Last Updated: Vankeerbergen,Bernadette Chantal 10/18/2024

Term Information

Effective Term Spring 2025

General Information

Course Bulletin Listing/Subject Area Chemistry

Fiscal Unit/Academic Org Chemistry - D0628
College/Academic Group Arts and Sciences
Level/Career Undergraduate

Course Number/Catalog 3301

Course Title Science and Policy of Drug Development

Transcript Abbreviation Sci&PolDrgDmt

Course DescriptionThe course focus is on the science and public policy that govern drug development. The principles of chemistry and biochemistry are applied to research and development of drug therapeutics. The drug

chemistry and biochemistry are applied to research and development of drug therapeutics. The drug approval process of drug safety, toxicity, and clinical trials will focus on pharmaceutical industry challenges of drug affordability, safety, and drug development impact on global public health.

Semester Credit Hours/Units Fixed: 3

Offering Information

Length Of Course 14 Week, 12 Week, 7 Week

Flexibly Scheduled Course Never

Does any section of this course have a distance No education component?

Grading Basis Letter Grade

RepeatableNoCourse ComponentsLectureGrade Roster ComponentLectureCredit Available by ExamNoAdmission Condition CourseNoOff CampusNever

Campus of Offering Columbus, Lima, Mansfield, Marion, Newark, Wooster

Prerequisites and Exclusions

Prerequisites/Corequisites Chem 1220 and Biology 1113

Exclusions Not open to students with credit for PHR3301

Electronically Enforced Yes

Cross-Listings

Cross-Listings Crosslisted in PHR

Subject/CIP Code

Subject/CIP Code 40.0501

Subsidy LevelBaccalaureate CourseIntended RankSophomore, Junior, Senior

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Requirement/Elective Designation

Health and Well-being

Course Details

Course goals or learning objectives/outcomes

- Students will gain an advanced understanding of the intersection of chemistry, biochemistry, and scientific policy as it applies to drug discovery, development, testing, safety, and global public health.
- Students will develop an understanding the concepts of global health how it influences other disciplines such as public health, social work, pharmaceutical sciences, and other chemistry and biology experiences.
- Students develop critical thinking skills as they analyze multiple dimensions of health and well-being by studying clinical trial results for drugs therapeutics and evaluate data on the side effects, safety, and efficacy of drugs.

Content Topic List

- Understanding the chemistry behind drug and therapeutic development.
- The policies and procedures necessary to bring therapeutics and vaccines safely to market.
- Identify diseases affecting mental and/or physical health and how therapeutics treat those diseases.
- Understanding therapeutic side effects that can negatively affect mental and/or physical health and well-being such as drug dependence.
- Develop an understanding that evolution of current therapeutics and next-generation advancements is continuing process.

Sought Concurrence

Yes

Attachments

- submission-health-well-being_CHEM 3301.pdf: GE Theme Submission
- (Other Supporting Documentation. Owner: Ramirez, Ana G)
- PHR concurrence for CHEM 3301.pdf: Concurrence Email PHR

(Concurrence. Owner: Ramirez,Ana G)

• CHEM-PHR 3301Syllabus Science & Policy of Drugs_9-16-24.docx: 9-16-24 Syllabus

(Syllabus. Owner: Ramirez, Ana G)

• ASC curriculum response 09-16-24.pdf: ASC Curriculum Response

(Other Supporting Documentation. Owner: Ramirez, Ana G)

• submission-health-well-being_CHEM 3301 09-16-24.pdf: GE Theme Submission

(Other Supporting Documentation. Owner: Ramirez, Ana G)

Comments

- Updated syllabus. Response ASC questions. (by Ramirez, Ana G on 09/17/2024 08:42 AM)
- Please see feedback email sent to department 10-27-2023 (by Steele,Rachel Lea on 10/27/2023 04:52 PM)
- Please see Subcommittee feedback email sent 09/05/2023. (by Hilty,Michael on 09/05/2023 03:37 PM)
- Concurrence obtained from Pharmacy for cross-listed course (by Jackman, Jane E on 06/07/2023 09:55 AM)
- Please request a concurrence from the College of Pharmacy (by Vankeerbergen, Bernadette Chantal on 02/16/2023 01:03 PM)

COURSE REQUEST 3301 - Status: PENDING

Workflow Information

Status	User(s)	Date/Time	Step
Submitted	Ramirez,Ana G	01/19/2023 02:03 PM	Submitted for Approval
Approved	Jackman,Jane E	02/06/2023 12:57 PM	Unit Approval
Revision Requested	Vankeerbergen,Bernadet te Chantal	02/16/2023 01:03 PM	College Approval
Submitted	Ramirez, Ana G	06/07/2023 09:23 AM	Submitted for Approval
Approved	Jackman,Jane E	06/07/2023 09:55 AM	Unit Approval
Approved	Vankeerbergen,Bernadet te Chantal	08/22/2023 08:34 AM	College Approval
Revision Requested	Hilty,Michael	09/05/2023 03:37 PM	ASCCAO Approval
Submitted	Ramirez,Ana G	09/06/2023 11:25 AM	Submitted for Approval
Approved	Jackman,Jane E	09/06/2023 11:52 AM	Unit Approval
Approved	Vankeerbergen,Bernadet te Chantal	09/06/2023 02:52 PM	College Approval
Revision Requested	Steele,Rachel Lea	10/27/2023 04:52 PM	ASCCAO Approval
Submitted	Ramirez,Ana G	09/17/2024 08:42 AM	Submitted for Approval
Approved	Jackman,Jane E	09/17/2024 08:42 AM	Unit Approval
Approved	Vankeerbergen,Bernadet te Chantal	10/18/2024 11:11 AM	College Approval
Pending Approval	Jenkins,Mary Ellen Bigler Hanlin,Deborah Kay Hilty,Michael Neff,Jennifer Vankeerbergen,Bernadet te Chantal Steele,Rachel Lea	10/18/2024 11:11 AM	ASCCAO Approval





Department of Chemistry and Biochemistry
Undergraduate Studies Office

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(614) 292-1204 Telephone (614) 292-2374 Fax

chemistry.osu.edu

September 15, 2024

Dear Rachel and Members of the ASC themes committee and TAG,

We have prepared a revised syllabus for our course (CHEM/PHARM 3301) based on the feedback received from the ASC Themes I Subcommittee and Theme Advisory Group for Health and Wellbeing. We have addressed all of the points raised by the committee as described in more detail below and on the revised syllabus that accompanies this submission. We look forward to your evaluation and to moving this course forward toward approval. Please contact us with any questions about our responses.

