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AGENDA

34TH INTERNATIONAL GOOD MANUFACTURING PRACTICES CONFERENCE

GMPs – SPOTLIGHTING RISK MANAGEMENT

March 15-18, 2010

Monday, March 15, 2010

5:00 – 7:00	Registration	Conference Registration Desk
6:00 – 8:00	Networking Reception	Hill Atrium

Tuesday, March 16, 2010 (CONFERENCE BEGINS)

ALL SESSIONS IN MAHLER AUDITORIUM

7:30 – 8:30	Late Registration	Conference Registration Desk
7:00 – 8:30	Breakfast Buffet	Banquet Area

Session Moderator: Ron Tetzlaff, PAREXEL

8:30	Conference Orientation >Gary Dykstra	
8:40	Welcome >Heidi Davidson, Athens Mayor	
8:45	FDA Welcome and Office of Regulatory Affairs Update >Malcolm Frazier, FDA, Office of Regulatory Affairs	

Wednesday, March 17, 2010 (Happy St Patrick's Day!)

PHARMACEUTICAL SAFETY – THE WORLD VIEW

7:00-8:30 Breakfast Buffet Banquet Area

Session Moderator: Maria Guazzaroni Jacobs, Pfizer

8:30 **ICH – Update and Implementation of Working Group Report**
 >Rick Friedman, FDA, Center for Drugs

9:00 **PIC-S - What is it?**
 >Tor Graberg, Sweden, Medical Products Agency

9:30 **Networking Break**

10:00 **New Canadian GMPs - Global Implications**
 >Robert Scales, Health Canada

10:30 **FDA – Beyond Our Borders**
 >TBA , Office of International Programs ,FDA

11:00 **WHO – World-wide Pharmaceutical Safety**
 >Dr. Sabine Kopp, WHO

11:30 **Q&A – Morning speakers**

12:00 **Networking Luncheon** Banquet Area

Session Moderator: Ballard Graham, Abbott Labs

1:00 **Generic Drugs – Regulatory Update**
 >Gary Buehler, FDA, Center for Drugs

1:30 **Criminal Investigations – Case Studies**
 >Kim Rice, FDA (retired), Office of Criminal Investigations

2:00 **Biologics - Field Regulation Update**
 >Evelyn Bonnin, FDA, Office of Regulatory Affairs

2:30 **Networking Break**

2:45 **Center for Drug Evaluation and Research – Breaking News**
 >Rick Friedman, FDA, Center for Drugs

3:15 **Quality By Design**
 >Leslie Bloom, Pfizer

- 4:00 **Q&A – Afternoon speakers**
- 4:45 **Adjourn**
- 5:00 **Board Buses – Travel to Georgia Botanical Gardens**
- 6:00 **Southern Dinner in the Gardens**

Thursday, March 18, 2010

Session Moderator - Barbara Wood, FDA

- 7:00-8:30 **Breakfast Buffet** Banquet Area
 - 8:30 **CBER Compliance Update**
> TBA
 - 9:30 **CDER Compliance Update**
> Edward Rivera, Center for Drugs
 - 10:00 **Networking Break**
 - 10:30 **FDA Investigations Update – What are the investigators finding**
>Ileana Pettit, FDA, Office of Regulatory Affairs
 - 11:00 **FDA Compliance Update – What actions are being recommended**
>Phil Campbell, FDA, Office of Regulatory Affairs
 - 11:30 **Q&A**
 - 12:00 **Adjourn**
 - 12:00 **Luncheon for Post-Conference Tutorial Participants** Banquet Area
- POST-CONFERENCE TUTORIAL**
- Moderator: Charles Gammill**
- 1:00 **CAPA Development and Implementation** Room K/L
>Bruce Little, Quality Management Systems
 - 4:00 **Adjourn**