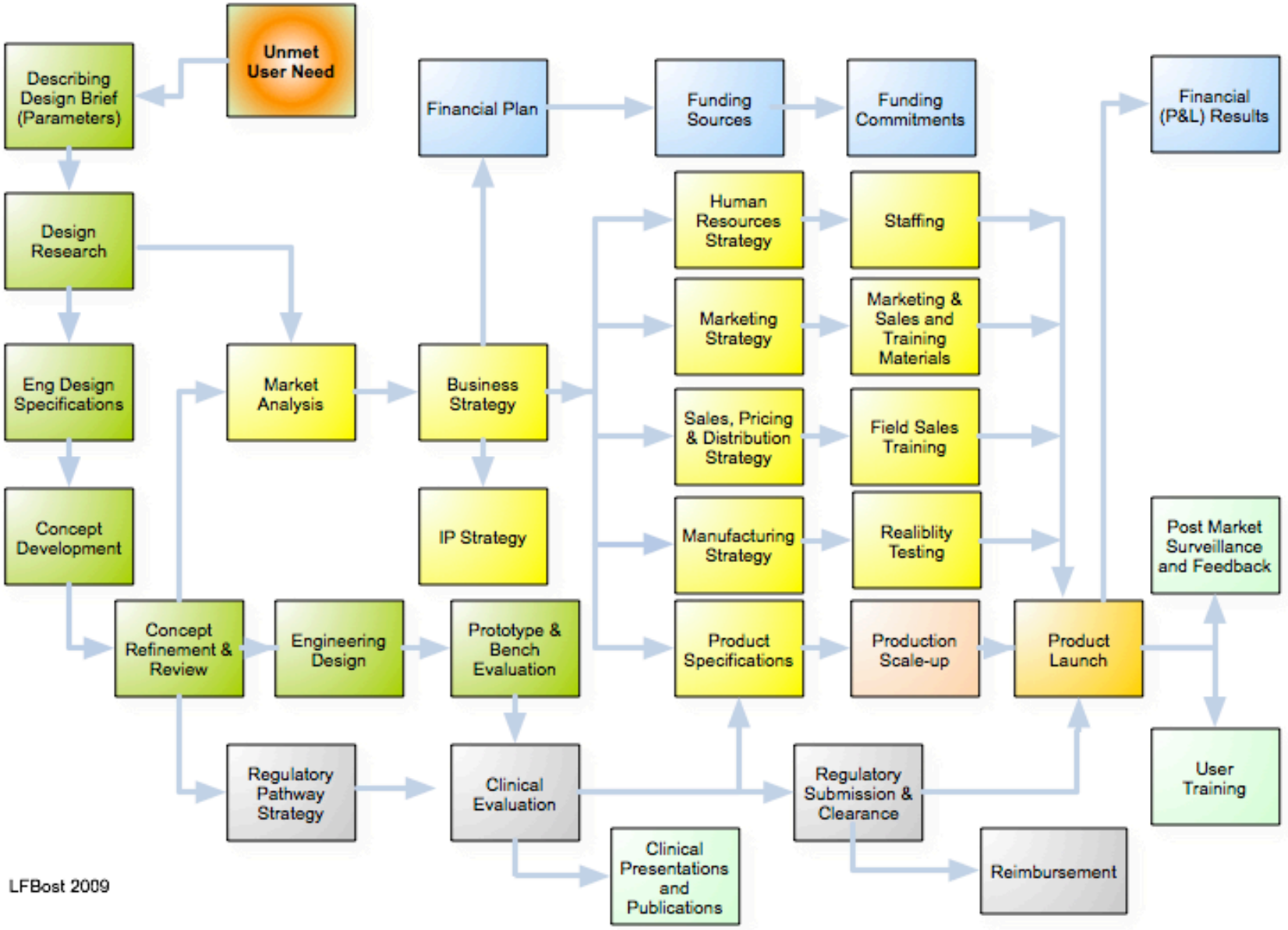
GT Biomedical Engineering

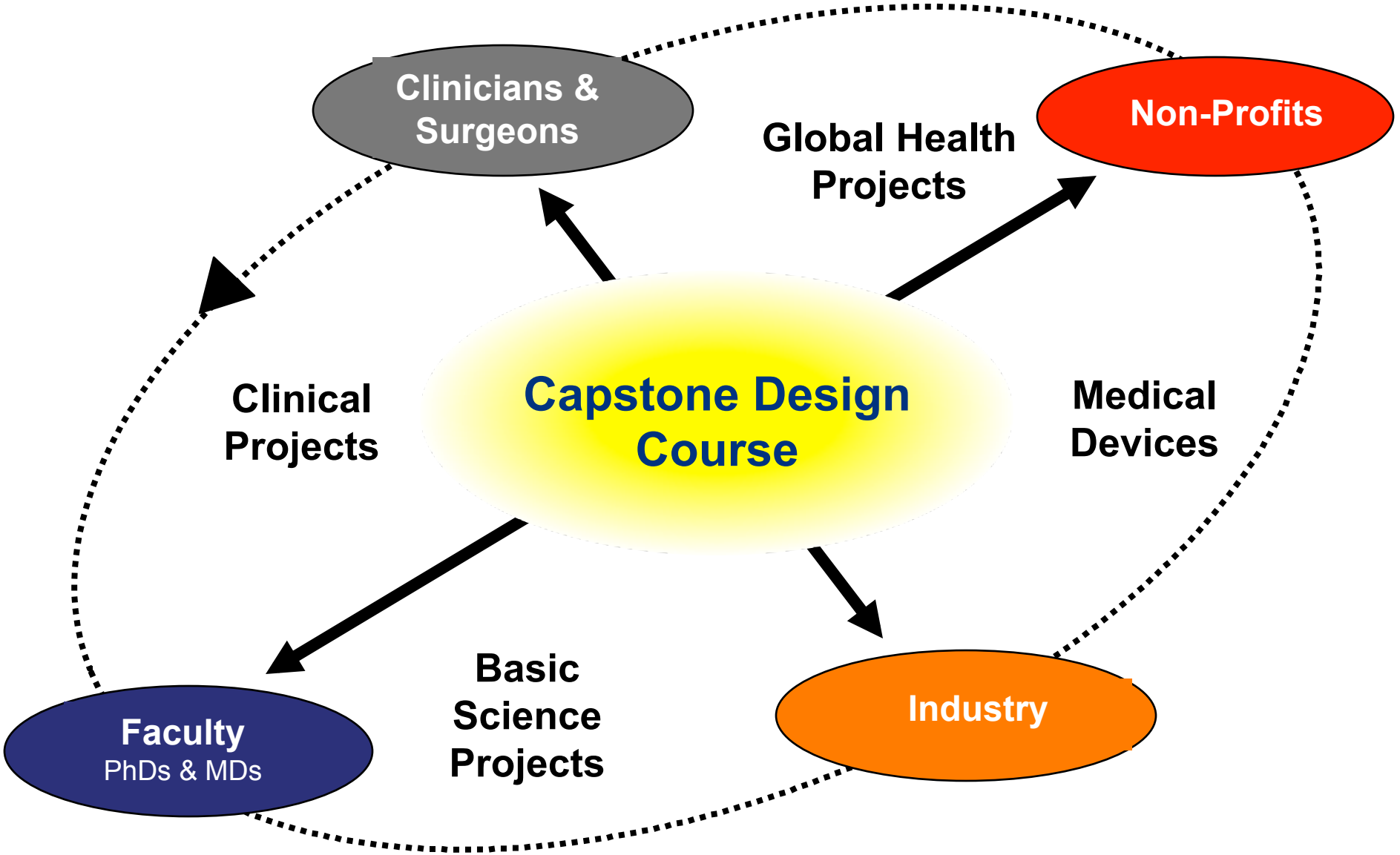
Capstone Design - BMED 4600 and 4601



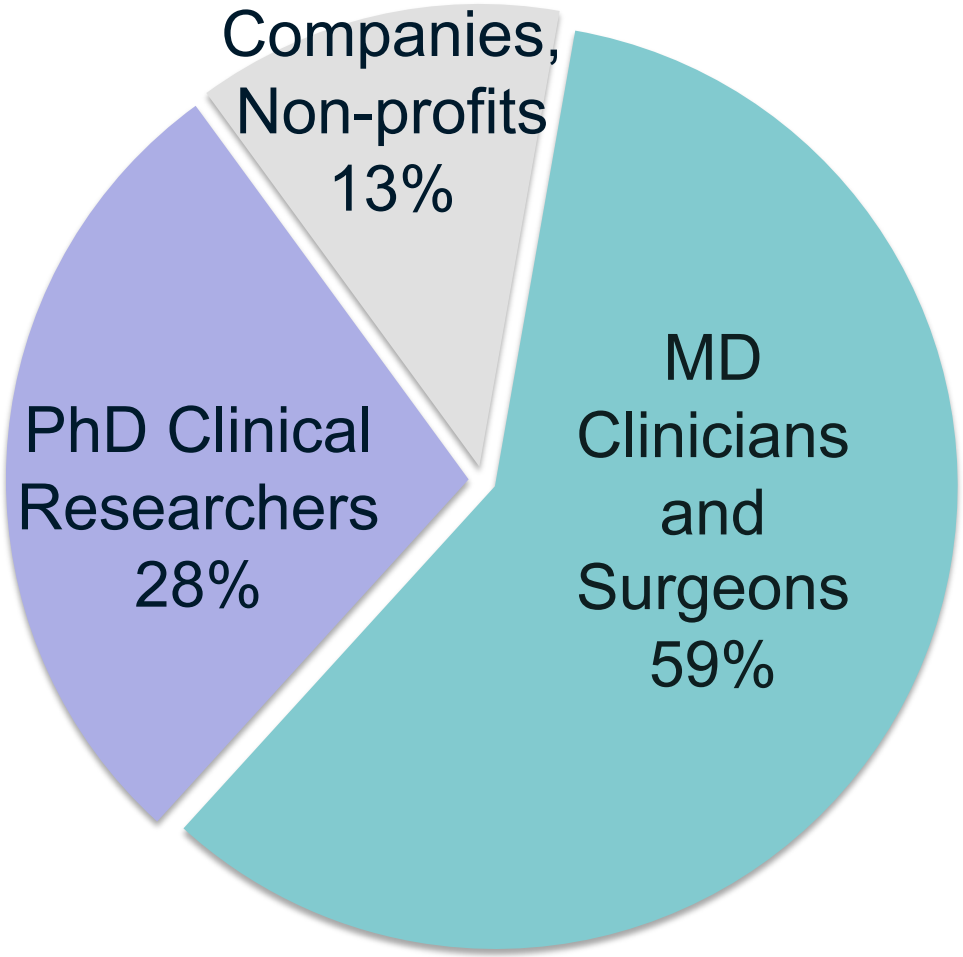
Medical Product Realization Process



Advisors for BME Projects

