

课程详述

COURSE SPECIFICATION

以下课程信息可能根据实际授课需要或在课程检讨之后产生变动。如对课程有任何疑问，请联系授课教师。

The course information as follows may be subject to change, either during the session because of unforeseen circumstances, or following review of the course at the end of the session. Queries about the course should be directed to the course instructor.

1.	课程名称 Course Title	新药研发导论 Introduction to Drug Development
2.	授课院系 Originating Department	医学院 School of Medicine
3.	课程编号 Course Code	MED115
4.	课程学分 Credit Value	3
5.	课程类别 Course Type	专业导论课 Introduction to Majors
6.	授课学期 Semester	春季 Spring
7.	授课语言 Teaching Language	中英文 Chinese & English
8.	授课教师、所属学系、联系方式 Instructor(s), Affiliation & Contact (For team teaching, please list all instructors)	李亮, 医学院, lil@sustech.edu.cn Liang Li, School of Medicine
9.	实验员/助教、所属学系、联系方式 Tutor/TA(s), Contact	
10.	选课人数限额(可不填) Maximum Enrolment (Optional)	

11. 授课方式 Delivery Method	讲授 Lectures	习题/辅导/讨论 Tutorials	实验/实习 Lab/Practical	其它(请具体注明) Other (Please specify)	总学时 Total
学时数 Credit Hours	48	0	0	0	48
12. 先修课程、其它学习要求 Pre-requisites or Other Academic Requirements	无NA				
13. 后续课程、其它学习规划 Courses for which this course is a pre-requisite	无NA				
14. 其它要求修读本课程的学系 Cross-listing Dept.	面向全校				

教学大纲及教学日历 SYLLABUS

15. 教学目标 Course Objectives

本课程设计为科普性、趣味性的通识导论类课程，旨在面向各个专业的本科学生提供关于新药研发的基本概念、精彩案例、里程碑式成就、以及来自新药研发一线的沉浸式体验，从而激发学生对新药研发的兴趣，也为学生对新药研发行业现状提供基本的概念，助力学生的专业选择和职业发展。

This course is designed as a popular science and interesting general introduction course for undergraduate students from various majors. The course aims to provide the students basic concepts, basic concepts, typical examples, and milestone achievements of drug development, so that the students can obtain an overview of the real-world practice of the drug development industry. Besides bringing the students' interest to innovative drug development, the course will also facilitate their future choice of profession and career development.

16. 预达学习成果 Learning Outcomes

- 了解包括新冠疫情爆发以来的抗体药物、核酸疫苗等新兴药物研发方向，获得来自新药研发一线的全景介绍和体验。Learn about recent innovations in drug development, including the development of antibody therapy and RNA vaccines during COVID-19 pandemic. Obtain an overview of the real-world practice of the drug development industry, and access to the firsthand experience of the top people in the field.
- 了解药物从研发初始到上市的各个环节相关内容，从研发到商品化的整体流程、新兴技术、监管体系、现有挑战。Learn about the main stages of drug development from initiation of research to commercialization, including the overall process of drug development from R&D to commercialization, innovative technologies, and practical challenges of developing a new medicine.
- 理解生物医药的发展是如何重塑新药研发、药物选择、疾病防治的，对新药研发的现状与未来形成基本的见解。Understand how advances in biomedicine revolutionize drug development, therapy options, and disease prevention and treatment. Obtain basic insights on the current practice of drug discovery and development, as well as where the future holds.

17. 课程内容及教学日历（如授课语言以英文为主，则课程内容介绍可以用英文；如团队教学或模块教学，教学日历须注明主讲人）

Course Contents (in Parts/Chapters/Sections/Weeks. Please notify name of instructor for course section(s), if this is a team teaching or module course.)

本课程将涵盖对药物开发和制药行业的基本见解。该课程将从介绍药物开发和行业的历史开始，然后介绍当前的实践，最后展望个性化医疗的未来趋势。该课程将介绍疾病的性质并指导治疗设计的原则。将介绍药物开发的主要阶段，包括 Target-Hit-Lead-Candidate 开发、临床前研究、临床研究、法规、知识产权问题、药物生产和药物商业化。此外，本课程还将介绍在 COVID-19 大流行期间满足紧急需求的药物开发案例，包括开发治疗性抗体、疫苗和其他药物。提出中医药现代化以将古今联系起来，并将个性化医疗作为未来趋势进行分析。本课程将以生物技术衍生的医学创新的简要总结结束，并呈现现代制药行业的整体图景：大型和小型制药公司、生物技术公司和仿制药制造商共同合作。

