# Clinical and Diagnostic Sciences

The Department of Clinical and Diagnostic Sciences is comprised of academic programs essential to today's healthcare system. Our programs provide training for future health care professionals in a variety of disciplines ranging from the diagnosis of illness and disease, the administration of advanced treatment therapies, to the performance of vital roles in surgical suites and in outpatient and inpatient healthcare settings. Graduates of our programs are well poised for a wide variety of job opportunities due to the outstanding education received at UAB. Current graduate program offerings include:

- · Biomedical and Health Sciences. M.S.
- Biotechnology, M.S., PhD, and Biotechnology Regulatory Affairs Graduate Certificate
- Medical Laboratory Science, M.S.
- · Genetic Counseling, M.S.
- · Health Physics, M.S.
- Industry Genetics and Genomics Graduate Certificate
- Nuclear Medicine and Molecular Imaging Sciences, M.S.
- Physician Assistant Studies, M.S.P.A.S.

## Biotechnology Regulatory Affairs Graduate Certificate

Degree Offered:	Graduate Certificate in Biotechnology Regulatory Affairs
Program Coordinator:	Kimberly McCall, Ph.D.
Phone:	(205) 934-3209
E-Mail:	ASKCDS@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/.

Entry Term	Deadline
Entry Term:	Fall Semester
Deadline for All Application Materials to be in the Graduate School Office:	February 28 (Early Acceptance); August 1 (Final Acceptance)
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; transcript evaluation by WES is required for applicants with foreign university degrees

## Biotechnology Regulatory Affairs Graduate Certificate Curriculum Requirements

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

#### **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

Website <a href="https://www.uab.edu/shp/cds/graduate">https://www.uab.edu/shp/cds/graduate</a>

## Industry Genomics and Genetics Graduate Certificate

Degree Offered:	Graduate Certificate in industry Genetics and Genomics
Program Coordinator:	Alicia Gomes, MS, LCGC
Phone:	205-934-7299
Email:	ASKCDS@uab.edu
Website:	https:\\www.uab.edu\shp\cds \industry-genetics-and-genomics- certificate

#### **Program Information**

The Industry Genetics and Genomics Graduate Certificate is designed to provide advanced skills and education that will prepare graduates for employment in genomic industries that focus on variant data and its interpretation. Advances in the application of genetics and genomics technology in clinical care to support the paradigm shift to personalized medicine has created a need for health care providers and genomics industry professionals to integrate genetics and genomic data with medicine. The certificate is intended to meet the educational needs for the current workforce in medical genetics and clinical laboratories for advanced analytical interpretation and applications related to genomics related topics.

The Industry Genetics and Genomics Certificate is designed to enable students to meet the following learning objectives upon completion of the certificate:

- Integration of advanced knowledge in the clinical applications of genetics and genomic technology to support the workforce demand in the genetics and genomics laboratory industry,
- Effectively utilize of genetics and genomics data in clinical care,
- Assess genomics technologies and determine appropriate use in the clinical genomics industry.
- Effectively integrate genomic and clinical knowledge with the legal, regulatory, marketing, and financial aspects of the clinical genomics industry,
- Effectively apply professional guidelines for genetic variant classification for clinical applications,
- Communicate effectively with clinical genomics laboratory personnel and work in teams within the clinical genomics laboratory, serve as a resource to clinicians to improve the utilization of genomics technology in clinical care, and
- Apply genomic industry standards within a clinical laboratory setting through direct application.

#### **Essential Functions**

The essential functions below extend beyond academic requirements for admission and are standards that all enrolled students must possess in order to successfully complete the graduate certificate.

 Communicate effectively and sensitively with members of the health care team.

- Possess the mental capacity for critical thinking including the ability to assimilate, analyze, synthesize, and integrate concepts and to problem solve in a timely fashion.
- Adapt to changing environments and function effectively under stress.

#### **Admission Requirements**

- Baccalaureate degree from a regionally accredited institution.
- Applicants must meet all requirements of the UAB Graduate School.
- A minimum overall GPA of 3.0 from prior coursework or degree program.
- Pre-requisite coursework: an undergraduate course in genetics

Requirement	Fulfilled By:
Entry Term:	Summer Semester
Application Deadline:	March 1
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)

### Industry Genetics and Genomics Graduate Certificate Curriculum Requirements Graduate Certificate in Industry Genetics & Genomics

IGC 625	Implementation of Variant Interpretation Practices in the Genetics and Genomics Industry		3
IGC 623	Genomic Variant Interpretation Using Clinical Application		3
IGC 622	Clinical Tools for Genomic Variant Curration and Analysis		3
IGC 621	Clinical Genomic Testing Technologies and Methodologies		3
or IGC 624	Genetics and Genomics Diagnostics Regulation		
IGC 620	Applied Advanced Medical Genetics and Genomics		3
Requirements		Hours	

#### **Contact Information**

For detailed information, contact the Program Coordinator, Industry Genetics and Genomics Graduate Certificate, UAB, School of Health Professions, 1716 9th Avenue South, SHPB 444, Birmingham, AL 35294-1212

Telephone 205-975-4CDS (205-975-4237)

E-mail: AskCDS@uab.edu

Website: www.uab.edu/shp/cds/industry-genetics-and-genomics-certificate

#### Courses

#### CDS 505. Professional Skills Development. 1 Hour.

Development of professional behaviors and attitudes required for success in healthcare.

## CDS 560. Foodborne and Waterborne Outbreak Investigations. 3 Hours.

Analysis of different aspects (basic microbiology, epidemiological analysis, surveillance tools, regulations, environmental and laboratory testing) of foodborne and waterborne outbreak investigations.

#### CDS 605. Survival Spanish for Health Professionals. 1 Hour.

Health care professionals will be introduced to basic vocabulary, useful questions and expressions in Spanish needed to communicate in practical health care situations. Students will participate in speaking exercises, dialogue, and role-play activities (field-specific scenarios).

#### CDS 610. Research Design and Statistics. 3 Hours.

This course will introduce the student to clinical research methods and review concepts involved in descriptive and inferential statistics. Topics covered include, overview of the research process, literature review, research hypothesis, research designs, sample selection, measurement methods, descriptive statistics, and inferential statistics.

#### CDS 625. Analysis of Scientific Publications. 3 Hours.

This course is designed to prepare students to critically evaluate medical/ scientific literature and to write a master¿s level papers. The ability to critically analyze scientific publications will be incorporated into the process of making medical decisions.