

# Regulatory and Quality Compliance Graduate Certificate Program

With emphasis on

Food and Drug Law  
Drug Discovery and Development  
Good Regulatory (GXP) Practices



# 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 the Purdue University West Lafayette campus. Participants will attend classes 1:00-6:00 p.m. Fridays, 8:00 a.m.-6:00 p.m. Saturdays and 9:00 a.m.-12:00 noon 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) U.S. Food and Drug Law I, (2) Drug Discovery and Development, and (3) Good Regulatory (GXP) Practices. 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 will also have the option to apply these 9 credit hours to a Master's Program 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 organization 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 & QA. Similarly, 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 – G. Thomas Wilson, Professor*

This first course in Food and Drug Law is aimed at having the student gain a basic understanding of the origins, structures, impacts, and relevance of the myriad of laws in place to regulate the manufacture and distribution of drugs and devices. The purpose is to have the student – while not knowing all the laws or where they are found – at least know that there are laws governing situations encountered. The emphasis is on the purpose of the laws and their applicability to drug development and manufacturing. Students will be able to describe the elements in the laws/regulations that trigger the application. The approach will be mainly a macro study, with some exceptions.

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

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## **2. Drug Discovery and Development – Stephen Byrn and Michael Schmidt, Professors**

This course reviews the process of drug discovery and drug development. Animal preclinical research and human clinical research are discussed in detail. In addition, 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. Food and Drug Law I is recommended.

**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

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## **3. Good Regulatory (GXP) Practices – Michael Schmidt and Stephen Byrn, Professors**

This course includes a review of the FDA and ICH regulations on good manufacturing, good laboratory, and good clinical practices. The meaning of these regulations, the globalization of the practices and the roles and responsibilities of various professionals implementing these regulations are addressed: Pre-clinical and clinical scientists; quality control and quality assurance representatives; and regulatory affairs professionals. Prerequisite: Food and Drug Law I and Drug Discovery and Development.

**Introduction** – M. Schmidt

**Philosophy and Principles of “quality and compliance management”** – T. Pearson

**GLP Module – Basis of GLPs, guidances, compliance** – M. Schmidt & guests

**GCP Module – Basis of GCPs, guidances, compliance** – M. Schmidt & guests

**GMP Module – Basis of GMPs, guidances, compliance** – S. Byrn & guests

## **Instructors**

**Dr. Stephen R. Byrn** is the Charles B. Jordan Professor at the School of Pharmacy, Purdue University, West Lafayette, Indiana. He is also Head of the Department of Industrial and Physical Pharmacy. 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 currently serves on the Council of Experts of the USP, the Drug Substance Technical Committee of PQRI, and is past chair of the Pharmaceutical Sciences Advisory Committee of the FDA. Dr. Byrn is co-founder of SSCI, a company providing analytical chemistry services and consultation.

**Dr. Michael J. Schmidt** graduated from the University of Wisconsin and then received his MS degree 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 as a laboratory researcher 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 2000. 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 serves 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.

## Instructors (continued)

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Dr. G. Thomas Wilson graduated from Purdue University School of Pharmacy in 1975 and entered practice in pharmacy. He worked in independent and chain pharmacies including being store manager in a small chain. He returned to Purdue three years later to work and teach in the Purdue University Pharmacy. He served 20 years as director of the experiential programs during which time he earned his J.D. from Indiana University School of Law, Indianapolis. He was admitted to the Indiana Bar in 1984. Since 1986 he has had sole responsibility for the Jurisprudence course in the Pharmacy School. His responsibilities include serving as

liaison to the Indiana Board of Pharmacy in which capacity he is often called upon to draft rules and statutes, many of which have been enacted. After nearly 22 years as a member of the Administrative Professional staff, Prof. Wilson accepted a tenure track position within the School as Assistant Professor, the post he currently holds.

**Guest lecturers.** Guest lecturers (experts in their field) will be recruited by the course directors. Individuals will come from academia, industry and the FDA.

## Admission Requirements

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Students must meet the following admission requirements for the graduate certificate and the masters 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 TOEFL score of 550 if English is not the student's native language
- Recommendation from the student's current supervisor
- Approval of the admissions committee and/or program director

*Applications must be submitted online through the Graduate School at the following URL:  
<http://www.purdue.edu/GradSchool/admissions/apply.cfm>*

## Completion Requirements

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- 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

## Tuition and Fees

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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 \$2500. Students will be responsible for their housing. Breakfast and lunch will be provided. Once enrolled, students will be provided with a list of hotels close to the site of the course. This cost may be paid for by

the individual student or the student's departmental budget (with management approval). Students may also 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

## **P**ayment of Fees

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Once you are admitted you will receive information about payment and other matters.

## **A**pplications

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You may enter the program by August 1 for the fall semester, December 1 for the spring semester, and April 1 for the summer semester.

## **F**or further information contact:

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