

Registration for  
Part 1: Two-week cGMP Training Program  
at Purdue University, August 9-20, 2004

Registration for Part 2, weeks 3 - 6, to be announced at a later date.

Name \_\_\_\_\_

Title \_\_\_\_\_

Company \_\_\_\_\_

Address \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_

Fax \_\_\_\_\_

E-mail \_\_\_\_\_

I require auxiliary aids and services because of a disability. Please contact me at the above address.

I request vegetarian meals.

#### Tuition Fee

Register me for Part 1 of the cGMP Training Program at a cost of \$5,000 per participant.

#### Lodging

Single rooms or group rates for housing are available. Please contact Prabir Basu by e-mail at [prabir1960@purdue.edu](mailto:prabir1960@purdue.edu) or Nancy Davis, [ndavis@pharmacy.purdue.edu](mailto:ndavis@pharmacy.purdue.edu), before July 1, 2004, for reservations.

#### Payment Method

Wire transfer in U.S. dollars made payable to **Purdue University**.

Other \_\_\_\_\_

#### Return this form with payment to:

OCEC Business Services      Fax: 765-494-0567  
Purdue University  
Stewart Center, Room 110  
128 Memorial Mall  
West Lafayette, IN 47907-2034  
USA

If payment is being made for more than one participant, please complete one registration form for each participant and mail or fax together.

#### Confirmation Notification

Upon receipt of this registration form and your payment, a confirmation e-mail will be sent to you from Prabir Basu ([prabir1960@purdue.edu](mailto:prabir1960@purdue.edu))

#### Continuing Education Units

You will receive 45 Continuing Education Units upon completion of the Two-week cGMP Training Program.

#### Cancellation Policy

A 50 percent refund for the two-week course will be issued if a request is made by June 30, 2004. Purdue University is not responsible for costs incurred due to cancellation.

*Purdue University is an equal access/equal opportunity university.*

**PURDUE**  
UNIVERSITY

## Training Program Current Good Manufacturing Practice (cGMP) Regulatory Principles

### National Center for Advanced Pharmaceutical Science, Manufacturing, and Education

*A six-week program presented by  
Purdue University in West Lafayette,  
Indiana, at the Chao Center for Industrial  
Pharmacy and Contract Manufacturing*

*With emphasis on:  
Food and Drug Law,  
Drug Discovery and Drug Development,  
Good Regulatory Practices,  
Preparation of Chemistry, Manufacturing  
and Control (CMC) Documents,  
Process Analytical Technology, and  
Practical Hands-on Learning*

For more information, please contact:  
Prabir Basu by calling (765) 494-9614 or  
by e-mail at [prabir1960@purdue.edu](mailto:prabir1960@purdue.edu)  
Nancy Davis by calling (765) 426-9089 or by  
e-mail at [ndavis@pharmacy.purdue.edu](mailto:ndavis@pharmacy.purdue.edu)

## Training Program Current Good Manufacturing Practice (cGMP) Regulatory Principles

#### Introduction

This six-week course entitled "Current Good Manufacturing Practice (cGMP) Regulatory Principles" was developed by Purdue University's Department of Industrial and Physical Pharmacy, one of the leading industrial pharmacy programs in the world.

This program will enhance your abilities to locate and interpret laws and regulations relevant to the pharmaceutical industry, and then design, implement, and monitor "best practices" in your organization to assure compliance. Also, the program provides a broad and thorough understanding of the entire process of drug development: from early discovery and toxicology research, through clinical trials and manufacturing, and finally registration.

The course provides education in the important areas of *regulatory and quality compliance*. In addition to a classroom education, the course is designed to provide hands-on practical experience working in the laboratory and at the Chao Center for Industrial Pharmacy and Contract Manufacturing at Purdue. Students will improve their knowledge of regulatory and compliance issues while developing familiarity with the manufacture of solid oral dosage forms following *Current Good Manufacturing Practices* (cGMP).

Students will attend classes, participate in roundtable discussions and problem solving sessions, perform laboratory experiments, write batch records, prepare an actual batch of Seromycin (placebo), review the completed batch, and release it as if it were for the marketed use.

The cGMP Training Program is based on a highly successful graduate certificate program in Regulatory and Quality Compliance already established by the Department of Industrial and Physical Pharmacy. The graduate certificate program has been developed as a joint effort of Purdue University

and the leading pharmaceutical companies, Abbott Laboratories, located in Chicago, Illinois, and Eli Lilly and Co., located in Indianapolis, Indiana.

#### Training Dates

The six-week course begins with a two-week session from August 9-20, 2004, at Purdue University's West Lafayette campus. The four-week course sessions will be held next year, 2005; final date to be announced.

