Regulatory and Quality Compliance Graduate Certificate Program

With emphasis on

Food and Drug Law I
Drug Development
Good Regulatory Practice

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Introduction

The purpose of this certificate program is to provide graduate level education in the important aspects of Regulatory and Quality Compliance in the pharmaceutical industry. In this way, students will have an opportunity to improve their knowledge of regulatory and compliance issues and to explore careers in these exciting areas. Additionally, this program provides background information on the drug development process from discovery to the marketplace.

This graduate certificate program consists of three courses, each 3 credit hours, that will be presented on weekends (about one weekend per month) at a convenient location in suburban Chicago. Participants will attend classes 12:30-5:30 p.m. Fridays, 8:00 a.m.-5:30 p.m. Saturdays and 8:00 a.m.-12:30 p.m. Sundays. A homework assignment and exams will be given for each major section of the course. The certificate program consists of the following courses: (1) Food and Drug Law I, (2) Drug Development, and (3) Good Regulatory Practice. If taken in successive semesters (fall, spring, and summer), the program can be completed in one calendar year.

The development of this program has been a joint effort between Purdue University, representatives from the pharmaceutical industry (mainly Lilly and Abbott), and the FDA.

Individuals who successfully complete the certificate program may have the option to apply these 9 credit hours toward or in partial fulfillment of a Master’s degree in Regulatory and Quality Compliance at Purdue.

Program Objectives

High quality and appropriate compliance are essential for the viability of American industry, and academia as well. Almost daily, examples come to light showing the downside of poor quality or compliance; operations or organizations closed, fines levied, careers affected, public images besmirched, credibility lost. Regulatory affairs and quality control are particularly important for the pharmaceutical industry. Quality control (QC) and quality assurance (QA) groups exist in all companies. In addition, a growing number of academic institutions now have QC and QA. Knowing the agencies, the regulations, the regulators, and keeping abreast of regulatory changes is vital for appropriate compliance. Regulatory Affairs staff are charged with these important responsibilities during the development, submission of an application, and marketing of a new drug or device. However, staff for QC and QA and regulatory affairs are most often recruited from operations areas; few have any formal education on the policy and regulations and core principles of their new professions, and most all have no detailed knowledge of specific skills for the job. The Certificate Program is aimed at providing basic education in Regulatory and Quality Compliance as related to drug discovery, development and registration.

Courses

1. Food and Drug Law I (PHAD 50100) – G. Thomas Wilson, Professor

This course uses a legal case-based approach to aid in the understanding of the basic statutory and regulatory building blocks of the pharmaceutical industry, those being adulteration and misbranding. The goals of the course include instilling an awareness of those events that have impacted our field and the legal remedies that have been adopted to deal with such catastrophes as thalidomide, elixir sulfanilamide, the acetaminophen poisonings, and others.

Prerequisite: A Bachelor’s degree.

Basic Definitions & Introduction – T. Wilson
History of the FDA – T. Wilson
Basic Concepts of Drug Law – T. Wilson
Adulteration, Misbranding – T. Wilson
IND, NDA – T. Wilson
Drug Recalls, Regulatory Actions – T. Wilson
Inspections – T. Wilson
Tampering – T. Wilson
Orphan Drugs – T. Wilson
This course reviews the process of drug discovery and drug development. Animal non-clinical research and human clinical research are discussed in detail. The content of the IND and NDA are discussed along with the Phases (I, II, III) of human clinical research. The CMC (chemistry manufacturing and control) aspects of drug development are also presented, ICH documents, and manufacturing process analytical technologies. The course includes a brief review of patents and proprietary protection. Prerequisite: A Bachelor’s degree.

