Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Seminar on Phase I GMPs

Philadelphia, PA

April 16th & 17th, 2019

9:00 AM to 6:00 PM

Price

Price: **$2,000.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees

Price: **$10,000.00**

Register for 10 attendees

Price: **$20,000.00**

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

Peggy Berry

President & CEO, Synergy Consulting

Peggy J. Berry, MBA, RAC, is the President & CEO at Synergy Consulting where she provides consulting services to companies in all aspects of drug development. She also provides group and one-on-one training in drug development, regulatory affairs and project management topics. Prior to founding Synergy Consulting in 2015, she was Vice President of Regulatory Affairs at Insmed (2/2015-5/2015) where she was responsible for the development and implementation of global regulatory strategies and the management and oversight of the regulatory affairs department. Prior to Insmed, she was Vice President of Regulatory Affairs and Quality at Amarin (3/2009-2/2014). She has also held a variety of senior level positions at Dyax (5/2006-3/2009), MGI Pharma (now Eisai; 7/2005-5/2006), AstraZeneca (10/2001-7/2005)

Overview :

Early clinical trials are conducted to establish initial safety of a drug. The studies are generally in small number of healthy subjects and use lower doses of the drug product. Therefore, only small amounts of investigational material are required. In order to not undertake substantial costs and to reduce regulatory burden during these early stages, the FDA has established guidelines to allow early stage investigational products to be manufactured under less stringent GMPs.

This workshop will review the current regulations, guidance documents for early stage manufacturing and GMPs in detail. Regulatory strategies and logistical considerations for early development stage product, including vendor selection and management, stability, labeling, and documentation requirements will also be reviewed and explored.

Agenda:

Day One

The following topics will be discussed to provide the foundation and basis for advancing drugs into clinical development from research and providing required information to the FDA regarding these products.

- Moving a Product out of R&D
- CMC Requirements for an IND Study and commercial
- Good Manufacuring Practices: Basics for Beginners
- Raw Material Management

Specificic topics include:

- Issues with research greade 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
- 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 device
- Manufacturing facility personnel eqquipment and requirements
- Core principles of GMP regulatory requirements for all different products… durgs to medical devices
- Customizing regulatory compliance to a given product
- Role of discussions with the FDA
- Planning for the early stage with an eye toward large scale manufacturing
- Vendor management
- Raw material handling issues for early stage products
- Manufacturing step development

Day Two

The following topics will be discussed to provide the requirements for early stage products of different types and for vendor selection and management.

- The scope of the FDA guidance
- Acceptable practices and tips
- GMP requirements for exploratory clinical studies
- Specific requirements for drugs, biologic, and combination 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 product
- Introduction to process validation for early stage manufacturers
- Step by step introductions for process validation
- Process validation reports and other documentation
- Developing SOPs based on valiidation processes
- 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

Why you should attend:

Attend this conference so that you may understand differences between GMP requirements for early and later stage clinical development. Explore and discuss ways to develop and implement strategies for early GMPs for phase I clinical studies.

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
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What You will get

1. Learning Objectives
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Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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