REG 6240: Applied Regulatory Processes of Vaccines and Biologics

Course Dates

Term: Summer I (6 week course)
Dates: Tuesday/Thursday (Begins May 23, ends June 27)
Time: 4-6 pm
Location: Online

Instructor Contact

Narendra Chirmule, Ph.D.

*syllabus is subject to change at professor's discretion

Course Description

Drug development is at a turning point in human medicine. Over the past three decades, the development of biotherapeutics has revolutionized innovation in medicines. Efficiency and Quality Compliance are critical to achieving innovation and affordability. This course will provide an overview of the multi-dimensional nature of drug development, which involves regulatory, new technologies, statistical, and quality considerations. This 6-week course will introduce the concepts of drug development, which include, pharmacology, toxicology, product development, clinical trials. All of these topics will be addressed based on regulatory requirements by the FDA. Risk assessment and mitigation will be discussed using a role-play process. The content of the course includes seminars, case studies, project reports, and journal article-reviews.

Course Objectives

Upon completion of the course, the participants should be able to:

1. Identify the basic aspects of drug, vaccine, and biologics development, especially as it relates to application in various steps of the process.
2. Examine the risks associated with medical product development processes.
3. Apply risk assessment processes (FMEA) to development scenarios.
4. Develop individual strategies for applying soft skills to organizational challenges faced during development.

5. Discuss the organizational structures and procedural/regulatory requirements of industry-based and academic drug development.
6. Examine the complex multidisciplinary nature of the drug development process, which intersect with several other biological processes.
7. Implement key professional skills (such as CV development, reflective writing, mentor engagement) for careers in regulatory affairs in academia or industry.

Participant Requirements

The course is aimed at providing an overview of the drug development processes. Attendees to the course should have:

- A bachelor's degree and/or advanced training in biological sciences, clinical trial development, or a related discipline. A master's degree in biological sciences is recommended.
- Some knowledge of one of the areas involved in drug development (e.g. discovery research, process development, pre-clinical studies, and clinical trials).
- Desire to understand the application of research to drug development.

Assignments & Grading

A grade of C- is considered passing for this course. However, if this course is to count towards your graduate degree then a grade of B- or higher is required.

- Attendance – 15%
- Active Participation – 15%
    - Discussion boards
    - "Above and beyond" participation in and outside of class
- Multiple Choice Test – 45%
- Team Presentation – 25%

Academic Policies:

Participation Expectations

Participation in class is crucial to students' education in this program. Students are expected to attend and actively participate in all courses. Examples of active participation in a synchronous session may include asking or answering questions, posting comments in

the chat, or collaborating with other students during group work. Examples of active participation in an asynchronous session may include asking or answering questions via Canvas or email, commenting on discussion boards, or interacting with other students outside of class.

This program is committed to providing a supportive and productive learning environment for all. Active participation requires professionalism and demonstration of respect for peers, course instructors, and guest lecturers.

Attendance Expectations
Students are allowed 1 excused absence. If you anticipate the need to be absent, please contact the course coordinator prior to your absence. If you have other concerns about your ability to meet the attendance requirements, you must contact the course coordinator prior to your absence.

Students are expected to be on time to all classes and stay for the duration of the class. If you anticipate being late to class or may need to leave early please email the course coordinator and instructor in a timely manner to let them know of may be late or need to leave early. Any student who is more than 15 minutes late will be considered absent from that class. Additionally, any student who leaves early may be marked absent. Attendance also includes keeping video feed on during synchronous sessions.

Academic Integrity:
As a University of Pennsylvania student, you are required to uphold Penn's Code of Academic Integrity. Specifically, this means that materials that you submit either online or in person should be independent works created by you that uphold all tenets of academic integrity (i.e. do not cheat, fabricate, or plagiarize, amongst others). We encourage you to reach out to the course director or coordinator if you are not clear on what potential violations are.

Course Management: Canvas
All course materials and assignments will be managed on Canvas. Log in with Pennkey and password at https://canvas.upenn.edu.

Course Evaluations:
Course evaluations are completed in the BLUE system. These are a required part of course participation. An email from the BLUE team will be sent to students with a link and directions on how to complete the course evaluation(s).