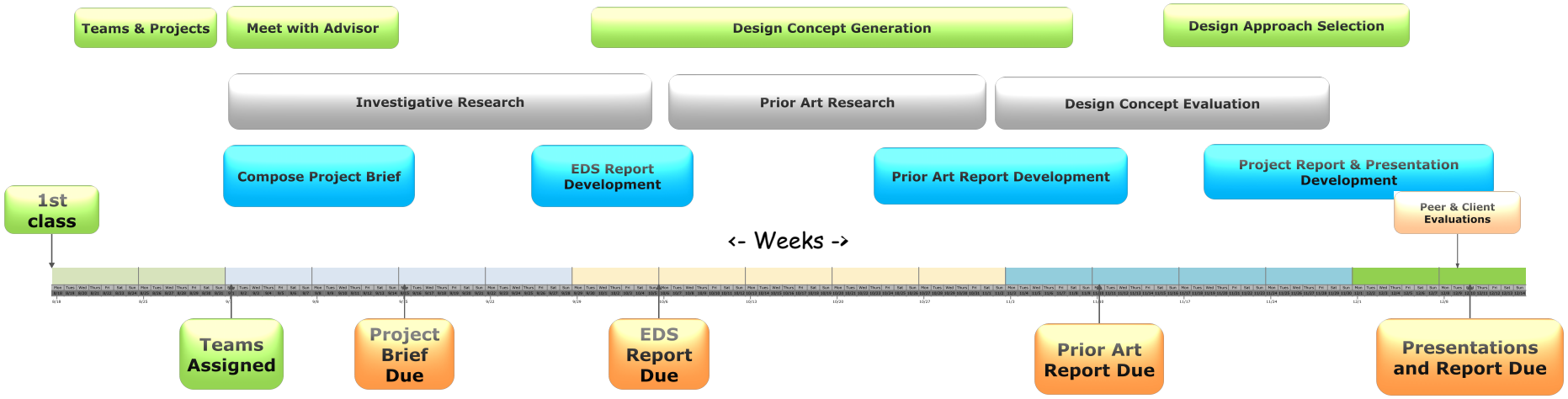


Fall'09: 39 BME Capstone Projects



Clinically Relevant: 90% +

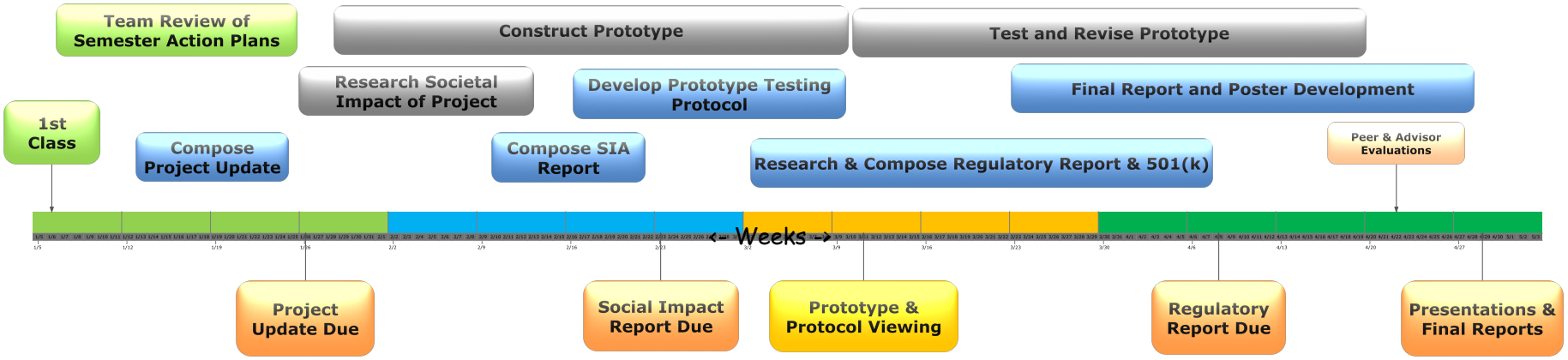
BME Senior Design – 1st Semester



Team Deliverables -

- Project Brief
