



UNIVERSITY OF
GEORGIA

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University Council

October 14, 2022

UNIVERSITY CURRICULUM COMMITTEE – 2022-2023

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Undergraduate Student Representative – Kate Lindgren

Graduate Student Representative – Yehia Abdelsamad

Dear Colleagues:

The attached proposal from the College of Pharmacy to offer a new Graduate Certificate in Chemistry, Manufacturing, and Controls will be an agenda item for the October 21, 2022, Full University Curriculum Committee meeting.

Sincerely,

Susan Sanchez, Chair

University Curriculum Committee

cc: Provost S. Jack Hu
Dr. Marisa Pagnattaro

PROPOSAL FOR AN ONLINE PROGRAM

Date: May 11, 2022

College/School: College of Pharmacy

Department/Division: International Biomedical Regulatory Sciences (IBRS)

Certificate Title: Online Graduate Certificate in Chemistry, Manufacturing, and Controls

Note: This certificate will only be offered online.

Will any approved areas of emphasis be offered under this major? No

CIP: 51201000

Proposed Effective Date: Spring 2023

Approved 4/18/2022 – College of Pharmacy Undergraduate and Graduate Education and Curriculum Committee. Vote: 11 Yea – 0 Nay

Approved 5/4/2022 – College of Pharmacy Faculty Vote: 46 Yea – 0 Nay

Proposal Abstract:

The University of Georgia (UGA) International Biomedical Regulatory Sciences (IBRS) program's objective is designed to increase knowledge in the regulatory framework and to develop competencies in regulatory (including sub-categories), clinical, and government processes that are critical in helping assure the development, manufacturing, and marketing of safe and effective medical products around the world. The assessments and evaluations during the course and project work enhance the competencies, such as critical thinking, problem solving, communication, and strategic thinking, needed to be successful in the medical industry.

Regulatory Affairs (RA) professionals, a collective term used for all specializations, are employed in industry, government, and academia, and provide a range of services related to the regulation, development, manufacturing, and marketing of pharmaceuticals, medical devices, *in vitro* diagnostics, biologics, biotechnology, nutritional products, cosmetics, and veterinary products. There are many specialized areas within the regulatory science and this proposed certificate will address one of the areas.

The UGA College of Pharmacy proposes an Online Graduate Certificate in Chemistry, Manufacturing, and Controls (CMC) to allow students to gain specialized knowledge and regulatory expertise for working in the medical products industry. The Online Graduate Certificate in Chemistry, Manufacturing, and Controls curriculum will include a total of 14 graduate-level credit hours and will cover a Good Manufacturing Practice course, a Process Control and Process Validation course, a Quality Control and Quality Assurance course, and a course on submission requirements for the quality module to regulatory authorities. These courses are essential for workforce preparedness for a CMC professional.

Roles and Responsibilities of Chemistry, Manufacturing, and Controls (CMC)

Professionals include:

- Manage all aspects related to drug substance (API) and drug product including changes in manufacturing, testing, and stability
- Member of product development project teams and commercial product stewardship teams
- Liaise with regulatory authorities to communicate and negotiate submissions and approvals
- Support management in due diligences and strategic business activities related to the product development and acquisition
- Support the quality group during inspections
- Ensure compliance with GMP & regulations

