



ICH REGIONAL PUBLIC MEETING

Hosted by:
U.S. Food and Drug Administration &
Pharmaceutical Research and Manufacturers of America

Tuesday, October 21, 2008, 2:30 – 5:30 p.m.
Hilton Washington DC / Rockville Hotel & Executive Meeting Center
Regency Room, 1750 Rockville Pike, Rockville, MD 20852

- **Welcome**
 - Michelle Limoli (FDA)
- **Opening Remarks**
 - Murray Lumpkin (FDA)
- **The ICH Process in Review**
 - Justina Molzon (FDA)
- **Implementation of ICH Guidelines in Japan**
 - Toshi Tominaga (MHLW)
- **Overview of Global Cooperation Group**
 - Mike Ward (Health Canada)
- **Overview and Update on Efficacy Topics**
 - E15 and E16: Lois Hinman (PhRMA)
 - E2F: Vernon Stringer (Health Canada)
 - Q&A
 - Public Presentations
- **Overview and Update on Quality Topics**
 - Jon Clark (FDA)
 - Q&A
 - Public Presentations
- **Overview and Update on Electronic Standards Topics**
 - eCTD: Louis Boulay (Health Canada)
 - M2: Mary Ann Slack (FDA)
 - Q&A
 - Public Presentations
- **Overview and Update on Safety Topics**
 - Abby Jacobs (FDA)
 - Q&A
 - Public Presentations
- **Adjourn**