- Engineering Design Specifications (EDS) with Metrics
- Prior Art (patent & literature) Research
- Project Report – Proposed Solution, Project Plan
- Project Presentation with study model

BME Senior Design – 2nd Semester



Team Deliverables -

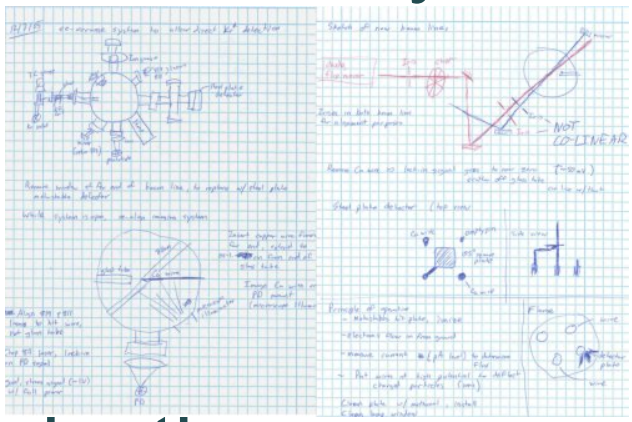
- Project Update
- Societal Impact Report
- Proof-of-Concept Prototype and Testing Protocol
- Regulatory Report & 501(k) Document Submission
- Poster and Oral Presentation
- Final Project Report – Summary Results & Final Design

