

Learn how to develop, implement, and maintain an efficient and effective pharmaceutical stability program that facilitates compliance with regulations....

Developing and Implementing Effective Pharmaceutical Stability Programs

**February 26-27, 2007
Las Vegas, Nevada**

Essential information for

- ✓ **Stability managers and staff**
- ✓ **Laboratory managers and staff**
- ✓ **Analytical R&D managers and staff**
- ✓ **Quality assurance and regulatory affairs professionals**
- ✓ **Executives planning to add a stability program to their organization**

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**Department of Engineering Professional Development
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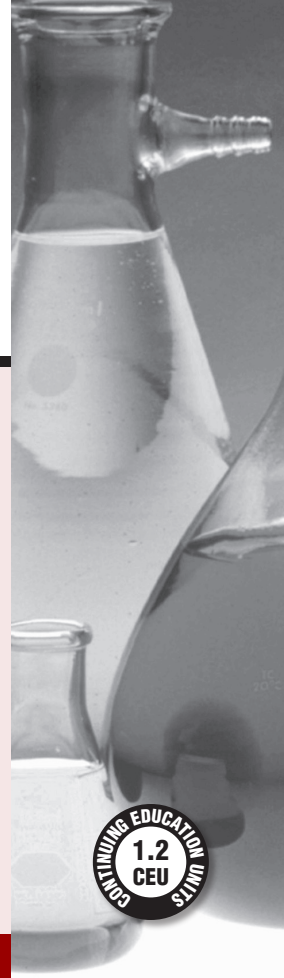
COLLEGE OF ENGINEERING ■ DEPARTMENT OF ENGINEERING PROFESSIONAL DEVELOPMENT

Pharmaceutical Engineering and Technology Series

Developing and Implementing Effective Pharmaceutical Stability Programs

**February 26-27, 2007
Las Vegas, Nevada**

- **The Quality Systems (QS) initiative and its role in building a stability systems infrastructure**
- **Operating a stability program in a cGMP environment**
- **How cGMPs impact stability programs**
- **The role of individual functional areas**
- **Exploring test method development strategies**



Developing and Implementing Effective Pharmaceutical Stability Programs

February 26–27, 2007 in Las Vegas, Nevada

Save time and money!
Inquire about our on-site courses.
Call 800-462-0876 today!

Implement Proven Strategies

The Food and Drug Administration (21 CFR Part 211) and international regulators (ICH) require that the stability of drugs, cosmetics and dietary supplements in commerce be determined and the time period during which they maintain strength and potency be made available to consumers in the form of a labeled expiration date. Deficiencies in the execution of these stability testing programs are among the most frequent causes for regulatory action.

This practical course is designed to provide you with the knowledge and tools you must have to develop, implement, and maintain an efficient and effective stability program that facilitates compliance with applicable regulations. Emphasis will be on addressing and presenting strategies for the resolution of organizational, scientific and compliance issues commonly encountered in pharmaceutical stability programs.

For Related Course Descriptions

<http://epd.engr.wisc.edu/catalogs/pharmaceutical.lasso>

Focus on Critical Topic Areas

Lectures and group discussions will focus on these areas vital to effective and efficient stability programs:

- The stability organization: examining organizational structure and administrative tools to ensure effective management
- The stability protocol: developing a meaningful document
- Stability operations: administering stability supplies and laboratory testing
- The stability laboratory: surveying technical and compliance issues
- Stability systems: examining support systems that comprise the stability infrastructure
- Quality assurance: identifying and examining tools to meet cGMP requirements
- The evolving direction of cGMP: its relationship to Quality Systems

Why This Course

This pragmatic, hands-on course differs from most others because we will emphasize the role of the organization in facilitating the success of the pharmaceutical stability program and point out the pitfalls you may encounter if these issues are not adequately addressed.

Benefits for You

- Find out how to build a stability systems infrastructure to accommodate your business environment
- Examine approaches to operating a stability program in a current Good Manufacturing Practice (cGMP) environment
- Explore the administrative and operational impact of the interaction of Quality Systems with cGMP in stability programs
- Understand the role of individual functional areas and how they contribute to the total effort
- Learn and understand the rationale behind the development of appropriate test methods to support stability programs and establishment of expiration date

Who Should Attend

- Stability managers and staff
- Laboratory managers and staff
- Analytical R&D managers and staff
- Quality assurance and regulatory affairs professionals responsible for the design and management of stability programs
- Executives planning to add a stability program to their organization

Bring Your Team

Gain maximum value for your organization by attending as a team. If you enroll two or more people, you will receive a fee discount (see enrollment form).

Expert Instructors

Robert Buta is director of quality assurance for the Cardiovascular Research Foundation. Prior to this position Mr. Buta was associated with Consumer Product Testing Co., Inc., American Technical Consultants, Johnson and Johnson, Inc., and Vanguard Research Industries. Mr. Buta's experience in manufacturing, consulting, regulatory affairs and quality assurance has enabled him to design and implement functional systems that support manufacturing and laboratory operations in cGMP environments.

Phillip Trager is director of analytical services at Consumer Product Testing Co., Inc. Prior to his current position he was associated with Zenith Laboratories, Inc., Warner Lambert Co., Ortho Pharmaceutical Corp., and Hoffmann-LaRoche, working in quality control management and analytical R&D capacities. Mr. Trager has, over many years, developed, managed and participated in stability programs supporting drugs, cosmetics, dietary supplements and food products.

