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University Council

October 14, 2022

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Dear Colleagues:

The attached proposal from the College of Pharmacy to offer a new Graduate Certificate in Drug Safety and Pharmacovigilance 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 DRUG SAFETY & PHARMACOVIGILANCE GRADUATE CERTIFICATE PROGRAM

Date: May 11, 2022

College/School: College of Pharmacy

Department/Division: International Biomedical Regulatory Sciences (IBRS)

Graduate Certificate Title: Online Graduate Certificate in Drug Safety and Pharmacovigilance
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: 48 Yea – 0 Nay

Proposal Abstract:
The University of Georgia (UGA) International Biomedical Regulatory Sciences (IBRS) program's objective is 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 products 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 sciences and this proposed certificate will address one of the areas.

The UGA College of Pharmacy proposes an Online Graduate Certificate in Drug Safety and Pharmacovigilance (DS & PV) to allow students to gain specialized knowledge and regulatory expertise for working in the medical industry. The Online Graduate Certificate in Drug Safety and Pharmacovigilance curriculum will include a total of 17 credit hours and will cover an overview of regulatory requirements for medical products, an overview of bioethics for research and development of medical products, biostatistics, good clinical practice, and an overview of drug safety requirement throughout the product lifecycle from development to post-marketing.

These courses are essential for workforce preparedness for a drug safety and Pharmacovigilance professional.

Roles and Responsibilities of Drug Safety and Pharmacovigilance Professionals include:

- Manage all aspects related to drug safety as members of product development project teams
- Manage all aspects of Pharmacovigilance as members of commercial product stewardship teams
- Liaise with regulatory authorities to communicate and negotiate study protocols and label language related to safety
- Support management in due diligences and strategic business activities
- Work with IRBs and data monitoring boards
- Specialize in FDA's adverse event reporting systems and signal detection approaches for safety

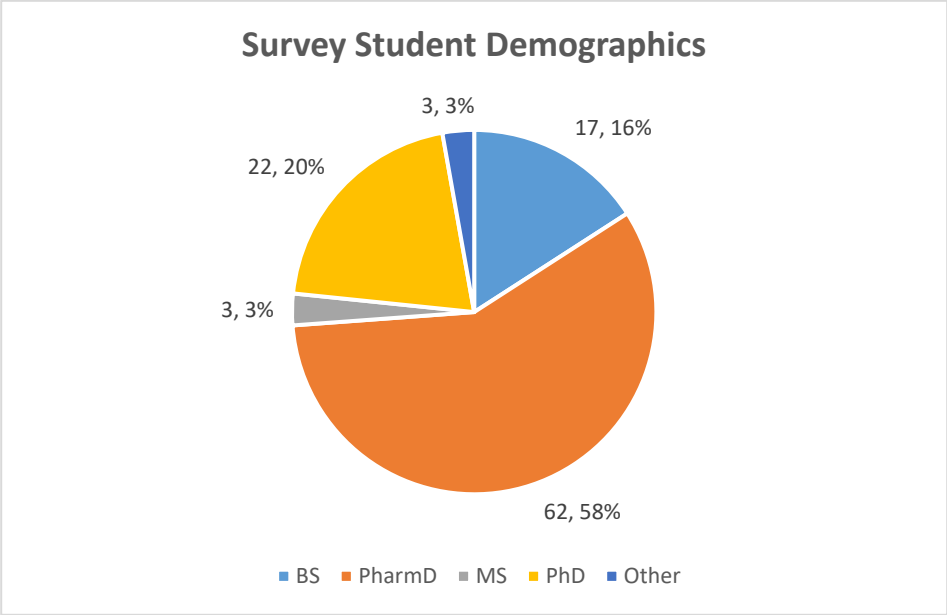
1. Assessment

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 sciences, 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 advance education and credentialing.

