FLORIDA ATLANTIC UNIVERSITY

NEW COURSE PROPOSAL
Graduate Programs

Department CHEMISTRY & BIOCHEMISTRY

College C.E. SCHMIDT COLLEGE OF SCIENCE

*(To obtain a course number, contact **erudolph@fau.edu**)*

UGPC Approval _____
UFS Approval _____
SCNS Submittal _____
Confirmed _____
Banner _____
Catalog _____

Prefix CHM

Number 6277

(L = Lab Course; C = Combined Lecture/Lab; add if appropriate)
Lab Code C

Type of Course Combined Lecture/Lab

Course Title Adv. Drug Development

Credits *(Review Provost Memorandum)* 3

Effective Date *(TERM & YEAR)* Fall 2020

Grading *(Select One Option)*
Regular
Sat/UnSat

Course Description *(Syllabus must be attached; see Guidelines)*

This course provides the overview on processes involved in drug discovery and development. The principles of current good manufacturing practices (cGMPs), quality control and quality assurance will be covered. This course also gives an overview of US FDA drug regulations and intellectual property rights. Experts in drug development and regulation will present lectures on these topics. A laboratory portion will be included that will involve the process of analytical method development, validation, stability analysis and the associated protocols and reports.

Prerequisites

GRADUATE STANDING

Prerequisites, Corequisites and Registration Controls are enforced for all sections of course.

Academic Service Learning (ASL) course

Academic Service Learning statement must be indicated in syllabus and approval attached to this form.

Corequisites
None

Registration Controls *(For example, Major, College, Level)*
None

Minimum qualifications needed to teach course:
Member of the FAU graduate faculty and has a terminal degree in the subject area (or a closely related field.)

List textbook information in syllabus or here
Drugs: From discovery to approval, Third Edition

Faculty Contact/Email/Phone
ShailajaAllani/skesaraj@fau.edu/561297-4972

List/Attach comments from departments affected by new course

Approved by	***Date***
Department Chair	02/26/2020
College Curriculum Chair	2020.03.06 11:45:38 -05'00'
College Dean	March 9, 2020
UGPC Chair	
UGC Chair	
Graduate College Dean	
UFS President	
Provost	

Email this form and syllabus to UGPC@fau.edu 10 days before the UGPC meeting.

ADV.DRUG DEVELOPMENT | CHM 6277 | 3 Credit hours

Instructor*:* Dr. Shailaja Kesaraju Allani
Office:PS 336A
Office hours: TBA
E-mail: skesaraj@fau.edu
Phone: 561-297-4972

Term: Spring 2021 (Aug 23 –Dec 8)
Class Meeting days: Wednesday
Class Meeting Hours: 9:00-11:45 AM
Class Location: RF119, Jupiter Campus
VC Location: SC 141 Boca Raton

II. Course description

This course provides the overview on processes involved in drug discovery and development. The principles of current good manufacturing practices (cGMPs), quality control and quality assurance will be covered. This course also gives an overview of US FDA drug regulations and intellectual property rights. Experts in drug development and regulation will present lectures on these topics. A laboratory portion will be included that will involve the process of analytical method development, validation, stability analysis and the associated protocols and reports.

III. Course Prerequisites

Graduate Standing

IV. Required texts

Texts required **: Drugs: From discovery to approval, Third Edition**
Recommended websites
www.fda.gov
www.uspto.org

V. Supplementary readings

ICH guidance documents
(https://www.fda.gov/RegulatoryInformation/Guidances/ucm122049.htm)

VI. Course objective

This course is targeted towards graduate students interested in learning the myriad aspects of drug discovery from early discovery of small molecules or compounds in a research laboratory to bringing these products to the market. This course is primarily a lecture-based course but includes other activities for example, individual student presentations, team projects and laboratory sessions. By the end of the course, students must be able to understand various steps involved in getting a drug to the market. They have to submit a team project and give a presentation on a particular topic of drug development such as drug discovery, regulatory affairs, stability of the drug, clinical studies etc., Students will give a team presentation on a hypothetical drug and will submit a summary document for an NDA (New Drug Application).

