This course will expose graduate-level students to the process of drug discovery and development. The course will be structured to cover topics from the identification of a disease-relevant target through to Phase III Clinical Trials. The course will be lecture based with student-led “journal club” presentations as part of the course. There will also be a writing project consisting of a ~3 page proposal of how to advance a drug discovery program based on the information learned in class. The students will present their proposals during the final week of class to a mock “VC board”. Grades will be weighted as follows: Attendance and participation, 35%; Presentation of “journal club” papers, 30%; Writing project, 35%.

An important component of the course is the use of guest lecturers from local biotech and pharma companies to ensure students have access to area experts. A typical week will include one session with both a lecture from the instructors and a student-led “journal club” presentation and a second session that will consist of a lecture and discussion with one of the guests from local biotech/pharma.

**Intro:** Overview of Course  This lecture will give an overview of the topics covered in the course. We will also review the writing project and journal club format.

January 11 - Course Introduction

**Topic 1:** Defining a Disease and Choosing a Target:  This week will focus on the process of identifying a target using genomics and cell signaling knowledge. Another key element will be to exemplify the process of progressing a laboratory observation into a proven target.

Jan 16 - Target Identification Lecture and Journal Presentation

Jan 18 - Guest Lecture— Selecting Epigenetic Targets

**Topic 2:** Overview of Drug Modalities

Jan 23 - Drug Modality Lecture and Journal Presentation

Jan 25 - Guest Lecture- Antibody Drug Conjugates in Cancer Treatment
**Topic 3:** **Hit Identification:** This week will focus on how high throughput screening techniques and validation strategies for initial hits, including proteomic methods.

Jan 30 - Hit ID Lecture and Journal Presentation

Feb 1 - Guest Lecture-- Tales of HTS in Pharma

**Topic 4:** **Biophysics-Biology-Chemistry Interface** This week will focus on the use of structural information for guiding the improvement of small molecule therapeutics. We will also discuss the impact that kinetics of binding can have on a drug discovery effort.

Feb 6 - Lecture and Journal Presentation --- **Short form for writing project due!**

Feb 8 – Guest Lecture on the role of computational biology in drug discovery

**Topic 5:** **Medicinal Chemistry: From Hit to Lead** This week will focus on how chemists build better molecules and introduce parameters that chemists optimize beyond target affinity.

Feb 13 - Guest Lecture- Intro to Medicinal Chemistry and Journal Presentation

Feb 15 - Guest Lecture- Case study of Hit to Lead Program

**Topic 6:** **The Four Pillars (Maybe Five) of Drug Development** We will pull together some of the topics from medicinal chemistry and animal models and discuss how these choices and data can predict efficacy in the clinic.

Feb 20 - Guiding Principles Lecture and Journal Presentation

Feb 22 - Guest Lecture- Finding the right formulation and why

**Topic 7:** **Animal Models** We will pull together some of the topics from medicinal chemistry and animal models and discuss how these choices and data can predict efficacy in the clinic.

Feb 27 – Preclinical Models Lecture and Journal Presentation

Mar 1 – Guest Lecture- Selecting the right model

**Spring Break:** **March 6/8**

**Topic 8:** **The Different Flavors of Biomarkers (Target Engagement and Patient Selection)** We will introduce the concept of personalized medicine and discuss how genomics, proteomics and targeted testing are impacting patient selection in the drug development process.

Mar 13 – Use of Genetics in Drug Discovery Lecture and Journal Presentation

Mar 15 – Guest Lecture – Developing a Biomarker for Clinical Use
**Topic 9: First Time in Human and Proof of Concept Clinical Studies** The next two weeks will be spent on the design and regulatory elements of a clinical trial design and execution

Mar 20 - Preclinical Safety Studies Lecture and Journal Presentation

Mar 22 – Guest Lecture on FTIH studies

**Topic 10: Additional Topics – Week 1**

Mar 27 – Phase 3 Trials and Approval Lecture and Journal Presentation

Mar 29 – Guest Lecture - The Role of Statistics in Drug Discovery

**Topic 11: Additional Topics – Week 2**

Apr 3 – Development of Vaccines Lecture and Journal Presentation

Apr 5 – Cell and Gene Therapy Lecture

**Topic 12: Intellectual Property and Generics** We will discuss how and why it is important to protect discoveries during the process and highlight the difficulties in establishing IP.

Apr 10 – Guest Lecture – Intellectual Property- and Journal Presentation

Apr 12 – Guest Lecture – Repurposing of Medicines

**Projects:** Writing Project Mini-talks/Discussions

April 17/19

**Journal Article Suggestions:**

**Target Selection**


**Drug Modalities**


**Screening**

**Biophysics Interface**


**Medicinal Chemistry**


**Four Pillars and Formulation**

**Preclinical Models**

**Biomarkers**

**Phase 1 and Phase 2 studies**

**Cell Therapy**