

Which data and systems are subject to Part 11

Date : Jan 16, 2018 - 10:00 AM

Event URL : <http://www.BostonEventsList.com/events/which-data-and-systems-are-subject-to-part-11-jan-2018>

Organizer : Netzealous LLC DBA - Compliance4All

Venue : online

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

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

Overview:

This webinar details the regulation and how it applies to computerized systems. Learn exactly what is needed to be compliant for all three primary areas: SOPs for the IT infrastructure, industry standards for software product features, and the 10-step risk-based validation approach.

Areas Covered in the Session:

Which data and systems are subject to Part 11

What Part 11 means to you, not just what it says in the regulation

Avoid 483 and Warning Letters

Explore the three primary areas of Part 11 compliance: SOPs, software product features, and validation documentation

Ensure data integrity, security, and protect intellectual property

Who Will Benefit:

IT

QA

QC

Laboratory Staff

Managers

GMP, GCP, GLP Professionals

Speaker Profile:

Edwin Waldbusser is a consultant retired from industry after 20 years in management of development of medical devices (5 patents). He has been consulting in the US and internationally in the areas of design control, risk analysis and software validation for the past 8 years.

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Event Categories :