- i. The reviewing faculty asks that the units indicate on the syllabus (pg. 3) whether the textbooks are required or recommended.
 - Response: The textbooks have been listed as required. We have also switched to an open-source textbook for the fundamental knowledge topics covered in Unit 1 to reduce the overall costs of textbooks.
- ii. The reviewing faculty note that using different colors of text on syllabi as the sole indicator of meaning is not in line with the university's accessibility standards, and they recommend that the units reconsider the use of color coding in the syllabus.
 - We previously used color coding as a supplement to identify the textbooks in addition to Text #1, #2, #3 labels. However, to reduce the confusion with color coding and to better adhere to university standard, we have removed color coding.
- iii. The reviewing faculty found the course to be intriguing and feel that it could be an excellent addition to the GEN themes. However, they ask that the units reconsider the level at which the course is taught. Although GEN Themes courses are intended to be taught at a higher level than the Foundations, this course engages with the stated concepts and topics at a pace and a level that may make the course inaccessible to the general student population. One possible solution may be to rely less on pre-requisites and/or to alter the course content so that it is accessible to a wider variety of students.

The prerequisites required are two foundational courses (Chem 1210 or equivalent and Biol 1113 or equivalent) along with Chem 1220. We added CHEM 1250 as an alternative option that will also make sure the course is open to engineering students (many take this one semester general chemistry course and it also covers the required topics). These courses will be taken by almost all STEM majors in their freshman year and will enable to students taking this class to engage at a higher level with the concepts of drug discovery and development. Since ~4000 students complete this series of courses each year, we believe that a large fraction of the general student population will be able to access this course. Therefore, we strongly believe that retaining the current prerequisites meets the goals of the themes courses to build on foundations, but to remain accessible to a large number of students at Ohio State.

To address the pace and level of concept and topics, we have changed Unit I and Unit III significantly to cover fewer topics. We have allotted more time to cover foundational concepts such as organic

structure, organic functional groups, amino acids, and protein structure. In Unit III, instead of covering many different drug classes we will focus on only three drug case studies. These drug case studies will be from a single class (such as opioids, antibiotics, anticancer, or antidepressants) chosen by the instructor. Relevant sections from Text #2 chapters will be covered at the beginning of Unit III to cover the mechanism of action and necessary background information about the selected drug case studies.

We do not plan to cover the entirety of the chapters identified in Text #1 in the course schedule on the syllabus. We have revised this to show the selected sections from each chapter that will be covered. The chapters from text #2 and #3 are fairly short and can generally be covered in one lecture session.

iv. The reviewing faculty note that the responses on the GEN Submission Form rely heavily on the analysis of clinical drug trial results to satisfy the ELOs of the category. However, this activity only accounts for one class meeting on the Course Schedule (syllabus pg. 4). This example speaks to the larger issue of the alignment of the course topics with the goals and ELOs of the GEN Themes category, as the majority of topics covered in the course do not seem to pertain to the Health and Wellbeing Theme. The Subcommittee asks that the unit reconsider the courses readings, topics, and activities so that the majority of the course aligns with the goals and ELOs of the category.

We have greatly expanded our explanations on how the course activities and assignments explicitly meet the ELOs. We have explained how our revised lectures and readings meet ELO 1.1, 2.1, and 3.2. We have explained how the quizzes and exams will meet ELO 1.1 and 1.2. The explanation for how two major assignments in the class, 1) analysis of clinical trial data and 2) the literature review and presentation of a FDA approved drug, meets ELO 1.1, 1.2, 2.1, and 3.2 has also been expanded. In addition, we have explained how assignment 1 will meet ELO 3.1 and assignment 2 will address ELO 2.2, demonstrating how these assignments differ in their scope. We have included time for three inclass discussions and debates; assignment 1, following reading a scientific article regarding the ethics of high-priced drugs, and following the drug case study lectures, which will meet ELO 2.1. We have also included Carmen discussion posts, which will be submitted prior to the in-class sessions and will help guide the discussions. Finally, we have added quiz/exam reflection assignments, which satisfy ELO 2.2.

We believe with these revisions of the lectures, readings, and assignments along with our expanded explanations on how all components of the class meet specific ELOs have greatly improved the alignment of the course topics with the ELOs and Health and Wellbeing theme.

v. The reviewing faculty observe that the course seems to cover a wide variety of complex topics. With the limited time on each topic, they are concerned that there will not be enough time for "advanced, in-depth scholarly exploration" or "critical...thinking about the topic or idea of the theme", especially for students who do not have a strong background in the sciences, or those who have met the rerequisites via Advanced Placement, International Baccalaureate or A-Level exams. For example, the reviewing faculty note that the subject of enzyme inhibitors is only covered for two class sessions in Week 11 of the Course Schedule (syllabus pg. 4), but it could easily be the subject of an entire semester of study. They ask that the course be modified to cover fewer topics, focusing on those topics that most closely align with the goals and ELOs of the Theme and the interaction between the different topics. The reviewing faculty offer the friendly observation that refraining from trying to align the course so closely with the textbook might be one possible way to address this concern.

We have changed Unit I and Unit III significantly to cover fewer topics to allow for a more in-depth exploration. Unit I will provide the necessary background knowledge in organic and biological chemistry to enable success in the following units and assignments in the course. The sections of

organic chemistry to be covered are similar to those taught in Chapter 24 in Chem 1220 (General Chemistry II) and thus should be accessible to students who have completed the pre-requisite Chem 1220 or equivalent. The biological chemistry topics to be covered will leverage the background knowledge gained in the pre-requisite Biol 1113. We believe we have revised this course to a level that is accessible to students who have completed the two re-requisites Chem 1220 and Biol 1113.

Unit III has been revised to focus on only two drug case studies, which will be selected by the instructor, and two lecture sessions will be used to cover background information on these drug case studies. These two sessions could be the topic of enzyme inhibitors, membrane signal and transduction, neurotransmitters, etc depending on the class of the two selected drug case studies. If enzyme inhibitors are covered, we will not delve into kinetics and their corresponding mathematical equations as done in a class like Biochem 4511, but rather compare and contrast the different classes of enzyme inhibition (competitive, irreversible, noncompetitive, uncompetitive).