VII. Course Evaluation

	% course grade
Attendance	**15%**
Midterm	**35%**
Oral presentation	**5%**
Team Project	**5%**
Homework	**5%**
Finals	**35%**
TOTAL	**100%**

Oral Presentations

- The presentation must be timed around 10-12 min.
- 3- 5 minutes time must be allotted for questions at the end of the presentation.
- You can make 10-12 slides with a slide/minute.
- **Organization of the presentation** can be as follows:

Background/Introduction of the topic
Objective or Hypothesis of the journal article
Results: In this section you could briefly discuss the methods/experiments used to obtain results. Explain how results supported or disproved the hypothesis.
Conclusions: Explain how results might help the cancer field; explain what are the applications from the research performed in this article.
Provide the journal article in advance so that it can be posted on Canvas.
Choose an article from pharmaceutical journal such as Pharmaceutical Research, The Pharmaceutical Journal etc., that focus on the entire journey of bench discovery to market availability.
Please choose only research articles no review articles as it is not possible to cover a review article in 10 -15 min of time.
Topics of great interest: Some of the topics include but not limited to
Small drug molecule discovery
Regulatory aspects
Formulation design
Clinical trial design

Team Projects

- Team members will be submitting a mock NDA using an established drug as reference. It should be between 3-5 pages.
- 2. Each team will summarize their NDA to the class.
- 3. You can use PowerPoint presentation if required but is not necessary.
- 4. **Team project**: Students will work on some of the "Section IV" components of electronic submissions of NDA's. Links below will aid in the preparation of NDA.
  (https://www.fda.gov/downloads/drugs/developmentapprovalprocess/formssubmissionrequirements/electronicsubmissions/ucm163187.pdf)
  (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.50)
  NDA application must include:

Summary : Summary of the NDA including CMC, toxicology, pharmacokinetics and clinical data.
CMC : Chemistry, Manufacturing and Controls (Drug substance , drug product etc.,) section of the NDA
Toxicology and nonclinical data: Toxicological effects of the drug; absorption, distribution, excretion and metabolism of the drug
Pharmacokinetics and Bioavailability: Analysis of pharmacokoninetics and metabolism of active ingredients and bioavailability in humans.
Clinical data section: Clinical investigations in human subjects.

Homework Assignments:
The students should read the following ICH guidances in support of their class work. The guidances that should be read are:

For EXAM 1

· Q1A(R2) Stability Testing of New Drug Substances
· Q2A Text on Validation of Analytical Procedures
· Q3B(R) Impurities in New Drug Products (Revision 2)
· Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substance and New Drug Products: Chemical Substances

For EXAM 2

· Q8(R2) Pharmaceutical Development
· Q9 Quality Risk Management
· Q10 Pharmaceutical Quality System

VIII. Course Grading Scale

A+ 93% & above
A 90-92%
B+ 87-89%
B 83-86%
B- 80-82%
C+ 77-79%
C 73-76%
C- 70-72%
D+ 67-69%
D 63-66%
D- 60-62%
F 59% & below

IX. Special Course Requirements
None

X. Policy on make-up exams, late work and incompletes
Students must be present for midterm and final exams. If there is an emergency situation, the instructor must be notified via e-mail prior to the exam with a legitimate proof**.** Late assignments will not be accepted and no exceptions will be made. Reasonable accommodation will be made for students participating in a religious observance.

XI. Classroom etiquette policy
Attendance is mandatory. There is no more than one excused absence. University policy on electronic devices ”In order to enhance and maintain productive atmosphere for education, personal communication such as cellular telephones and pagers, are to be disable in class sessions”. Use of laptop or tablets and arriving late or leaving early is not permitted.

