Workshop Agenda

Monday, April 21

5:00 pm - 7:00 pm Grand Ballroom South Foyer
Registration

Tuesday, April 22

7:00 am - 5:45 pm Grand Ballroom South Foyer
Registration

8:00 am - 5:45 pm Grand Ballroom South
General Session

8:00 am
Introduction and Welcome
John M. Taylor, Esq.
Food and Drug Administration

8:30 am
Keynote Address: Overview and Current Status of the Initiative
Janet Woodcock, M.D.
Food and Drug Administration

9:15 am
Industry Perspective on the Initiative
C. Greg Guyer, Ph.D.
Merck and Company, Inc.

10:00 am Grand Ballroom Foyer Break

10:30 am
International Regulatory Perspective and Consideration
Gordon Munro, Ph.D.
Medicines Control Agency

11:00 am
Part 11 Update
Joseph Famulare
Food and Drug Administration

11:15 am
Risk-Based cGMPs: Defining Risk and Quality
Bruce Burlingon, M.D.
Wyeth Pharmaceuticals

11:45 am
Risk-Based cGMPs: Defining Risk and Quality—Academic Perspective
Nuzer Singpurwalla, Ph.D.
George Washington University

12:15 pm Grand Ballroom Central Lunch
Complimentary to all registrants

1:30 pm
Integrating CMC Review and Inspection
John M. Taylor, Esq.
Food and Drug Administration

2:00 pm
Integrating CMC Review and Inspection
Christine Mundkur
Barr Laboratories

2:30 pm
Changes Without Prior FDA Approval
Dennis M. Bensley, Jr., Ph.D.
Food and Drug Administration

3:00 pm
Changes Without Prior FDA Approval
Kenneth Seamon, Ph.D.
Amgen, Inc.

3:30 pm Grand Ballroom Foyer Break

4:00 pm
Manufacturing Science
G.K. Raju, Ph.D.
Massachusetts Institute of Technology

4:30 pm
Manufacturing Science - Industry Perspective
Gerry Migliaccio
Pfizer, Inc.

5:00 pm
Quality Systems and Regulatory Innovation for the 21st Century
Joyce Ramsbotham
European Federation of Pharmaceutical Industries and Associations

5:15 pm
Panel Discussion
Objectives and Logistics for Breakout Sessions
Wednesday, April 23

7:30 am - 5:00 pm Grand Ballroom South Foyer
Registration

8:30 am - 10:00 am
BREAKOUT SESSIONS

Breakout Session A Grand Ballroom South
Risk-Based cGMPs: Defining Risk and Quality
PhRMA Lead

Breakout Session B Renaissance East
Changes Without Prior Approval
GPhA Lead

Breakout Session C Renaissance West A
Manufacturing Science
BIO Lead

Breakout Session D Renaissance West B
Integrating CMC Review and Inspection
ADA/AHI Lead

10:00 am Grand Ballroom Foyer
Break

10:30 am - 12:00 pm
BREAKOUT SESSIONS REPEATED

Breakout Session A Renaissance West B
Risk-Based cGMPs: Defining Risk and Quality
ADA/AHI Lead

Breakout Session B Grand Ballroom South
Changes Without Prior Approval
PhRMA Lead

Breakout Session C Renaissance East
Manufacturing Science
GPhA Lead

Breakout Session D Renaissance West A
Integrating CMC Review and Inspection
BIO Lead

3:00 pm Grand Ballroom Foyer
Break

3:30 pm - 5:00 pm
Breakout Sessions Repeated

Breakout Session A Renaissance East
Risk-Based cGMPs: Defining Risk and Quality
GPhA Lead

Breakout Session B Renaissance West A
Changes Without Prior Approval
BIO Lead

Breakout Session C Renaissance West B
Manufacturing Science
ADA/AHI Lead

Breakout Session D Grand Ballroom South
Integrating CMC Review and Inspection
PhRMA Lead

Thursday, April 24

8:00 am - 12:30 pm Grand Ballroom South Foyer
Registration

8:30 am - 12:30 pm Grand Ballroom South
General Session
Workshop Agenda

8:30 am
Benchmarking Semiconductor Manufacturing and Its Applicability to Pharmaceutical Manufacturing
Jackson Nickerson, Ph.D.
John M. Olin School of Business, Washington University
Jeffrey Macher, Ph.D.
McDonough School of Business, Georgetown University

9:00 am
Breakout Session Summary: Changes Without Prior Approval
Rick Smith
Aventis Pasteur, Inc.

9:30 am
Breakout Session Summary: Manufacturing Science
Gerry Migliaccio
Pfizer, Inc.

10:00 am  Grand Ballroom Foyer
Break

10:30 am
Breakout Session Summary: Risk-Based cGMPs: Defining Risk and Quality
Edward Kaminski, Ph.D.
Wyeth Pharmaceuticals

11:00 am
Breakout Session Summary: Integrating CMC Review and Inspection
Joseph J. Anisko, Ph.D.
Alkermes, Inc.

11:30 am
Panel Discussion

12:30 pm
Adjournment