#### Program Objectives

Throughout the world, there is a need for cGMP education. This course is an important first step and provides an overview of all-important areas of cGMP. Highlights in this course are strategies for the manufacture of drugs for tuberculosis and other infectious diseases. A university level course is offered because cGMP regulations are rapidly changing due to changes in the industry, improved methods of analysis, and changes in the FDA and other regulatory bodies.

High quality and appropriate compliance are essential for the success of pharmaceutical companies. Poor quality and non-compliance result in closed operations or organizations, fines, ruined careers and public images, and loss of credibility. The objective of this course is to introduce closed scientists throughout the world to the essentials of quality assurance, quality control, and quality systems.

The course was developed to address the lack of broad education in regulatory sciences in conventional university curricula. For example, operations scientists are well trained in manufacturing and methods of analysis but few have any formal education on the policy and core principles of cGMP. This course provides a basic overview of regulatory issues enabling operations scientists, chemists, manufacturing professionals, and other researchers to perform well in their assigned capacities.



*Charles O. Rutledge, Purdue University*

## Purdue, Lilly form international drug manufacturing partnership

Last year, at the World Health Organization headquarters in Geneva, Switzerland, Eli Lilly and Co. announced that it will team with Purdue University to teach other nations how to manufacture drugs to fight tuberculosis.

The partnership involves the World Health Organization, the U.S. Department of Health and Human Services, the Centers for Disease Control and Prevention, Harvard Medical School, and Purdue University.

The partnership yields Purdue's first drug manufacturing contract for the School of Pharmacy's Good Manufacturing Practices facility, which will be located in the Purdue Research Park. When completed in late 2004,

the facility will allow Purdue to teach students and professionals worldwide about commercial drug production and management.

"Purdue's manufacturing facility will be more than just a great place to receive training in drug manufacturing," said Charles O. Rutledge, executive director of Discovery Park. "By nature of its relatively small size, it will be able to produce drugs profitably in small quantities. Often, these drugs are needed only by a small segment of a population. With such small profit margins, this is something that larger manufacturers cannot do because of their larger overhead."

Purdue's first products will be antibiotics that cure multiple drug-resistant tuberculosis (MDR-TB). Lilly is the original manufacturer of the drugs, and the company is now assisting developing countries with manufacturing the drugs themselves, as the disease is far more prevalent outside the industrialized world.

"Our efforts will fill a shortage in the drug market, not only by manufacturing the drugs, but also by assisting other countries with their own manufacturing efforts," Rutledge said.

# Complete Six-week Training Program

## CGMP Regulatory Principles

### Part 1: Two-week cGMP Training Course

August 9 to August 20, 2004, will focus on the following:

Food and Drug Law —

*G. Thomas Wilson, professor, and guest lecturers*

#### Objectives

- List the critical concepts of *adulteration* and *misbranding* as they apply to drugs, devices, and cosmetics.
- Define the need for strict controls on the production of drugs, devices, and cosmetics.
- Understand the application of the basic constructs of the laws and regulations as they seek to hold manufacturers, packers, and distributors accountable for the quality of drugs, devices, and cosmetics.
- List the potential for harm sought to be prevented by passing the various laws and regulations.
- Write an objective analysis of an assigned issue utilizing available information from cases and statutes.
- Demonstrate the ability to read and analyze a court decision and present the “case” to the class. It is also expected that the student will be able to prepare an active outline tracing the progress of law through the presented cases.

Drug Development —

*Steve Byrn and Michael Schmidt, professors, and guest lecturers*

#### Objectives

- Define roles in the drug development process and describe key job functions.
- Learn about the positive contributions of the pharmaceutical industry and the benefits of employment.
- Gain an appreciation of other components and job functions in order to be a more understanding and better cross-functional team participant.
- Learn about new approaches in drug discovery research and development today: technologies, practices, and strategies.

Good Regulatory (GXP) Practices (GLP, GCP, cGMP) —

*Michael Schmidt and Stephen Byrn, professors, and guest lecturers*

#### Objectives

- Describe the regulations of the pharmaceutical industry, the reasons for the regulations, and the perils and consequences of non-compliance.
- Identify the challenges and pitfalls in each phase of drug development and explore how problems can be avoided logically and in compliance.
- Interact with other drug development professionals to share problems, concerns, experiences, and solutions.
- Explore career options in the pharmaceutical industry.

