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2-day In-person Seminar

FDA's GMP Expectations for Phase I and First-in-Man Clinical Trials

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

Location 1: March 24-25, 2016 | San Francisco, CA

Location 2: August 18-19, 2016 | Philadelphia, PA

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). His 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. Dr. Kumar is a PhD in Biochemistry and has worked as a research scientist at the NIH, Baylor College of Medicine, Houston, and premier institutions in India. He is a certified regulatory affairs professional by the Regulatory Affairs Professional Society, USA.

COURSE DESCRIPTION

Manufacturing an investigational product for the initial pilot clinical trials could pose a considerable logistical and financial challenge to developers. The first-in-man and pilot clinical trials are usually conducted in very small number of healthy participants with lower doses primarily to establish safety and hence do not need a significant amount of investigational material. The US FDA allows developers to test early stage investigational products under relaxed GMP requirements.

The manufacturing requirements for early stage clinical trials are designed to assure adequate quality of the investigational product being tested without the excessive regulatory burden of full-scale GMP manufacturing.

This workshop will present the current regulations, guidance documents and regulatory strategies available for manufacturing an early development stage product for Phase I and first-in-man clinical trials. Also discussed will be logistical issues with managing the supply of an early stage investigational product, and requirements for stability testing, storage and shipping, labeling, and documentations. Issues specific to special products in early stages of development such as combination products and 505(b)(2) drugs will be discussed. Basics of process validation along to standard process development will be presented. Perspectives for different classes of products will be presented using case studies.

AGENDA

COURSE OUTLINE AND APPROXIMATE TIMES

DAY 1 (8:30 AM – 4:00 PM)

- **8:30 – 9:00 AM: Registration**
- **9:00 – 10:30 AM: Lecture 1: Moving a Product out of R&D**
  - Issues with research grade material used for laboratory and non-clinical testing
  - Optimizing manufacturing processes
  - Raw material requirements and process development
  - Assessing scalability of manufacturing
  - Planning the CMC for a potential IND
- **10:30 – 10:45 AM: Break**
- **10:45 – 12:30 noon: Lecture 2: CMC Requirements for an IND Study**
  - Essential elements of the CMC section of an IND
  - Characterization of the active ingredient and finished product
  - Various kinds of products: drugs, biologics, botanicals, diagnostics, medical devices
  - Manufacturing facility, personnel and equipment requirements
- **12:30 – 1:15 PM: Lunch**
- **1:15 – 2:45 PM: Lecture 3: Good Manufacturing Practices: Basics for Beginners**
  - Core principles of GMP
  - Regulatory requirements for different products: drugs to medical devices
  - Customizing regulatory compliance to a given product
  - Role of discussions with the FDA
- **2:45 – 3:00 PM: Break**
- **3:00 – 4:00 PM: Lecture 4: Raw Material Management**
  - Planning for the early stage with an eye towards large scale manufacturing
  - Vendor management
  - Raw material handling issues for early stage products
  - Manufacturing step development

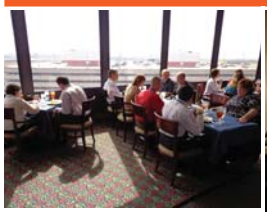
DAY 2 (8:30 AM – 3:30 PM)

- **8:30 – 10:00 AM: Lecture 5: GMPs for Phase 1 IND products**
  - The scope of the FDA guidance document
  - Acceptable practices and practical tips
  - GMP requirements for exploratory clinical studies
  - Specific requirements for drugs, biologics and combination products
- **10:00 – 10:15 AM: Break**
- **10:15 – 12:00 noon: Lecture 6: GMPs for Combination Products and 505(b)(2) Products**
  - Specific issues for various kinds of combination products
  - Combination products with one or more new components
  - CMC issues for 505(b)(2) products
  - GMP and QSR: which to follow for a combination products
- **12:00 – 12:45 PM: Lunch**
- **12:45 – 2:15 PM: Lecture 7: Process Validation for Early Stage GMP**
  - Introduction to process validation for early stage manufacturers
  - Step by step instructions for process validation
  - Process validation reports and other documentation
  - Developing SOPs based on validation processes
- **2:15 – 2:30 PM: Break**
- **2:30 – 3:30 PM: Lecture 8: Outsourcing Early Stage Manufacturing**
  - Logistics of using contract manufacturing organizations for early stage products
  - Pilot scale manufacturing requirements
  - GMP-grade and non-GMP grade manufacturing
  - Benefits and challenges with using local and international vendors

WHO WILL BENEFIT

- Directors
- Managers
- Supervisors, and lead workers in Regulatory Affairs
- Quality Assurance and Quality Control
- Workers who will prepare GMP documents for early phase products as well as those who will review these documents
- Regulatory affairs workers who will need to deal with submissions covering early phase products.

TESTIMONIALS



"I enjoyed the practical answers and lessons learned as shared by the presenter. Grateful for the sharing of presentation material (soft copy). Thanks to ComplianceOnline for timely response and communication. Variety of choices is extensive good and easy to register."

- Manager, Process Optimization, Prolong Pharmaceuticals, LLC

"Excellent instructor and he was easy to follow and I like the thorough and thoughtful answers of my questions."

- Senior Scientist, CCS Associates

"Instructor is very knowledgeable and good in explaining regs and guidance. Information provided along with soft copy of slide is a great idea and very helpful."

- Sr. QA Manager, Theravance

"Overall a good general overview. The amount of interaction between the participants and presenter was good."

- Asst. Director QA, Clinical Packaging, Abbott Labs

"GMP expectations was the most valuable topic for me. Face to face interaction and networking was good."

- Director of Pharmacy, Pfizer New Haven Clinical Research Unit

"Speaker's knowledge was higher than I had hoped."

- Director, BioMed IRB

"For me the whole event was very good. I had no knowledge of the topic prior to this seminar. The presentation was excellent and the speaker was very knowledgeable and respectful."

- Quality Assurance Specialist, Therapure Biopharma Inc.

"I had registered for a seminar but unfortunately I was not able to attend. The company was very understanding and extremely helpful. I plan on attending a future event soon."

- Director of Regulatory Affairs, Nickell Physician & Pharmacy Services

Registration Form

Registration Information:

- **Register Online**. Use your American Express, Visa or MasterCard.
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Seminar Topic: FDA's GMP Expectations for Phase I and First-in-Man Clinical Trials

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