We have revised our class to cover only selected sections of the textbooks in Units I and III to reduce the number of topics covered and allow for a better alignment of the topics with the ELOs. Specifically, in Unit III relevant sections from textbook #3 can be used as a resource for the selected drug case studies in addition to primary literature sources.

vi. The reviewing faculty ask that the units give greater attention to the fulfillment of ELO 2.2, creating more opportunity for reflection and self-assessment via course assignments and activities.

We have added four reflection assignments following each quiz and the unit I midterm, which satisfy ELO 2.2. We have also expanded our explanation of how assignment 2 addresses ELO 2.2. Students will provide feedback to their peers and perform self-assessments following the completion of assignments 1 & 2.

Sincerely,

Jane E. Jackman

Professor and Vice Chair for Undergraduate Studies



CHEM/PHR 3301- SP 2025: Science & Policy of Drug Development

COURSE OVERVIEW

Instructor: Dr. Marie Southerland & TBD (Pharmacy) **Email Address:**

<u>Undergraduate Office:</u> 614-292-6009, Celeste Laboratory, room 110 (CE 110). Stop by any time Monday–Friday, 8:00am–4:30pm for assistance.

Office Hours & Communication: A schedule for office hours will be posted to the course website on Carmen. To schedule an alternative appointment, contact one of the instructors via email and include times that may be convenient for you to meet. *Please include CHEM 3301 in the subject line of any email correspondence*. We will do what we can to work with your schedule and would encourage you to directly reach out whenever you feel the need, whether your concerns relate to the material or the course itself or anything else. We will do our best to get back to you via email within 24 hours during the week and 48 hours on the weekend. The instructors will only use official OSU channels for communication both with individual students and the course as a whole (OSU Email, Carmen Inbox, etc.).

Lecture: TBD (3 credit hours)

Prerequisites: CHEM 1220 or Chem 1250 and BIOL 1113.

Course Description: This theme course takes students on a journey to learn more about the science and processes that govern how molecules become drugs. Fundamental ideas of chemistry and biochemistry will be established, which will allow a study of how those principles are applied to the research and development of drug and therapeutic candidates. The approval process for drugs to come to market will be discussed, focusing on aspects such as safety, toxicity, and clinical trials. Challenges within the pharmaceutical industry, namely affordability, will also be highlighted. Several classes of drugs that treat a variety of afflictions will serve as case studies that students will analyze together in small groups.

GE Health and Wellness Theme: This class is part of the Health and Wellness Theme of the General Education program. This course is classified as a 3-credit hour theme class. This course will deeply engage with the process of drug discovery and development, allowing students to understand the various facets involved in this process such as potency, specificity, safety, toxicity, metabolism. This class will also discuss the process of clinical trials and allow students to analyze actual data from a recent drug that went through phase III clinical trials. Students will be able to understand how drug development supports the constant improvement of health and wellness by exploring the intersection of chemical/biochemical principles and global health impacts. In addition, there will be case studies on various drug classes to appreciate how various diseases such as bacterial infection, cancer, and depression are treated. This will enable students to better grasp the complexities of each disease and how drugs are used safely to improve health and wellness through rigorous development and testing.

GE Course Goals for Health and Wellness Theme:

- 1) Successful students will analyze an important topic or idea at a more advanced and in-depth level than in the Foundations component.
- 2) Successful studens will integrate approaches to the theme by making connections to out-of-classroom experiences with academic knowledge or across disciplines and/or work they have done in previous classes and that they anticipate doing in the future.
- 3) Students will explore and analyze health and wellbeing through attention to at least two dimensions of wellbeing (e.g. physical, mental, emotional, career, environmental, spiritual, intellectual, creative, financial, etc).

Learning Outcomes:

Upon the completion of this course, students will be able to:

- 1) Understand and articulate the chemistry behind drug and therapeutic development.
- 2) Explain the policies and procedures necessary to bring therapeutics and vaccines safely to market.
- 3) Identify diseases that affect mental and/or physical health and how therapeutics are able treat those diseases.
- 4) Summarize possible therapeutic side effects that can negatively affect mental and/or physical health and well-being such as drug dependence.
- 5) Be conscious of drug discovery and development from a variety of perspectives.
- 6) Be aware of the continuing evolution of what is known about current therapeutics and next-generation advancements and be equipped with the knowledge to understand future work in the subject area.

GE Learning Outcomes for Health and Wellness Theme:

ELO 1.1 Engage in critical and logical thinkin	g Students will engage in critical and logical thinking about how
about the topic or idea of the theme.	drugs impact physical and/or mental health and wellbeing.

Lectures and readings: Unit I will enable students to think critically about the chemical structure of drugs and how they interact with protein biological targets. Unit II will expose students to societal and ethical implications in drug development and evaluate decisions in the FDA approval process. Unit III will present drug case studies to think critically about how specific drugs work and their development, leveraging knowledge from Units I and II.

Exams and quizzes: These assignments will test critical and logical thinking by expecting students to solve scientific problems based on the knowledge they accrue from all units during the course.

Assignment 1: The critical analysis of real clinical trial data will allow students to understand how drug safety must be balanced with drug potency and weigh the pros and cons of a new drug using the knowledge gained from Unit II concepts. The students will need to think about whether this new drug would *improve* health and wellness significantly. Students will use evidence-based logic to make decisions and participate in discussion and debate in class.

Assignment 2: Students will analyze primary literature and government sources to understand the structural characterisitics (using concepts covered in Unit I) of an FDA approved drug, clinical trial information (using concepts covered in Unit III), and the disease the drug treats.

ELO 1.2 Engage in advanced, in-depth, scholarly exploration of the topic or idea of the theme.

Exams and quizzes: Students will demonstrate their in-depth comprehension of the course material.

Assignment 1: In the analysis of clincal trial results, students will perform an in-depth analysis of experimental data on a real drug. Students will leverage knowledge gained from Units I and II to perform this analysis and reach conclusions.

Assignment 2: Students will generate a literature report on an FDA approved drug and read the primary literature to understand how the drug works, the disease it treats, and its safety profile.

