

How to Comply with 21 CFR 11 Requirements

Date : May 02, 2018 - 10:00 AM

Event URL : <http://www.BostonEventsList.com/events/how-to-comply-with-21-cfr-11-requirements-may-2018>

Organizer : Compliance4All DBA NetZealous

Venue : online

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

Ticket Price: One Dial-in One Attendee Price: \$150.00

Overview:

In this webinar would apply to computerized systems that create source documents (electronic records) that satisfy the requirements in 21 CFR 312.62(b) and 812.

Areas Covered in the Session:

What are source documents and why are they important? (FDA and ICH GCP E6 Guideline)

What are required characteristics for source documents?

What is 21 CFR Part 11?

How can you apply 21 CFR 11 and ICH E6 to source documents?

How EMR Data is used in Clinical investigations

How to plan electronic source document deficiencies

Who Will Benefit: Investigators

Clinical Research Coordinators

Device and Drug Study Clinical Research Associates

Clinical Research Associate Managers

Project Managers

Quality Assurance Personnel

Regulatory Affairs Personnel

Speaker Profile:

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Angela Bazigos Seasoned Executive with 40 years of experience in the Life Sciences & Healthcare Industries. Positions include Chief Compliance Officer <http://morfllearning.com/angelabazigos/>. Experience combines Quality Assurance, Regulatory Compliance, Business Administration, Information Technology, Project Management, Clinical Lab Science, Turnarounds and Business Development.

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

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Event Categories :