



## **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**