FLORIDA ATLANTIC UNIVERSITY

NEW COURSE PROPOSAL
Undergraduate Programs

Department Chemistry & Biochemistry

College C.E. Schmidt College of Science

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

UUPC Approval _____
UFS Approval _____
SCNS Submittal _____
Confirmed _____
Banner Posted _____
Catalog _____

Prefix CHM

Number 4270

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

Lab Code C

Type of Course: Lecture/Lab

Course Title: INTRO. TO DRUG DEVELOPMENT

Credits *(Review Provost Memorandum)*: 3

Effective Date *(TERM & YEAR)*: FALL 2020

Grading *(Select One Option)*

- **Regular** (●)
- **Pass/Fail** ( )
- **Sat/UnSat** ( )

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

This course provides the basics in US FDA drug regulations, facilities and process qualification and the processes involved in drug discovery and development. Students will learn how specific activities fit into the overall scheme of drug development and evaluate the impact of each activity on the overall progression of a new drug candidate. The principles of good documentation practices and basic analytical assays will be introduced by hands-on activities.

Prerequisites, with minimum grade*

CHM 2211

Corequisites

None

Registration Controls *(Major, College, Level)*

None

Default minimum passing grade is D-.** **Prereqs., Coreqs. & Reg. Controls are enforced for all sections of course

WAC/Gordon Rule Course

( ) **Yes** (●) **No**

WAC/Gordon Rule criteria must be indicated in syllabus and approval attached to proposal. See WAC Guidelines.

Intellectual Foundations Program (General Education) Requirement *(Select One Option)*

None

General Education criteria must be indicated in the syllabus and approval attached to the proposal. See GE Guidelines.

Minimum qualifications to teach course

PhD in Chemistry or a related discipline

Faculty Contact/Email/Phone

ShailajaAllani/skesaraj@fau.edu/5612974972

List/Attach comments from departments affected by new course

Approved by	***Date***
Department Chair: *Jerry Haky (via email confirmation)*	*3-23-20*
College Curriculum Chair: *Jerry Haky (via email confirmation)*	*3-23-20*
College Dean: *Evonne Rezler (via email confirmation)*	*3-27-20*
UUPC Chair: *Jerry Haky (via email confirmation)*	*3-30-20*
Undergraduate Studies Dean: *Edward Pratt (via email confirmation)*	*3-31-20*
UFS President: _____	_____
Provost: _____	_____

Email this form and syllabus to mjenning@fau.edu seven business days before the UUPC meeting.

INTRO. TO DRUG DEVELOPMENT | CHM 4270|3 Credit hours

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

Term: FALL 2020
Class Meeting days: TBA
Class Meeting Hours: TBA
Class Location: TBA Boca Raton

II. Course description

This course provides the basics in US FDA drug regulations, facilities and process qualification and the processes involved in drug discovery and development. Students will learn how specific activities fit into the overall scheme of drug development and evaluate the impact of each activity on the overall progression of a new drug candidate. The principles of good documentation practices and basic analytical assays will be introduced by hands-on activities. The basics of regulatory compliance, the global nature of regulations and their importance of validation in the Pharmaceutical and Biotechnology Industries will be presented.

III. Course Prerequisites

CHM 2211

IV. Required texts

Textbook: Drugs: From discovery to approval, Third Edition
Author: Rick Ng

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 is an introductory course to general concepts in Drug Development and Regulation. It will cover a range of topics from basic research in the bench to the market place. Experts in drug development and regulation will present lectures on these topics. It will include the early phase formulation and analytical development, non-clinical studies, Phases I, II and III of the clinical development, chemistry, manufacturing and controls required for the FDA.

Learning outcomes:
Understand different steps in drug development and regulation.
Understand the necessary procedures to bring a new drug to the market.
Understand the regulatory requirements under Good Manufacture Practices (GMP).

VII. Course Evaluation

The course grade is based on attendance 15%, Midterm and Final 70%, and 15% homework assignments. Homework assignments will be given bi –weekly throughout the course which includes short one page written assignments.

- **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 (ADA), students who require reasonable accommodations due to a disability to properly execute coursework must register with the Office of 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.

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