Proposal to

Transfer Administration of the Graduate Certificate in Regulatory and Quality Compliance

from

Department of Industrial and Physical Pharmacy in the School of Pharmacy

to

Department of Technology Leadership & Innovation in the College of Technology

with the new title of Biotechnology Quality and Regulatory Compliance

Campus:
Purdue University West Lafayette

Request received in the Graduate School:
4/24/14

Received ICHE Approval and Code Assigned in Banner
8/12/14
GRADUATE CERTIFICATE PROGRAM PROPOSAL

BIOTECHNOLOGY QUALITY AND REGULATORY COMPLIANCE

Graduate Certificate Program Offered by

Department of Technology Leadership & Innovation
College of Technology

West Lafayette Campus

Proposed Date of Initiation: Fall Semester 2014

Certificate Type: Graduate

Methods of Delivery: On-campus and distance or combination

Suggested CIP Code: 26.1201
B. OVERVIEW

The mission and purpose of the Biotechnology Quality and Regulatory Compliance graduate certificate program is to provide graduate students introductory graduate level education in the important aspects of drug development and manufacturing within the context of regulatory compliance and quality assurance. This certificate program will provide a "continuing education" program for people in the pharma industry and people in quality control and quality assurance who are seeking ways to improve their skills or differentiate themselves from their counterparts. A version of this program offered previously in IPPH has been highly successful in educating over 200 graduates, most of which were non-degree seeking students. The experience in IPPH is that about 15% of the certificate students choose to continue to receive a MS degree in the companion program.

The certificate program will provide basic graduate level education for employment in regulatory affairs, quality control, and quality assurance departments in large corporations, start-up companies, innovative medical products companies, or in analogous departments in academic institutions.

The rationale of the certificate program is aligned to the overall purpose of this basic graduate level program. High quality within regulatory environments including compliance (QA/QC) is essential for the viability of American industry, and academia as well. Almost daily, exciting examples of accomplishments and examples showing the downside of poor quality or compliance appear. In many cases poor quality leads to organizations closed, fines levied, careers affected, public images besmirched, and credibility lost. Interestingly, within industry, staff for QRC, QC and QA are most often recruited from operations areas; few have any formal education on the core principles of their new professions and most, if not all, have no detailed knowledge on specific skills for the job. In fact, only a few formal education programs in Biotechnology Quality and Regulatory Compliance exist in America.

Evidence of the need for the Biotechnology Quality and Regulatory Compliance graduate certificate program has come from the significant enrollment in our initial offerings and from industry reports including an important Biocrossroads report calling for increased education in this area within the State of Indiana.

Relationship of Certificate Program to TLI Academic Plan

This program requires three complementary areas of expertise. First, it requires expertise in Biochemistry which will be provided by Dr. Kari Clase a TLI professor who has an established research and academic track record at Purdue through her collaborative work with Dr. Steve Byrn in Pharmacy, and with both science and engineering faculty in Bindley Bioscience Center and the Department of Agricultural and Biological Engineering (ABE). Second, it requires expertise in Quality and Regulatory Systems, a core expertise among most faculty members in TLI. Third is expertise in Pharmacy. Dr. Stephen Byrn of IPPH will continue to participate in the program and is very experienced in this area.
Through the efforts of Dr. Kari Clase and other faculty, including those with strong regulatory and quality background in TLI, we believe the new certificate program concentration has content that will make it more relevant and will continue to meet an important need both globally and within the State of Indiana.

No contracts with any non-accredited entity are required to offer this program. Attached is also a completed Purdue University Gainful Employment (GE) Certificate Worksheet. Students who complete this certificate would not qualify or be eligible for any license or certifications. At the current time no license or certification is required to enter the field.

C. ADMISSIONS REQUIREMENTS

The admissions requirements are the same as those of the graduate school which include a bachelor’s degree, a GPA> 3.0/4.0, and acceptable TOFEL/IELTS scores for applicants whose native language is not English. In addition students must also have completed at least a Bachelor’s degree from an accredited institution in a STEM field to be eligible to enroll in the Certificate Program.

Students admitted to the MS degree in TLI degree with a concentration in Biotechnology Innovation and Regulatory Science are eligible to earn the certificate. The certificate coursework is highly complementary and would enhance the skills and capabilities of students seeking the MS degree. Students enrolled in other STEM majors are also eligible to earn the certificate.

D. COMPLETION REQUIREMENTS

The total number of credit hours required is 12. All credits must be taken for a grade. A grade of B or better is required to receive the certificate.

Four courses are required for the certificate program (12 credit hours), of which two courses may be credited to the MS degree in the event that the student opts to continue in the MS degree in TLI program. The courses required for the certificate are:

<table>
<thead>
<tr>
<th>Course</th>
<th>Title</th>
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<tbody>
<tr>
<td>TLI 521</td>
<td>Drug Development <em>(transferred from IPPH 521)</em></td>
</tr>
<tr>
<td>TLI 522</td>
<td>Good Regulatory Practices <em>(transferred from IPPH 522)</em></td>
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<tr>
<td>TLI 523</td>
<td>Quality Management Audits and Inspections <em>(transferred from IPPH 523)</em></td>
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<tr>
<td>TLI 525</td>
<td>Molecular Basis of Manufacturing</td>
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The TLI 521-523, and TLI 525 are a sequence of courses designed to provide content knowledge in biotech and pharma related to quality and compliance.

