Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Designing and Monitoring Approvable Medical Device (cardiovascular) Protocols

Baltimore, MD

February 4th & 5th 2016

9:00 AM to 6:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

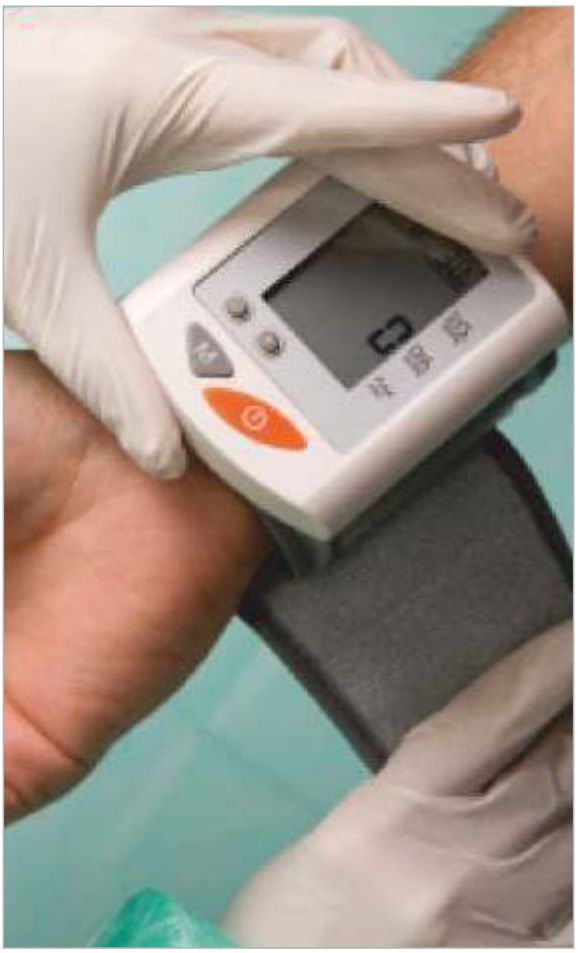
ENROLL

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

Charlene M. Jett

President- 3R's Management Consulting and Therapeutics Inc

Charlene M. Jett is currently President of 3R's Management Consulting and Therapeutics, Inc. She has provided clinical research, regulatory and quality services to the pharmaceutical, medical device, diagnostic and chemical industries. This has encompassed over 30 different companies in 20 years. Charlene was employed by G.D. Searle and Abbott Laboratories for about 17 years. She achieved the positions of Sr. Research Biochemist , Sr. Clinical Research Associate (CRA) and Project Manager. She has worked in the specialties of cardiology, anesthesiology and surgery, anti-infective, rheumatology and cancer, plus others. She has written numerous protocols, consents, monitored clinical trials, written literature reviews, and medical summaries. She has created several publications and presentations. She has also taught graduate statistics and ethics; was a caregiver for her mother. Charlene obtained her BS in Physiology(Pre-Med) from the University of Illinois, MS in Biology from Northeastern Illinois University and another MS from Lake Forest Graduate School of Management. She currently is a member of Sigma Xi and the American Chemical Society, where she enjoys their many webinars.



Why should you attend:

This seminar should be attended to ensure the proper compliance and development of traditional and new cardiovascular medical devices. Failure to attend could result in poorly managed clinical trials, wasted financial resources and liability based law suits. The development of well-designed clinical trials and rigorous monitoring is required. From the literature review to the last appendix, a protocol is THE tool required to be approved by IRBs, FDA and the sponsor/developer of the device.

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Overview

Construction of an approvable clinical trial protocol requires, excellent scientific writing and organization skills. Also paramount is gathering necessary information to manage the statistical analysis and data management of the study. This usually starts with a literature review, establishing key efficacy and safety parameters and determining proper sample size. Sample size calculations are a very important aspect of clinical trials, as are the consent and data collection forms, therefore the statistics and data management departments must be included for their input into the protocol and timelines.

An initial input, draft review and final protocol review meeting of all concerned departments should also include labeling, manufacturing, quality, regulatory, project management. It is also a good idea to get individual investigators input into the protocol design and data collection forms. At this point they can also create a draft budget for their participation. Once all input has been gathered the sponsor approval process can proceed.Once the sponsor has approved the protocol, all relevant IRBs must approve the protocol.

Who will benefit:

- Scientists
- Nurses
- Pharmacists
- Clinical Research Associates (CRAs)
- Medical Monitors
- Medical Directors
- Statisticians
- Project Managers
- Quality
- Regulatory
- Manufacturing and Labeling
- Administration

AGENDA:

Day One

Lecture 1:
- Medical devices and purpose of testing and experimentation
- Regulations and project management
- Organizations: people and processes

Lecture 2:
- Designing a protocol, meetings and writing
- Consents, statistics, data management
- CBP and FDA computer programs
- Questions

Lecture 3:
- Training by sponsor of staff
- Training of sites and staff
- Tracking

Lecture 4:
- Monitoring trips and reports
- Device safety reports and adverse events tracking
- Questions

Day Two

Lecture 1:
- Data based management, queries and errors
- Statistical analysis and reports
- Medical Summaries

Lecture 2:
- Overviews
- Combined Summaries
- Questions

Lecture 3:
- Technology
- Security
- Bottlenecks

Lecture 4:
- Expectations
- Legal
- Questions

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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

NetZealous LLC, DBA GlobalCompliancePanel
161 Mission Falls Lane, Suite 216,
Fremont, CA 94539, USA
Toll free: +1-800-447-9407
Fax: 302 288 6884
Email: support@globalcompliancepanel.com

www.globalcompliancepanel.com

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

Look forward to meeting you at the seminar

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