FDA regulations and the ICH GCP recommendations

Date : Mar 06, 2018 - 10:00 AM

Event URL : http://www.BostonEventsList.com/events/fda-regulations-and-the-ich-gcp-recommendations-mar-2018

Organizer : Netzealous LLC DBA - Compliance4All

Venue : Online Event

Location : 161 Mission Falls Lane, Suite 216,, Mission Falls Ln
Fremont, California, US, ZIP: 94539
Phone: 8004479407

Ticket Price: One Dial-in One Attendee Price: $150.00
Overview:
It will be important to see what the FDA regulations and the ICH GCP recommendations are in this regard. The key is that the PI and all clinical staff know and follow the research plan (Protocol) exactly as it is written. To do this is ethical research. To not follow the protocol and document study conduct carelessly is folly.

Why should you Attend:
All CRO's, Sites, and Sponsors of Clinical Research involved in the drug and device development process have an interest in being prepared for the audit process. Attending this Webinar is a good step toward learning the FDA processes and why the Sponsor's / CRO's Monitors are so important.

Areas Covered in the Session:
What does the FDA look at when Auditing/Inspecting a study?
The Sponsor's responsibility in monitoring study conduct
Components of a sponsor monitoring system beyond SOPs
The nature of adequate oversight of all staff and non-staff
The importance of Protocol knowledge in preventing errors
How do sites prepare for an audit / inspection

Who Will Benefit:

This Webinar will provide invaluable assistance to all personnel in the Pharmaceutical, Biotechnology, and CRO industry Conducting Clinical Trials including:
Senior Management
Project Managers
CRA Managers
QA/Compliance Persons

Speaker Profile:
Charles H. Pierce MD, PhD, FCP, CPI is a consultant in the Clinical Research / Drug-Device Development arena specializing in bringing the message of GCP Regulations and Investigator Responsibility to the entire investigative team to help them understand the regulations as well as the ethics of research involving human subjects.

Event Fee: One Dial-in One Attendee Price: US$150.00

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Event Categories :