

# Regulatory and Quality Compliance Masters Degree Program

With emphasis on

Food and Drug Law

Drug Discovery Development and Registration

Good Regulatory (GXP) Practices

Quality Management Audits and Inspections

Documents and Dialogues of Drug Development and Registration

Process Analytical Technology

Chemistry Manufacturing and Control Issues



## Introduction

The purpose of this master's degree program is to provide graduate level education in the important aspects of regulatory and quality compliance as applied to the pharmaceutical and medical device industries. Upon completion, graduates will have acquired an in-depth knowledge and hands-on experiences in the organization and operation of the major departments of a pharmaceutical company, as well as ways of dealing with regulatory and compliance issues.

Instruction is provided by academics, consultants, or industry representatives with years of experience and who are experts in their fields.

This master's degree program consists of ten courses (each 3 credit hours) and a special project (6 credit hours) for a total of 36 credit hours. There are four required courses, two specified elective courses, four elective courses and a 6 credit hour project. The four required courses are (1) US Food and

Drug Law; (2) Drug Discovery and Development; (3) Good Regulatory (GXP) Practices; and (4) Food and Drug Law II. The two specified electives must be chosen from the following list: (5) Quality Management Audits and Inspections; (6) Documents and Dialogues of Drug Development and Registration; and (7) Process Analytical Technologies. The seven courses are presented on weekends (about one weekend per month) at Purdue University, West Lafayette, Indiana. Participants 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. Four additional 3 credit "elective courses" will be needed and those are at the student's discretion. However, courses self-elected must be approved by the student's M.S. degree advisory committee.

## Masters Degree 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, quality, and compliance are particularly important for the pharmaceutical industry. Quality control (QC) and quality assurance (QA) groups exist in all companies to help assure effective submissions to agencies worldwide. In addition, a growing number of academic institutions now have QC & QA groups. 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 and submission of an application, and the 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 policies and regulations and core principles of their new professions, and most have no detailed knowledge of specific skills for the job. The Purdue masters degree program is aimed at providing advanced education in regulatory and quality compliance.

## 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

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## ***4. Food and Drug Law II – Tom Wilson, Professor***

The purpose of this advanced course is to orient the students to the use of the United States Code and the Code of Federal Regulations, with the emphasis (not exclusively) on Title 21 of those two Codes. Exercises are designed to assure that the student has the ability to: (1) categorize the laws/regulations applicable to the drug industry; (2) interpret the laws and regulations in strict constructs; (3) evaluate the changes brought about by amendments and revisions, and (4) identify the effects on the statute/regulation of the sections incorporated by reference. Prerequisite: Food and Drug Law I.

**Introduction** – T. Wilson  
**Drug-related Laws** – Laws applicable to the drug industry - T. Wilson  
**Interpretation of Laws** – Strategies for interpreting the laws within strict constructs – T. Wilson  
**Evaluation of Amendments** – Developing an understanding of the effects of amendments – T. Wilson  
**Effects of Laws and Amendments on Regulations** – A discussion of how the laws and amendments affect regulations – T. Wilson.

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## ***5. Quality Management, Audits and Inspections - Tom Pearson and Michael Schmidt, Professors***

The purpose of this advanced course is to build on the information presented in earlier courses relating to quality and compliance practices (employed or imposed) during drug discovery and development. Emphasized will be major proven quality management procedures, such as “Six Sigma”, “Baldrige”, “Total Quality Management”, “Lean Management” and “Project Design and Management”. Details of GLP, GCP

or GMP agency inspections will be reiterated with special emphasis on areas most inspected and troublesome. Also, other types of audits and inspections that occur in pharmaceutical companies will be described. Lectures by specialists will be supplemented extensively with individual and group hands-on exercises. Upon completion, students will have gained a critical understanding of quality programs and practices;

(2) conducted and evaluated “mock” agency and QA department audits, and (3) planned and presented a prototype M.S. “special project” proposal including objectives, milestones and timelines. Prerequisites: Food and Drug Law I, Drug Discovery and Development, and Good Regulatory (GXP) Practices.

**Introduction** – T. Pearson & M. Schmidt  
**Quality Management Programs** – T. Pearson & Guests  
**Cost-Benefit Comparisons of Quality Programs** – T. Pearson  
**GXP and Other Agency Inspections** – M. Schmidt & Guests  
**“Hands-on” Inspections and Audits: Group Activities** – M. Schmidt  
**Project Design and Management** – T. Pearson

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### ***6. The Documents and Dialogues of Drug Development and Registration: Preparation and Presentation - Stephen Byrn and Michael Schmidt, Professors***

This capstone advanced course will integrate previous learning relating to laws and regulations, quality principles and practices, and the preparation and submission of documents for clinical trials and new drug approvals. Some special topic lectures will be given, but the majority of the time will be devoted to preparing regulatory documents and conducting “mock” dialogs and negotiations with “pretend” agency officials. Prerequisites: Food and Drug Law I, Drug Discovery

and Development, Good Regulatory (GXP) Practices, Regulatory Law II and Quality Management, Audits and Inspections.