On being a project advisor…

- 2-3 meetings a semester with project team
- Provide feedback on project deliverables
- End of semester assessment of team
- Probably 10 – 12 hours per semester
- Attend end of semester presentation?

Student responsibilities…

- 75 hours per student each semester on the team's project
- Design research, analysis, creativity
- Design notebook
- Bi-monthly updates
- A "team communicator"



- Oral and written communications
- Students and teams must meet all capstone design course requirements & deliverables

Typical Past Projects

- T40 - Ultrasonic Gel Warmer for Portability
- T41 - Endoscopic Accessory for Drainage of Pancreatic Cysts
- T42 - Bioprosthetic Heart Valve
- T43- Spinal Immobilization Device for Accident Extraction
- T44 - MRI Compatible EEG Filter
- T45 – Minimally Invasive Annuloplasty System for Mitral Valve Repair
- T47 - Non-Invasive Personal Monitor
- T49 - Central Venous Line Placement Trainer for Physicians
- T50 - Lancing Device for Capillary Blood Sampling
- T53 - Microbead Stem Cell Injection Device
- T54 - 4-Channel Neural Signal Brain to Computer Device
- T55 – Blood Pressure Monitor for Lowland Gorillas
- T56 - Continuous Blood Glucose Monitor
- T59 - Laparoscopic Hyperthermia System for Nephritic Surgeries
- T60 - Nerve Regeneration Scaffold for Peripheral Nerve Injury
- T61 - Prevention of Guidewire Loss in CVC Placement
- T63 – Memory Polymer Injector for Device Treating Triple-A
- T66 – Lumbar Region Spinal Implant

Getting started…

- A few sentences outlining clinical need or potential project idea.

  At the beginning of the semester, a student team will meet with the advisor to discuss background and develop an initial Project Brief and Description.

- Send: your name and contact information to:

  franklin.bost@gatech.edu

Franklin Bost (Tel: 404-385-2115)
Professor and Director of Design Instruction
Coulter Department of Biomedical Engineering
Georgia Institute of Technology

- Projects begin summer, fall and spring semester

THE WALLACE H. COULTER DEPARTMENT OF BIOMEDICAL ENGINEERING
at Georgia Tech and Emory University

BME Capstone Design Project I (BMED 4600) and II (BMED 4601)

Instructor: Prof. Franklin Bost, Whitaker 3113, 404-385-2115, franklin.bost@bme.gatech.edu

Office hours: Tue 1:00 – 3:00 pm, Wed 8:30 am – 12:00 pm & by appointment (email request)

Prerequisites: BMED 2300, BMED 3610 and BMED 3510 prerequisite or w/concurrency

Text: P.H. King and R.C. Fries, ***Design of Biomedical Devices and Systems, Second Edition*** *2009,* CRC Press (ISBN: 987-1-4200-6179-6)

Georgia Tech BME undergraduate students develop excellent analytical and process skills while taking a broad range of biomedical-focused classes. BME students, whether planning to enter industry, graduate school or medical school, can benefit from knowledge and experience in the interdependence of design and development processes with the multiple business and regulatory functions essential to biomedical product development. The following considerations are essential components of the BME capstone design courses: clinical or research relevant projects, human factors and ergonomics, economic and societal impacts, regulatory standards and compliance, environmental and sustainability issues, ethical, health and safety issues, and political/legislative influences.

The BME capstone senior design course provides student teams with hands-on experience with commercial development processes; project planning, concept and prototype development, design verification testing, FDA Quality Systems Regulations, design controls and regulatory pathways for commercialization of medical devices. Additionally, requirements of business functions such as marketing, sales, manufacturing, finance, intellectual property and their affects on the product development process are integrated into class presentations, projects and reports.