Student Disabilities Services

The University of Pennsylvania provides reasonable accommodations to students with disabilities who have self-identified and been approved by the office of Student Disabilities Services (SDS). Please make an appointment to meet with me and the course coordinator as soon as possible in order to discuss your accommodations and your needs. If you have not yet contacted SDS, and would like to request accommodations or have questions, you can make an appointment by calling SDS at 215-573-9235 or accessing the **MyWeingartenCenter** portal. The office is located in the Weingarten Learning Resources Center at Hamilton Village, 220 S 40th St Suite 260. All services are confidential.

Curriculum & Schedule

Date	Lecture	Topic	Outside of Class
Week 1 Tuesday 5/23 Thursday 5/25	Lecture 1	The drug development and risk assessment workshop Activities: Lecture; Role-play exercise *Soft skills: Decision-Making* *Inflection points, courage, and public speaking* Group Breakout #1	Assignments: Pre-class drug development knowledge survey; Group Charter Readings; Asynchronous lecture video
Week 2 Tuesday 5/30 Thursday 6/1	Lectures 2, 3 and 4 *Statistical Concepts*	Design of Vaccine and Biologics *Normal Distribution; overview of DOE.* Activities: Lectures; 30 mins of breakout room time in groups *Soft skills: The Perfect CV*	Readings
Week 3 Tuesday 6/6 Thursday 6/8	Lecture 5 and 6 *Statistical Concepts*	Pharmacology and Toxicology *Inferencing and Statistical Significance, Anova* Activities: Case Studies *Soft skills: Self-awareness*	Readings
Week 4 Tuesday 6/13 Thursday 6/15	Lecture 7 and 8 *Statistical Concepts*	Process development and manufacturing *Process capability, Process Stability* Activities: Lectures; 30 mins of breakout room time in groups *Soft skills: Getting things done*	Readings

Week 5 Tuesday 6/20 Thursday 6/22	Lecture 9 and 10 *Statistical Concepts*	Clinical Trials and Regulatory Approval process *Comparability and Specifications* Activities: Lectures *Soft skills: Scientific eminence; Organization of a pharma company*	Assignment: Submit draft/outline for team presentation; Multiple Choice Test Asynchronous lecture video
Week 6 Tuesday 6/27	Final Workshops 11 and 12	Risk Assessment Summary and Conclusions Activities: Team presentations	Assignment: Team Presentations

- Each Session will discuss recent case-studies of failures and successes of products
- The course will include relevant manuscripts, regulatory guidance documents, and statutory requirements.

Assignments Due Dates

Assignment	Due
Group Charter	May 31
Discussion Boards (4)	Contribute by June 27; They open in Weeks 1, 2, 3, and 4
Team Presentation Draft/Outline	June 20 by 4 pm
Multiple Choice Test	June 25 by 6 pm
Team Presentation	June 27 *Presentation materials due by 4 pm, June 27*
Active Participation	Throughout course

Instructor Profile

Co-founder and CEO of SymphonyTech Biologics, a data analytics company focused on engineering solutions to biology. Former Head, R&D, Biocon (Bangalore), leadership positions in Amgen (Thousand Oaks, CA), and Merck (West Point, PA).

Narendra Chirmule has contributed to the development of vaccines and biopharmaceuticals over the past three decades. The drug development experiences include vaccines for cervical cancer [HPV], shingles [Varicella zoster], childhood diarrhea [Rotavirus]), and biopharmaceuticals for osteoporosis (Prolia), rheumatoid arthritis (Enbrel), platelet loss (NPlate), breast cancer (Ogrivi), biosimilar insulins among many others. He has worked on gene therapy using viral vectors at UPenn in the late 1990s. He has published extensively and presented seminars on subjects of immunology, biologics, and vaccines. He has recently written a book on lessons learned from failures in drug development “Good Genes Gone Bad”.

The subject of his Ph.D. was on the development of a leprosy vaccine, from Cancer Research Institute, Mumbai; post-doctoral studies on the pathogenesis of AIDS from Cornell University Medical College-North Shore Hospital, New York; teaching and research as an assistant professor in gene therapy at the University of Pennsylvania, Philadelphia.