This course will cover essential insight into drug development and the pharmaceutical industry. The course will start with an introduction to the history of drug development and the industry, followed by the current practices, and look into the future trend of personalized medicine. The course will introduce the nature of diseases and guide through the principles of therapy design. Main stages of drug development, including Target-Hit-Lead-Candidate development, preclinical study, clinical study, regulations, intellectual property issues, drug production, and drug commercialization will be introduced. Drug development cases to meet the urgent needs during COVID-19 pandemic will be introduced, including development of therapeutic antibodies, vaccines, and other drugs. Modernization of Traditional Chinese Medicine is presented to link the past to present, and personalized medicine is analyzed as a future trend. The course will end with a brief summary of biotechnology-derived medical innovations, and present an overall picture of the modern pharmaceutical industry where big and small pharma, biotechnology companies, and generic drug makers work together.

Section	Topic	Hours
1	药物研发概论一：过去、现在和未来 <ul style="list-style-type: none"> ● 疾病的概念和治疗的方案 ● 药品基本知识 ● 药物发展史：植物药-工业化制药-合成制药-生物制药 Introduction to drug development I: Past present and future <ul style="list-style-type: none"> ● Concepts of disease and the aims of therapeutics ● Basic knowledge of medicines ● History of drug development: botanical medicine-industrial pharmaceutical-synthetic pharmaceutical-biopharmaceutical 	3
2	药物研发概论二：从实验室到应用 <ul style="list-style-type: none"> ● 药品监管 ● 涉及的学科 ● 研发之路 ● 国内外药品研发现状 Introduction to drug development II: from benchtop to bedside <ul style="list-style-type: none"> ● Drug supervision ● Involved field ● Road to R&D ● Current status of domestic and foreign drug research and development 	3
3	研究阶段一：候选药物的筛选和验证 <ul style="list-style-type: none"> ● 候选药物发现（靶分子的确、优化，先导化合物的确定、优化） 	3

	<ul style="list-style-type: none"> ● 新方法的辅助：（高通量筛选的崛起，传统结构生物学与人工智能的 PK） <p>Research phase 1: screening and validation of drug candidates</p> <ul style="list-style-type: none"> ● The discovery of candidate drugs (target molecule identification and optimization, lead compound identification and optimization) ● The aid of new methods (the rise of high-throughput screening, the battle between traditional structural biology and artificial intelligence) 	
4	<p>研究阶段二：临床前研究</p> <ul style="list-style-type: none"> ● 药品质量标准评价 ● 药物制剂评价 ● 药效学评价 ● 药物代谢评价 ● 药物安全评价 <p>Research phase II: preclinical research</p> <ul style="list-style-type: none"> ● Evaluation of drug quality standards ● Evaluation of pharmaceutical preparation ● Pharmacodynamic evaluation ● Drug metabolism evaluation ● Drug safety evaluation 	3
5	<p>研究阶段三：临床试验</p> <ul style="list-style-type: none"> ● 设计临床试验 ● 一期临床（安全性） ● 二期临床（有效性） ● 三期临床（大规模长期试验） ● 四期临床（上市后研究） <p>Research phase III: clinical trials</p> <ul style="list-style-type: none"> ● Clinical trial design ● Phase I (safety) ● Phase II (effectiveness) ● Phase III (large-scale long term trials) ● Phase IV (post-marketing surveillance) 	3
6	<p>研究阶段四：新药申请、审批、生产及经营</p> <ul style="list-style-type: none"> ● 药物申请与审批（药事管理与法规，申请与审批流程） ● 药物生产（药品生产线的组成部分，药物生产设施，良好的生产规范） ● 药物经营(产品生命周期,药品经营许可,变化的环境-变化的营销) <p>Research phase IV: new drug application, approval, manufacturing and marketing</p> <ul style="list-style-type: none"> ● Application and approval (pharmaceutical management and regulations, application and approval process) 	3

