Spring 2020

CHEM 701-102: Special Topic - Regulatory Compliance in Applied Cell & Gene Therapy

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New Jersey Institute of Technology

College of Science & Liberal Arts

Department of Chemistry and Environmental Science

Course Syllabus

CRN: 11449

Course: CHEM 702: ST: Regulatory Compliance in Applied Cell & Gene Therapy

Spring 2020, 15-Weeks

January 23, 2020 – May 14, 2020

Meeting Time: Thursdays, 6:00 PM – 8:50 PM

Meeting Location: TIER 113

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In general, please contact me by e-mail and you will get a response within 24-48 hours. I can meet you by appointment only.

Overview:

The objective of the course is to provide an overview of Regulatory Affairs for Cell and Gene Therapy Product approval. We will examine every step of the regulatory process for Cell and Gene Therapy products from preclinical testing through commercialization and post-marketing. This course will offer students an opportunity to conduct a comprehensive and up-to-date analysis of the complete U.S. pharmaceutical Cell and Gene Therapy regulatory and product approval processes. We will discuss the FDA's standards for preclinical testing, quality assurance, good laboratory and manufacturing practices, investigational new drug (IND) and NDA applications, therapeutic market applications and FDA's review process. In addition, the regulatory process for approval of Gene and Cell Therapy products in the EU and Japan will be discussed.

Weekly Time Commitment:

It is estimated that students will spend an average of 3 hours per week on this course. The amount of time that will be required will vary from week to week. This time commitment is consistent with the accepted standards for a three-credit, graduate-level course.

Academic Integrity:

All students must observe and support high standards of honesty and integrity in all aspects of education, practice, and research. For this reason, all students in this course are expected to abide by the School's Faculty/Student Honor Code and accept responsibility to help ensure that these standards are maintained by reporting violations of the Honor Code observed in others. All academic integrity violations will be considered with the gravest concern and may be punishable with sanctions as severe as suspension or dismissal.

Grading Explanation:

Deliverable	Percentage	Due Date
Midterm	30 %	3/5/20
Oral Presentation	30 %	4/16/20- 4/23/20
Participation in Class	10 %	All semester
Final Exam	30 %	4/30/20
Total	**100 %**	

Topics to be Covered:

(This is a plan and may be subject to change)

Week	Topic	Description
1- 1/23/20	Overview of Regulatory Affairs	• What is Regulatory Affairs? • The Role of The Regulatory Professional • Pharmaceutical Regulatory Affairs. • Pharmaceutical Regulatory Agencies and Organizations. • What is the US Food and Drug Administration (FDA) roles? • The roles of the US Food and Drug Administration (FDA).
2- 1/30/20	The Drug and Biologic Product Development Process	• Different types of human medicines.

		• What drug and biologic products are? And what are the differences between them? • The general stages of therapeutic product development from R&D to marketing. • The various types of manufacturer – FDA interactions that can and should occur during the drug development process.
3- 2/6/20	The Gene and Cell Therapy	• What is Gene and Cell Therapy mean? • The difference between Cell and Gene therapy. • Examples of Gene and Cell Therapy. • Major companies and their products in Gene and Cell Therapy. • An overview of the additional manufacturing challenges with these types of products.
4- 2/13/20	Deviations and CAPAs	• What are deviations and CAPAs? • Why Deviations and CAPAs are important for getting approval of new therapy products with FDA. • Types of deviations and CAPAs. • Examples and case studies.
5- 2/20/20	FDA registration	• How to register a new GMP center with FDA. • Challenges and solutions. • Overview of FDA registration website.
6- 2/27/20	Pre-Investigational New Drug (Pre-IND)	• Explain the purpose of Good Laboratory Practices (GLPs).

		• Identify the non-clinical required components of the IND for initial IND approval. • Describe the differences in nonclinical testing of drugs and biologics. • Explain the informal pre-IND process of the Office of Tissues and Advanced Therapies. • Describe the pre-IND Meeting process.
7- 3/5/20	**Midterm**	Will cover materials from week 1- week 6.
8- 3/12/20	Commercializing a Gene and Cell Therapy	• Overview of the Regulatory Path to Commercializing a Gene Therapy. • Overview of the Regulatory Path to Commercializing a Cell Therapy. • Overview of FDA's Expedited-Approval Designations.
9- 3/19/20	**Spring Break**	**No class**
10- 3/26/20	Regulatory Issues in Gene Therapy	
11- 4/2/20	Regulatory Issues in Cell Therapy	
12- 4/9/20	Regulatory Oversight on Gene and Cell Therapy in EU and Japan	• Regulatory Oversight on Gene and Cell Therapy in EU. • Regulatory Oversight on Gene and Cell Therapy in Japan.
13- 4/16/20	**Oral Presentations and case studies**	Will give details later.
14- 4/23/20	**Oral Presentations and case studies**	Will give details later.
15- 4/30/20	**Final Exam**	Will cover materials from week 8- week 12.