	They will need to perform an in-depth analysis of scholarly resources to determine if this drug <i>improves</i> health and wellness. Students will leverage knowledge gained from all units to complete this assignment.
ELO 2.1 Identify, describe, and synthesize approaches or experiences as they apply to the theme.	This class will expose students to how chemistry is used to design new drugs, which are then evaluated biologically to determine things like potency and safety. Then these drugs are studied in clinical trials in the medical field.
	Unit 1: The lectures and readings for Unit I will come from two textbooks and build key foundational knowledge in organic, biological, and medicinal chemistry needed for the rest of the course. This unit will enable students to identify and describe the chemical structure of drugs. Students will be able identify and describe how drugs interact with their biological protein target. Students will be exposed to different approaches to creating and developing drugs.
	Unit II: A majority of lectures and readings for Unit II will come from a textbook to provide background knowledge regarding the drug approval process. Students will read a scientific journal article regarding ethics in drug prices. Students will be able to describe the approaches used to screen drugs for safety and toxicity. Students will be able to describe the clinical trial process for drug approval.
	Unit III: A textbook will be used to select readings and lectures related to two drug case studies chosen by the instructor. Students will read 1-2 primary literature articles corresponding to each drug case study, assigned by the instructor. The drug case studies will synthesize the concepts covered in units I and II. Students will be able to describe the mechanism of action, safety, clinical trial results, and chemical structures of the two drugs.
	Discussions: Students will discuss and debate in class the ethics of high-priced drugs using a scientific article. Students will discuss and debate in class the approval of a drug using clinical trial data.
	Assignments 1 & 2: Analysis of clinical trial data and the literature report will require students to analyze data from various sources and synthesize them together to build a compelling argument for approval. In-class discussion of the clinical trial results will foster appreciation for different viewpoints, approaches, and experiences. These varying experiences may impact how the pros and cons may be weighted when evaluating a drug.
ELO 2.2 Demonstrate a developing sense of self as a learner through reflection, self-assessment, and creative work, building on prior experiences to respond to new and challenging contexts.	The challenges of the drug discovery process will be discussed throughout this class. New avenues of drug discovery and case studies will be discussed.
	Discussion: Students will partipate in Carmen discussion boards for key topics (ethics of a high-priced drug and drug case studies), which will be leveraged for in-class discussions.

Quiz/Exam reflections: Students will participate in metacognition following each quiz and the unit I midterm to identify effective study habits and develop plans to improve their learning. Assignment 2: Students will conduct scholarly research on a FDA approved drug that was not already discussed in the class. Students will prepare a report by the end of this class, which will allow them build upon the concepts introduced through lectures and readings, previous coursework in chemistry and biology, and previous personal experiences with diseases and prescription drugs. Students will discuss various contexts that impact a drug's ability to improve health and wellness such as cost, availability, and other cultural aspects. Students will present on their findings from their literature report to the class, which will also gives students an opportunity to assess their peers. Students will then read their peer and instructor feedback to reflect on their presentation.

ELO 3.1 Explore and analyze health and well-being from theoretical, socio-economic, scientific, historical, cultural, technological, policy and/or personal perspectives.

Lectures and readings: FDA policies that guide drug development and clinical trails will be discussed in Unit II. A case study on the ethics of high prices for a critical drug will be discussed to understand the socio-economic side of drug development, confronting the financial impact of therapeutics, but also the broader effect of certain therapeutics on society. Various technological and scientific advances in the drug discovery pipeline will be discussed in regard to their impact on the industry. The historical, socio-economic, scientific, and policy perspectivies relevant to 2 drug case studies in Unit III will be explored and analyzed.

Assignment 1: Students will analyze scientific clinical trial data and need to discuss the various policies set by the FDA in deciding whether to vote to approve the drug or not.

ELO 3.2 Identify, reflect on, or apply strategies for promoting health and well-being.

Unit 1: Through the lectures and readings, students will be able to identify and reflect on the different strategies for developing effective drugs for treating human diseases.

Unit II: Through lectures, readings and discussions, students will be able to identify and reflect on the strategies employed to identify effective drugs that are effective and safe therapeutics.

Unit III: Through lectures, readings, and discussions students will be able to identify and reflect on how the strategies discussed in Unit I and Unit II were employed to develop a FDA-approved drug. Students will identify how these specific drugs promote health and wellbeing.

Assignments 1 & 2: Students will identify in their literature report and final presentation how a specific FDA-approved drug significantly improves the health and well-being of the public by treating a specific disease/disorder. Students will reflect on how the specific drug balances a therapeutic effect with safety/toxicity concerns. Students will also identify and reflect on these factors in analyzing real clinical trial data at the end of Unit II. Students

will apply these strategies to make a decision on whether to approve the presented drug and guide their in-class discussion
and debate.

HOW THIS COURSE WORKS

Credit hours and work expectations: This is a **3-credit-hour course**. According to Ohio State policy, students should expect around 3 hours per week of time spent on direct instruction in addition to 6 hours of study and preparation to achieve an overall C grade in the course. Students should expect to spend additional time outside of class to receive a higher grade.

Student Responsibility: General course policies will be covered in this first lecture section. It is your responsibility to read this material and be familiar with the course content, procedures, and grading. You are also responsible for any announcements concerning course procedures that are made in class or out of class (via Carmen or your OSU email) throughout the semester. If you are absent for any class, it is your responsibility to notify the instructor and get notes or any announcements. Weekly readings, assignments, lecture materials, and due dates will be regularly updated in Carmen. Grades for assignments will be regularly updated in Carmen and will allow you to track your current standing in the course throughout the semester.

