IMPORTANT: This syllabus form should be submitted to OAA (gsbs_academic_affairs@uth.tmc.edu) a week before the start of each semester.

NOTE to STUDENTS: If you need any accommodations related to attending/enrolling in this course, please contact one of the Graduate School's 504 Coordinators, Cheryl Spitzenberger or Natalie Sirisaengtaksin. We ask that you notify GSBS in advance (preferably at least 3 days before the start of the semester) so we can make appropriate arrangements.

Term and Year: **Spring 2024** Course Number and Course Title: **GS04 1103: Principles of Therapeutics** **Credit Hours: 3** Meeting Location: **GSBS Computer Lab** Building/Room#: **BSRB S3.8112**	**Program Required Course: Yes** Approval Code: **No** **Audit Permitted: Yes** Classes Begin: **January 8, 2024** Classes End: **April 26, 2024** Final Exam Week: **April 29-May 3, 2024**

Class Meeting Schedule

Day	Time
Monday	1-2 PM
Wednesday	1-2 PM
Friday	1-2 PM

Course Director: Name and Degree: **Daniel A. Harrington, PhD** Title: Assistant Professor Department: Diagnostic and Biomedical Sciences Institution: UTH Email Address: Daniel.Harrington@uth.tmc.edu Contact Number: 713-486-4487 **Course Director/s:** Name & Degree: **Chandra Bartholomeusz, MD/PhD** Title: Associate Professor Department: Breast Medical Oncology Institution: MDACC Email Address: CHBartho@mdanderson.org Contact Number: 713-745-1086	**Instructor/s:** **(See attached Class Schedule)**

Course Director/s:

Name and Degree: **Venugopal Reddy Venna, PhD**

Title: Assistant Professor

Department: Neurology

Institution: UTH

Email Address: Venugopal.R.Venna@uth.tmc.edu

Contact Number: 713-500-7037

NOTE: Office hours are available by request. Please email us to arrange a time to meet.

Teaching Assistant:
Name and Email Address: **Shraddha Subramanian**
Shraddha.Subramanian@uth.tmc.edu

Course Description:

The course establishes a foundation of therapeutic principles from understanding disease pathophysiology to the whole pipeline of drug discovery and moving a drug from laboratory to regulatory filing and clinical implementation. This course includes didactic lectures from >35 experts including 1/3 basic research faculty, 1/3 clinical faculty, and 1/3 pharma/biotech industry veterans. It starts with discussions on disease processes, through therapy development, then to clinical translation.

The course is grouped into a series of general topics. The first topic includes disease mechanisms in microbial, viral, fungal, neurodegenerative, cardiovascular, aging, and malignant settings to better understand the nature of the problems. The second topic focuses on the development of lead molecules and drug design, including x-ray crystallography, molecular modeling, hit identification, lead optimization, and pharmacokinetic/pharmacodynamic studies. The third topic puts emphasis on drug screening methodologies, including high-throughput/content technologies and molecular imaging as well as *in vitro* and *in vivo* preclinical model systems. The fourth topic covers different therapeutic modalities and improved drug delivery systems. It also describes the latest development in immunotherapy, cell therapy, gene therapy, and stem cell transplantation. The fifth topic focuses on the identification of novel molecular targeting strategies and efforts toward individualization of therapy with state-of-the-art –omics technologies and biomarker development. The final topic group focuses on translating therapeutic strategies to the clinic, including the phases of preclinical studies, clinical trial design and execution, and regulatory considerations.

Textbook/Supplemental Reading Materials (if any)

- **No textbook but lecturers will provide supplemental reading materials relevant to their topic.**

Course Objectives:

The goals of this class include the following:

- Establish a conceptual idea of therapeutics as a discipline and a process that transcends specific disease processes
- Develop an understanding of the general principles underlying the development of new therapeutics. These concepts are useful for students interested in therapeutic development, whether in an academic, biotech, industrial, or regulatory setting.
- Expose students to current approaches used to discover and develop new therapeutic agents for clinical use
- Provide students with the knowledge tools to cultivate critical thinking for therapeutics discovery
- Enable students to network with numerous faculty/PI members and experts for dissertation research, committee membership, and future career opportunities.

***Specific Learning Objectives*:**

1. Gain knowledge on disease mechanisms in microbial, viral, fungal, neurodegenerative, metabolic, and malignant settings to better understand potential targets for therapeutic development.

2. Understand the approaches used in the identification and development of hit and lead molecules as well as their optimization, including structural biology, molecular modeling, chemical library development with medicinal chemistry and structure-activity relationship (SAR), pharmacokinetics and pharmacodynamics (PK/PD), high-throughput and high-content screening approaches, along with a variety of cellular and animal models to evaluate and elucidate drug mode of action (MOA).

3. Obtain an appreciation of complementary therapeutic approaches including surgery, radiotherapy, immunotherapy, anti-viral therapy, gene and siRNA therapy, and stem cell transplantation.

4. Develop in-depth knowledge of current problems and approaches for improving the current therapies including the need to: identify new therapeutic targets, understand pharmacogenomic characteristics, individualize treatment for each patient's heterogeneous disease, and develop strategies to minimize side effects through normal tissue protection and improved drug delivery.

