Nationally recognized and regional experts from government, industry and academia will discuss the current initiatives to enhance regulatory science, pharmaceutical manufacturing and product quality.

**AGENDA**

**TUESDAY • OCTOBER 20, 2009**

<table>
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<th>Time</th>
<th>Event</th>
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<tr>
<td>7:30 am - 5:00 pm</td>
<td>Registration (Held in Main Hall AB Foyer)</td>
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<tr>
<td>8:00 am - 8:15 am</td>
<td>Opening Remarks (Held in Main Hall AB)</td>
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<tr>
<td>8:15 am - 9:00 am</td>
<td>Keynote Address – Global Challenges Facing the Pharmaceutical Industry</td>
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<tr>
<td>9:00 am - 9:40 am</td>
<td>Supply Chain Integrity: An FDA Overview of Recent Challenges</td>
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<tr>
<td>9:40 am - 10:20 am</td>
<td>Supply Chain Challenges, Viewpoints from the FDA Forensic Chemistry Center</td>
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<tr>
<td>10:20 am - 10:45 am</td>
<td>BREAK</td>
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<td>10:45 am - 11:30 am</td>
<td>The Heparin Case Study</td>
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<tr>
<td>11:30 am - 11:50 am</td>
<td>The Global Recession Impact on the Pharmaceutical Supply Chain</td>
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<tr>
<td>11:50 am - 12:20 pm</td>
<td>Panel Discussion (Speakers with Robert Gaenslen, Ph.D., UIC)</td>
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<tr>
<td>12:20 pm - 1:30 pm</td>
<td>LUNCH</td>
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**SESSION I • SUPPLY CHAIN INTEGRITY • 9:00 AM - 12:20 PM • MAIN HALL AB**

Moderator: Andrew Bonanno

Divisional Vice President, Abbott Quality and Regulatory Global Compliance

- Edwin Rivera Martinez
  Acting Associate Director for Product Quality, FDA

- Cheryl L. Flurer, Ph.D.
  Supervisory Chemist, FDA, Forensic Chemistry Center

- Raymond Godlewski Sr., R.Ph.
  Vice President Quality, Baxter Pharmaceuticals and Technology, Baxter Healthcare Corporation

- Laura Obenauf
  Director, Supply Chain Risk Management, Global Pharmaceutical Operations, Abbott
AGENDA (Continued)

SESSION II • DRUG SAFETY • 1:30 PM - 4:30 PM • MAIN HALL AB
Moderator: Lisa Skeens, Ph.D.
Vice President Global Regulatory Affairs Pharmaceuticals, Baxter Healthcare Corporation

1:30 pm - 2:00 pm  FDA MedWatch and the Communication of Safety Information
  • Norman S. Marks, M.D., MHA
     Medical Director, MedWatch, FDA/OC/Office of Scientific and Medical Programs
2:00 pm - 2:30 pm  Detecting and Evaluating Safety Signals from Claims and Spontaneous Event Report Databases
  • Robert D. Gibbons Ph.D.
     Director, Center for Health Statistics, University of Illinois at Chicago
2:30 pm - 3:00 pm  An Industry Perspective on Pharmacovigilance and Recent FDA Initiatives
  • Sarah Sellers, Pharm.D., MPH
     Director of Epidemiology, Global Pharmacovigilance
     Baxter Healthcare Corporation
3:00 pm - 3:30 pm  The VA Perspective on Pharmacovigilance and Safety Communication
  • Francesca Cunningham, Pharm.D.
     Director of the Center for Medication Safety PSCI,
     National Center for Patient Safety (NCPS), and Program Director of Outcomes Research at the Department of Veterans Affairs (VA)
3:30 pm - 4:00 pm  BREAK
4:00 pm - 4:30 pm  Current Initiatives Associated with Drug Name Confusion Research
  • Bruce L. Lambert, Ph.D.
     Professor, Department of Pharmacy Administration & Director, Center for Education and Research on Therapeutics, University of Illinois at Chicago
4:30 pm - 5:00 pm  Panel Discussion

SESSION III • CURRENT FDA HOT TOPICS (FDA) • 5:00 PM - 5:30 PM • MAIN HALL AB

5:00 pm - 5:30 pm  FDA Hot Topics
  • Lorelei Jarrell
     Compliance Officer, FDA Chicago District Office
5:30 pm - 5:45 pm  Travel to Dinner
5:45 pm - 8:00 pm  Dinner and Cocktails
     Franconello Restaurant, 1301 S. Halsted Avenue, Chicago
AGENDA (Continued)

WEDNESDAY • OCTOBER 21, 2009

8:00 am - 12:00 pm  Registration

SESSION IV • DESIGNING QUALITY IN • 8:00 AM - 10:15 AM • MAIN HALL AB

Moderator: Zena Kaufman
Divisional Vice President Global Pharmaceutical Operations Quality Assurance, Abbott

8:00 am - 8:30 am  Quality by Design - Lessons Learned From Experience

- Jeffrey N. Levy, Ph.D.
  Vice President, Quality Assurance, API and Product Research and Development  Eli Lilly

8:30 am - 9:00 am  Linking Quality by Design, Control Strategy and Risk Management
In an Integrated Approach

- Stephen Tyler
  Director, Quality Assurance Global Pharmaceutical Operations  Strategic Quality & Technical Operations, Abbott

9:00 am - 9:45 am  FDA approach to inspection in a Quality by Design Environment: Differences and Similarities

- Jason Chancey
  Investigator, FDA Chicago District Office

9:45 am - 10:15 am  Panel Discussion (Speakers with Lorelei Jarrell, FDA)

10:15 am - 10:30 am  BREAK

SESSION V • cGMP OBSERVATIONS FROM THE FIELD • 10:30 AM - 12:30 PM • MAIN HALL AB

Moderator: William Weissinger, MS
District Special Assistant, US Food and Drug Administration

10:30 am - 11:15 pm  Pharmaceutical Manufacturing Deficiencies

- Steven B. Barber
  Director, Compliance Branch Detroit District Office, U.S. Food and Drug Administration

11:15 am - 11:45 am  Common Laboratory Control Deficiencies

- Mark Parmon
  Compliance Officer, FDA Cincinnati District Office

11:45 am - 12:30 pm  Panel Discussion

12:30 pm - 1:00 pm  Closing Remarks

- Todd Chermak, R.Ph., Ph.D.
  Divisional Vice President of CMC, Global Pharmaceutical Regulatory Affairs  Abbott

1:00 pm  Boxed Lunches and Informal Round Table Discussions
A special thank you to the following:

**Forum Sponsor**

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and

Great Lakes cGMP & Regulatory Science Forum Committee Members

**Committee Chair**

Todd Chermak, R.Ph., Ph.D. • Abbott

**Members**

Barbara Allen • Lilly

Arlyn Baumgarten • NCAFDO and retired FDA

Andrew Bonanno • Abbott

Mark Fenton • Takada

Richard Gemeinhart, Ph.D. • UIC College of Pharmacy

Raymond Godlewski Sr., R.Ph. • Baxter Healthcare Corporation

Zena Kaufman • Abbott

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Paul Pluta, Ph.D. • Institute of Validation Technology / UIC College of Pharmacy

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