COURSE MATERIALS

Textbooks:

- 1. Required: Open Education Resource LibreTexts. General, Organic, and Biological Chemistry (E-text FREE through LibreText)
- 2. Required: Textbook of Drug Design and Discovery, 5th ed. Edited by Kristian Stromgaard, Povl Krogsgaard-Larsen, and Ulf Madsen. (Rent from Vital Source for 180 days, \$66.00)
- 3. Required: Basic Principles of Drug Discovery and Development, 1st ed. Benjamin Blass. (E-text FREE through <u>OSU</u> <u>Library</u>)

Primary literature sources:

- 1. Gornall, J and Hoey, A. A pill too hard to swallow: how the NHS is limiting access to high priced drugs. *BMJ* (2016) 354, i14117. https://doi.org/10.1136/bmj.i4117
- 2. Rasmussen, S.G.F., DeVree, B.T., Zou, Y. et al. 2011. Crystal structure of the ß2 adrenergic receptor-Gs protein complex. *Nature* 477:549–555
- 3. Penmatsa, A., Wang, K.H., and Gouaux, E. 2013. X-ray structure of dopamine transporter elucidates antidepressant mechanism. *Nature* 503:85–91
- 4. Borgelt, L.M., Franson, K.L., Nussbaum, A.M., and Wang, G.S. 2013. The pharmacologic and clinical effects of medical cannabis. *Pharmacotherapy* **33**:195–209.
- 5. Kwak, E.L., Bang, Y.-J., Camidge, D.R. et al. 2010. Anaplastic lymphoma kinase inhibition in non-small-cell lung cancer. *New Engl. J. Med.* 363:1693–1703.

COURSE SCHEDULE

WEEK	Monday	Wednesday
1	Syllabus and course introduction Unit I: Fundamentals of Drug Structures and Design Text #1 Ch.8: Organic Chemistry of Hydrocarbons, Sections 3-7	Text #1 Ch.8: Organic Chemistry of Hydrocarbons, Sections 8-12
2	NO CLASS	Text #1 Ch. 9: Organic Functional Groups, Sections 1-6
3	Text #1 Ch. 9: Organic Functional Groups, Sections 7-11 Text #1 Ch. 16: Proteins and Enzymes, Sections 1-2	Quiz 1 Text #1 Ch. 16: Proteins and Enzymes, Sections 3-5
4	Approaches to drug discovery Text #2 Ch. 3: Ligand-Based Drug Design Text #2 Ch. 4: Biostructure-Based Drug Design	Text #2 Ch. 5: Drug-like properties and decision making in medicinal chemistry
5	MIDTERM EXAM	Unit II: Policies of Drug Development Text #3 Ch. 2: History of drug discovery, from ancient times to today
6	Text #3 Ch. 2: Societal and governmental impacts	Text #3 Ch. 8: Safety and Toxicity
7	Text #3 Ch. 8: Safety and Toxicity	Quiz 2 Text #3 Ch. 9: Basics of Clinical Trials
8	Text #3 Ch. 9: Basics of Clinical Trials	Text #3 Ch. 11: The Pharmaceutical Industry
9	In class discussion and debate of ethics of a high- priced drug Primary literature source #1	ANALYSIS OF REAL CLINCAL TRIAL RESULTS
10	SPRING BREAK	SPRING BREAK
11	Introduction to Drug Literature Report project: how to search literature databases, clincaltrials.gov, and fda.gov for information	Unit III: Drug Case Studies Drug case study #1 Text #2 Selected section from Ch. 15-23 & 1 primary literature article
12	Drug case study #1 Text #2 Selected section from Ch. 15-23 & 1 primary literature article	Drug case study #2 Text #2 Selected section from Ch. 15-23 & 1 primary literature article
13	Drug case study #2 Text #2 Selected section from Ch. 15-23 & 1 primary literature article	Quiz 3 Drug case study #3 Text #2 Selected section from Ch. 15-23 & 1 primary literature article
14	Drug case study #3 Text #2 Selected section from Ch. 15-23 & 1 primary literature article	In-class discussion of case studies
15	Student Presentations on FDA approved drugs	Student Presentations on FDA approved drugs
F	Take-home final exam due	

COURSE TECHNOLOGY

Course Technology: For help with your password, university email, Carmen, or any other technology issues, questions, or requests, contact the Ohio State IT Service Desk. Standard support hours are available at ocio.osu.edu/help/hours, and support for urgent issues is available 24/7.

Self-Service and Chat support: <u>ocio.osu.edu/help</u>

Phone: 614-688-4357(HELP)
 Email: servicedesk@osu.edu
 TDD: 614-688-8743

Baseline Technical Skills and Required Equipment/Software:

- Navigating Carmen: for questions about specific functionality, see the Canvas Student Guide.
- <u>CarmenZoom virtual meetings</u>: Please read the Zoom App handout posted on Carmen on the Modules page.
- <u>Microsoft Office 365:</u> All Ohio State students are eligible for free Microsoft Office 365 through Microsoft's Student Advantage program. Full instructions for downloading can be found <u>at go.osu.edu/office365help.</u>

Carmen Access (https://carmen.osu.edu): You will need to use BuckeyePass multi-factor authentication to access your courses in Carmen. To ensure that you are able to connect to Carmen at all times, it is recommended that you take the following steps: If none of these options will meet the needs of your situation, you can contact the IT Service Desk at 614-688-4357 (HELP) and IT support staff will work out a solution with you.

HOW YOUR GRADE IS CALCULATED

Your performance in the course will be evaluated on the basis of total points earned for the semester. The goal of the instructor is for the course average at the end of the semester to fall as close as possible to the dividing line between a C+/C. Thus, should individual assignments have averages well below that threshold, adjustments in points could be made to certain assignments. Assignments in the course schedule below (and the schedule itself) are subject to change. The distribution of points and the OSU grading scale are shown below.

Assignment Type	Points	Description of Assignment and Points	Percentage
Pre-lecture assignments	110	11 pre-lecture assignments worth 10 pts each	11%
Quizzes	120	3 quizzes each worth 40 pts	12%
Exam	120	Midterm exam	12%
Quiz & Exam reflections	60	3 quiz reflections and 1 exam reflection worth 15 pts each	6%
Clinical Trial Analysis	120	Analysis of real clinical trial results	12%
Carmen discussion posts	40	4 Carmen discussion posts each worth 10 pts	4%
In-class participation	50	In-class participation points	5%
Drug literature report	130	Literature report on an FDA approved drug	13%
Final Presentation	100	Presentation on literature report, peer-feedback, and self-reflection	10%
Take-home final exam	150	Take-home (open-note/book) cumulative final exam	15%
Total Points	1000		100%

OSU Grading Scale

93-100: A	73–76.9: C
90–92.9: A-	70 –72.9: C-
87-89.9: B+	67 -69.9: D+
83-86.9: B	60 –66.9: D
80-82.9: B-	Below 60: E
77–79.9: C+	

ASSIGNMENT DESCRIPTIONS:

Pre-lecture assignments: Students will answer questions and summarize key terms from the assigned each week. These assignments will be worth 10 pts each and turned in on Carmen prior to the start of class.

