

**PURDUE**  
UNIVERSITY

# ***Principles of*** **Current Good Manufacturing and Regulatory Practices**

***With emphasis on:***

- **Preparation of Chemistry, Manufacturing and Control (CMC) Documentation,**
- **Process Analytical Technology (PAT), and**
- **Practical Hands-on Learning**

***Discovery* Park**

**National Institute for Pharmaceutical  
Technology and Education**

***Presented by Purdue University  
in West Lafayette, Indiana***

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# **Principles of Current Good Manufacturing and Regulatory Practices**

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This six-week residential Current Good Manufacturing Practices (cGMP) training program is based on a highly successful graduate certificate course in Regulatory and Quality Compliance already established by the Department of Industrial and Physical Pharmacy at Purdue University. The graduate certificate course was developed as a joint effort by Purdue University and leading pharmaceutical companies. Subjects covered in detail in this program include the latest developments in Food and Drug Law, Drug Development, Good Regulatory Practices (GXP), cGMP Compliance, and Process Analytical Technology (PAT).

***Courses simulate everyday situations with hands-on learning.***

This program is a unique combination of fundamentals, theory and practice. Students attend classes, work on case studies, participate in roundtable discussions and problem-solving sessions, perform laboratory experiments, write batch records, prepare an actual batch, review the completed batch, and release it as if it were to be marketed. Students have the opportunity to improve their knowledge of regulatory and compliance issues while developing familiarity with the manufacture of solid oral dosage forms following cGMP.

***This program covers all important areas of cGMP applicable to the development and manufacture of solid oral dosage forms.***

Learning in a university setting is critical for acquiring real-time knowledge in rapidly changing cGMP regulations and advancements in analytical methodologies and manufacturing practices. The program is designed to provide cutting-edge information and hands-on practical experience working in the laboratory and at the *Chao Center for Industrial Pharmacy and Contract Manufacturing* at Purdue. Quality assurance is one of the keys to success for pharmaceutical companies. The program introduces scientists and manufacturing professionals to the essentials of quality assurance, quality control, and quality systems. It also addresses policy and core principles of cGMP aimed toward improving job performance and effectiveness in pharmaceutical development and manufacturing.

# Course Descriptions

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## **Good Regulatory Practices (GXP), (GLP, GCP, cGMP)**

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

**GMP Manufacturing and Laboratory** explains the principles of GMP manufacturing and will be partially taught in Purdue's state-of-the-art GMP laboratory. Students in the GMP Manufacturing and Laboratory course will manufacture some representative drugs as an example. The course includes detailed reviews of Industrial Operating Processes (IOPs), Standard Operating Procedures (SOPs) and documents used for GMPs, plus 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 drugs using batch records SOPs and IOPs as required for the practice.

This course enables course participants to:

- Describe the regulations of the pharmaceutical industry, the reasons for the regulations, and the perils and consequences of noncompliance;
- Understand Good Clinical Practices (GCP) and 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;
- Learn about new approaches in drug discovery research and development today, such as new technologies, practices, strategies, and their implication to manufacturing;
- Identify the challenges and pitfalls in each phase of drug development and explore how problems can be avoided logically and in compliance; and
- Interact with other drug development professionals to share problems, concerns, experiences, and solutions.

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## **CMC Documentation**

**Chemical Manufacturing Control (CMC) Documentation** provides a forum for discussion and learning of the CMC aspects of drug development. Elevated requirements for stable therapeutic dosage forms present challenges to production technology, manufacturing processes, and analytical technology. The course includes ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) documents and a review of documentation in all these domains.

The objective of this course is to:

- Identify challenges to producing stable therapeutic dosage forms;
- Understand the requirements for proper documentation; and
- Learn about the important elements to be considered for the documentation process.

## **Process Analytical Technology**

**Process Analytical Technology (PAT)** addresses important CMC issues related to process analytical technology and the aspects that are relevant to reporting the data to regulatory agencies. The course includes laboratory exercises, laboratory tours, and/or workshops outlining how to interpret the data.

This course will teach course participants to:

- Develop strategies for monitoring processes on-line;
- Study the best approaches to analyzing data;
- Learn about how the data can be used to find process critical control points; and
- Understand the strategies for reporting the data to the FDA.

# Instructors



**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 his 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.

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



**Professor Kenneth R. Morris** received his Ph.D. from the University of Arizona in 1987 and joined E.R. Squibb in the Preformulation group. There he developed the Physical Characterization group and co-developed the company's Materials Science function. He went on to form the Physical Pharmacy group in the Bristol-Myers

Products organization, which he led along with the Analytical Chemistry group. During this time he also served as a teaching and advising adjunct professor at Rutgers College of Pharmacy with Dr. N. Lordi. Prof. Morris moved to the Department of Industrial and Physical Pharmacy at Purdue University in the fall of 1997 where he continues his work in pharmaceutical materials science and industrial pharmacy. His research and publishing interests include: developing tools for and the study of the impact of processing on the physical characteristics of formulation components and on subsequent dosage form performance; unit process optimization; advanced applications of powder x-ray diffraction and dielectric analysis; the study of the association of water with pharmaceutical solids; and methods for monitoring processing unit operations. His most recent work centers around modeling the dissolution process from crystals using AFM and Monte Carlo simulation.

## Who should attend?

Scientists, technologists, and engineers in pharmaceutical manufacturing, regulatory affairs, quality control, and quality assurance who need a fundamental understanding of cGMPs related to pharmaceutical operations. This course also is useful to all levels of management as a refresher course to stay current with cGMP regulations and brush up on relevant skills.

### For further information contact:

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