

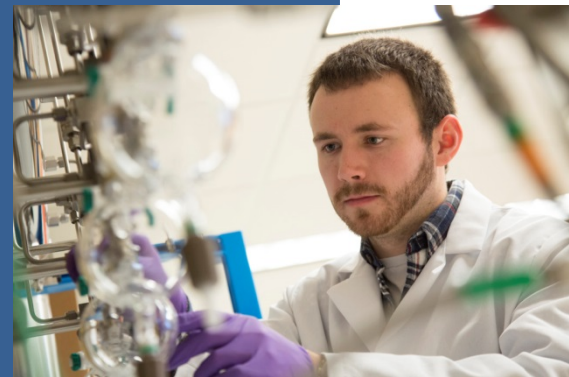


Control Strategies for Pharmaceutical Manufacturing: Real Time Release Testing and Design Space Determination

Mark your calendars for the Control Strategies for Pharmaceutical Manufacturing: Real Time Release Testing and Design Space Determination conference, co-sponsored by the University of Maryland Center for Excellence in Regulatory Science and Innovation (M-CERSI) and the American Association of Pharmaceutical Scientists (AAPS).

The Control Strategies for Pharmaceutical Manufacturing: Real Time Release Testing and Design Space Determination conference will be held on **Thursday, May 23, 2013**, at the University of Maryland School of Pharmacy, located at 20 North Pine Street in Baltimore, MD.

This one-day conference will bring academics, government regulators, and industrial researchers together to learn about the latest advances in Real Time Release Testing (RTRT) and to share their experiences with implementing RTRT systems. The goal is to examine the issues associated with the manufacture of pharmaceutical products. In particular, methods for developing a manufacturing control strategy and to examine the steps needed to develop a RTRT system using PAT technologies will be discussed.



Registering by mail? Please detach this form and submit it with your check. All participants can also register online at www.pharmacy.umaryland.edu/manufacturing, which accepts credit cards.



Control Strategies for Pharmaceutical Manufacturing: Real Time Release Testing and Design Space Determination Mail-In Registration

Please make check payable to **UMBF/CERSI** and mail to:

University of Maryland School of Pharmacy
Attn: Sharese Essien
20 Penn Street
HSF II, Room 518
Baltimore, MD 21201

Please provide the following information:

Name

Address

Phone

Email

Title and Company/School/Agency

Please indicate highest degree obtained:

- High School Master's Degree
- Bachelor's Degree Doctorate

Please indicate which category best describes you:

- Faculty, Staff, Student from the University of Maryland Baltimore or College Park Campus (FREE)
- M-CERSI Industrial Consortia Members (FREE)
- Federal Government Employees (FREE)
- Other Participant (\$50.00)

CONFERENCE AGENDA

May 23, 2013

10:00-10:10 a.m.

Meeting Overview

Stephen Hoag, PhD
Professor of Pharmaceutical Sciences
Director, Good Manufacturing Practice Facility
University of Maryland School of Pharmacy

10:10-10:40 a.m.

“Overview of Pharmaceutical Manufacturing Control”

Christine Moore, PhD
Acting Director, Office of New Drug Quality Assessment
Food and Drug Administration

10:40-11:20 a.m.

“Case Study Strategy for Developing A New Drug Product for Real Time Release and Regulatory Requirements”

Raafat Fahmy, PhD
Science Advisor
Food and Drug Administration

11:20 a.m.-12:00 p.m.

“Developing the Control Strategy for Pharmaceutical Manufacturing Across Scales of Manufacturing”

Stephen Hoag, PhD
Professor of Pharmaceutical Sciences
Director, Good Manufacturing Practice Facility
University of Maryland School of Pharmacy

12:00-1:00 p.m.

Lunch is Provided

1:00-1:40 p.m.

“Statistical Methods for Establishing the Design Space and Control within Design Space”

Gregg Claycamp, PhD
Senior Scientist, Risk Analysis and Decision Analysis
Food and Drug Administration

1:40-2:20 p.m.

“Industrial Perspective on the Use of Models in the QbD Framework”

Christian Airiau, PhD
Chemometrician, Manager
GlaxoSmithKline

2:20-3:00 p.m.

“Industry Experiences in Launching, Managing, and Transferring A Real-Time Release Testing Method Globally from 2006 to Today”

Gert Thurau, PhD
Director, Process Analytical Technology (PAT)
Merck

3:00-3:15 p.m.

Break

3:15-4:00 p.m.

Speaker Breakout Session

Discussion of Key Issues:

- Link between science of controlling a process and real time experience and testing
- Steps needed to prove control and TRT using PAT technology