Quiz and Exam Reflections: Students will complete a reflection assignment following each quiz and the Unit I midterm exam in which they will answer questions regarding their study habits and their quiz/exam performance. These assignments will be worth 10 pts each and turned in on Carmen within 1 week of reviewing their graded quiz/exam.

Clinical trial analysis: This assignment will be completed during an in-person class session, however students will be provided with real clinical trial results several days prior to the class session. During the in-person class session the students will work together in groups to analyze the results and make a decision on the approval of the drug. These groups will be randomly assigned by the instructor. Each group will need to summarize their results to the class and discuss and debate the pros and cons of the drug. Groups will turn in a completed worksheet with written results summaries at the end of the in-person class session. Students will be graded as a group, however individual contributions will be taken into account and individual scores may be modified accordingly. Each group member will fill out a group evaluation form to report on the individual contributions of each member of the group.

Carmen Discussion Posts: Students will need to post at least once on the Carmen discussion board for each drug case study presented in Unit III and prior to the ethics on high-priced drugs class session (10 pts each).

In-class participation: Students are expected to contribute to their assigned groups during the in-class discussions during the ethics of high-priced drugs, clinical trial analysis, and case study in-class sessions (10 pts each). Point will also be awarded for participation in TopHat questions or in-class worksheets (20 pts).

Drug literature report: Students will choose an FDA approved drug to research following Spring Break at the beginning of Unit III (week 11). Students will compile a literature report on that drug with information about the effectiveness of the drug, its biological target, and safety and toxicity. This project will be completed individually.

Final Presentation, Feedback, and Reflection: Each student will prepare a short presentation on their literature report on an FDA approved drug and present in class (70 points). Students will also provide feedback to each other during these presentations (10 points). Finally, students will submit a reflection on their presentation after they have read over the peer and instructor feedback (20 points).

Take-home final exam: Students will complete a cumulative take-home final exam, in which they will be able to use their notes and books/literature sources to complete. Each student will complete the exam individually and will have one week to complete the exam. The final exam must be submitted on the assigned final exam day for this class.

OTHER COURSE POLICIES

Copyright Disclaimer: The materials used in connection with this course may be subject to copyright protection and are only for the use of students officially enrolled in the course for the educational purposes associated with the course. Copyright law must be considered before copying, retaining, or disseminating materials outside of the course.

STATEMENT ON ACADEMIC MISCONDUCT

It is the responsibility of the Committee on Academic Misconduct to investigate or establish procedures for the investigation of all reported cases of student academic misconduct. The term "academic misconduct" includes all forms of student academic misconduct wherever committed; illustrated by, but not limited to, cases of plagiarism and dishonest practices in connection with examinations. Instructors shall report all instances of alleged academic misconduct to the committee (Faculty Rule 3335-5-48.7 (B)). For additional information, see the Code of Student Conduct.

DISABILITY SERVICES

The university strives to maintain a healthy and accessible environment to support student learning in and out of the classroom. If you anticipate or experience academic barriers based on your disability (including mental health, chronic, or temporary medical conditions), please let me know immediately so that we can privately discuss options. To establish reasonable accommodations, I may request that you register with Student Life Disability Services. After registration, make arrangements with me as soon as possible to discuss your accommodations so that they may be implemented in a timely fashion.

If you are ill and need to miss class, including if you are staying home and away from others while experiencing symptoms of a viral infection or fever, please let me know immediately. In cases where illness interacts with an underlying medical condition, please consult with Student Life Disability Services to request reasonable accommodations. You can connect with them at slds@osu.edu; 614-292-3307; or slds.osu.edu

RELIGIOUS ACCOMMODATIONS

Ohio State has had a longstanding practice of making reasonable academic accommodations for students' religious beliefs and practices in accordance with applicable law. In 2023, Ohio State updated its practice to align with new state legislation. Under this new provision, students must be in early communication with their instructors regarding any known accommodation requests for religious beliefs and practices, providing notice of specific dates for which they request alternative accommodations within 14 days after the first instructional day of the course. Instructors in turn shall not question the sincerity of a student's religious or spiritual belief system in reviewing such requests and shall keep requests for accommodations confidential.

With sufficient notice, instructors will provide students with reasonable alternative accommodations with regard to examinations and other academic requirements with respect to students' sincerely held religious beliefs and practices by allowing up to three absences each semester for the student to attend or participate in religious activities. Examples of religious accommodations can include, but are not limited to, rescheduling an exam, altering the time of a student's presentation, allowing make-up assignments to substitute for missed class work, or flexibility in due dates or research responsibilities. If concerns arise about a requested accommodation, instructors are to consult their tenure initiating unit head for assistance.

A student's request for time off shall be provided if the student's sincerely held religious belief or practice severely affects the student's ability to take an exam or meet an academic requirement and the student has notified their instructor, in writing during the first 14 days after the course begins, of the date of each absence. Although students are required to provide notice within the first 14 days after a course begins, instructors are strongly encouraged to work with the student to provide a reasonable accommodation if a request is made outside the notice period. A student may not be penalized for an absence approved under this policy.

If students have questions or disputes related to academic accommodations, they should contact their course instructor, and then their department or college office. For questions or to report discrimination or harassment based on religion, individuals should contact the Office of Institutional Equity. (Policy: Religious Holidays, Holy Days and Observances)

MENTAL HEALTH

As a student you may experience a range of issues that can cause barriers to learning, such as strained relationships, increased anxiety, alcohol/drug problems, feeling down, difficulty concentrating and/or lack of motivation. These mental health concerns or stressful events may lead to diminished academic performance or reduce a student's ability to participate in daily activities. The Ohio State University offers services to assist you with addressing these and other concerns you may be experiencing. If you or someone you know are suffering from any of the aforementioned conditions, you can learn more about the broad range of confidential mental health services available on campus via the Office of Student Life's Counseling and Consultation Service (CCS) by visiting ccs.osu.edu or calling 614-292-5766. CCS is located on the 4th Floor of the Younkin Success Center and 10th Floor of Lincoln Tower. You can reach an on call counselor when CCS is closed at 614-292-5766 and 24 hour emergency help is also available 24/7 by dialing 988 to reach the Suicide and Crisis Lifeline.

