

 <b>FLORIDA ATLANTIC UNIVERSITY</b>	<b>NEW/CHANGE PROGRAM REQUEST</b> <b>Undergraduate Programs</b>	UUPC Approval <u>10/12/20</u> UFS Approval _____ Banner Posted _____ Catalog _____
	<b>Department</b> Chemistry & Biochemistry  <b>College</b> C.E. Schmidt College of Sciences	
<b>Program Name</b> Pharmaceutical Technology Certificate Program	<input checked="" type="checkbox"/> <b>New Program</b>  <input type="checkbox"/> <b>Change Program</b>	<b>Effective Date</b> (TERM & YEAR)  Spring 2021
<b>Please explain the requested change(s) and offer rationale below or on an attachment</b>  <p>Bioscience industry is one of the fastest growing private industry in the US that created 1.7 million jobs in the year 2016. According to Enterprise Florida, Florida ranks second in the nation in the number of pharmaceutical and medical devices companies. Biosciences industry is diversified as-pharmaceutical, medical devices, medical laboratories and research- into more than 6,000 establishments in Florida and provides employment for 87,061 people. South Florida plays a key role in the expansion of Biosciences industry in Florida. Beacon Pharmaceuticals has recently announced an ambitious project to develop a life science accelerator in Jupiter, Florida, that can provide state-of-the-art cGMP (Current good manufacturing practices) facility to almost 50 early life science startup companies, which could lead to hundreds of job opportunities.</p> <p>Jobs in bioscience industry rely on knowledge and technological skill set. The average wage for workers employed in Bioscience industry is \$99,000, that is 85% higher than average wage of worker employed in any other private sector. The high wages demand high skill set and knowledge that can meet industry standards. Academic training has to be tailored to industry needs. We expect that our certificate program will fill those gaps and build a bridge from academia to industry. The courses in the certificate program will prepare students for jobs in the bioscience industry, provide opportunity of guidance from industry experts and facilitate hands-on learning of key laboratory skills.</p> <p>See attd. document for more details.</p>		
<b>Faculty Contact/Email/Phone</b>  Shailaja Allani; Associate Scientist skesaraj@fau.edu; x68224	<b>Consult and list departments that may be affected by the change(s) and attach documentation</b>  Biological Sciences	
<b>Approved by</b> Department Chair <u>Jerry Haky (for chair)</u> College Curriculum Chair <u>Jerry Haky</u> College Dean <u>[Signature]</u> UUPC Chair <u>Jerry Haky</u> Undergraduate Studies Dean <u>Edward Pratt</u> UFS President _____ Provost _____	<b>Date</b> <u>10-5-20</u> <u>10-6-20</u> <u>10/8/2020</u> <u>10-12-20</u> <u>10-12-20</u> _____ _____	

Email this form and attachments to [mjenning@fau.edu](mailto:mjenning@fau.edu) one week before the UUPC meeting so that materials may be viewed on the UUPC website prior to the meeting.

## **Pharmaceutical Technology Certificate Program (PTCP)**

### **Overview**

The Pharmaceutical technology certification program will provide students, a unique opportunity to understand the drug development process, emphasizing the role of biology, chemistry, biochemical, analytical, formulation and regulatory aspects of drug discovery.

### **Why do we need a certificate program?**

Bioscience industry is one of the fastest growing private industry in the US creating 1.7 million jobs in the year 2016<sup>1</sup>. According to Enterprise Florida, Florida ranks second in the nation in the number of pharmaceutical and medical devices companies <sup>2</sup>. Biosciences industry is diversified as-pharmaceutical, medical devices, medical laboratories and research- into more than 6,000 establishments in Florida and provides employment for 87,061 people <sup>3</sup>. South Florida plays a key role in the expansion of Biosciences industry in Florida. Beacon Pharmaceuticals has recently announced an ambitious project to develop a life science accelerator in Jupiter, Palm Beach county that can provide state-of-the-art cGMP (Current good manufacturing practices) facility to almost 50 early life science startup companies, which could lead to hundreds of job opportunities <sup>4</sup>.

Jobs in bioscience industry rely on knowledge and technological skill set. The average wage for workers employed in Bioscience industry is \$99,000, that is 85% higher than average wage of worker employed in any other private sector<sup>1</sup>. The high wages demand high skill set and knowledge that can meet industry standards. Academic training has to be tailored to industry needs. We expect that our certificate program will fill those gaps and build a bridge from academia to industry. The courses in the certificate program will prepare students for jobs in the bioscience industry, provide opportunity of guidance from industry experts and facilitate hands-on learning of key laboratory skills.

### **Key Learning outcomes**

- Introducing the drug development process from drug discovery to market launch
- Understanding the regulatory requirements under Good Manufacture Practices (GMP).
- Understanding the underlying chemistry and drug design of biological target molecules
- Understanding of drug metabolism, toxicology and pharmacokinetics of drug products
- Understanding fundamentals of analytical development in pharmaceutical industry.

