Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

What is a Clinical Trial, Regulatory Challenges and How to Successfully Manage them?

Atlantic City, NJ

February 22nd & 23rd, 2018

9:00 AM to 6:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$4,485.00** You Save: $2,990.0 (40%)*

~~$7,475.00~~

Register for 10 attendees

Price: **$8,222.00** You Save: $6,728.0 (45%)*

~~$14,950.00~~

ENROLL

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

Richard (Dick) Chamberlain

VP of Compliance,
Touchstone Technologies Silicon Valley

Richard (Dick) Chamberlain has provided executive consulting services to numerous Pharmaceutical, Biotechnical, Medical Device companies, and international Contract Research Organizations in the areas of strategic planning project management for the development of computerized project management tools and Computer Systems Validation.

Richard managed large-scale clinical projects from the project planning phase until project closure. He has taught numerous public and in-house courses on various topics such as: Computer Systems Validation, Auditing Computer, Clinical Data Management, Managing Large Scale

Overview :

This course will start with an introduction to the different types/phases of clinical trials. The different types are intended to test for the safety and efficacy of the treatment in question. The key document in any clinical trial is the study Protocol. The general contents of this document are specified in the FDA Regulations - Code of Federal Regulations (CFR) section 21.

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Agenda:

Day One

Lecture 1: What are Clinical Trials

- Introduction to a Clinical Trial
- Phase I, II, III, and IV
- Phase 0 and IV
- Key Concepts
- Electronic/Raw Data

Lecture 2: Study Protocol, IRB and Other Committees

- Clinical Trial Protocol
- Institutional Review Boards
- Drug Safety Monitoring Committees

Lecture 3: Laboratory, Pharmacy and other Groups

- Clinical Laboratories
- Procedures
- Pharmacies
- X-ray and Other Examinations Procedures, Documentation

Lecture 4: Quality Assurance During the Trial

- What is QA?
- QA Responsibility
- Quality Management
- Procedures
- Processes

The Seminar:

This hands on seminar provides a practical approach what Clinical Trials are, what goes into their conduct, and how to manage them and how to estimate the costs associated with conducting a clinical trial.

- Examining the different types of clinical trials and when they are used.
- Identifying characteristics that distinguish various types of Clinical Trials.
- Developing a rationale for scaling activities and effort based upon the type of trial.

Day Two

Lecture 1: Managing the Trial

- Responsibilities
- Documentation
- Study Start
- Study Execution
- Study Close-out
- Reporting

Lecture 2: Standard operating Procedures

- Role of SOPs
- Format of SOPs
- Contents

Lecture 3: The FDA and Regulations

- Historical Formation
- Legal Role of FDA
- FDA Inspections

Lecture 4: Using Excel to Forecast Costs and Dates

- Default Spreadsheet
- Estimating Resources
- Estimating Costs
- Annual and Monthly

Why should you attend:

- Clinical Researchers
- Lab Scientists
- Nursing Staff
- Information Technology (IT) personnel
- Quality Assurance
- Management and Laboratory System users
- Hospital Management Staff
- Suppliers of Computerized Systems for EMR/EHR
- Regulators

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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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