8:00–8:30  Registration and Continental Breakfast

8:30–8:45  Welcome and Opening Comments
Anne Johnson, Program Director, BIMO East, FDA
The speaker will address the role of the FDA District Office relative to the Bioresearch Monitoring Program.

8:45–9:00  FDA's Good Clinical Practice Program
Patrick McNeilly, PhD, RPh, Senior Health Policy Analyst, Good Clinical Practice Program, Office of GCP, Office of the Commissioner, FDA
Dr. McNeilly will provide a brief overview of FDA's Good Clinical Practice Program and information about various initiatives related to the clinical trials underway within FDA.

9:00–9:30  Break (with opportunity for conversations and discussion)

9:30–10:45  What FDA Expects in a Pharmaceutical Clinical Trial
Susan Leibenhaut, MD, Medical Officer; Division of Scientific Investigations, Office of Compliance, Center for Drug Evaluation and Research, FDA
The regulations regarding clinical trials are clear and published. FDA guidance, policies, and requirements abound. Dr. Liebenhaut will offer a discussion of the FDA's oversight of the conduct of pharmaceutical clinical research, including trends FDA has found when comparing research with FDA standards for design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials.

10:45–11:45  Medical Device Aspects of Clinical Research
Nicole Bell, MS, Consumer Safety Officer, Division of Bioresearch Monitoring, Office of Compliance, Center for Devices and Radiological Health, FDA
Ms. Bell will discuss how studies with investigational devices differ from those with drugs and biologics. These differences can create issues, especially for companies that may have dealt only with pharmaceuticals in the past. There are some similarities between devices and drugs and biologics. Device differences include the nature of firms and studies, statutory distinctions, and regulatory distinctions.

11:45–12:30  Ethical Issues in Subject Enrollment
Joal Hill, JD, MPH, PhD, Director, Research Ethics; Chairman, Institutional Review Board, Advocate Health Care
As applied to human subject studies, the ethical principle of justice underlies responsible participant selection requiring fair distribution in the burdens and benefits of research. Although some groups have been specifically identified in federal regulations as particularly vulnerable to exploitation in research, subjects who are not members of those groups may also require special consideration because of cognitive, medical, or other deficits. Dr. Hill will address how the current research climate (e.g., increased industry investment in research, online research, etc.) affects the ethics of subject enrollment and will suggest ways of recognizing and safeguarding susceptibilities of research subjects.

12:30–1:30  Lunch (Provided)

1:30–2:30  Adverse Event Reporting – Science, Regulation, Error and Safety
John Kessler, PharmD, Founder and Chief Clinical Officer of SecondStory Health; Clinical Associate Professor, University of North Carolina School of Pharmacy, Chairman of the Duke University Health System Institutional Review Board
The science, regulation and assessment of adverse events will be discussed in a context that brings forth the motivations and ethics of human research protections. The role of system errors and safe medication practices will be discussed.

2:30–3:30  Working with FDA's Center for Biologics Evaluation and Research
Dennis Cato, BS, Consumer Safety Officer, Office of Compliance and Biologics Quality/Bioresearch Monitoring, Center for Biologics Evaluations and Research, FDA
The Center for Biologics Evaluation and Research regulates research, development, production, and marketing of biologic drug products. This session will consider the organization, mission, and activities of the Center as well as the Center's inspection program.

3:30–3:45  Break

3:45–4:30  Clinical Trial Registration and Results Reporting on ClinicalTrials.gov
Patrick McNeilly, PhD, RPh, Senior Health Policy Analyst, Good Clinical Program, Office of GCP, Office of the Commissioner, FDA
Dr. McNeilly will provide information about the roles and responsibilities of NIH and FDA around submission of clinical trial information to ClinicalTrials.gov. This session will also describe the basic definitions and requirements for clinical trial registration and results submission, as well as FDA's compliance activities in this area.

FDA CLINICAL TRIAL REQUIREMENTS REGULATIONS, COMPLIANCE AND GCP CONFERENCE
4:30–5:00 Question and Answer Session / Panel Discussion

DAY TWO – THURSDAY
8:00–8:30 Registration and Continental Breakfast

8:30–9:00 Keeping Informed and Working Together
Anne Johnson, Program Director, BIMO East, FDA
The speaker will explain how the FDA can assist members of the research community in their efforts to find information and understand FDA regulations.

9:00–9:45 FDA Conduct of Clinical Investigator Inspections
Barbara Wright, BGS, Supervisory Investigator, Foreign BIMO Cadre, FDA
The speaker will explain the responsibilities of the Clinical Investigator including the regulations and guidelines to which the FDA expects the Clinical Investigator to adhere in their participation, review and oversight of clinical investigations.

9:45–10:00 Break (with opportunity for conversations and discussion)

10:00–10:45 Investigator Initiated Research
George D’Addamio, PhD, President, PharmConsult, Inc.
The Sponsor/Investigator takes on numerous additional responsibilities including protocol development, assurance of peer review, development and quality assurance related to Data Capture Procedures. They must secure financial and clinical resources, and they have the opportunity for Publication. This session will offer details about the Sponsor/Investigator’s legal responsibilities and insight into the additional activities the Sponsor/Investigator must provide.

10:45–11:30 Meetings with the FDA—Why, When and How
Judit Milstein, Chief Project Management Staff, Center for Drug Evaluation and Research, FDA
It is of the utmost importance to the research project to assure good communication and timely interactions with the FDA. This speaker will discuss the regulatory tools available to the sponsors/investigator to enhance the communication process with the FDA and offer some practical tips that can greatly facilitate the review process.

11:30–12:15 Part 11 Compliance—Electronic Signatures
Phillip Kronstein, MD, Lead Medical Officer, Division of Scientific Investigations, Office of Compliance, Center for Drug Evaluation and Research, FDA
This session offers discussion of Part 11 compliance, including scope, implementation, and definitions. The regulations in Part 11 establish the criteria under which the agency considers electronic records, handwritten and electronic signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

12:15–1:15 Lunch (Provided)

1:15–2:00 IRB Regulations and FDA Inspections
LauraLee Staples, Certified BIMO Specialist, New Orleans District Office, FDA
During this session, the speaker will discuss FDA regulations covering the operations of Institutional Review Boards, the procedures used by FDA investigators during inspections of IRBs, and FDA enforcement options.

2:00–2:45 Informed Consent Regulations
Barbara Wright, BGS, Supervisory Investigator, Foreign BIMO Cadre, FDA
This discussion considers regulations addressing the Informed Consent process and documentation from the inspector’s point of view.

2:45–3:00 Break (with opportunity for conversation and discussion)

3:00–3:15 The Inspection is Over—What Happens Next? Possible FDA Compliance Actions
Dennis Cato, BS, Consumer Safety Office, Office of Compliance and Biologics Quality/Bioresearch Monitoring, Center for Biologics Evaluation and Research, FDA
Mr. Cato will discuss the array of actions taken when research fails to meet standards enforced by the FDA.

3:15–4:35 Question and Answer Session / Panel Discussion

4:35 Closing Remarks and Adjournment