5. Comprehend how therapeutic strategies developed in the preclinical setting are translated into clinical trials, including the phases of clinical trial design and execution, regulatory considerations, and the use of molecular imaging and biomarkers.

Student responsibilities and expectations:

Students enrolled in this course will be expected to perform the following activities each week.

1. Attend three lectures each week
2. Participate in class discussions
3. Take three short answer type exams based on material covered

Grading System: Letter Grade (A-F)

Student Assessment and Grading Criteria :

Percentage	Description
Midterm Exams (30% and 30%)	2 midterm exams @30% each
Final Exam (30%)	
Participation and/or Attendance (10%)	

CLASS SCHEDULE

Date	Duration (Hour(s) taught by lecturer)	Lecture Topic	Lecturer(s)
Topic I. Disease Mechanisms			
Monday, January 8	**1**	Course Introduction	Venugopal Venna Daniel Harrington
Wednesday, January 10	**1**	Principles of Drug Development	Michael Pavia
Friday, January 12	**1**	Mechanisms of Microbial Diseases	Sam Shelburne
Monday, January 15	**Martin Luther King Day - no class**		
Wednesday, January 17	**1**	Viral Diseases and Therapies	Jagan Sastry
Friday, January 19	**1**	Antifungal Therapy	Sebastian Thomas Wurster
Monday, January 22	**1**	Cardiovascular Diseases and Therapy	Vihang Narkar
Wednesday, January 24	**1**	Malignant Disease Development	Aria Vaishnavi
Friday, January 26	**1**	CNS Diseases and Therapy	Jim Ray
Monday, January 29	**1**	Aging and development of therapeutic approaches	Yejing Ge
Wednesday, January 31	**1**	Biological Basis for Therapeutic Targets	Bartholomeusz

Date	Duration (hr)	Lecture Topic	Lecturer(s)
Topic II. Lead Molecules, Drug Design, and Pharmacology			
Friday, February 2	**1**	Protein Crystallography for Drug Discovery	John Horton
Monday, February 5	**1**	Pharmacokinetics and Pharmacodynamics in Drug Development	Yongyiang Jiang
Wednesday, February 7	**1**	Molecular Modeling in Drug Design	Jason Cross
Friday, February 9	**1**	Hit Discovery, Hit to Lead, and Lead optimization	David Kummer
Monday, February 12	**Exam 1: Topics I and II**		
Topic III. Models and Drug Screening			
Wednesday, February 14	**1**	Animal Models for Therapeutics Development	David Peng
Friday, February 16	**1**	Functional Genomics and Genetic Screening	Traver Hart
Monday, February 19	**1**	Model Organisms for Drug Target Discovery	Andrew Pickering
Wednesday, February 21	**1**	High Throughput–High Content Screening	Clifford Stephan
Friday, February 23	**1**	In Vivo Imaging in Drug Development	Ali Azhdarinia
Topic IV. Therapeutic Approaches			
Monday, February 26	**1**	Peptide-based therapies	Mikhail Kolonin
Wednesday, February 28	**1**	Particle-based Drug Delivery	Anil Sood
Friday, March 1	**1**	Journal Club	Shraddha Subramanian
Monday, March 4	**1**	microRNAs and Long Noncoding RNAs	Don Gibbons
Wednesday, March 6	**1**	Immunology	Alexandre Reuben
Friday, March 8	**1**	Immunotherapy	Alexandre Reuben
Monday, March 11	**1**	Antiviral and Gene Therapy	Jagan Sastry
Wednesday, March 13	**1**	Antibodies and Antibody-drug conjugates	Xin Ge
Friday, March 15	**Exam 2: Topics III and IV**		
March 18 - 22	**Spring Break - No class**		

Date	Duration (hr)	Lecture Topic	Lecturer(s)
Topic V. -Omics, Targets, and Individualization			
Monday, March 25	**1**	Genomics Medicine	Christopher Bristow
Wednesday, March 27	**1**	Stem Cell Transplantation	Muzaffar Qazilbash
Friday, March 29	**1**	Organoids as a Platform	Daniel Harrington
Monday, April 1	**1**	Pharmacogenetics and Pharmacoinformatics	Michelle Hildebrandt
Wednesday, April 3	**1**	Cancer Chemoprevention	Eduardo Vilar-Sanchez
Friday, April 5	**1**	Metabolomics in Drug Discovery	Daniel Frigo
Monday, April 8	**1**	Single-cell Studies for Therapy	Lingua Wang
Wednesday, April 10	**1**	Targeting Epigenetics for Drug Discovery	Kunal Rai
Topic VI. Preclinical and Clinical Considerations			
Friday, April 12	**1**	Biostatistics and Clinical Trial Design	Jack Lee
Monday, April 15	**1**	Precision Cancer Therapy	Jordi Rodon
Wednesday, April 17	**1**	March Biosciences	Sarah Hein
Friday, April 19	**1**	Preclinical and IND-enabling Studies	Michael Soth
Monday, April 22	**1**	Development of Phase I, II, and III Trials	Funda Meric
Wednesday, April 24	**1**	Intellectual Property Protection and Regulatory Filing	Andrew Dennis and Sean O'Connor
Friday, April 26	**1**	Biomarkers for Diagnosis and Treatment	John Heymach
Monday, April 29 Final Exam	**Exam 3: Topics V and VI**		

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