### Part 1: Two-week cGMP Training Course

	Week 1 August 9-13	Week 2 August 16-20
Monday	Introduction to MDR-TB Project, Course Introduction	CMC, GMP
Tuesday	Food and Drug Law	CMC, GMP
Wednesday	Drug Discovery & Drug Development	CMC, GMP
Thursday	GLP, GCP	CMC, GMP
Friday	Plant Tour	Exam; Course Assessment; Local Plant Tour

### Part 2: Four-week cGMP Training Course in 2005

	Week 3 dates to be announced	Week 4 dates to be announced
Monday	CMC Filing and Regulatory	Process Analytical Technology (PAT) Pharmacy Laboratory
Tuesday	CMC Filing and Regulatory	PAT Pharmacy Laboratory
Wednesday	CMC Filing and Regulatory	PAT Pharmacy Laboratory; Pharmaceutical Engineering
Thursday	CMC Filing and Regulatory	PAT Pharmaceutical Engineering
Friday	CMC Filing and Regulatory	Pharmaceutical Engineering; Exam; Course Assessment
	Week 5 dates to be announced	Week 6 dates to be announced
Monday	cGMP Plant Orientation; Analytical Methods; Validation; Methods Validation	Hands on Preparation of a simulated GMP batch in the Chao cGMP Center; Analyze Product
Tuesday	Raw Material Release; Packaging Specifications	Hands on Preparation of a simulated GMP batch in the Chao cGMP Center; Analyze Product
Wednesday	Raw Material Release; Packaging Specifications	Quality Review; Batch Record Review
Thursday	Batch Records; SOPs	Course Review; Seromycin Manufacture
Friday	Hands on Preparation of a simulated GMP batch in the Chao cGMP Center; Analyze Product	Exam; Course Assessment

**Abbreviation Key:** GLP — Good Laboratory Practices; GCP — Good Clinical Practices; CMC — Chemistry Manufacturing and Control; PAT — Process Analytical Technology; SOPs — Standard Operating Procedures

## Description of the Six-week Course

*The cGMP course addresses four areas.*

**Food and Drug Law** provides an overview of the origins, structures, impacts, and relevance of the many laws regulating the manufacture and distribution of drugs in the United States. The course will also focus on why different regulations were established, what are the major legal issues, and how these legal issues shape our regulations today. The emphasis will be on the purpose of the laws and their applicability to drug manufacturing.

**Drug Development** addresses drug discovery and drug development with emphasis on the regulatory aspects of these activities. This section is aimed at providing a general background in pre-clinical research, clinical research and chemistry, manufacturing, and control, or CMC. Animal pre-clinical research and human clinical research are discussed. In addition, the content of the IND and NDA are discussed, along with the phases (I, II, III) of human clinical research. The CMC aspects of drug development are summarized along with the ICH documents and pharmacopieal documents.

**Good Regulatory Practices** includes a review of the regulations and how they are implemented into quality systems, quality control polices, and quality assurance policies.

**GMP Manufacturing and Laboratory** explains the principles of GMP manufacturing and will be partially taught in the state-of-the art GMP laboratory at Purdue University. Students in the GMP Manufacturing and Laboratory course will manufacture Seromycin or some other representative drug as an example. The course includes detailed reviews of IOPs, SOPs and documents used for GMPs, and includes modules on facilities and other GMP requirements such as cleaning validation. In addition, hands-on laboratory practice is part of this course using cGMP to manufacture Seromycin (placebo) using batch records SOPs and IOPs as required for the practice.

## Instructors

*Professor G. Thomas Wilson* graduated from the Purdue University School of Pharmacy in 1975 and entered the practice of pharmacy. He worked in independent and corporately owned pharmacies, including being store manager. He returned to Purdue three years later to work and teach in Purdue’s School of Pharmacy. He served 20 years as director of 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 Purdue’s School of Pharmacy. His responsibilities include serving as liaison to the Indiana Board of Pharmacy. In this role 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.

*Professor Stephen R. Byrn* is the Charles B. Jordan Professor at the School of Pharmacy at 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. Prof. 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. Prof. Byrn is cofounder of SSCI, a company providing analytical chemistry services and consultation.

*Michael Schmidt, Ph.D.*, graduated from the University of Wisconsin in 1964, and received his M.S. degree from the University of Missouri School of Pharmacy at Kansas City and his Ph. D. from Vanderbilt University Medical School. He was a postdoctoral scholar at the National Institutes of Health. He then joined Eli Lilly and Co., where he first worked as a laboratory researcher and then in a number of management positions in discovery research, toxicology, and worldwide quality assurance for pre-clinical and clinical drugs, and retired from Eli Lilly in 2000. He has published over 50 papers and worked with numerous scientific associations. Post-retirement, he consults in the pharmaceutical industry, has served as a quality and compliance advisor to Indiana University, and serves as a board member with several science education and youth-serving organizations. Schmidt is founder and president of Dr. Bones Education Indianapolis, Inc., which is a science education outreach company.

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

## Tuition and Fees

Tuition and fees for the first two-week program in August, 2004, will be \$5000 per student. The tuition and fees for the four-week program in 2005 will be \$10,000 per student. Housing and dinner fees are in addition to the tuition fee. See registration form. Breakfast and lunch will be provided during the two-week course in August, 2004.

The laboratory manufacturing exercise will exactly simulate the cGMP manufacturing process for Seromycin (placebo) run in the Chao Center for Industrial Pharmacy & Contract Manufacturing.