TITLE IX STATEMENT

Title IX makes it clear that violence and harassment based on sex and gender are Civil Rights offenses subject to the same kinds of accountability and the same kinds of support applied to offenses against other protected categories (e.g., race). If you or someone you know has been sexually harassed or assaulted, you may find the appropriate resources at http://titleix.osu.edu or by contacting the Ohio State Title IX Coordinator at titleix@osu.edu.

DIVERSITY STATEMENT

The Ohio State University affirms the importance and value of diversity of people and ideas. We believe in creating equitable research opportunities for all students and to providing programs and curricula that allow our students to understand critical societal challenges from diverse perspectives and aspire to use research to promote sustainable solutions for all. We are committed to maintaining an inclusive community that recognizes and values the inherent worth and dignity of every person; fosters sensitivity, understanding, and mutual respect among all members; and encourages each individual to strive to reach their own potential. The Ohio State University does not discriminate on the basis of age, ancestry, color, disability, gender identity or expression, genetic information, HIV/AIDS status, military status, national origin, race, religion, sex, gender, sexual orientation, pregnancy, protected veteran status, or any other bases under the law, in its activities, academic programs, admission, and employment. (To learn more about diversity, equity, and inclusion and for opportunities to get involved, please visit: https://odi.osu.edu/ or https://cbsc.osu.edu/

Academic Conduct

ACADEMIC CONDUCT IN CHEMISTRY

The university expects us all to know and adhere to the University Code of Student Conduct, so please do check it out here. Below are some highlights you need to know for the purposes of this course.

Any graded material you submit (for any component of this course) must be your own work. We are obligated by university rules to report any suspicions that you have compromised academic integrity or committed academic misconduct.

Here are some examples of academic misconduct in chemistry courses:

On exams:

- Having another person take your exam.
- Receiving assistance from another person while taking the exam (including looking at another student's exam without their knowledge).
- Taking screenshots or photos of the exam.
- Using screen sharing software during the exam.
- Sharing or receiving exam questions or materials in group chats, text messages, phone calls, or on websites, apps, and the like.

And here are some hints on how you can avoid academic misconduct¹:

- **1.** Acknowledge Your Sources. Whenever you use words or ideas that are not your own, use quotation marks, cite your source in a footnote, and end your work with a list of sources consulted.
- **2.** Protect Your Work. In examinations, do not allow your neighbors to see what you have written; you are the only one who should receive credit for what you know.
- **3.** Avoid Suspicion. Do not put yourself in a position where you can be suspected of having copied another person's work, or of having used unauthorized notes to complete an assignment or exam.
- **4.** Do your own work. The purpose of assignments is to develop your skills and measure your progress. Letting someone else do your work defeats the purpose of your education and may lead to serious charges against you.
- 5. Never fabricate data, citations, or experimental results.
- **6.** Know Your Rights. Do not let other students in your class diminish the value of your achievement by taking unfair advantage. Report any academic dishonesty you see.

If you are unsure about what constitutes academic misconduct, PLEASE ASK a member of your instructional team

ACADEMIC CONDUCT IN THE UNIVERSITY

It is the responsibility of the Committee on Academic Misconduct to investigate or establish procedures for the investigation of all reported cases of student academic misconduct. The term "academic misconduct" includes all forms of student academic misconduct wherever committed; illustrated by, but not limited to, cases of plagiarism and dishonest practices in connection with examinations. Instructors shall report all instances of alleged academic misconduct to the committee (Faculty Rule 3335-5-487). For additional information, see the Code of Student Conduct http://studentlife.osu.edu/csc/.

¹ From Northwestern University, <u>"Academic Integrity: A Basic Guide."</u> Pg. 5. Sept 2020.

 From:
 Kwiek, Nicole

 To:
 Jackman, Jane

 Cc:
 Bowman, Michael

 Subject:
 Letter of concurrence

Date: Wednesday, May 10, 2023 4:21:05 PM

Attachments: <u>image001.png</u>

Dear Dr. Jackman,

Thank you for the opportunity to work with the Department of Chemistry and Biochemistry to develop a new course, CHEM/PHR3301: Science & Policy of Drug Development. The College of Pharmacy's Undergraduate Studies Committee reviewed the course proposal in its April 2023 meeting and provided a unanimous vote of approval. We are excited about this instructional collaboration on the Columbus campus – please accept this email as a statement of our unit's concurrence.

We look forward to feedback from the curricular panels about the course's potential designation as Health and Wellbeing Theme course.

Warm regards, Nicole

Cc: Michael Bowman, College of Pharmacy Registrar



Nicole Cartwright Kwiek, PhD, FAPE

Clinical Professor of Pharmacy Education and Innovation Associate Dean of Undergraduate Studies

College of Pharmacy

The Ohio State University Office of Academic Affairs Faculty Fellow

138A Parks Hall | 500 W. 12th Avenue, Columbus, OH 43210 kwiek.1@osu.edu | pharmacy.osu.edu

Pronouns: she/her/hers

GE Theme course submission worksheet: Health & Wellbeing

Overview

Courses in the GE Themes aim to provide students with opportunities to explore big picture ideas and problems within the specific practice and expertise of a discipline or department. Although many Theme courses serve within disciplinary majors or minors, by requesting inclusion in the General Education, programs are committing to the incorporation of the goals of the focal theme and the success and participation of students from outside of their program.

Each category of the GE has specific learning goals and Expected Learning Outcomes (ELOs) that connect to the big picture goals of the program. ELOs describe the knowledge or skills students should have by the end of the course. Courses in the GE Themes must meet the ELOs common for **all** GE Themes <u>and</u> those specific to the Theme, in addition to any ELOs the instructor has developed specific to that course. All courses in the GE must indicate that they are part of the GE and include the Goals and ELOs of their GE category on their syllabus.

The prompts in this form elicit information about how this course meets the expectations of the GE Themes. The form will be reviewed by a group of content experts (the Theme Advisory) and by a group of curriculum experts (the Theme Panel), with the latter having responsibility for the ELOs and Goals common to all themes (those things that make a course appropriate for the GE Themes) and the former having responsibility for the ELOs and Goals specific to the topic of **this** Theme.