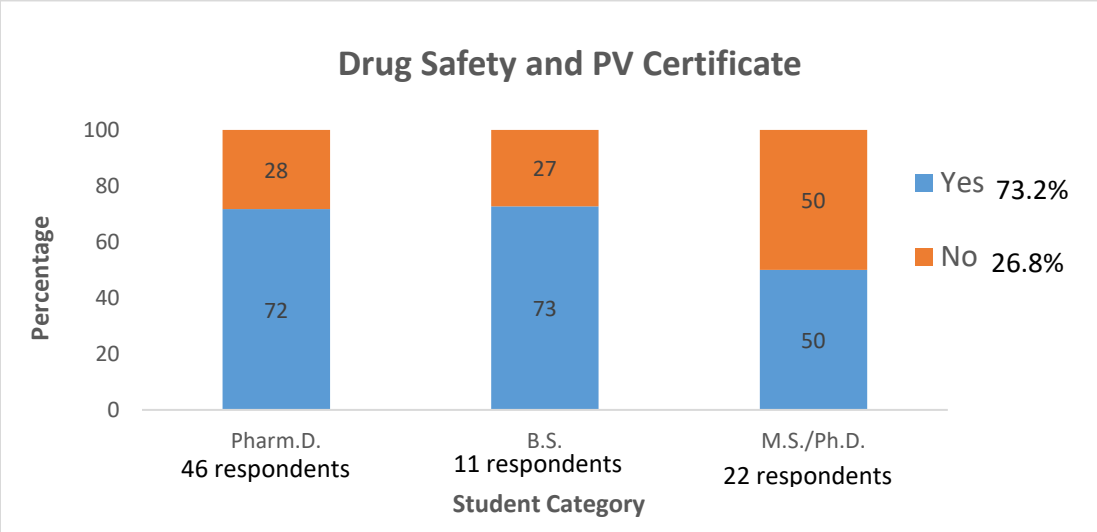
A needs assessment demonstrating that there is a sufficient pool of qualified applicants was evaluated within the College of Pharmacy.

Fig.1: Demographics of Participants



"Other" includes non-students like faculty and advisory committee members

Fig. 2: Student Feedback on Interest to Obtain a Drug Safety and PV Certificate



To assess the interest of the College of Pharmacy students in obtaining an Online Graduate Certificate in Drug Safety and Pharmacovigilance 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, 73% percent of the students that participated in the survey were interested in obtaining the certificate. Most respondents in the B.S. curriculum and Pharm.D. program (72% and 73%, respectively) and 50% of the graduate students were interested in pursuing the certificate. This assessment clearly supports that there is a sufficient pool of qualified students with interest in obtaining the Drug Safety and Pharmacovigilance graduate certificate that could be adjacent to their current academic aspirations.

2. Admission Requirements

All requirements for admission to the Online Graduate Certificate in Drug Safety and Pharmacovigilance 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 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 Drug Safety and Pharmacovigilance is to prepare the student for the working in the highly regulated medical industry in the specialized area of Drug Safety or Pharmacovigilance.

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

- Be knowledgeable in laws, regulations, and guidelines related to drug safety and pharmacovigilance principles
- Outline the product development process for medical products
- Locate information necessary in their role as drug safety and pharmacovigilance professionals
- Describe the pre-approval and approval requirements for safety of new products, including the maintenance of those products after marketing through pharmacovigilance systems
- Familiar with the complex interaction between regulatory requirements and development processes for new products
- Apply established principles of submission processes that regulatory authorities use to evaluate new medical product applications
- Familiar with safety signal monitoring and detection technologies

Below is the outline of the curriculum for **Drug Safety and Pharmacovigilance (17 semester hours):**

- **PHAR 6010E, Pharmaceutical, Biotechnology, and Device Industries (4 hours):** Foundational knowledge of the pharmaceutical, biotechnology, and medical device industries. Emphasis on organization, product development, new product applications, and commercialization-associated activities, including drug discovery, chemical synthesis, laboratory practices, quality assurance, regulatory affairs, manufacturing, design control, marketing, and post-marketing surveillance.

- **PHAR 6140E, Overview of Drug Safety Throughout Medical Product Lifecycle (4 hours):** Integration of foundational knowledge of clinical drug safety and pharmacovigilance requirements, combined with real-world application of these concepts. Emphasis on practical interpretation and application of relevant regulations and methods for optimizing the use of evolving technologies.

- **PHAR 6310, Good Clinical Practice Regulations for Drugs, Biologic Products, and Medical Devices (3 hours):** Review of the Good Clinical Practices regulations that apply

to conducting clinical trials for drugs, biologic products, and medical devices involving human subjects. Knowledge and understanding of the regulations and compliance challenges associated with conducting human clinical studies from a regulatory affairs perspective.

- **PHAR 7100E, Biostatistical Applications for Pharmaceutical & Biotechnology Industries (3 hours):** Biostatistical issues regarding the introduction and regulatory agency (FDA) approval of new drugs, biologics, medical devices, and combination products, and their post-market surveillance are considered. Data quality assurance, experimental design, clinical trials, power and sample size determination, uncertainty assessment, regression, survival analysis, and variable and model selection are considered.

- **PHRM(HPAM) 7230E, Ethical Issues in Research (3 hours):** Ethics of research in animals and human subjects, fraud, scientific misconduct, and conflicts of interest.

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 process. All enrolled students will be subject to UGA’s residency requirements.

6. Program Management

The Online Graduate Certificate in Drug Safety and Pharmacovigilance 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 Drug Safety and Pharmacovigilance

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