### **Who is it intended for?**

The certificate is designed for individuals who have completed higher undergraduate level courses including Organic Chemistry II and Biochemistry I. This certificate is also intended for individuals who plan to pursue a career in biopharmaceutical industry.

**Certificate Requirements: A minimum of 14 total credits**

**Required Courses (10 credits)**

Course	Credits	Fall	Spring	Summer
Introduction to Drug Development (CHM 4270)	3	X		
Introduction to Drug Design (CHM 4273)	3		X	
Bioanalytical Instrumentation (CHM 4139)	2	X		
Bioanalytical Instrumentation Lab (CHM 4139L)	2	X		

**Elective Courses (4 credits)**

Course	Credits	Fall	Spring	Summer
Drug Discovery & Formulation (CHM 4274)	3		X	
CMBB Research Seminar (BSC 4932)	1	X	X	
Structural Biochemistry (CHM 4350)	3	X		
Adv. Biochemistry 2 (BCH 4035))	3	X		
Biochemistry Laboratory (BCH 3103L)	3	X	X	X
Organic chemistry 3 (CHM4220))	3	X		
Organic Spectroscopy (CHM 4933)	3			
Chemical Biology (CHM 4933)	3	X		
Science Internship Course (IDS 3941)	1-3			

**CORE COURSES:**

**Introduction to Drug Development (CHM 4270):** 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.

**Introduction to Drug Design (CHM 4273):** This course provides an in-depth overview of the approaches utilized by medicinal chemists to design novel, pharmacologically active molecules to treat human diseases.

**Bioanalytical Instrumentation (CHM 4139):** An introduction to the theory, design, and operation of advanced instrumentation currently used in research and quality control/quality assurance laboratories for the analysis and characterization of biomolecules. Topics include spectroscopic techniques, separation techniques, electrochemical methods, and statistical treatment of data.

**Bioanalytical Instrumentation Lab (CHM 4139L) 2 credits**

Advanced experiments in the isolation, analysis, and characterization of biomolecules using spectroscopic, chromatographic, and electrochemical methods.

**ELECTIVES:**

**Drug Discovery & Formulation (CHM 4274):** This course provides an introduction to drug formulation. Students will learn about drug discovery, pharmacology, toxicology and formulation. Students will be introduced to different forms of drug formulation, various routes of administration and assays to analyze these dosage forms. A laboratory portion will be included that will involve analytical assays for suspensions and solid dosage forms.

**CMBB Seminar (BSC 4932) 1 credit**

A variable title seminar series in which students experience information exchange among professional scientists. This course offers a more informal, less intimidating environment to talk with faculty, graduate students and other researchers. Invited speakers are from various institutions allowing students to network regarding further schooling/jobs. *Grading: S/U*

**Structural Biochemistry (CHM 4350) 3 credits**

Course emphasizes a computer-based approach to teaching structural biochemistry. It uses hands-on experience to develop essential skills for understanding relationships between structure and function of biomolecules. Classes are held in computer labs. State-of-the-art software for visualization, manipulation and simulation of various biomolecules is used throughout.

**Advanced Biochemistry (BCH 4035) 3 credits**

This course is a comprehensive introduction to the study of proteins and their importance within biological systems. Topics will cover the structure and function of proteins, their biological diversity, and examples for biotechnological, medical and scientific use of proteins.

**Biochemistry Laboratory (BCH 3103L) 3 credits**

An introduction to experimental techniques in physical chemistry as applied to biological systems; quantitative measurements in biochemistry.

**Organic Chemistry 3 (CHM 4220) 3 credits**

An in-depth study of a wide variety of organic reactions drawing on both valence bond

and molecular orbital theories to explain reactivity. Strong emphasis on curved-arrow mechanisms.

**Chemical Biology & Organic Spectroscopy (CHM 4933):** Special topics.

**Science Internship Course (IDS 3941):** The College of Science partners with the FAU Career Center to offer the (1-3 credit) Science Internship Course. Registration is open for fall 2019. Requirements for this course are as follows: must be a JUNIOR or SENIOR in class standing and have a 3.0 GPA or above.

### References:

1. [https://www.bio.org/sites/default/files/legacy/bioorg/docs/TEconomy\\_BIO\\_2018\\_Report.pdf](https://www.bio.org/sites/default/files/legacy/bioorg/docs/TEconomy_BIO_2018_Report.pdf)
2. <http://www.enterpriseflorida.com/wp-content/uploads/brief-life-sciences-florida.pdf>.
3. [https://cdn.ymaws.com/www.bioflorida.com/resource/resmgr/industry\\_data/TEconomy\\_BIO\\_2018\\_FloridaFac.pdf](https://cdn.ymaws.com/www.bioflorida.com/resource/resmgr/industry_data/TEconomy_BIO_2018_FloridaFac.pdf)).
4. <https://www.beaconpharmaceutical.com/>