WHAT IS REGULATORY AFFAIRS?

Regulatory Affairs professionals help make safe and effective healthcare products available worldwide, ensure regulatory compliance, prepare submissions, and participate in quality assurance.

Ivy Tech Community College-Bloomington offers courses that provide essential skills and knowledge to prepare students for regulatory affairs careers which are in growing demand in the life science industry.

Ivy Tech program partners:

FDA · Health Canada · Australian Government Department of Health and Ageing · KFDA · emea · Pmda

ivytech.edu/biotechnology
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IVY TECH COMMUNITY COLLEGE BLOOMINGTON

REGULATORY AFFAIRS

CERTIFICATE PROGRAM FOR LIFE SCIENCES PROFESSIONALS

Ivy Tech Community College-Bloomington

Ivy Tech Community College-Bloomington

REGULATORY AFFAIRS

CERTIFICATE:

Our redesigned regulatory affairs (RA) program is built around the regulatory affairs job skill set standards identified by Community College Consortium for Bioscience Credentials (c3bc). We designed the four RA courses to build the knowledge and skills of our students to be job ready from day one.

All bioscience companies are in need of regulatory affairs professionals for their expertise in deciding the best regulatory pathway for a new or modified medical product, and to serve as the go-to person in a company to interact with the governing regulatory agency, e.g., Food and Drug Administration (FDA). Our program is designed to give students the necessary skills, knowledge, and abilities to make an immediate positive contribution to any regulatory affairs division.

If students take 2 or 3 courses per semester, the entire certificate can be completed within two semesters (1 year). It would be possible for a full-time student to complete the certificate in one semester.

For qualified students through FAFSA, federal student aid is available.

The courses within the certificate will use various types of assessments including exams, assignments, projects, etc. to measure mastery of the course material. When students have successfully completed all six courses, they will be awarded the RA certificate. The four regulatory affairs courses included in this certificate will cover the following topics: FDA structure, Food & Drug Law, selected Code of Federal Regulations (CFR) Title 21 and 45 that govern medicinal products design, development, manufacturing, marketing, and post-marketing surveillance reporting; the application process for drugs (IND &NDA), biologics (BLA), medical devices (IDE, 510K, &PMA), and combo-devices; regulatory documentation requirements for pre-clinical, clinical, and post-marketing; pharmacovigilance; medical device reporting; ISO and ICH standards. Our Regulatory Affairs Certificate program develops our students to be job ready from day one. We also give them Regulatory Affairs Professional Society (RAPS) US RAC type questions through out RA courses to prepare them for the US RAC exam later in their careers.

Certificate required courses:

ENGL 111 English Composition	3 credits
ENGL 211 Technical Writing	3 credits
BIOT 214 Food and Drug Law	3 credits
BIOT 215 Clinical Trials	3 credits
BIOT 216 Risk Management	3 credits
BIOT 218 Product Life Cycle	3 credits
Total	18 credits

REGULATORY AFFAIRS COURSES:

Four sequential regulatory affairs (RA) courses, each designed to build on the previous course in the suite:

1. **BIOT 214 Food and Drug Law (online) (3 CREDITS):** Covers US Food and Drug law, Code of Federal Regulations (CFR) that govern the total product life cycle of medical and medicinal products in the US.

2. **BIOT 215 Clinical Trials (online) (3 CREDITS):** Covers CFR and standards that govern clinical research that collects data to support effectiveness and safety of medical and medicinal products in the US. Learning is applied through the use of 2 FDA Case Studies.

3. **BIOT 216 Risk Management of Drugs and Medical Devices (3 CREDITS):** Covers Risk Management CFRs and standards that govern the total product life cycle of medical and medicinal products in the US and Globally. The learning is applied through 4 FDA Case Studies.

4. **BIOT 218 Total Product Life Cycle (3 CREDITS):** Covers Total Product Life Cycle (TPLC). Students will learn in depth about TPLC, CFRs, and standards that govern the TPLC of medical and medicinal products in the US and Globally. Students will use FDA Case Studies as a capstone project to create an IDE or IND or NDA or BLA or 510k or PMA.

Enroll today!

Apply online at **ivytech.edu/apply-now** or visit us on campus!

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Monday–Thursday (8am – 6pm) Friday (9am-5pm)
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FOR QUESTIONS ABOUT REGULATORY AFFAIRS OR BIOTECHNOLOGY, CONTACT:

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