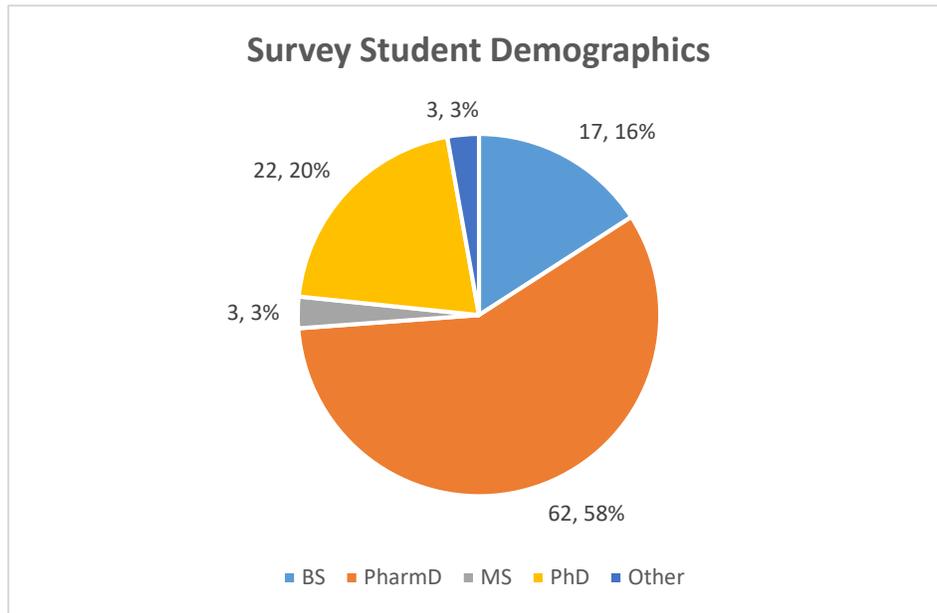
1. Assessment

The University of Georgia College of Pharmacy offers both a Graduate Certificate in Pharmaceutical and Biomedical Regulatory Affairs and a Master of Science (M.S.) degree in Pharmacy with an emphasis in Pharmaceutical and Biomedical Regulatory Affairs. The graduate certificate provides a foundational core for individuals who wish to transition into entry-level regulatory affairs positions. These graduate education offerings are geared for both working professionals and traditional students using an online learning environment designed to allow individual flexibility yet provide a standard academic structure to advance student learning from one semester to the next.

Currently, there is no standard undergraduate or terminal degree for Regulatory Affairs Professionals; however, according to the Regulatory Professional Society (RAPS), more than half have an advanced credential. With the growth of the discipline of regulatory affairs, companies continually need new and increasingly sophisticated talent and there is a growing expectation for advanced education and credentialing. Faculty anticipate that the graduate certificates and master's degree offered by the IBRS program will support the expected need in advanced education and credentialing.

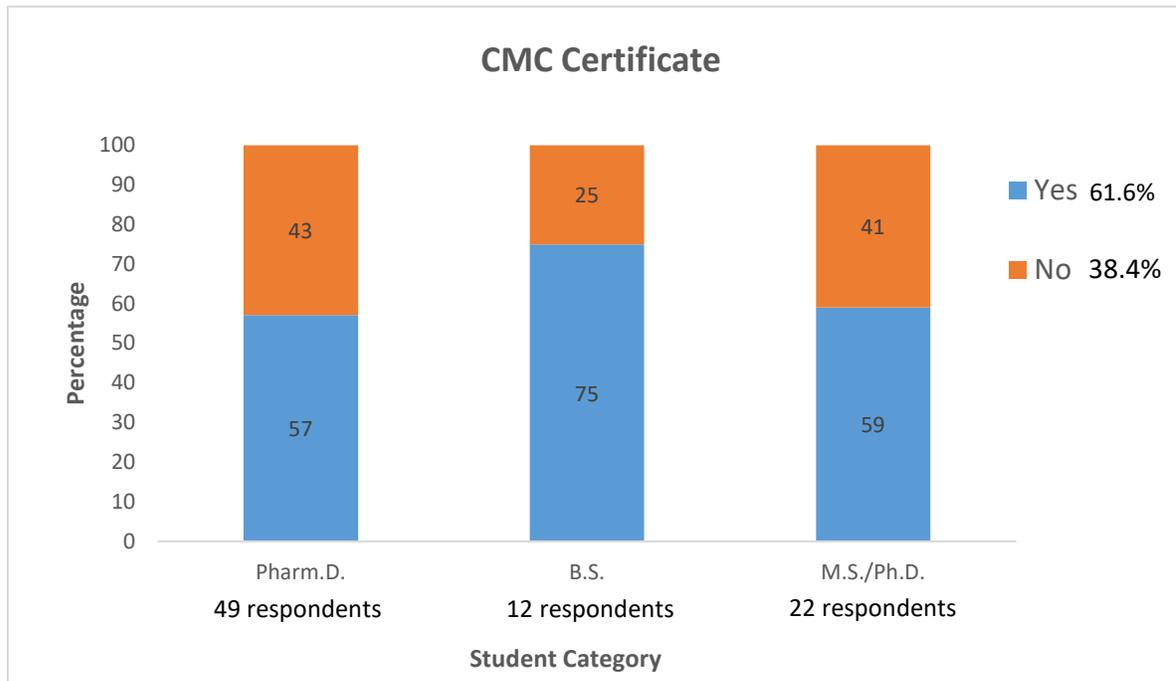
A needs assessment demonstrating that there is a sufficient pool of qualified applicants was evaluated within the College of Pharmacy.