XII. Attendance Policy
Students are expected to attend all of their scheduled University classes and to satisfy all academic objectives as outlined by the instructor. The effect of absences upon grades is determined by the instructor, and the University reserves the right to deal at any time with individual cases of non-attendance.
Students are responsible for arranging to make up work missed because of legitimate class absence, such as illness, family emergencies, military obligation, court-imposed legal obligations or participation in University- approved activities. Examples of University-approved reasons for absences include participating on an athletic or scholastic team, musical and theatrical performances and debate activities. It is the student's responsibility to give the instructor notice prior to any anticipated absences and within a reasonable amount of time after an unanticipated absence, ordinarily by the next scheduled class meeting. Instructors must allow each student who is absent for a University-approved reason the opportunity to make up work missed without any reduction in the student's final grade as a direct result of such absence.

XIII. Disability Policy Statement

In compliance with the Americans with Disabilities Act Amendments Act (ADAAA), students who require reasonable accommodations due to a disability to properly execute coursework must register with Student Accessibility Services (SAS) and follow all SAS procedures. SAS has offices across three of FAU's campuses – Boca Raton, Davie and Jupiter – however disability services are available for students on all campuses. For more information, please visit the SAS website at http://www.fau.edu/sas/

XIV. Code of Academic Integrity Policy Statement

Students at Florida Atlantic University are expected to maintain the highest ethical standards. Academic dishonesty is considered a serious breach of these ethical standards, because it interferes with the university mission to provide a high quality education in which no student enjoys an unfair advantage over any other. Academic dishonesty is also destructive of the university community, which is grounded in a system of mutual trust and places high value on personal integrity

and individual responsibility. Harsh penalties are associated with academic dishonesty. For more information, see University Regulation 4.001".
http://www.fau.edu/ctl/4.001_Code_of_Academic_Integrity.pdf

***XV. Religious Accommodations**:*
Students have the right to reasonable accommodations from the University in order to observe religious practices and beliefs. If a student is going to miss class due to a religious observance, they must notify the instructor no later than the second week of the term. For more information, go to:
http://www.fau.edu/regulations/chapter2/.

XVI. Counseling and Psychological Services (CAPS) Center
Life as a university student can be challenging physically, mentally and emotionally. Students who find stress negatively affecting their ability to achieve academic or personal goals may wish 4 to consider utilizing FAU's Counseling and Psychological Services (CAPS) Center. CAPS provides FAU students a range of services – individual counseling, support meetings, and psychiatric services, to name a few – offered to help improve and maintain emotional well-being. For more information…http://www.fau.edu/counseling/

XVII. Course Outline

***Tentative Course outline (subject to change):**

#	Lecture *	Homework
1	Course Introduction	Q1 guidance
2	Intro. Drug Development	
3	Drug Discovery: Targets & Receptors	Q1 Guidance
4	Small Molecules	Q1 Guidance
5	Large Molecules	Q2 Guidance
6	Good Documentation Practices	Q2 Guidance
7	HTP screening	Q2 Guidance
8	**LAB 1-** Content Uniformity	
9	Drug Formulation	
10	Analytical development	Q3 Guidance
11	Preclinical Toxicology	Q3 guidance
12	Transdermal Patches	Q3 Guidance
13	Clinical trials -Part 1	Q 6 Guidance
14	MIDTERM	Q 6 Guidance
15	Clinical trials –Part 2	Q 6 Guidance
16	**LAB 2-** Spectrophotometer Analysis of drug concentration	Q8 Guidance
17	Clinical trials – Part 3	Q8 Guidance
18	Regulatory –Early phase	Q8 Guidance
19	Regulatory Submissions	Q8 Guidance
20	Intellectual Property	Q9 Guidance
21	GMP: Regulatory requirements	Q9 Guidance
22	GMP: Drug manufacturing	Q9 Guidance
23	Quality Systems	Q9 Guidance
24	**LAB 3-** Drug release from Transdermal patches	Q10 Guidance
25	Medical devices	Q10 Guidance
26	Commercialization	Q10 Guidance