Biotechnology Regulatory Affairs Certificate

Degree Offered:	Graduate Certificate in Biotechnology Regulatory Affairs
Program Coordinator:	Kimberly McCall, PhD
Phone:	(205) 934-3209
E-Mail:	biotech@uab.edu
Website:	https://www.uab.edu/shp/cds/biotechnology-regulatory-affairs

Program Information

Program Mission

As the biotechnology industry grows and life science companies mature, there is an increasing demand for a workforce trained in regulatory affairs to ensure that therapeutics, biologics, diagnostics and medical device products progress successfully through the development, manufacturing and marketing processes. Currently, there are thousands of ongoing clinical trials of new drugs, with many of them soon to be approved and ready for full-scale production, resulting in an all-time high demand for individuals with regulatory training.

The Biotechnology Regulatory Affairs certificate program is designed to provide students with targeted training and education in:

- The philosophies and roles of the domestic and international regulatory agencies that oversee drug, biologic, device, and diagnostics development,
- The laws that govern the development, manufacturing and commercial distribution of drugs, biologics and medical devices,
- The analysis of how emerging developments and trends are reshaping drug development and medical device regulation,
- The biological processes and laboratory techniques utilized for the discovery, development and evaluation of therapeutic drugs,
- Major concepts under which clinical trials are designed and run,
- The roles of the U.S. Food and Drug Administration (FDA), Institutional Review Boards, the Code of Federal Regulations and ethical principles,
- The complexities of clinical trial initiation and the issues of site and data management.

Essential Requirements

Fundamental tasks, behaviors, and abilities necessary to successfully complete the requirements of the Program are available upon request from the Biotechnology program office. If you have a disability, but have not contacted Disability Support Services (DSS), please call 934-4205 or visit http://www.uab.edu/students/disability/.

Additional Information

Entry Term:	Fall Semester
Deadline for All Application Materials to be in the Graduate School Office:	February 28 (Early Acceptance); August 1 (Final Acceptance)
Number of Evaluation Forms Required:	None
Entrance Tests:	For international applicants from non-English speaking countries, scores for the Test of English as a Foreign Language (TOEFL) and the Test of Written English (TWE)
Comments:	Financial aid (fellowship, stipend, or assistantship) is not available from the program; scholarship availability is limited; transcript evaluation by WES is required for applicants with foreign university degrees

Contact Information

For detailed information, contact the Department of Clinical and Diagnostic Sciences, Biotechnology Program, UAB School of Health Professions, SHPB 430, 1716 9th Avenue South, Birmingham, Alabama 35294-1212.
Telephone 205-934-3209.
E-mail AskCDS@uab.edu

Graduate Certificate in Biotechnology Regulatory Affairs

Requirements		Hours
BTR 605	Biotechnology Regulatory & Quality Systems	3
BTR 615	Applications of Biological Processes in Drug Development	3
BTR 620	Regulation of Food and Drugs	3
BTR 640	Clinical Development of Drugs, Biologics, Diagnostics, and Medical Devices	3
BTR 690	Clinical Trial Implementation	3
Total Hours		**15**

Courses

BTR 605. Biotechnology Regulatory & Quality Systems. 3 Hours.
U.S. and European Union regulatory affairs frameworks and practices governing the development, approval, manufacturing and surveillance of pharmaceuticals and medical devices, including in vitro diagnostic products. Regulations covered include investigational new drug applications (IND), new drug applications (NDA), good laboratory practices (GLP), good clinical practices (GCP) and current good manufacturing practices (cGMP).

BTR 605. Biotechnology Regulatory & Quality Systems. 3 Hours.
U.S. and European Union regulatory affairs frameworks and practices governing the development, approval, manufacturing and surveillance of pharmaceuticals and medical devices, including in vitro diagnostic products. Regulations covered include investigational new drug applications (IND), new drug applications (NDA), good laboratory practices (GLP), good clinical practices (GCP) and current good manufacturing practices (cGMP).

BTR 615. Applications of Biological Processes in Drug Development. 3 Hours.
Overview of biological processes and laboratory techniques for discovery, development and evaluation of therapeutic drugs. Focus on drug development processes such as gene cloning, culture scale-up, downstream processing, and product purification. Emphasis on theory and application of laboratory methods used in drug development.

BTR 615. Applications of Biological Processes in Drug Development. 3 Hours.
Overview of biological processes and laboratory techniques for discovery, development and evaluation of therapeutic drugs. Focus on drug development processes such as gene cloning, culture scale-up, downstream processing, and product purification. Emphasis on theory and application of laboratory methods used in drug development.

BTR 620. Regulation of Food and Drugs. 3 Hours.
Administrative procedures followed by the FDA; enforcement activities of the FDA, including searches, seizure actions, injunctions, criminal prosecutions, and civil penalties authorized by statutes.

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BTR 640. Clinical Development of Drugs, Biologics, Diagnostics, and Medical Devices. 3 Hours.
Major concepts under which clinical trials are designed and run. Focus on phases of clinical trial development, role of the U.S. Food and Drug Administration, Institutional Review Boards, and the Code of Federal Regulations and ethical principles.

BTR 640. Clinical Development of Drugs, Biologics, Diagnostics, and Medical Devices. 3 Hours.
Major concepts under which clinical trials are designed and run. Focus on phases of clinical trial development, role of the U.S. Food and Drug Administration, Institutional Review Boards, and the Code of Federal Regulations and ethical principles.

BTR 675. Special Topics in Biotechnology Regulatory Affairs. 1-4 Hour.
Exploration of current issues in Biotechnology Regulatory Affairs.

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BTR 690. Clinical Trial Implementation. 3 Hours.
Activities involved in running a clinical trial from study initiation to study close-out. Complex details and issues associated with study initiation, site and data management, preparation of the final report and study close-out.

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