Fig.1: Demographics of Participants



“Other” includes non-students, such as faculty and advisory committee members

Fig. 2: Student Feedback on Interest to Obtain a CMC Certificate



To assess the interest of the College of Pharmacy students in obtaining a CMC graduate certificate as part of their educational program at UGA, an anonymous Qualtrics survey was sent to all students within the College of Pharmacy. More than 100 students took the survey. Overall, 62% percent of the students that participated in the survey were interested in obtaining the certificate. Most respondents in the B.S. curriculum (70%), Pharm.D. program (57%), and graduate program (59%) were interested in pursuing a CMC certificate. This assessment clearly supports that there is a sufficient pool of qualified students with interest in obtaining the CMC graduate certificate that could be adjacent to their current academic aspirations.

2. Admission Requirements

All requirements for admission to the Online Graduate Certificate in Chemistry, Manufacturing, and Controls will be the same as those for the other graduate certificates currently offered by IBRS, as outlined below:

Admission Criteria:

- A Bachelor's degree or higher is required. Preference will be given if applicant's degree is in sciences, healthcare, or engineering.
- The minimum undergraduate GPA standard for admission to the Graduate School at the University of Georgia for applicants who do not have a prior graduate degree is 3.0.
- Preference will be given if an applicant is employed in the pharmaceutical, medical device, biotechnology industries, or related field.
- Applicants must also apply to the UGA Graduate School.
- Applicants are encouraged to include a letter of support in their application materials.
- Applicants must include a statement of purpose, of no more than 3 pages, that addresses why they wish to enroll in this program.
- TOEFL scores are required for international applicants.
- Applicants must have daily access to a computer with required specifications and a working knowledge of the Microsoft Windows Operating System, Microsoft Office Suite (including MS Word, Excel), Internet Explorer, and Adobe Reader.

Note: Some of these requirements may be waived for students who want to pursue a graduate certificate while currently enrolled in another University graduate or terminal degree program.

International Applicants:

International students are encouraged to apply to the Regulatory Sciences programs. At this time, however, the Regulatory Sciences Department does not offer visa sponsorship or departmental assistantships as this is an online program.

Deadlines for International Applicants

All application materials including TOEFL scores must be received as follows: For Fall Semester, April 15; and for Spring Semester, October 15.

English Proficiency

Applicants whose primary language is not English must submit official TOEFL or IELTS scores that are not more than two years old.

Minimum TOEFL score requirement: overall score of 80 with at least 20 on speaking and writing

Minimum IELTS score requirement: overall bandwidth of 6.5, with no single band (score) below 6.0

TOEFL and IELTS scores should be reported electronically by the testing agency.

3. Program Content

The learning objective of the Online Graduate Certificate in Chemistry, Manufacturing, and Controls is to prepare the student for the working in the highly regulated medical product industry in the specialized area of CMC.

Upon completion of the certificate, students should be able to:

- Be knowledgeable in laws, regulations and guidelines related to good manufacturing practices (GMP) and quality by design (QbD) principles
- Outline the product development process for medical products
- Locate information necessary to their role as CMC professionals
- Describe the pre-approval and approval CMC requirements for new products, including the maintenance of those products after marketing
- Be familiar with the complex interaction between regulatory requirements and development processes for new products
- Be knowledgeable of the key aspects of the manufacturing process as it relates to regulatory review and inspection policies.
- Apply established principles of submission processes that regulatory authorities use to evaluate new medical product applications

