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2-day In-person Seminar:

How to Prepare for an FDA Meeting: Making the Most of Pre-IND/IDE, pre-NDA and Other Critical Meetings

By: **Dr. Mukesh Kumar**, PhD, RAC, Senior Director, Regulatory Affairs, Amarex Clinical Research

Location: February 25-26, 2016 | Washington, DC

SPEAKER

Dr. Mukesh Kumar, Senior Director, Regulatory Affairs, Amarex Clinical Research

Dr. Mukesh Kumar leads the Regulatory Affairs and Quality Assurance departments at Amarex, a full service pharmaceutical product development company based in Germantown, MD (www.amarexcro.com). Mr. Kumar's key expertise is in regulatory affairs, clinical trials and multi-national project management for medicinal and diagnostic products. He has written more than 40 new INDs for FDA submission and reviewed more than 100 INDs. He has been involved in about 100 clinical trials in more than 40 countries, has made several hundred US FDA submissions, and arranged a number of meetings with the US FDA.

In addition, he has had made regulatory submission in the EU and India. He has conducted GCP, GLP, GMP and GACP audits in the US and several countries in Europe and Asia. He has conducted numerous training workshops in FDA compliance related issues. He has authored numerous articles in peer-reviewed journals. He is a well-known expert in global regulatory affairs and has been an invited speaker at several professional and academic organizations worldwide. He is a certified regulatory affairs professional by the Regulatory Affairs Professional Society, USA.

LEARNING OBJECTIVES

- Understanding different stages of FDA meetings: pre-IND, Pre-IDE, Pre-NDA, pre-PMA, End-of-Phase 2
- Creating rationale for FDA meetings
- Requesting process for FDA meetings
- Creating a meeting information package and its regulatory requirements
- Logistics of an FDA Meeting
- Learn FDA meeting follow ups

COURSE DESCRIPTION

Despite a few guidance documents to help sponsors prepare for meetings with the FDA, it is a challenge to understand the most efficient and productive ways to strategize, prepare, conduct, and follow-up for these meetings. There are many misconceptions about the expectations from these meetings both for the sponsor and the FDA, and hence many sponsors fail to get the most benefit from them. Over the years, the FDA has also revised processes and practices for meeting with sponsors.

This two day seminar will provide valuable tips about the logistics, planning, conduct and best practices for all kinds of meetings with the FDA. Throughout the workshop, the author will discuss case studies and examples to highlight the common errors and potential solutions. This workshop contains a collection of practical tips from the instructor's extensive FDA meeting experience. This one-of-a-kind workshop will provide step-by-step instructions and practical tips to the most productive meeting with FDA for all FDA-regulated organizations.

AGENDA

DAY ONE: 8:30 AM - 4:00 PM

8:30 – 9:00 AM: Registration Process

9:00 AM: Session Start

- **9:00 – 10:30 AM: Session 1: Kinds of FDA Meetings: Understanding FDA Meetings**
  - Types of meetings: Type A, B, and C
  - Meetings at different stages of development: pre-IND, End-of-Phase 2, Pre-IDE, Pre-NDA, pre-PMA, etc.
  - Differences and similarities in meetings for drugs, devices and biologics
  - FDA criteria for granting or refusing a meeting
  - Criteria for In-Person and over-the-phone meetings
- **10:30 – 10:45 AM: Break**
- **10:45 – 12:30 Noon: Session 2: Deciding When to Meet FDA**
  - The "Pre-" meetings: Pre-IND, pre-NDA, pre-PMA, Pre-Phase 3
  - Creating the rationale for a FDA meeting: Pro and con analysis
  - Potential issues for FDA discussion
  - Evaluating available answers
  - Timing the FDA meeting: When is the best time?
- **12:30 – 1:15 PM: Lunch**
- **1:15 – 2:45 PM: Session 3: Strategy for an FDA Meeting**
  - Collecting available information
  - Gap Analysis
  - Listing potential questions
  - Potential solutions and their FDA acceptability evaluation
  - To have or not to have a meeting with FDA
- **2:45 – 3:00 PM: Break**
- **3:00 – 4:00 PM: Session 4: Process for Requesting an FDA meeting**
  - Identifying the contact Division and persons at FDA
  - The two-step process for a meeting request
  - Identifying sponsor team members and FDA experts
  - Identifying information to be included and avoided
  - Division specific meeting grant criteria: Drugs, biologics and medical devices

DAY TWO: 8:30 AM - 3:30 PM

- **8:30 – 10:00 AM: Session 5: Meeting Information Package**
  - Format for the meeting information package
  - Regulatory requirements for content
  - Scope of the meeting information package
  - Class exercise: Creating a meeting information package
- **10:00 – 10:15 AM: Break**
- **10:15 – 12:00 Noon: Session 6: Logistics of an FDA Meeting**
  - Pre-meeting preparatory activities
  - Reviewing preliminary comments from FDA
  - Meeting presentations
  - Role of team leaders and other members
  - Security processes at FDA and other logistical issues
- **12:00 – 12:45 PM: Lunch**
- **12:45 – 2:15 PM: Session 7: Conduct of an FDA Meeting: Mock Meeting**
  - Class exercise: Mock FDA meeting to highlight the dos and don'ts of an FDA meeting
  - Meeting minutes
  - Follow-up to an FDA meeting
- **2:15 – 2:30 PM: Break**
- **2:30 – 3:30 PM: Session 8: Special Considerations for Special meetings**
  - Periodic meetings: Pre-IND/IDE, End-of-Phase 2, Pre-NDA meetings
  - Type A urgent issue meetings
  - Type C miscellaneous meetings
  - Advisory Committee meetings

WHO WILL BENEFIT

- Regulatory affairs professionals
- Senior management executives (CEO, COO, CFO, etc.)
- Project managers
- Clinical trial specialists
- Regulatory compliance associates and managers
- People investing in FDA-regulated product development projects

Registration Form

GROUP REGISTRATIONS

Send Your Team for Maximum Benefit Get your team up to speed!

2 Attendees	-	Get 10% off
3 to 6 Attendees	-	Get 20% off
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Seminar Topic: How to Prepare for an FDA Meeting: Making the Most of Pre-IND/IDE, pre-NDA and Other Critical Meetings

Date & Location: .....

Attendee Details:

Register for 3 and 4th person gets a free pass.

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