Briefly describe how this course connects to or exemplifies the concept of this Theme (Health & Wellbeing)

In a sentence or two, explain how this class "fits' within the focal Theme. This will help reviewers understand the intended frame of reference for the course-specific activities described below.

(enter text nere)		

Connect this course to the Goals and ELOs shared by all Themes

Below are the Goals and ELOs common to all Themes. In the accompanying table, for each ELO, describe the activities (discussions, readings, lectures, assignments) that provide opportunities for students to achieve those outcomes. The answer should be concise and use language accessible to colleagues outside of the submitting department or discipline. The specifics of the activities matter—listing "readings" without a reference to the topic of those readings will not allow the reviewers to understand how the ELO will be met. However, the panel evaluating the fit of the course to the Theme will review this form in conjunction with the syllabus, so if readings, lecture/discussion topics, or other specifics are provided on the syllabus, it is not necessary to reiterate them within this form. The ELOs are expected to vary in their "coverage" in terms of number of activities or emphasis within the course. Examples from successful courses are shared on the next page.

Goal 1: Successful students will analyze an important topic or idea at a more advanced and in-depth level than the foundations. In this context, "advanced" refers to courses that are e.g., synthetic, rely on research or cutting-edge findings, or deeply engage with the subject matter, among other possibilities.

Goal 2: Successful students will integrate approaches to the theme by making connections to out-of-classroom experiences with academic knowledge or across disciplines and/or to work they have done in previous classes and that they anticipate doing in future.

	Course activities and assignments to meet these ELOs
ELO 1.1 Engage in critical and	
logical thinking.	
ELO 1.2 Engage in an advanced,	
in-depth, scholarly exploration of	
the topic or ideas within this	
theme.	
ELO 2.1 Identify, describe, and	
synthesize approaches or	
experiences.	
ELO 2.2 Demonstrate a	
developing sense of self as a	
learner through reflection, self-	
assessment, and creative work,	
building on prior experiences to	
respond to new and challenging	
contexts.	

Example responses for proposals within "Citizenship" (from Sociology 3200, Comm 2850, French 2803):

ELO 1.1 Engage in critical	This course will build skills needed to engage in critical and logical thinking
and logical thinking.	about immigration and immigration related policy through:
	Weekly reading response papers which require the students to synthesize
	and critically evaluate cutting-edge scholarship on immigration;
	Engagement in class-based discussion and debates on immigration-related
	topics using evidence-based logical reasoning to evaluate policy positions;
	Completion of an assignment which build skills in analyzing empirical data
	on immigration (Assignment #1)

Completion 3 assignments which build skills in connecting individual experiences with broader population-based patterns (Assignments #1, #2, #3)

Completion of 3 quizzes in which students demonstrate comprehension of the course readings and materials.

ELO 2.1 Identify, describe, and synthesize approaches or experiences.

Students engage in advanced exploration of each module topic through a combination of lectures, readings, and discussions.

Lecture

Course materials come from a variety of sources to help students engage in the relationship between media and citizenship at an advanced level. Each of the 12 modules has 3-4 lectures that contain information from both peer-reviewed and popular sources. Additionally, each module has at least one guest lecture from an expert in that topic to increase students' access to people with expertise in a variety of areas.

Reading

The textbook for this course provides background information on each topic and corresponds to the lectures. Students also take some control over their own learning by choosing at least one peer-reviewed article and at least one newspaper article from outside the class materials to read and include in their weekly discussion posts.

Discussions

Students do weekly discussions and are given flexibility in their topic choices in order to allow them to take some control over their education. They are also asked to provide

information from sources they've found outside the lecture materials. In this way, they are able to

explore areas of particular interest to them and practice the skills they will need to gather information

about current events, analyze this information, and communicate it with others.

Activity Example: Civility impacts citizenship behaviors in many ways. Students are asked to choose a TED talk from a provided list (or choose another speech of their interest) and summarize and evaluate what it says about the relationship between civility and citizenship. Examples of Ted Talks on the list include Steven Petrow on the difference between being polite and being civil, Chimamanda Ngozi Adichie's talk on how a single story can perpetuate stereotypes, and Claire Wardle's talk on how diversity can enhance citizenship.

the contexts.

ELO 2.2 Demonstrate a developing sense of self as a learner through reflection, self-assessment, and creative work, building on prior experiences to respond to new and challenging contexts.

Students will conduct research on a specific event or site in Paris not already discussed in depth in class. Students will submit a 300-word abstract of their topic and a bibliography of at least five reputable academic and mainstream sources. At the end of the semester they will submit a 5-page research paper and present their findings in a 10-minute oral and visual presentation in a small-group setting in Zoom.

Some examples of events and sites:

The Paris Commune, an 1871 socialist uprising violently squelched by conservative forces

Jazz-Age Montmartre, where a small community of African-Americans—
including actress and singer Josephine Baker, who was just inducted into
the French Pantheon—settled and worked after World War I.
The Vélodrome d'hiver Roundup, 16-17 July 1942, when 13,000 Jews were
rounded up by Paris police before being sent to concentration camps
The Marais, a vibrant Paris neighborhood inhabited over the centuries by
aristocrats, then Jews, then the LGBTQ+ community, among other groups.

Goals and ELOs unique to Health & Wellbeing

Below are the Goals and ELOs specific to this Theme. As above, in the accompanying Table, for each ELO, describe the activities (discussions, readings, lectures, assignments) that provide opportunities for students to achieve those outcomes. The answer should be concise and use language accessible to colleagues outside of the submitting department or discipline. The ELOs are expected to vary in their "coverage" in terms of number of activities or emphasis within the course. Examples from successful courses are shared on the next page.

GOAL 3: Students will explore and analyze health and wellbeing through attention to at least two dimensions of wellbeing. (Ex: physical, mental, emotional, career, environmental, spiritual, intellectual, creative, financial, etc.).

	Course activities and assignments to meet these ELOs
ELO 3.1 Explore and analyze health and	
wellbeing from theoretical, socio-economic,	
scientific, historical, cultural, technological,	
policy, and/or personal perspectives.	
ELO 3.2 Identify, reflect on, or apply	
strategies for promoting health and well-	
being.	