

Understanding U.S. FDA Regulatory Requirements

New Delhi, Pune and Hyderabad, May 2011

Course at a Glance

DAY 1

- 8:15 - 9:00 Registration & Morning Coffee
- 9:00 - 9:30 Welcome, Felicitations, and Introduction of Course Objectives, Susan Finston
- 9:30 - 10:30 Overview of the Food & Drug Administration (FDA), Wayne Pines
- 10:30 - 11:45 Company Interactions with FDA: Pre-IND through Advisory Committee, Thomas Donnelly & Wayne Pines
- 11:45 - 12:00 Networking / Coffee Break
- 12:00 - 1:00 Nonclinical & GLP Issues, 505(b)(2), IND preparation, Thomas Donnelly
- 1:00 - 2:15 IND/NDA/ANDA Chemistry & Manufacturing Issues, Small Molecules and Biologicals, Michael Gross
- 2:15 - 3:15 Buffet Lunch
- 3:15 - 4:00 IND/NDA Clinical Issues, Thomas Donnelly
- 4:00 - 4:15 Networking / Coffee Break
- 4:15 - 5:15 Device/Diagnostic Overview, Michael Gross
- 5:15 - 6:00 Emerging Issues Panel I: Thomas Donnelly, Susan Finston, Michael Gross, Wayne Pines
- 6:00 - 6:15 Discussion & Wrap-Up of Day 1
- 6:30 - 8:00 Welcome Reception
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DAY 2

- 8:15 - 9:00 Registration & Morning Coffee
- 9:00 - 9:15 Recap of Day 1 & Introduction of Day 2, Susan Finston
- 9:15 - 10:30 NDA/BLA Content, Format & Review, Thomas Donnelly
- 10:30 - 11:45 ANDAs, DMFs, and Data Exclusivity, Michael Gross, Thomas Donnelly & Wayne Pines
- 11:45 - 12:00 Networking / Coffee Break
- 12:00 - 1:00 Labeling & Advertising Regulation & REMS, Wayne Pines
- 1:00 - 2:15 Buffet Lunch
- 2:15 - 3:15 Special FDA Programs, Thomas Donnelly
- 3:15 - 4:00 Crisis Management, Wayne Pines
- 3:00 - 4:15 Networking / Coffee Break
- 4:15 - 5:15 Emerging Issues Panel II: Thomas Donnelly, Susan Finston, Michael Gross, Wayne Pines
- 5:15 - 5:45 Discussion & Wrap-Up of Day 2
- 7:30 - 9:30 Closing Dinner & Award of Certificates

For more details please see <http://www.FINSTONCONSULTING.COM>
or contact Ms. Anjami Nayyar, India Project Manager 095-5254-9858



Faculty Profiles, May 2011

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[Wayne Pines](#) is President of Healthcare and Regulatory Services at Apco Worldwide. He helps clients address issues involving the FDA regulation of drugs, devices and foods. He served as Associate Commissioner for Public Affairs at the FDA and has authored or edited about a dozen books about the FDA, crisis management and advertising regulation. He also is a director of the Alliance for a Stronger FDA, the MedStar Research Institute and Scolr Pharma.



[Thomas E. Donnelly](#), PhD., is a global regulatory affairs consultant specializing in all aspects of FDA regulation of drug development, drug registration and marketing of small and large molecule drug substances. He has 23 years experience in senior level regulatory positions in U.S., Europe and Indian companies relating to therapeutic categories including CNS, cardiovascular, anti-viral, anti-fungal and metabolic disorders and led development of many other compounds, and now provides regulatory services to companies through Donnelly Regulatory Consulting, LLC.



[Michael Gross](#), Ph.D., RAC, is a Senior Consultant with Biologics Consulting Group specializing in quality, regulatory affairs and development strategy for drugs, biologics, medical devices and combination products. He has worked in the medical products industry for thirty years, including experience as a research chemist at FDA, responsible for regulating and inspecting biological products manufacture, and, in a range of therapeutic areas including cardiovascular, neurological, pulmonary, urology, oncology, ophthalmology, dermatology, anti-infectives and blood products.

