SoCRA and FDA Cosponsored Program
FDA Clinical Trial Requirements
Regulations, Compliance and GCP

DETROIT - April 21 and 22, 2004 (Wednesday and Thursday)

April 21

8:15 - 8:30 **Registration and Continental Breakfast**

8:30- 8: 45 **Welcome and Opening Comments**
Joann Givens, District Director, Detroit District FDA

Ms. Givens will address the role of the FDA District Offices, how they are structured, their responsibilities, and how they are available to academia and industry to assist in bringing therapies and products to the marketplace.

8:45 – 9:30 **What FDA Expects in a Pharmaceutical Clinical Trial**
Joseph Salewski, Division of Scientific Investigations, Center for Drug Evaluation and Research

The regulations regarding clinical trials are clear and published. FDA guidance, policies, and requirements abound. This presentation 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.

9: 30 - 10: 15 **Adverse Event Reporting – Science, Regulation, Error and Safety**
John Kessler, PharmD, BCPS
Assistant Director in the Department of Pharmacy, Duke University Hospital
Clinical Associate Professor in the University of North Carolina School of Pharmacy

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 systems-errors and safe medication practices will be discussed.

10:15-10:30 **Break (with opportunity for conversation and discussion)**

10:30 -11:30 **Medical Device Aspects of Clinical Research**
Jean Toth-Allen, Ph.D. Biophysicist/Consumer Safety Officer, Division of Bioresearch Monitoring
Office of Compliance, FDA Center for Devices and Radiological Health

Dr. Toth-Allen 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.

11:30-12:15 **Informed Consent Requirements**
Robert Wesley, Division of Inspections and Surveillance
Center for Biologics Evaluation and Research, FDA

This session will consider the regulations that apply to the Informed Consent forms and documentation as well as the process of assuring Informed Consent by the patient/subject.

12:15 – 1:15 **Lunch (Provided)**

1:15-2:00 **Ethical Issues in Subject Enrollment**
Joal Hill, JD, MPH, PhD(c), Advocate Health Care IRB

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 not members of those groups may also require special consideration because of cognitive, medical, or other deficits. This session 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.

2:00 2:45 **IRB Regulations and FDA's Mechanisms to Assure Compliance**
Leigh Anne Myers, Consumer Safety Officer, Detroit District

This session will consider the regulations applicable to the Institutional Review Board and how the FDA becomes involved in assuring compliance. IRB membership, deliberations, meeting documentation and decision making will be discussed.

Program continues

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

3:00 – 3:45 **FDA Inspections of Clinical Investigators**
Nancy Bellamy, Supervisory Consumer Safety Officer, Detroit District FDA

Ms. Bellamy will explain the responsibilities of the Clinical Investigator and the regulations and guidelines to which the FDA expects the Clinical Investigator to adhere in their participation, review and oversight of clinical investigations.

3:45-4:15 **Keeping Informed and Making Your Views Known to FDA**
Marie Falcone, Small Business Representative FDA, Central Region

Ms. Falcone will explain how the FDA Small Business Representatives assist the research community with information, with referrals, and in understanding FDA regulations. She will explain how to participate in agency decisions that impact research activities.

4:15- 4: 45 **Panel Discussion and Q&A**

April 22

8:30 - 8:45 **Registration and Continental Breakfast**

8:45 -9:30 **FDA and Confidence in the Conduct of Clinical Research**
David A. Lepay, M.D., Ph.D.
Senior Advisor for Clinical Science and Director, Good Clinical Practice Program
Office of Science and Health Coordination, Office of the Commissioner, FDA

Dr. Lepay will describe how the FDA Office of Science and Health Coordination, Good Clinical Practice Program, promotes confidence in clinical research through oversight of FDA regulated studies and coordination with international and interagency efforts.

9:30-10:15 **Investigator Initiated Research**
Yuka Sato, MS, B Pharm, Clinical Research Associate, Sankyo Pharma Clinical Development

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. All of these activities fall under the regulations and are subject to FDA oversight. This session will offer details about the Sponsor/Investigators' legal responsibilities and insight into the additional activities the Sponsor/Investigator must provide.

10 15-10:30 **Break (with opportunity for conversation and discussion)**

10:30-11:15 **Pre IND Meetings and the FDA Meeting Process**
David A. Lepay, M.D., Ph.D.
Senior Advisor for Clinical Science and Director, Good Clinical Practice Program
Office of Science and Health Coordination, Office of the Commissioner, FDA

It is of utmost importance to the research project to assure good communication and timely interactions with FDA. The speaker will discuss the regulatory tools available to sponsors/investigators to enhance the communication process with FDA and offer some practical tips that can greatly facilitate the review process.

11:15 – 11:30 **Working with FDA's Center for Biologics Evaluation and Research**
Patricia Holobaugh, Division of Inspections and Surveillance
Center for Biologics Evaluation and Research, FDA

The Center for Biologics Evaluation and Research regulates research, development, production and marketing of biologic drug products.

11:30 - 12:00 **The Inspection is Over - What Happens Next? Possible FDA Enforcement Actions**
Patricia Holobaugh, Division of Inspections and Surveillance
Center for Biologics Evaluation and Research, FDA

This session will discuss the array of actions taken when research fails to meet standards enforced by the FDA.

Noon – 12:30 **Panel Discussion and Q&A**

12:30 **Closing remarks and adjournment**