	<ul style="list-style-type: none"> ● Manufacturing/production (components of pharmaceutical production lines, facilities and good manufacturing practices) ● Marketing (product life cycle, business license, dynamic environment-dynamic marketing) <p>附加周末 Field Study 3 学时:</p> <p>由任课教师带领, 实地参观药物研发与检测部门, 了解药物研发与审批准备的实际场景、操作, 获得第一手认识</p> <p>Additional 3 hours of field study:</p> <p>A guided tour by the course instructor at the R&D department of drug development. The students will visit and experience the frontline of drug development and regulation.</p>	
7	<p>药物研发案例一: 实验室走向市场的明星药物 1</p> <ul style="list-style-type: none"> ● 抗感染药物: 抗疟疾药物的副产物——左氧氟沙星 (Levofloxacin) ● 抗肿瘤药物: 小分子靶标的春天——克唑替尼 (Crizotinib) ● 心脑血管药物: 从模仿创新到同类最佳——阿伐他汀 (Atorvastatin) ● 神经类药物: 从品牌药到仿制药——奥氮平 (Olanzapine) <p>Drug R&D case study 1: star drugs from laboratory to the market 1</p> <ul style="list-style-type: none"> ● Antibacterial infection drugs: by-product of antimalarial drugs-levofloxacin ● Antitumor drugs: the spring of small molecular targets-crizotinib ● Cardiovascular and cerebrovascular drugs: from imitation innovation to best-in-class-atorvastatin ● Neurological drugs: from brand-name drugs to generic drugs – olanzapine 	3
8	<p>药物研发案例一: 实验室走向市场的明星药物 2</p> <ul style="list-style-type: none"> ● 抗病毒感染药物: 从研发到上市: 7 年传奇——奥司他韦 (Oseltamivir) ● 抗癫痫药物: 产学研合作的典范之作——普瑞巴林 (Pregabalin) ● 国药之光——蒿甲醚 (Artemether) ● 反面教材——沙利度胺 (Thalidomide) ● 来自明星药物的重要启示: 知识产权与创新保护 <p>Drug R&D case study 1: star drugs from laboratory to the market 2</p> <ul style="list-style-type: none"> ● Antiviral infection drugs: from R&D to marketing: a 7-year legend – oseltamivir ● Antiepileptic drugs: a model of industry-university-research cooperation – pregabalin ● The light of Chinese medicine-artemether ● Negative teaching material – thalidomide ● Important inspiration from star drugs: intellectual property and innovation protection 	3
9	<p>药物研发案例二: 来自 COVID-19 的召唤 1: 疫苗</p> <ul style="list-style-type: none"> ● 疫苗发展史 	3

	<ul style="list-style-type: none"> ● 预防性疫苗（脊髓灰质炎疫苗、狂犬疫苗，流感疫苗，HPV 疫苗） ● 新冠疫苗：大国间的科技博弈（灭活疫苗、腺病毒载体疫苗、重组蛋白疫苗、mRNA 疫苗） ● 预防还是治疗？ <p>Drug R&D case study 2: call from COVID-19 1: Vaccines</p> <ul style="list-style-type: none"> ● History of vaccine development ● Preventive vaccines (polio vaccine, influenza vaccine, HPV vaccine) ● COVID-19 vaccine: technological game between major countries (inactivated vaccine, adenovirus vector vaccine, recombinant protein vaccine, mRNA vaccine) ● Prevention or treatment 	
10	<p>药物研发案例三：来自 COVID-19 的召唤 2：治疗性抗体</p> <ul style="list-style-type: none"> ● 针对新病原体的新挑战 ● 抗体基本知识 ● 治疗性抗体研发（多克隆抗体 VS 单克隆抗体） ● 对抗 SARS-CoV-2 变异 ● 给药方式的选择：注射还是吸入 <p>Drug R&D case study 3: call from COVID-19 2: therapeutic antibodies</p> <ul style="list-style-type: none"> ● New challenges for new pathogens ● Basic knowledge of antibodies ● Therapeutic antibody development (polyclonal antibody vs monoclonal antibody) ● Against SARS-CoV-2 mutation ● Choice of administration method: injection or inhalation 	3
11	<p>药物研发案例四：细胞治疗</p> <ul style="list-style-type: none"> ● 肿瘤细胞免疫治疗（细胞过继免疫治疗，肿瘤疫苗，非特异性免疫刺激，免疫检验点单抗） ● 干细胞治疗（干细胞存储脐带血库，干细胞移植，干细胞药物研发及治疗） <p>Drug R&D case study 4: cell therapy</p> <ul style="list-style-type: none"> ● Tumor cell immunotherapy (cellular adoptive immunotherapy, tumor vaccine, non-specific immune stimulation, immune checkpoint monoclonal antibody) ● Stem cell therapy (stem cell storage, cord blood bank, stem cell transplantation, stem cell drug development and therapy) 	3
12	<p>药物研发案例五：基因工程药物与个性化医疗</p> <ul style="list-style-type: none"> ● 基因工程技术介绍 ● 基因工程药物（小核酸药物，重组载体药物，重组多肽及蛋白药物） ● 科技与伦理的博弈（基因兴奋剂和基因编辑婴儿） ● 个性化医疗（生物样本库，学习型医疗系统） <p>Drug R&D case study 5: genetically engineered drugs and personalized medicine</p>	3