The capstone design courses include weekly class presentations and project-based learning experiences. Students are expected to attend classes, actively participate team meetings and contribute in work to meet milestones for projects and course deliverables in a timely and professional manner. Each student is expected to dedicate at least 5 hours per week (80 hours per semester) outside class time toward meeting project goals and course requirements.

Course Objectives: To inform and engage students in understanding the medical and clinical relevance of healthcare product opportunities and problems, the importance of proper definition of user requirements and functional metrics, to encourage developing creative solutions that address project parameters and metrics, to develop functional or simulated prototypes and in order to perform verification testing and to document proper engineering justification for project solutions. The BME capstone design courses prepare students for future team activities through a project design experience incorporating relevant biomedical and engineering practices, constraints, timelines, deliverables and professional oral and written communications.

Classes**:** Student attendance at all class sessions is strongly advised. Weekly class session presentations will focus on the engineering design process as typically practiced in the medical device industry including user definition and requirements, functional requirements, developing and evaluating concepts for solutions, project planning methods, human factors and ergonomics, communications and engineering ethics. Class presentations are coordinated with chapters in the text and also include significant references to current practices in biomedical engineering development, web based resources and industry examples. Students are advised to study the assigned chapters prior to class and understand the processes and techniques covered in the text. Information presented in class along with techniques and processes described in the text should be used the project work and deliverables.

Projects: Project topics are suggested by a wide variety of healthcare professionals such as physicians, nurses, emergency technicians, biomedical industry personnel and academic researchers. Projects may also be suggested by students and submitted for instructor approval. Teams of four (4) students will be formed for the two-semesters. Each project will have a professional healthcare, clinical, industry or academic advisor. Teamwork skills, active participation, oral and written technical communications are key factors for success.

Advisor Communications: Each team is responsible for maintaining regular communications with their advisor. Semi-weekly e-mail memo updates should be sent to the advisor, instructor and assigned teaching assistant. Student teams are encouraged to meet face-to-face with the advisor 2-3 times during each semester. All communications, meetings, research and project work should be documented in the student's project notebook.

Project Notebooks: Each student is required to maintain an up-to-date project notebook to document their work on the project. Students are expected to follow standard lab/design notebook guidelines, as described in the handout, "How to Keep a Project/Lab Notebook". Students are advised to bring their notebook to every class meeting. Random notebook collections for grading will be announced during class sessions.

4600 Proposed Design Solution: At the conclusion of BMED 4600, each team will submit a project report highlighting key factors, the proposed project solution, along with a plan and schedule for the 4601 activities, team member responsibilities and deliverables. The project and proposed solution will be presented in a class poster or oral presentation session and study model..

4601 Design Solution and Prototypes: Based on the design solution proposed in BMED 4600, in the second semester each team will construct and evaluate a functional prototype(s), technical simulation, or related proof-of-concept device for their project. Performance verification testing should be conducted on the prototype(s) based on a written protocol to evaluate the design output against the Engineering Design Specifications. A final project report is required. The project and final prototype will be presented in a class poster or oral presentation session.

External Factors: Societal influences, economic and regulatory factors significantly affect the development and adaptation of medical products and delivery of healthcare. Teams will investigate factors influencing their project and provide reports on prior art and intellectual property, potential societal impact of their proposed solution and a 510(k) regulatory submission.

Project Funds: Design projects that provide students with a clinical relevance are eligible to compete for funds (typically < $500) for prototyping and project expenses during BMED 4601. Funds are provided from an endowment to support student clinical design experiences in the Wallace H. Coulter Department of Biomedical Engineering. Guidelines for submission of project expenses will be posted on T-Square. Lectures topics, schedules and assignments are subject to modification based on circumstances during the semester.

Special notes:

- The syllabus, schedule and deliverables for this course are subject to change during the semester. The syllabus, course assignments and reference materials will be posted on T-Square. Changes will be announced but students are responsible for keeping up-to-date on all course requirements.

