QUALITY ASSURANCE AND REGULATORY AFFAIRS GRADUATE CERTIFICATE

The Quality Assurance and Regulatory Affairs (QA/RA) Certificate Program is an interdisciplinary program designed to upskill or reskill aspiring or working professionals interested in expanding their knowledge of how to bring a medical product to market including regulations, quality management systems, risk management, compliance, auditing and inspection metrics, design controls, and best practices. QA/RA employees are critical to designing, running, and reporting the testing required to show medical products comply with quality standards and regulations at each stage of the product lifecycle. QA/RA positions lead hiring demands in biotech, however, nearly 32% of companies surveyed ranked QA/RA openings as the most difficult roles to fill, providing a clear opportunity for upskilling and reskilling.

To meet employer needs, the QA/RA certificate will include access to career-enhancing experiential learning opportunities and mentorship. A partnership including the Colorado Bioscience Institute, and 16+ industry leaders will facilitate an innovative approach to providing participants with opportunities to increase economic mobility in high-demand, high-skill, high-wage occupations. The four courses that make up the certificate will be delivered online and asynchronously with a 3-day, in-person experience hosted by local Denver Metro area companies in the final capstone class. The curriculum is customized with input from our Advisory Board members to meet the QA/RA needs of the local bioscience community. The program provides specialized job training as well as mentorship and job matching activities offered by the Institute.

General Requirements

Students must satisfy all requirements as outlined below and by the department offering the certificate.

Certificate Requirements

A total of 12 credit hours will be completed over one academic year.

Code	Title	Hours
Students must complete the following course:		**3**
BIOE 5054	Introduction to Regulatory Affairs	3
BIOE 5055	Introduction to Quality Assurance	3
BIOE 5094	Post-Market Quality Assurance and Regulatory Affairs	3
BIOE 5095	Quality Assurance Product Lifecycle Capstone	3
Total Hours		**15**

Following completion of this program learners will have the following skills:

1. **Quality Assurance**: demonstrate comprehensive knowledge and practical skills in quality management systems, risk assessments, and design controls. Students will develop proficiency in conducting risk assessments, identifying and implementing Corrective and Preventive Actions (CAPA), and preparing for audits and regulatory inspections.
2. **Regulatory Affairs**: demonstrate a thorough understanding of the regulatory landscape governing medical products, enabling them to navigate the complex processes involved in the design, testing, approval, and sale of medical devices, drugs, biologics, biosimilars, cell- and gene-based therapies, and combination products. Students will learn to classify medical products according to FDA-defined risk levels, recommend appropriate regulatory pathways, and create mock regulatory submission packages.