Regulatory Science, Graduate Certificate

This certificate was designed in response to a need in the biotechnology industry for individuals, in particular regulators, to obtain a strong foundation in the science behind good regulatory practice today, specifically in relation to biopharmaceuticals.

Program Requirements

Complete all courses and requirements listed below unless otherwise indicated.

Core Requirements

A grade of C– or higher is required in all courses.

Code	Title	Hours
BIOT 5330		3
BIOT 5500	Introduction to Regulatory Science	3
CHEM 5620	Protein Chemistry	3

Elective

Code	Title	Hours
Complete 3 semester hours from the following:		3
BIOT		
BINF 6308	Bioinformatics Computational Methods 1	
BIOL 5307	Biological Electron Microscopy	
BIOL 5499	Plant Biotechnology	
BIOL 5543	Stem Cells and Regeneration	
BIOL 5549	Microbial Biotechnology	
BIOL 5569	Advanced Microbiology	
BIOL 5573	Medical Microbiology	
BIOL 5581	Biological Imaging	
BIOL 5583	Immunology	
BIOL 6381	Ethics in Biological Research	
BIOL 6399	Dynamics of Microbial Ecology	
BIOT 5040	Fundamentals of Biochemistry for Biotechnology	
BIOT 5050	Organic Chemistry for Biotechnology	
BIOT 5120	Introduction to Biotechnology	
BIOT 5130	Team Skills in Biotechnology	
BIOT 5145	Basic Biotechnology Lab Skills	
BIOT 5219	The Biotechnology Enterprise	
BIOT 5220	The Role of Patents in the Biotechnology Industry, Past and Future	
BIOT 5225	Managing and Leading a Biotechnology Company	
BIOT 5226	Biotechnology Entrepreneurship	
BIOT 5227	Economics and Marketing for Biotechnology Managers	
BIOT 5340	Introduction to Biotherapeutic Approvals	
BIOT 5360	Drug Stability	
BIOT 5400	Scientific Information Management for Biotechnology Managers	
BIOT 5500	Introduction to Regulatory Science	
BIOT 5560	Bioprocess Fundamentals	
BIOT 5631	Cell Culture Processes for Biopharmaceutical Production	
BIOT 5635	Downstream Processes for Biopharmaceutical Production	
BIOT 5640	Drug Product Processes for Biopharmaceuticals	
BIOT 5700	Molecular Interactions of Proteins in Biopharmaceutical Formulations	
BIOT 5810	Cutting-Edge Applications in Molecular Biotechnology	
BIOT 5820	Cellular Therapies	
BIOT 5821	Introduction to Biopharmaceutical Technologies	
BIOT 5850	Higher-Order Structure Analytics	
BIOT 5976	Directed Study	
BIOT 6214	Experimental Design and Biostatistics	
BIOT 6400	Pre-co-op Experience	
BIOT 6500	Professional Development for Co-op	
BIOT 6962	Elective	
BIOT 6964	Co-op Work Experience	
BIOT 7245	Biotechnology Applications Laboratory	
CHEM 5550	Introduction to Glycobiology and Glycoprotein Analysis	
CHEM 5616	Protein Mass Spectrometry	
CHEM 5617	Protein Mass Spectrometry Laboratory	
CHEM 5621	Principles of Chemical Biology for Chemists	
CHEM 5625	Chemistry and Design of Protein Pharmaceuticals	
CHEM 5638	Molecular Modeling	
CHEM 7247	Advances in Nanomaterials	
CHME 7340	Chemical Engineering Kinetics	
ENTR 6200	Enterprise Growth and Innovation	
ENTR 6210	Managing Operations in Early Stage Ventures	
ENTR 6211	Entrepreneurship: Services and Retail Business Creation	
ENTR 6212	Business Planning for New Ventures	
HINF 5105	The American Healthcare System	
HINF 6201	Organizational Behavior, Work Flow Design, and Change Management	
MGMT 6210	Law for Managers and Entrepreneurs	
MGSC 6200	Information Analysis	
NNMD 5270	Introduction to Nanomedicine	
NNMD 5470	Nano/Biomedical Commercialization: Concept to Market	
PHSC 6218	Biomedical Chemical Analysis	
PHSC 6224	Behavioral Pharmacology and Drug Discovery	
PHSC 6226	Imaging in Medicine and Drug Discovery	

PHSC 6290	Biophysical Methods in Drug Discovery
PHSC 7010	Pharmaceutical Sciences Laboratory
TECE 6230	Entrepreneurial Marketing and Selling
TECE 6250	Lean Design and Development

Program Credit/GPA Requirements

12 total semester hours required
Minimum 3.000 GPA required