Clinical and Regulatory Sciences Certificate Program Curriculum

Winter Trimester 1 (January–April)
Course: Regulation of Pharmaceuticals, Biologics, and Medical Devices

Regulation of Pharmaceuticals, Biologics, and Medical Devices provides a comprehensive introduction to the regulatory landscape and developments processes for medical products in the United States. It spans the full product lifecycle, from initial discovery and development through the regulatory approval and post-market quality assurance across various pathways. The topics offered through this program will equip professionals with the essential tools and knowledge to navigate the complex intersection of regulations, science, and law when developing products and bringing them to the market.

Topics covered in this course include:

Overview of regulatory pathways: drugs, biologics, and medical devices
Overview of Drug Discovery
Fundamentals of the FDA Regulatory Process for Drugs, Biologics, and Medical Devices
Development of Novel Therapies
A Beginner's Guide to Chemistry, Manufacturing, and Controls
Introduction to the American Legal System for Medical Product Professionals
Quality Assurance for Drugs, Biologics, and Medical Devices

Summer Trimester 2 (June–July)
Course: Foundations of Clinical Trials

Foundations of Clinical Trials provides students with a foundational understanding of clinical research. It covers an introduction to the design and conduct of clinical trials, including study design, informed consent, participant recruitment and interactions with the Institutional Review Board (IRB). Foundational statistical concepts relevant to clinical research are introduced alongside best practices in data collection and quality control. The legal framework surrounding medical products in the United States is explored to provide students with real-world examples and view of both scientific and regulatory responsibilities.

Topics covered in this course include:

Introduction to Clinical Trials
Informed Consent, Participant Identification and Recruitment, and Working with the IRB
Introduction to statistical concepts for basic and clinical research and survival analysis
Data Collection and Quality Control
American Legal System and Medical Products

Fall Trimester 3 (October–November)
Course: Next Generation Regulatory Topics

Next Generation Regulatory Topics explores the evolving landscape of the pharmaceutical and healthcare industries, covering topics on emerging technologies and regulatory considerations. Real-world examples are provided to examine how the areas listed below may generate transformative impact on automation and decision-making with regulatory insights.

Topics covered in this course include:

Emerging Innovative Technologies in the Pharmaceutical Industry
Real-World Evidence
Digital Therapeutics and Regulations
Curative Therapies and Manufacturing
Cosmetics
Artificial Intelligence and Precision Medicine

Note: Curriculum and schedule may be modified at the discretion of the institution.