IMPORTANT: This syllabus form should be submitted to OAA (<u>gsbs_academic_affairs@uth.tmc.edu</u>) 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 2025	Program Required Course: Yes
Course Number and Course Title:	Approval Code: No
GS04 1103: Principles of Therapeutics	(If yes, the Course Director or the Course
Credit Hours: 3	Designee will provide the approval code.)
Meeting Location: GSBS	Audit Permitted: Yes
Building/Room#: BSBB \$3,8112 (Computer Lab)	Classes Begin: January 13, 2025
WebEx/Zoom Link: N/A	Classes End: May 2, 2025
	Final Exam Week: May 5 – May 9, 2025

Class Meeting Schedule

Day	Time
Monday	1:00-2:30 PM
Wednesday	1:00-2:30 PM
Friday	1:00-2:30 PM
Course Director Name and Degree: Daniel A. Harrington, PhD Title: Associate Professor Department: Diagnostic and Biomedical Sciences Institution: UTH Email Address: daniel.harrington@uth.tmc.edu Contact Number: 713-486-4487 Course Director/s: Name and Degree: Chandra Bartholomeusz, M.D., Ph.D. Title: Associate Professor Department: Breast Medical Oncology Institution: MDACC Email Address: chbartho@mdanderson.org Contact Number: 713-745-1086	Instructor/s (Use additional page as needed) 1. Name and Degree Institution: Email Address : 2. Name and Degree Institution: Email Address : 3. Name and Degree Institution: Email Address

Course Director/s:	4.
Name and Degree: Venugopal Reddy Venna, PhD	Name and Degree
Title: Associate Professor	Institution:
Department: Neurology	Email Address
Institution: UTH	Cont. Instructor/s
Email Address: <u>Venugopal.R.Venna@uth.tmc.edu</u>	
Contact Number: 713-500-7037	5. Name and Degree
NOTE: Office hours are available by request. Please email us to arrange a time to meet.	Institution:
	Email Address
Teaching Assistant:	
Name and Email Address:	
TBD	
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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 basic research faculty, clinical faculty, and 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:

Topic I includes disease mechanisms in microbial, viral, fungal, neurodegenerative, cardiovascular, aging, and malignant settings to better understand the nature of the problems.

Topic II focuses on the development of lead molecules and drug design, including x-ray crystallography, molecular modeling, hit identification, lead optimization, and pharmacokinetic/pharmacodynamic studies. Topic III 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.

Topic IV 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. Topic V 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. Topic VI 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 Objective/s:

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
Exam 1 (30%)	Exam over Topics I and II
Exam 2 (30%)	Exam over Topics III and IV
Exam 3 (30%)	Exam over Topics V and VI
Participation and/or Attendance (10%)	

CLASS SCHEDULE:

Specific class dates and topics will be provided in the full course syllabus, on the first day of class. Classes are anticipated to begin Mon Jan 13, and finish on Friday, May 2. Preliminary exam dates are anticipated to be Mon Feb 17 (Exam 1), Fri Mar 28 (Exam 2), and Mon May 5 (Exam 3).

ADDITIONAL NOTES:

All classes will be in-person with no remote virtual option unless otherwise specified. Virtual class sessions may be provided during the AACR Meeting, and will be announced in advance. Classes will be recorded when possible, as an aid to student learning, but recordings are not guaranteed. Students should not rely on the availability or quality of recordings as a substitute for in-person attendance. Lectures will comprise a standard 50 minute lecture, as well extended time to ask questions and encourage class discussion. Typical Q&A sessions may last 10-15 minutes, and extend slightly beyond 2:00pm; the noted 2:30pm endtime is listed only out of transparency, to ensure that students do not expect an earlier endpoint.

<u>Participation and Attendance grading</u>: 10% of the course grade will rely on student participation in class discussions, and adherence to the attendance policy.

<u>Attendance policy</u>: Students are strongly encouraged to attend all classes, but each may miss up to 5 classes during the semester, for any reason (illness, timing conflicts, etc.). Students must email the TA prior to a class absence to indicate that they will not attend. If a student misses more than 5 classes, then their score for the entire Participation and Attendance grade will be 0, which typically results in a loss of one full letter grade.

<u>Exam policy</u>: Exams will be held in-class on the specified dates. Requests to adjust the timing or format of exams cannot be accommodated. Students who miss an exam due to an emergency or other extreme, unexpected circumstance will be addressed individually.