	<ul style="list-style-type: none"> ● Introduction of genetic engineering technology ● Genetic engineering drugs (small nucleic acid drugs, recombinant carrier drugs, recombinant polypeptide and protein drugs) ● The game between technology and ethics (gene doping and gene editing babies) ● Personalized medicine (biobank, learning medical system) 	
13	<p>药物研发案例六：新希望：老药新用 (Old Drug, New Tricks) 及罕见病药物研发</p> <ul style="list-style-type: none"> ● 老药新用研究策略 (对副作用进行开发、基于已有作用机制进行开发、基于基因组、药理学网络和信号通路分析) : ● 老药新用案例：西地那非 (Sildenafil) , 二甲双胍 (Metformin) , 砒霜 (Arsenic) ● 罕见病药物研发的困境及希望 <p>Drug R&D case study 6: new hope: old drug repurposing and rare disease drug development</p> <ul style="list-style-type: none"> ● Research strategies for drug repurposing (studies of side effects, developments based on existing mechanisms, genome, pharmacological network and signaling pathway analysis) ● Case study of drug repurposing: sildenafil, metformin, arsenic ● Dilemma and hopes of rare disease drug development 	3
14	<p>药物研发案例七：中医药现代化</p> <ul style="list-style-type: none"> ● 从历史到现在：“天人合一”中医药面临的挑战 ● 中医药现代化发展战略 (研究开发复核市场需求的现代中药，建立我国中药研究开发体系，形成我国科技先导型中药产业，推动我国中药进入国际医药市场) ● 组分中药学的理论构想 (根据经典方剂配方，明确组分使其配伍量化，确定标准，完善质量体系；利用中药组分，重新筛选配方；开发单体化合物；从单体化合物中筛选配伍，研究由单体组成的复方新药) ● 针灸、经络埋线等科学依据探究 <p>Drug R&D case study 7: modernization of traditional Chinese medicine (TCM)</p> <ul style="list-style-type: none"> ● From history to the present: the challenges faced by ‘harmony between man and nature’ of TCM ● Modernization development strategy of traditional Chinese medicine (research and develop modern TCMs that based on market demand, establish R&D system of TCMs, form leading Chinese medicine industry and promote TCM to enter the international pharmaceutical market) ● Conception of component TCM (study the classical formula, clarify the components to quantify the compatibility, determine the standard, and improve the quality system; use the components of TCM to re-screen the formula; develop single component compounds; invent compound drugs consisting of single component compounds) ● Research on scientific basis for acupuncture, meridian catgut embedding, etc. 	3
15	<p>药物开发的未来</p> <ul style="list-style-type: none"> ● 最新的科技进步成果 	3

	<ul style="list-style-type: none"> ● 生物技术制药的未来 ● 现代制药行业：大小制药企业、生物科技公司 and 仿制药制造商 ● 对未来的展望 <p>The future of drug development</p> <ul style="list-style-type: none"> ● The latest scientific and technological achievements ● The future of biotech pharmaceuticals ● Modern pharmaceutical industry: big and small pharma, biotech companies and generic drug manufacturers ● Outlook for the future 	
16	<ul style="list-style-type: none"> ● 课程项目报告 ● 作业讲解与反馈 ● 课程总结与课堂讨论 <ul style="list-style-type: none"> ● Class presentation for the course project ● Feedback on homework ● Summary and in-class discussion of the course 	3

18. 教材及其它参考资料 **Textbook and Supplementary Readings**

<ol style="list-style-type: none"> 1. Drug Discovery and Development - Technology in Transition. By Raymond G Hill and Duncan Richards. 3rd Edition - May 16, 2021. Published by Elsevier. ISBN: 9780702078040 2. 参考读物: The Drug Hunters. By Donald R. Kirsch and Ogi Ogas. 1st Edition – Jan 3, 2017. Published by Tantor Media, Inc. ISBN: 9781515964681

课程评估 **ASSESSMENT**

19. 评估形式 Type of Assessment	评估时间 Time	占考试总成绩百分比 % of final score	违纪处罚 Penalty	备注 Notes
出勤 Attendance	平时	10	缺席一次扣1%，迟到早退出现的每节课扣0.5%	
课堂表现 Class Performance				
小测验 Quiz				
课程项目 Projects	第 16 周	30		
平时作业 Assignments	第 10 周	30		

期中考试 Mid-Term Test				
期末考试 Final Exam				
期末报告 Final Presentation	第 16 周	30		
其它（可根据需要 改写以上评估方式） Others (The above may be modified as necessary)				

20. 记分方式 GRADING SYSTEM

- A. 十三级等级制 Letter Grading
 B. 二级记分制（通过/不通过） Pass/Fail Grading

课程审批 REVIEW AND APPROVAL

21. 本课程设置已经过以下责任人/委员会审议通过
This Course has been approved by the following person or committee of authority

