

QUALITY ASSURANCE AND REGULATORY AFFAIRS IN BIOTECHNOLOGY, CAPSTONE CERTIFICATE

Biotechnology companies are always looking for talented professionals who not only understand *what* but more importantly *how* and *why* they fit into their company's global plan of product development, manufacturing and marketing. This capstone certificate is designed to expand upon *how* and *why* quality assurance and regulatory affairs are important drivers to any successful team and product launch.

This 100% online program is designed to give talented professionals a competitive edge. With just 9 credits, this certificate program can be completed in 1 year.

You will focus on developing practical and professional quality assurance and regulatory affairs skills needed when working within diverse teams and government agencies. The program is designed in cooperation with biotechnology industry experts, using real-world problems, to prepare you to investigate *why* problems occur and *how* to develop strategies to solve them.

HOW TO GET IN

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The Capstone Certificate in Quality Assurance and Regulatory Affairs in Biotechnology is intended for University Special (non-degree seeking) students who hold a bachelor's degree or equivalent. It is designed to "cap off" the undergraduate educational experience or to offer a focused professionally oriented educational experience.

ADMISSIONS

Admission requirements for the Capstone Certificate in Quality Assurance and Regulatory Affairs in Biotechnology are:

- A bachelor's degree
- A 3.0 undergraduate GPA
- Completion of one general biology course with laboratory at the undergraduate level

DEADLINES

The Capstone Certificate in Quality Assurance and Regulatory Affairs in Biotechnology accepts applications year-round.

- Applications are accepted for Fall through July 15
- Applications are accepted for Spring through December 15
- Applications are accepted for Summer through April 15

APPLICATION

Application requirements include:

- Statement of purpose
- Resume/CV
- Transcripts from all post-secondary institutions. Unofficial transcripts may be submitted with the application; official transcripts will be required upon admission to the program.
- Two letters of recommendation
- Submit evidence of English language proficiency, if applicable. The required proficiency scores are: TOEFL IBT 92, PBT 580; or IELTS 7.0

Please refer to the program website for the application.

Adult Career and Special Student Services (ACSSS) is the admitting office for all University Special students, including capstone certificate students. However, the department offering the capstone certificate program makes the final admission decision upon review of all applicant materials.

REQUIREMENTS

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REQUIRED COURSES

Complete 9 credits with the following courses.

| Code | Title | Credits |
|--------------|---|---------|
| BIOMDSCI 720 | Survey of Quality Assurance and Regulatory Affairs in Biotechnology | 3 |
| BIOMDSCI 721 | Topics in Quality Assurance and Regulatory Affairs in Biotechnology | 3 |
| BIOMDSCI 722 | Leadership in Quality Assurance and Regulatory Affairs in Biotechnology | 3 |

Total Credits 9

MINIMUM REQUIREMENTS FOR CAPSTONE CERTIFICATE COMPLETION

- Students must earn a minimum grade of C in each course used to meet Capstone Certificate requirements.
- Courses in which a student elects the pass/fail or audit option will not count toward completion of Capstone Certificate requirements.
- All of the Capstone Certificate credits must be earned "in residence" (which includes on campus and distance-delivered courses) at UW-Madison.
- All of the Capstone Certificate credits must be earned while enrolled in the Capstone Certificate program.

Individual Capstone Certificate programs may have additional requirements for completion, which will be listed above as/if applicable.

LEARNING OUTCOMES

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1. Demonstrate effective listening, written, verbal, and nonverbal communication skills that recognize, foster, and apply principles of ethical and professional conduct while working within diverse teams.
2. Describe local, national, and international agencies involved in ensuring quality, safety, and regulatory practice within the biotechnology industry.
3. Integrate how testing and manufacturing biotechnology products rely upon quality assurance and regulatory affairs requirements.
4. Analyze product development and project management innovations in line with quality assurance standards and regulatory requirements.
5. Apply the use of quality and regulatory strategies to achieve organizational objectives.