**Introduction** – M. Schmidt  
**The Documents: What and Why** – Professors  
**Special Topic Lectures** – Professors & Guests  
**Preparation of Documents** – Professors  
**Dialogue and Negotiation Practice** – Professors

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### ***7. Process Analytical Technology – Ken Morris and Stephen Byrn, Professors***

This advanced course addresses important CMC issues related to process analytical technology. The course provides important information on strategies for monitoring processes on-line, the best approaches to analyzing data, how the data can be used to find process critical control points, and strategies for reporting the data to the FDA. The course may include laboratory exercises, laboratory tours, and/or workshops outlining how to interpret the data. Prerequisites: Food and Drug

Law I, Drug Discovery and Development, and Good Regulatory (GXP) Practices or consent of instructor.

**Introduction** – K. Morris & S. Byrn  
**PAT Overview** – K. Morris & S. Byrn  
**Sensors** – K. Morris & S. Byrn  
**Data Analysis** – K. Morris & S. Byrn  
**Workshops** – K. Morris & S. Byrn  
**Project Design and Management** – T. Pearson

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### ***8. Special Project - Stephen Byrn, Michael Schmidt, Stan Shaw, Tom Wilson, Professors***

An individual “Special Project” is required of each student completing the MS degree. The project is to be conceived by the student, but dialogue with course instructors, other students in the MS program, and colleagues at work is encouraged. Especially important is counsel with their supervisor in order to devise a project that is value-added to the company. Examples of projects are: an analysis of a regulation and interpretation for the company; developing a course-of-action or response to a new agency guideline; or the design and implementation of a process improvement.

All projects will be reviewed and critiqued by the student’s advisory committee and, if appropriate, approved. Projects that are rejected will be accompanied by written rationale.

At the completion of the project, each student will prepare a 30-40 page “project thesis” for review. Then each project will be presented to other students and the MS examining committee. Students will be encouraged and assisted to publish the project in a quality/compliance related journal and/or make a presentation at a gathering of regulatory or compliance professionals. Prerequisites: Food and Drug Law I, Drug Discovery and Development, Good Regulatory (GXP) Practices and acceptance into the Masters Degree program. It is recommended that the course Quality Management, Audits and Inspections be completed prior to initiating the special project.

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## 9. Elective Course Tracks

A number of relevant elective tracks are acceptable for the four remaining courses to complete the MS degree. The program and the electives will be tailored to the needs and desires of each student and outlined on the plan of study. Electives in the following areas are of particular relevance to the program:

- Basic Biology or Chemistry
- Law
- Business or Marketing
- Manufacturing and Risk-Based GMP
- Clinical Research
- Project Management
- Discovery or Toxicology Research
- Quality Management and Compliance Practices
- Ethics
- Regulatory Affairs

## Graduate Committee

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After admission, students will choose an MS committee. This committee will consist of the Head of the Department of Industrial and Physical Pharmacy, the academic director of the program and one other person. This committee will help for-

mulate a plan of study such that students are able to select the proper courses during your years in the program. Until a plan of study is filed, the Head or Associate Head of the department, will serve as the student's informal advisor.

## Program Co-Directors

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**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.

## 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
- Minimum TOEFL score of 550 if English is not the student's native language
- Recommendation and all other requirements for the Purdue University Graduate School
- Approval of the admissions committee and/or a program co-director

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

## **C**ompletion Requirements

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- All courses must be completed within 6 calendar years
- A grade of B or better is required in all required courses

## **P**ayment of Fees

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It is recommended that individuals interested in this masters degree in Regulatory and Quality Compliance should talk first with their supervisor concerning participation in the program. Tuition and fees for each three (3) weekend course will be \$2500 and must be paid prior to the beginning of each academic semester. This cost may be paid for by the individual student or the student's departmental budget. Students might be eligible for tuition reimbursement if certain conditions are met within their company. For additional information about

tuition reimbursement, interested individuals should contact their Educational Assistance Plan Administrator within their organization. Fees for elective courses taken at Purdue will be set by Purdue. Fees at other universities will be set by those universities. All credits for all courses will be registered and maintained at Purdue University. Records and transcripts may be obtained from the Registrar's Office, Purdue University, West Lafayette, IN 47907.

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

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