

21 CFR Part 11, SaaS/Cloud, EU GDPR Live Webinar

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Organizer : WCS

Venue : online

Location : WCS Consulting Inc.3190 Stirling Rd, Unit K4 ,Hollywood, FL 33021,
Hollywood, FL, US, ZIP: 33021
Phone: 844-267-7299 | 954-947-5671

Overview

This webinar describes exactly what is required for compliance with Part 11 and the European equivalent Annex 11 for local, SaaS/Cloud hosted applications. It explains how to write a Data Privacy Statement for compliance with EU General Data Protection Regulation (GDPR). What the regulations mean is described for all four primary compliance areas: SOPs, software features, infrastructure qualification, and validation. It gets you on the right track for using electronic records and signatures to greatly increase productivity and ensure compliance.

Session Highlights

Which data and systems are subject to Part 11 and Annex 11

- How to write a Data Privacy Statement
- What the regulations mean, not just what they say
- Avoid 483 and Warning Letters
- Requirements for local, SaaS, and cloud hosting
- Understand the current industry standard software features for security, data transfer, audit trails, and electronic signatures
- How to use electronic signatures, ensure data integrity, and protect intellectual property
- SOPs required for the IT infrastructure
- Product features to look for when purchasing COTS software
- Reduce validation resources by using easy to understand fill-in-the-blank validation documents

Who will benefit

- GMP, GCP, GLP, regulatory professionals
 - QA/QC
 - IT
 - Auditors
 - Managers and directors
- Software vendors, hosting providers

Event Categories :