Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

GMP and Regulatory Expectations for Early IND Products

Taipei, Taiwan

November 13th & 14th, 2017

9:00 AM to 6:00 PM

Price

Price: **$1,095.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$3,285.00** You Save: $2,190.0 (40%)*

~~$5,475.00~~

Register for 10 attendees

Price: **$6,022.00** You Save: $4,928.0 (45%)*

~~$10,950.00~~

ENROLL

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

Steven Kuwahara

Founder & Principal, GXP Biotechnology, LLC

Dr. Steven Kuwahara, Ph.D. is the founder and Principal of GXP BioTechnology LLC, a consulting firm that works in the areas covered by the GLP and GMP of drugs, biologics, and nutraceuticals. Steve has over 30 years of experience in supervising quality control laboratories, including an animal testing facility, and in performing GLP and GMP audits of internal and external testing laboratories . Steve has participated in the development of drugs and biologicals through all phases of clinical research and final product production.

Overview :

This course will present, in one place, the regulations and guidelines that apply to early phase products. In some cases these will not be regulations, but needs that, if met, will increase the efficiency of activities as a product proceeds through the development process. The course will present these items in the order of product development from the point of R & D activities to the completion of Phase 2 clinical trials.

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Agenda:

Day One

Lecture 1: Very Early Stages
- The need for documentation of matters that will affect downstream work.
- The effects of ICH Q8
  - Impact on R & D activities
  - Risk analysis and design control at this stage.

Lecture 2: GLP requirements
- Animal studies
  - Toxicology and pharmacokinetics.
- Estimating the Maximum Safe Starting Dose
  - A review of the guidance document.

Lecture 3: Early Pre-IND Studies
- Understanding exploratory Studies
  - Definitions and the IND that will be withdrawn.
- Orphan Drugs
- Drugs studied under the Animal Rule
  - What they are and how to conduct the studies.

Lecture 4: Meetings and Preparing for the IND
- Information required for the Phase 1 IND
  - The CMC requirements that will be needed.
- Pre-IND Meetings with FDA

Why you should attend:

Any pharmaceutical worker who must deal with products both in early and latter phases of development should attend this course in order to be aware of the regulatory requirements that will affect operations dealing with these products. The modifications to the GMPs for early phase products have modified the GMPs in such a way as to reduce requirements to allow more efficient work. At the same time some of the things that may appear to have changed, have not, and the pharmaceutical worker should be aware of this.

Day Two

Lecture 1: GMPs for Phase 1 IND products
- The scope of the guidance document
- The second guidance document covering the GMPs.

Lecture 2: GMPs for Phase 1 continued
- A presentation covering what GMPs are required at this stage.
- What has been omitted from the GMPs for Phase 1.

Lecture 3: Requirements for Phase 2 INDs
- The full GMPs resume, but do they?
- Phase 2 studies and the transition to full GMPs.
- CMC requirements.

Lecture 4: Preparing for IND Meetings
- Phase 1 meetings
- Pre-phase 2 meetings
- Phase 2 meetings

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

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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
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
4. Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals

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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