Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Onsite GCP Review and Update including the all-important 'Investigators Responsibility'

Baltimore, MD

November 2nd & 3rd, 2017

9:00 AM to 4:00 PM

Price

Price: **$1,295.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees

Price: **$3,885.00** You Save: $2,590.0 (40%)*

~~$6,475.00~~

Register for 10 attendees

Price: **$7,122.00** You Save: $5,828.0 (45%)*

~~$12,950.00~~

ENROLL

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

Charles H. Pierce

Charles H Pierce, MD, PhD, FCP, CPI From an original Master's thesis (MSc in Pharmacology) in 1961 (Minnesota) through a Doctorate in Surgery-Pharmacology in 1974 (Saskatchewan) and continuing throughout 48+ years in the practice of clinical medicine as a family physician (7 years as an ER doc) and 28+ years in the medical research industry (7 years as a Principal Investigator), Charles has an experienced based knowledge of the Clinical Research part of Drug Development.

Overview :

This seminar is designed to acquaint all Participants with the Rules and Regulations that form the background of what is know as the GCP of Clinical Research. To follow "The Good Clinical Practices" (GCP) is to follow the standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trails that provides assurance that the data and reported results are credible and accurate and, most importantly, that the safety, rights, integrity, and confidentiality of trial subjects is protected.

That all members of the team must know and practice "GCP" guarantees, that the Protocol is followed

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Agenda:

Day One

Lecture 1:

What is GCP and how does this concept improve data integrity and subject safety.The International Council on Harmonization leads the way

Lecture 2:

The Responsibilities of the Investigator and the relationship of the Investigator to the Sponsor and the IRB. The Regulations are quite clear in this regard. This includes the Informed Consent Process

Lecture 3:

In The Beginning: A solid Protocol; The basis of Drug Development starts with a medically sound Phase I Protocol, which defines Feasibility. Phase II and II Protocols must also be scientifically, medically, as well as ethically sound

Lecture 3:

How to Prevent or Handle Protocol Deviations and Violations to be GCP and Regulatory Compliant?

Day Two

Lecture 5:

To conduct the Clinical Research study as if a persons life depended on it - because it does

Lecture 6:

The Importance of Proper AE Determination and Reporting: How to handle AE's not in the Investigators brochure (IB) and properly assess the relationship between the AE and the product.

Lecture 7:

The Value of the Monitoring Process to an FDA Audit: including how a site or CRO prepares for an Audit and what the Auditors are finding.

Lecture 8:

The Importance of Standard Operating Procedures (SOPs) in the operation of a FDA form 483 absent CPU/CRU

Areas Covered in the Session:

It is now reasonable to expect that theSponsor's should become more discerning regarding the GCP qualifications and training of the staff of any unit conducting studies on human volunteers. Investigators, as well as all site staff, must know how to assess how well the unit is complying with the regulation and the essence of GCP to assure the safety of the volunteers as this ultimately affects the safety of the public. Following GCP is also an assurance of a clean audit.

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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
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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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