Below is the outline of the curriculum for **the Online Graduate Certificate in Chemistry, Manufacturing, and Controls: (14 semester hours)**

- **PHAR 6030E, Current Good Manufacturing Practices (4 hours):** Current Good Manufacturing Practice regulations implemented to assure quality and safety of marketed products. Inspection techniques used by the FDA to ensure best practices within a manufacturers organization, personnel, facilities, equipment, control systems, production, process controls, laboratory procedures and records, and clinical testing.
- **PHAR 6100E, Quality Control and Quality Assurance (3 hours):** Principles to understand and establish quality control/quality assurance processes, procedures, and compliance reports for the production of biologics, drugs, and devices.
- **PHAR 6120E, Process Control and Validation (3 hours):** Broad coverage of validation and control processes for the pharmaceutical, biologic, and medical device industries.
- **PHAR 6160E, Chemistry, Manufacturing, and Controls (4 hours):** Foundational knowledge of chemistry manufacturing and controls for pharmaceuticals, biologics, and biotechnology products. Emphasis on active ingredient development, product

development, preparing new product applications worldwide, and maintaining compliance of products post-approval.

The certificate will be assessed as per the established goals and criteria for quality by the College of Pharmacy. These include determination of the effectiveness by measuring the success of students earning the certificate. These may include:

- Longitudinal review of graduates, their employment status, and salaries.
- Longitudinal enrollment numbers including statistics on the demographic makeup and academic qualifications of those students who enroll.
- Participation in formal exit surveys to assess students' experiences and perceptions of the program.

4. Student Support Services/Advising

Each student will have access to all the College of Pharmacy learning and student support services to ensure full participation in the learning experience. Services include academic advising or technology support, career planning, and disability services.

In general, students will be advised by the Assistant Director for the IBRS program. The Assistant Director will be available for meetings with the students. Students currently enrolled in another graduate or terminal degree program will also be advised by their regular advisor.

5. Resident Requirements

Residence requirements will be identical to those established for other certificate programs within IBRS. The program is open to both degree-seeking and non-degree students. Applicants must meet the minimum Graduate School standards and non-degree students are required to apply through the Graduate School application. All enrolled students will be subject to UGA's residency requirements.

6. Program Management

The Online Graduate Certificate in Chemistry, Manufacturing, and Controls will be administered by the Program Director of the IBRS program, in collaboration with the Assistant Director of the IBRS program. The courses will be instructed by part-time and adjunct faculty who already teach the courses listed above for other programs currently offered by IBRS and supported by the same course coordinators. The certificate can be completed at the learner's pace, so there is no time limit, except within the graduate school's timeline requirements of six years before courses begin to expire.

7. Library and Laboratory Resources

Students will be provided with learning resources within the course, including textbooks if appropriate, and will also include access to regulatory authority websites such as FDA or EMA, published papers, and presentations to supplement their learnings.

8. Budget

No additional fiscal investment is anticipated as a result of creating this graduate certificate. It is anticipated to enroll about 10+ students. All academic courses identified in the program of

study for the proposed certificate are currently being offered as required or elective courses in the current Area of Emphasis in Pharmaceutical and Biomedical Regulatory Affairs under Pharmacy (M.S.). Faculty anticipate a gradual increase in student enrollment. If the enrollment goes up, additional faculty or staff resources may be necessary for the administration of the program and timely graduation of the students. At that time, a fiscal evaluation will be conducted to determine future resource requirements and the additional resources are anticipated to be supported by student tuition and fees.

9. Program Costs Assessed to Students

Standard graduate student costs will be utilized for the program.

10. E-Rate

An e-rate of \$350, for a total of \$720/credit hour, will be charged. This mirrors the rate for the Graduate Certificate in International Biomedical Regulatory Sciences.

Documentation of Approval and Notification

Proposal: Online Graduate Certificate in Chemistry, Manufacturing, and Controls

College: College of Pharmacy

Department: International Biomedical Regulatory Sciences

Proposed Effective Term: Spring 2023

Approvals:

- College of Pharmacy Dean, Dr. Kelly Smith, 5/11/22
- Graduate School Associate Dean, Dr. Anne Shaffer, 9/22/22