- Plagiarism and dishonesty are violations of the Student Honor Code. In fairness to the honest majority, **ALL** incidents of suspected academic misconduct will be reported to the Office of the Dean of Students. Students are cautioned to be mindful that the submission of material that is wholly or substantially identical to that created or published by another person or persons, without adequate credit notations indicating authorship constitutes plagiarism. When references of work (written, graphic or otherwise) of others are used in projects and reports, proper reference citations must be used.
  Ref: www.honor.gatech.edu, www.deanofstudents.gatech.edu/codeofconduct

- Student with special needs, must registered with the ADAPTS service (adapts.gatech.edu). Please inform the instructor by the second week of class.

Finals grading will be based on the Georgia Institute of Technology system (A, B, C, D, F). No plus or minuses will be applied to the final grade. Individual course deliverables will receive number grades.

A (100-90)	B (89-80)	C (79-70)	D (69-60)	F (<60)
Exceptional	Proficient	Acceptable	Novice	Failure

BMED 4600 – Senior Design Project I

(First semester)

1. Student teams will work with a client/advisor from the biomedical engineering community such as a physician, biomedical researcher, or industry contact on a defined project.

2. Teams will research the approved topic, then develop and submit an Engineering Design Specification (EDS) report that includes: a problem statement, functional requirements, customer requirements (user and patient definition), design constraints, performance metrics and project deliverables.

3. Teams will conduct a literature and prior art patent search, compose and submit a report on relevant findings relating to their project.

4. Each team is expected to identify several design solution alternatives, evaluate them against the project criteria with their client/advisor and define a final project direction.

5. Each team member is to maintain a project notebook, which includes documentation of team meetings and communications, individual/independent work and task performed on the project, meetings/conversations and communications with their client/sponsor.

6. At the end of the semester, each team will submit a project report highlighting work conducted, the proposed project solution along with a plan and schedule for the 4601 work.

7. At the end of the semester, each team will present a poster in scientific format describing the project, the selected design solution with justification, and project plan for BMED 4601. Each team shall also present a study model/representation of their proposed design.

BMED 4600 Grading - 70% Team and 30% Individual Performance	%
Project Brief	10%
EDS Report*	15%
Prior Art & Intellectual Property Report*	15%
Project Poster, Presentation and Study Model*	15%
Project & Design Report with 4601 Plan*	15%
Student's Design Notebook	15%
Peer, Client & Instructor Assessments	15%
Total	100%

* Each member must serve as primary editor for one of the assignments. Each team should actively and timely contribute to the content, but one member should be assigned responsible for organization and editing the report.

BMED 4601 - Senior Design Project II

(Second Semester)

Prerequisite: BMED 4600

1. Based on the design solution proposed in BMED 4600, each team will construct and evaluate a functional prototype, technical simulation, or related proof-of-concept device for their project.

2. Performance verification testing should be conducted on the prototype(s) based on a written protocol to evaluate the design output against the Engineering Design Specifications.

3. Each team will investigate the potential societal impact of their design solution and submit a report

4. Each team will research and establish the regulatory pathway for their project and compose a "traditional" 510(k) submission in accordance with FDA guidance documents.

5. At the conclusion of the semester, each team will complete a project report which includes a detailed description of the product design solution and function, engineering justification of critical processes, components or assemblies, engineering drawings (including tolerances and assembly drawings), component material selection and rational, manufacturing considerations (process selection and rationale), estimated manufacturing costs.

6. At the conclusion of the semester, each team will prepare and present a poster in a general session describing the design solution, their prototype(s) and results of the project.

BMED 4601 Grading - 70% Team and 30% Individual Performance	%
Project Update	5%
Societal Impact Report*	10%
Regulatory Report*	15%
Prototype - Development, Protocol for Verification Testing*	15%
Final presentation (poster or slide presentation depends on class size)*	10%
Final Project Report*	15%
Student's Design Notebook	15%
Peer, Client & Instructor Assessments	15%
Total	100%

* Each member must serve as primary editor for one of the assignments. Each team should actively and timely contribute to the content, but one member should be assigned responsible for organization and editing the report.