BioE 297 – Special Study: Physics-Based Modeling and In Silico Clinical Trials
Fall 2019

Instructors: Julius Guccione, PhD (julius.guccione@ucsf.edu) – Instructor of Record
Steven Levine, PhD (steven.levine@3ds.com) – Guest Faculty

Units: 2.0

Day/Time: Wednesdays, 5:00pm – 7:00pm

Location: UCSF Mission Bay, Genentech North 114 (Mission Hall 1407 on Nov 13 & Dec 4)

Office Hours: By Appointment

Required Course Materials

There is no required textbook for this class. All readings and assignments will be available and provided via the course website (UCSF CLE); therefore, Internet access is necessary for successful completion of this course. Lectures will be posted to the course website after each lecture.

Course Description

What if physicians and surgeons could virtually analyze their patients' health and plan therapies and surgeries using the same advanced modeling and simulation (M&S) technology that the automotive, aerospace, energy and hi-tech industries rely on to test their product before they are built? On 25-March-2019 the Director of the National Institute of Biomedical Imaging and Bioengineering told the American Institute for Medical and Biological Engineering that M&S "is at the center of everything we do." M&S adds value by providing knowledge and insights not available from existing data modalities and making evidence generation more efficient by reducing the need for more burdensome types of data and information. The FDA can more fully utilize M&S to minimize burden on patients, investigators, manufacturers and regulators with mechanisms that support efficient review of novel products and approaches without compromising safety or effectiveness.

This course introduces students to: (1) physics-based M&S applied to solve a variety of clinical problems; and (2) the FDA-funded CDRH Critical Path Project titled "Transforming the Medical Device Innovation Ecosystem: from 'In Silico Clinical Trials' to a 'Review of the Future'." The main elements of M&S such as the derivation and solution of boundary-value problems will be taught in the contexts of multi-physics and multi-scale. Students will be provided with an overview on the creation of 3D models or "digital twins" from medical images. The course will be taught by clinicians, theoreticians and industry experts who will use examples and case studies from their professional experience to apply the concepts being covered.

Upon completion of the course, students will be able to understand how to more fully harness M&S, digital evidence, and reduce the size of prospective clinical trials for medical devices.

Course Objectives

- Recognize how fundamental components of a boundary-value problem such as geometric configuration, physical properties and boundary conditions are measured clinically.
- Assess challenges in the derivation and solution of boundary-value problems for a variety of clinical applications.
- Examine case examples of physics-based M&S that have led to seminal mechanistic (e.g., structure-function) insights concerning a disease and its treatment.

Key Topics

- M&S inputs: medical image segmentation, 3D model/mesh creation, boundary condition measurement, multi-axial physical property testing, constitutive equations
- Boundary-value problem solution: finite element methods
- M&S verification and validation: functional medical imaging

Course Format:

- Lectures by clinicians, theoreticians and members of industry
- Discussions and workshop-type exercises

- Reading literature as assigned by faculty
- Homework to assess student comprehension

Grading and Expectations

Homework 60% (written assignments)
Participation 40% (involvement in class discussions/exercises and professional conduct)

Homework

Following every lecture, each student will be responsible for writing a reflection paper. This will be the basis for the homework grade and will be graded on a credit/no credit basis. For each reflection, students should choose a topic or idea from the lecture that s/he found particularly interesting and write a personal reflection or commentary on the material. The reflection is meant to synthesize key points learned in the lecture and allow the student to agree/disagree with the content presented and provide feedback. The length is expected to be 250-500 words and will be due prior to the next lecture. Other homework assignments may be assigned as relevant to each lecture. Late assignments will not be accepted.

Participation

Attendance will be taken for every class session. Please arrive promptly for class, which will start at 5 pm (and not on Berkeley time). Tardiness and unexcused absences will affect the maximum possible class grade. It is expected that students will participate in class discussions and exercises. Electronics are not allowed during lecture and will reduce participation credit if used (see Professional Conduct). An absence may be excused under certain circumstances (e.g. job interview, medical emergency, etc.) and will be determined on a case by case basis. Students will be allowed one unexcused absence without penalty.

Professional Conduct

The subject matter experts from academia and industry are graciously contributing their time to prepare presentations and provide real world experience and feedback. Students are expected to be on time and provide the guest lecturers their full attention. Attendance and class participation are essential components of this course. Please note that use of electronic devices (laptop, tablet, phones, etc.) are not allowed during the class unless expressly directed by the instructor or guest faculty. The use of social media, working on related/non-related class assignments, web surfing, and gaming is distracting and disrespectful to the speakers and fellow classmates.

Email Policy

The instructors will attempt to answer emails and questions in a timely manner. Please allow for one business day for a response. Send general emails and questions to the industry instructor, Steven Levine, at steven.levine@3ds.com.

Session Schedule

Date	Key Speakers and Sessions
Lecture 1 GHN114 10/2/19	Steven Levine, PhD – Dassault Systemes, Inc. *Introduction; Role of M&S in industry; In silico clinical trials*
Lecture 2 GHN114 10/9/19	David Steigmann, PhD – Professor of Mechanical Engineering, UC Berkeley. *Derivation of boundary-value problems involving nonlinearly-coupled phenomena*
Lecture 3 GHN114 10/16/19	*Yue (Melody) Xuan, PhD – Postdoctoral Scholar, Surgery, UCSF* *Devices for transthoracic aortic valve replacement*
Lecture 4 GHN114 10/23/19	Nuno Rebelo, PhD – Dassault Systemes, Inc. *Nitinol properties; Numerical solution of 3D, nonlinear boundary-value problems*
Lecture 5 GHN114 10/30/19	*Tobias Deuse, MD – Professor of Surgery, UCSF* *Minimally invasive treatment of mitral valve regurgitation*
Lecture 6 GHN114 11/6/19	*Hobart Harris, MD – Professor of Surgery, UCSF* *Devices for repair of ventral hernias*
Lecture 7 **MH 1407** 11/13/19	*Michael Conte, MD – Professor of Surgery, UCSF* *Bioengineering solutions to problems in vascular & endovascular surgery*
Lecture 8 GHN114 11/20/19	*Andrew Wisneski, MD – Resident Physician, Surgery, UCSF* *Patient-specific finite element analysis of ascending thoracic aortic aneurysm*
Lecture 9 GHN114 11/27/19	*Jasleen Kukreja, MD – Professor of Surgery, UCSF* *Bioengineering solutions to problems in lung surgery*
Lecture 10 **MH 1407** 12/4/19	*Julius Guccione, PhD – Professor of Surgery, UCSF* *In silico design of novel treatments for heart failure*