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Course Outline

Monday, February 26

8:00 Registration and Continental Breakfast

Tropicana Resort and Casino
3801 Las Vegas Boulevard South
Las Vegas, Nevada

8:30 Welcome and Introduction

Michael F. Waxman
Professor and Program Director
University of Wisconsin–Madison

Overview

- Rationale
- Governing regulations
- Definitions

The Stability Organization

- Organizational strategies
 - central
 - distributed
 - blended
- Organizational impact
 - on communication
 - on execution

9:30 Break

9:45 The Stability Organization (continued)

- Administration
 - overall management
 - responsibility for infrastructure
 - stability systems oversight
 - stability alerts
 - stability investigations
 - stability reporting
 - annual reviews

12:00 Lunch

1:00 The Stability Organization (continued)

- Equipment and metrology
 - equipment qualification and calibration
 - measurement equipment
 - monitoring systems/redundant systems
- instrument qualification and calibration

2:30 Break

2:45 The Stability Protocol

- Assignment of responsibilities
- The test article
- The storage environment
- Time intervals
- Test design and execution
- Rationale
- Goals

5:00 Summary and Discussion of Day One

Tuesday, February 27

8:30 Stability Operations

- Stability systems
 - scheduling, study supplies
- Infrastructure management
 - equipment calibration
 - maintenance
 - monitoring activities
- Stability laboratory
 - method development
 - method validation
 - R&D test support
- Marketed products
 - technology transfer
 - manufactured products test support

9:45 Break

10:00 Stability Operations (continued)

- Data management
- Trending
- Investigations
- Laboratory data storage, stability predictors
- Establishment of expiration date

12:00 Lunch

1:00 Quality Assurance

- Document control
 - standard operating procedures
 - test methods
 - protocols
- Compliance
 - standard operating procedures
 - test methods
 - stability alerts
 - stability investigations
 - stability reporting
 - annual reviews

3:00 Break

3:15 Quality Assurance (continued)

- Information management
 - enterprise management
 - database maintenance

Stability Resources

- Regulatory bodies
 - FDA
 - ICH
 - CTFA

4:00 Summary and Conclusions

- Summary of sessions
- Questions and answers

5:00 Final Adjournment

Related Courses

For details on the following courses, contact program director Michael Waxman (800-462-0876 or waxman@engr.wisc.edu) or check our Web site at <http://epd.engr.wisc.edu/catalogs/pharmaceutical.lasso>.

Writing and Managing Pharmaceutical SOPs in Compliance with cGMP

February 28–March 1, 2007
Las Vegas, NV
Course #J075

Test Method Validation in Pharmaceutical and Biopharmaceutical Development and Production

March 5–7, 2007, Las Vegas, NV
Course #J021

Cleaning Validation Practices for Pharmaceutical and Biopharmaceutical Production

March 12–13, 2007, Las Vegas, NV
Course #J022

Tablet and Capsule Manufacturing: Introduction and Update for Competitive Organizations

March 19–21, 2007, Las Vegas, NV
Course #J023

Pharmaceutical Laboratory Controls for FDA Compliance: A Systematic Priority-Setting Approach

March 26–27, 2007, Las Vegas, NV
Course #J032

Pharmaceutical and Device Project Management

April 4–6, 2007, Las Vegas, NV
Course #J024

Four Easy Ways to Enroll

Need to Know More?

Call toll free **800-462-0876** and ask for

Program Director:

Professor Michael Waxman
waxman@engr.wisc.edu

Program Associate:

Diane Lange

Or e-mail custserv@epd.engr.wisc.edu

General Information

Fee Covers Notebook, course materials, break refreshments, lunches and certificate.

Cancellation If you cannot attend, please notify us by February 19, and we will refund your fee. Cancellations received after this date and no-shows are subject to a \$150 administrative fee. You may enroll a substitute at any time before the course starts.

Location This course will be held at The Tropicana Resort and Casino, 3801 Las Vegas Boulevard South, Las Vegas, Nevada. If you must be contacted during the course, phone messages may be left for you at 702-739-2222.

Accommodations We have reserved a block of sleeping rooms (\$95/single/double) for course participants at The Tropicana Resort and Casino, the course site. To reserve a room at the special rate, call 800-634-4000 or 702-739-2222 by January 26 and state that you will be attending this course.

Continuing Education Credit By participating in this course, you will earn 1.2 Continuing Education Units (CEU).

Best Practices in Biopharmaceutical Raw Materials Testing and Vendor Qualification

April 16–17, 2007, Las Vegas, NV
Course #J025

Good Manufacturing Practice for Regulated Consumer Products

April 23–24, 2007, Las Vegas, NV
Course #J026

Pharmaceutical Water Systems

April 25–27, 2007, Las Vegas, NV
Course #J029

Advanced Practices in Pharmaceutical Tablet and Capsule Technology

May 7–9, 2007, Las Vegas, NV
Course #J027

Auditing Suppliers to the Pharmaceutical Industry

May 10–11, 2007, Las Vegas, NV
Course #J028

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Phone:
800-462-0876 or
608-262-1299 (TDD 265-2370)



Internet:
<http://epd.engr.wisc.edu/webJ031>

Mail to:

Engineering Registration, The Pyle Center
702 Langdon Street, Dept. 106
Madison, Wisconsin 53706



Fax:

800-442-4214 or 608-265-3448



Course Information

- Please enroll me in **Developing and Implementing Effective Pharmaceutical Stability Programs Course #J031** February 26–27, 2007 in Las Vegas, NV Fee: \$1895
Team Discount: \$1795 each when two or more persons enroll from the same company
- I cannot attend at this time. Please send me brochures on future courses.

Personal Information (Please print clearly.)

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