**2. Drug Development (IPPH 52100) – Michael Schmidt and Stephen Byrn, Professors**

**Introduction** – M. Schmidt  
**Drug Discovery** – How drugs are discovered: strategies & processes – M. Schmidt & guests  
**Preclinical Safety Research** – Toxicology, ADME, and regulatory pharmacology – M. Schmidt & guests  
**Clinical Research: Industry and Academia** – The process of clinical research – M. Schmidt & guests  
**CMC** – CMC issues including the ICH processes – S. Byrn & guests  
**Project Management, Product Decisions and Marketing** – M. Schmidt & guests  
**Patents and Intellectual Property Protection** – S. Byrn & guests  
**Conclusion** – S. Byrn

**3. Good Regulatory Practice (IPPH 52200) – Albert Peyton and Stephen Byrn, Professors**

This course includes a review of the FDA and ICH regulations on good laboratory, clinical, and manufacturing practices. The meaning of these regulations, the globalization of the practices, and the roles and responsibilities of various professionals implementing these regulations are addressed. Specifically non-clinical and clinical scientists, quality control and quality assurance representatives, and regulatory affairs professionals.

Prerequisite: Drug Development (IPPH 52100).

**Introduction** – A. Peyton  
**GLP Module** – Basis of GLPs, guidances, compliance – A. Peyton & guests  
**GCP Module** – Basis of GCPs, guidances, compliance – A. Peyton & guests  
**GMP Module** – Basis of GMPs, guidances, compliance – S. Byrn & guests

**Instructors**

**Dr. Stephen R. Byrn** is the Charles B. Jordan Professor at the College of Pharmacy, Purdue University, West Lafayette, Indiana. He received his B.A. degree from DePauw University and his Ph.D. degree in Chemistry from the University of Illinois, Urbana. He did postdoctoral research at UCLA. His research focuses on the solid-state chemistry of drugs. Dr. Byrn has extensive experience as a consultant in the pharmaceutical industry and is past chair of the Pharmaceutical Sciences Advisory Committee of the FDA. Dr. Byrn is co-founder of SSCI, an Aptuit Company, that provides analytical chemistry and consultation. He has received several awards including the David Grant award from the AAPS and in September 2010, he had an issue of the Journal of Pharmaceutical Sciences dedicated to him.

**Dr. Michael J. Schmidt** graduated from the University of Wisconsin and then received his M.S. degree in pharmacology from the University of Missouri School of Pharmacy at Kansas City and his Ph.D. in pharmacology from Vanderbilt University Medical School. He did postdoctoral research at the National Institutes of Health. He then joined Eli Lilly where he worked first in the laboratory in brain research and then in a number of management positions in the areas of discovery research, toxicology, and worldwide quality assurance for preclinical and clinical studies. He retired in 2001. He has published over 50 papers and worked with numerous scientific associations. Post-retirement he consults in the pharmaceutical industry, served as a quality and compliance advisor to Indiana University, and served as a board member with several science education and youth-serving organization. Dr. Schmidt is founder and president of Dr. Bones Education Indianapolis, Inc., which is a science education outreach company.
Admission Requirements

Students must meet the following admission requirements for the graduate certificate and the master’s degree program:

- Bachelors degree from an accredited institution
- Minimum undergraduate GPA of 3.0/4.0 (consideration will be given for relevant work experience)
- Minimum overall TOEFL iBT score of 77 if English is not the student’s native language. See http://ipph.purdue.edu for further information
- Recommendation by the department’s admission committee and approval of the Graduate School

You are encouraged to apply to the Graduate School by
- July 1 for the fall semester
- November 1 for the spring semester
- April 1 for the summer semester

Applications must be submitted online through the Graduate School at the following URL: http://www.purdue.edu/GradSchool

Completion Requirements

- Successful completion of 9 credit hours from the three core courses
- A grade of B or better must be attained for each course
- All courses must be completed within 5 years of beginning the program
- All weekends of all courses must be attended

Tuition and Fees

Individuals interested in this Certificate in Regulatory and Quality Compliance should talk with their supervisor concerning participation in the program. Tuition and fees for each course will be $3000. Students will be responsible for their housing. A hotel room block will be arranged by the RQC Graduate Coordinator, and hotel information will be sent upon enrollment. Students are welcome to utilize the room block or find other accommodations. Breakfast and lunch will be provided.

Tuition and fees may be paid for by the individual student or the student’s departmental budget (with management approval).

Students may be eligible for tuition reimbursement if certain conditions set by their employer are met. For additional information about tuition reimbursement, interested individuals should contact their Educational Assistance Plan Administrator within their organization.
Payment of Fees

Once you are admitted to the Graduate School you will receive information about payment and other matters.

For further information contact:

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