No credits may be transferred from another institution. No undergraduate credits may be used. The certificate must be completed in 4 years. No courses may be applied to certificates in other areas. All credit hours must be taken during the certificate program.
E. STUDENT LEARNING AND ASSESSMENT OUTCOMES

Several competencies and learning outcomes are required for graduates from a quality and regulatory compliance certificate program. The competencies and learning outcomes are listed in the Table below.

Table 1. Key learning outcomes and concepts for the Graduate Certificate Program

<table>
<thead>
<tr>
<th>Key Competencies</th>
<th>Concept</th>
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<tbody>
<tr>
<td>Basic Scientific Comprehension</td>
<td>Basic principles of regulatory science, and drug development, discovery, and manufacturing</td>
</tr>
<tr>
<td>Regulations</td>
<td>Necessary knowledge of FDA regulations, and guidance documents for at least one category of medical products (drugs, biological products, devices).</td>
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<tr>
<td>Quality</td>
<td>Rudimentary understanding of quality systems and standards and their impact on public safety as well as the reliance on quality by health care providers.</td>
</tr>
<tr>
<td>Clinical</td>
<td>Introductory level understanding of FDA requirements for the approval and conduct of pre- and post-market clinical studies with regulated products.</td>
</tr>
<tr>
<td>Communication</td>
<td>Develop critical thinking and interpretation skills commensurate with that of a second semester graduate student. Develop written and oral communication skills, with the scope and flexibility to address audiences with differing knowledge and priorities. Write/present clearly in an audience-appropriate manner.</td>
</tr>
<tr>
<td>Responsible use of ethical principles</td>
<td>Display professional understanding of the most important ethical dilemmas in Quality and Regulatory Compliance. Demonstrate values consistent with provision of quality health outcomes</td>
</tr>
<tr>
<td>Critical Thinking</td>
<td>Synthesize information and draw logical conclusions, provide support of arguments and recommendations consistent with that of a second semester graduate student.</td>
</tr>
</tbody>
</table>
F. Administration

Admission to the program will be handled by the College of Technology Center for Professional Studies (ProSTAR) that processes admissions for both weekend Masters and Certificate programs. In the case of non-degree seeking students, the admissions process will parallel that for degree-seeking students at the graduate level (i.e. students must apply for admission to the Graduate School as non-degree seeking students.)

1. Admission to the program will be handled by the College of Technology Center for Professional Studies (ProSTAR) that processes admissions for both weekend Masters and Certificate programs. In the case of non-degree seeking students, the admissions process will parallel that for degree-seeking students at the graduate level (i.e. students must apply for admission to the Graduate School as non-degree seeking students.)
   a. Students must submit proof of at least a bachelor’s degree, professional, or graduate degree from an accredited institution.
   b. Students are required to have a minimum undergraduate GPA of 3.0/4.0. However, consideration will be given for relevant work experience.
   c. The ProSTAR/TLI department waives the English (TOEFL or IELTS) requirement for the graduate certificate program. However should these students later decide to pursue the MS degree, they will be required to show proof of English Proficiency. Also for internationals holding foreign degrees, the English proficiency requirement will be waived if they are from an English speaking country or if the medium of instruction for their foreign degree was in English.
   d. Students already admitted into a Purdue University graduate or professional degree program are eligible to earn a certificate.
   e. All final admission decisions will be made by the admissions committee and/or the director of the program.

2. To facilitate tracking of students who are enrolled in certificate programs, the Office of the Registrar will establish a special admission status for such individuals.

3. The audit process for certifying completion of requirements is the responsibility of ProSTAR/TLI. When a student completes requirements for a certificate, ProSTAR will notify the Graduate School. The Graduate School will then notify the Office of the Registrar.

4. Transcripting
   a. Transcripting will be consistent with other graduate certificate programs in the Purdue system.
   b. Each certificate earned will be posted separately upon completion of the requirements.
   c. Graduate certificates will be recorded in the following manner:

   Awarded: Graduate Certificate
   Program: Technology Leadership & Innovation
   College: Graduate School
   Campus: West Lafayette
   Major: Biotechnology Quality and Regulatory Compliance
5. The certificate, itself, will be printed by the Office of the Registrar at the West Lafayette campus.

6. The certificate will be awarded jointly by the appropriate academic unit and the Graduate School. It will bear the signature of the head of the academic unit and the dean of the Graduate School.

7. Certificates will be awarded at the normal times when degrees are awarded.

8. The ProSTAR/TLI Department will submit an annual report to the Graduate Council containing the following information:
   a. the number of students currently admitted to the certificate program
   b. for each admitted student: date admitted and whether or not the student is also currently admitted to a degree program at Purdue, and if so, which degree and the number of credits completed toward fulfillment of certificate requirements
   c. the number of certificates awarded annually

   The Office of the Registrar will assist in generating this information.