ADVANCED BIOTHERAPEUTICS MANUFACTURING & REGULATORY AFFAIRS (MS)

Contacts

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Program Description

Thomas Jefferson University, in collaboration with Temple University School of Pharmacy, proudly announces the launch of the new Master of Science (MS) in Advanced Biotherapeutics: Manufacturing & Regulatory Affairs (ABMRA) degree program in the Fall 2022 semester.

While global pharmaceutical companies continue to discover new small-molecule therapeutic agents, an important paradigm shift to large-molecule biopharmaceutical products, as well as individualized medicines (advanced biotherapeutics) has been made possible due to new advances in the biotechnology and bioprocessing communities.

Originally focused on protein replacement and monoclonal antibody-based therapies, the profoundly rapid development and production of new therapeutics like cell and gene therapies (CGT) and COVID-19 vaccines based on messenger-RNA technology has further expanded the market and the need for a skilled and trained workforce. This expansion affects every aspect of drug development, including manufacturing techniques, analytical methods and regulatory processes.

As this is a highly specialized industry, starting salaries are approximately $90,000.

The MS in Advanced Biotherapeutics: Manufacturing & Regulatory Affairs program has been established to address the shortage of individuals trained in regulatory affairs and the manufacturing process of biotherapeutic agents.

Curriculum: 2 Years; 30 Credits

Code	Title	Credits
Thomas Jefferson University Curriculum		
ENGR 609	Bioprocess Engineering for Sci	3
ENGR 621	Intro Biopharm &Biologics Prod	3
ENGR 611	Princ BioPharm Proc Engineerin	3
ENGR 604	Biopharm Process Ops	3
Select at least one of the following:		1.5-3
ENGR 601	Intro Upstream Unit Operations	
ENGR 602	Intro Downstream Unit Ops	
EMGR 613		
ENGR 622	Bio-Therapeutic Formulation	
ENGR 614	Vaccine Formulation	
ENGR 618	Tech & Regulatory Aspects	
ENGR 612	Emerging Therapeutics	
Temple University Curriculum		
5459	Drug Development	3
5515	Biologics / Biosimilars: A Regulatory Overview	3
5575	Global CMCs - Biologics	3
5572	Vaccines: RA and QA Aspects	3
Select at least one of the following:		3
5471	Biotechnology: Bioprocess Basic	
8005	Pharmaceutical Biotechnology	
5451	Statistical Quality Control	
5468	Validation of FUE (Facilities, Utilities and Equipment	
5474	Process Validation	
5479	Advanced Good Manufacturing Practices - Defining "c"	
5492	Production of Sterile Products	
5493	Sterilization Processes	
5501	Development of Sterile Products	
5512	Microbiological Concepts in Pharmaceutical Manufacturing	
5514	Regulatory eSubmissions	
5516	Cleaning Validation	
5538	Clinical Drug Safety and Pharmacovigilance	
5444	Regulatory Intelligence	
5571	Post-Marketing Safety Surveillance	
5574	Quality Systems Management	
5575	Regulatory Sciences: Managing the Guidelines for Quality	
5625	Process Analytical Technology (PAT)	
56	Statistical Design of Experiments (DOE)	
5629	Process Monitoring	
Total Credits		**28.5-30**