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EVENTS LIST

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

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Event URL : http://www.sfbayeventslist.com/events/onsite-gcp-review-and-update-including-the-all-important-investigators-res

Organizer : New York Media Technologies LLC in association with Netzealous LLC

Venue :

Location : DoubleTree by Hilton Hotel San Diego Downtown1646 Front StreetSan Diego, CA 92101United States,
San Diego, CA , US, ZIP: 92101

Description

***** LIMITED TIME OFFER: FREE $100 AMAZON GIFT CARD! *****
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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, that the Informed consent is complete, that the study conduct is according to the protocol, that Adverse Events are correctly recorded and that the Principal Investigator knows well her/his responsibilities to follow what "GCP" stands for

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Why you should attend:

It is now reasonable to expect that the Sponsor'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.

Areas Covered in the Session:

Session 1:

- What was the reason the ICH was formed
- What is the essence of GCP
- How does You QA group insure GCP
- The PI/Investigators role in GCP
- The Sponsors role in GCP
- What is the end result of Dose response studies
- Does your Unit/CPU/CRU follow the 13 GCP Principles?
- How following the signed Protocol is GCP

Session 2:

- Investigators key role in the Clin. Research process
- How following GCP helps assure a clean Audit
- What are the main Investigator responsibilities?
- How is the investigator is responsible for the IC?
- What is the legal language of the FDA form 1572?
- Why is Financial Disclosure information important?

Session 3:

- The Primacy of the study Protocol
- The Pi responsibility in the Protocol development

- The Sponsors Responsibility in Protocol development
- How to be sure the protocol is safe for the subjects
- How to be sure the protocol is scientifically valid
- How to insure the to protocol is ethically valid

Session 4:

- What is a Protocol "Deviation" and other terms
- The Regulatory requirements for handling protocol deviations and violations
- Importance of documentation of protocol deviations
- What is the reason different IRBs define deviations and violations differently
- What is the basis of the difference between a "Deviation" and a "Violation"

Session 5:

- The historical background of why accurate data is essential for ensuring safety of study participants/Pt
- The purpose of ensuring that all data is accurate, legible, contemporaneous, original and attributable
- The regulatory requirements for care of source documents
- What "To Do" and "Never Do" with regard to data including corrections?
- What documents does the FDA review - always?

Session 6:

- How to Assess and report AEs and SAEs
- The CFR definitions of AEs, SAEs, and many more
- How to know an Adverse Event and when to report it
- Understanding laboratory AEs and the "Reference Range" concept
- Common Mistakes in AE / SAE Reporting
- Reporting of Adverse Events - when and to whom
- how Data safety Monitoring in Protects Volunteers

Session 7:

- The Sponsor's responsibility in quality monitoring
- Why Monitor Clinical Studies
- What does a Monitor look for?
- How does a Sponsor or Site prepare for an Audit
- What are the strategies to improve an audit outcome?
- What does the FDA look at when Auditing/Inspecting a study?
- What types of studies are targeted for auditing

Session 8:

- The function of/reasons for an SOP in a CPU/CRU
- How SOPs are set up

- What areas of CPU management need SOPs
- Who creates an/the SOPs
- Who is responsible for the Unit's SOPs

Who will benefit:

This lecture series will provide invaluable assistance to industry study sponsors and those involved in Setting up the IND to follow the regulatory / legal responsibilities and also the ethical considerations in pharmaceutical product (IMP) research involving human subjects. Those benefiting the most would be:

- The Study Sponsor
- Principal Investigators and sub investigators
- Clinical Research Scientists (PKs, Biostatisticians, ...)
- Safety Nurses
- Clinical Research Associates (CRAs) and Coordinators (CRCs)
- Recruiting staff, QA / QC auditors and staff, & Clinical Research Data managers.

Event Categories :