

REGULATORY AFFAIRS

CERTIFICATE PROGRAM FOR LIFE SCIENCES PROFESSIONALS

Ivy Tech Community College Bloomington ivytech.edu/bloomington

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. 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). 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.

Required Courses:

ENGL 111: **English Composition** (3 credits)

ENGL 211: **Technical Writing** (3 credits)

BIOT 214: **Food and Drug Law** (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.

BIOT 215: **Clinical Trials** (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.

BIOT 216: **Risk Management** (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.

BIOT 218: **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. This course should be completed last.

Total 18 credits

For questions about our regulatory affairs or biotechnology programs, contact:

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Ivy Tech RA Certificate:

This certificate can be completed in one year and is financial aid eligible. Certificate courses are offered online, allowing students scheduling flexibility, the ability to complete the courses from anywhere, and the opportunity to work on their certificate while employed. Transfer credit may be accepted for students already completing some college. Students completing the certificate are prepared to take the US RAC exam later in their careers through the use of Regulatory Affairs Professional Society (RAPS) US RAC type questions. This certificate prepares students to hit the ground running from their first day on the job. Don't wait - advance your career today with the Regulatory Affairs Certificate from Ivy Tech!

More: our Regulatory Affairs (RA) certificate is designed to give students the necessary skills, knowledge, and abilities to make an immediate positive contribution to any regulatory affairs division. The regulatory affairs courses were developed using the regulatory affairs job skill set standards identified by Community College Consortium for Bioscience Credentials (c3bc)*. This national group spent a number of years working with industry partners to identify the skills and knowledge required for individuals in this field. Identified topics covered in this certificate include: 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 (Investigational New Drug (IND) & New Drug Application (NDA), Biologics License Application (BLA), medical devices (Investigational Device Exemption (IDE), Premarket Notification (510K), & Premarket Application (PMA)), and combo-devices; regulatory documentation requirements for pre-clinical, clinical, and post-marketing; pharmacovigilance; medical device reporting; ISO and ICH standards.

*<https://www.skillscommons.org/bitstream/handle/taaccct/8777/c3bc%20Medical%20Device%20Skill%20Standards%20brochure.pdf?sequence=1&isAllowed=y>

Enroll today!

Apply online at ivytech.edu/apply

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For more information, email
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