

# The Emergence of Digital Signatures in Clinical Operations

Event #10244 • October 5, 2010

11:00 AM-12:30 PM EDT  
10:00 AM-11:30 AM CDT

9:00 AM-10:30 AM MDT  
8:00 AM-9:30 AM PDT



## PRESENTERS

### RODD SCHLERF

FDA and USDA Markets Manager, ARX

### TIM KROBOTH

Pharma and CRO Accounts  
NextDocs

**“Digital signatures are being used widely by the majority of the largest CROs and sponsors across many areas of clinical operations to support regulatory compliance, speed trial initiation, reduce reporting and approved documentation cost, and facilitate secure document exchange and electronic submissions.”**

Rodd Schlerf, FDA and USDA Markets Manager, ARX

## WHO SHOULD ATTEND

Professionals involved in IT, clinical informatics, clinical operations, QA and RA at:

- CROs
- Study sponsors
- Clinical technology vendors
- Site monitoring and field operations
- Investigator portals
- Medical device companies

Functional responsibilities: clinical research associates, project managers, clinical operations, quality assurance, regulatory affairs, training, IT, information security, document management, records management, validation and compliance.

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The past five years have shown a dramatic growth of digital signature use in clinical applications. Regulatory compliance, expedited processes, and significant cost savings are among the many benefits that have enabled clinical organizations to gain a competitive advantage by taking their approval processes electronic.

Digital signatures enable clinical organizations to:

- Create, control, and share documentation internally and externally in a trusted, compliant, and secure manner
- Adhere to 21 CFR part 11, GxP audits, HIPAA, SOX, and other regulations and effectively support regulatory audits
- Eliminate the hard costs of paper-based approval processes, i.e. printing, routing, archiving, etc.
- Expedite processes and enhance collaboration including secure document exchange and electronic submissions

This webinar will address business benefits, technical challenges, and deployment considerations from CRO, sponsor, and SaaS/CSO perspectives based on real-world use of digital signatures in the clinical market today.

## FEATURED TOPICS

- Case studies of actual digital signature deployments within:
  - Quality, audit, and compliance operations
  - Site monitoring and field operations
  - Investigator Portals
- Case studies presented on live installations at large Pharma, Medical Device, and Software-as-a-Service (SaaS) based clinical services.
- Applications discussed range from quality and compliance documentation, investigator site monitor reporting, clinical trial management (CTMS) and Investigator Portal for Trial Master File forms.

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#### Browser

Microsoft® Internet Explorer 5.2 or higher  
Netscape® Navigator 7

#### Computer

166Mhz Pentium-based PC with Microsoft® Windows® 98, NT, ME, XP or 2000

Sun JVM 1.4\* for Microsoft JVM (all versions supported by Microsoft Windows OS shown above)

Sun SPARCstation with Solaris 8 or 9

Audience: 64 MB RAM

*\*If you need to install Java Virtual Machine (JVM) on your system, please download it from the Sun Microsystems website.*

#### Internet Connection Speed

56k or faster

#### Display

800x600 pixel resolution or greater (1024x768 pixels recommended)

#### Attendees using Macintosh OS

Microsoft IE 5.2

Macintosh OS 10.2X

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### LEARNING OBJECTIVES

At the conclusion of this webinar, participants should be able to:

- Describe the business benefits and deployment considerations for digital signatures within clinical operations
- Identify the ROI (return on investment) that digital signatures bring to clinical organizations
- Explain the importance of selecting digital signature technology that complements existing infrastructure (low total cost of ownership), integrates with common business applications and end user requirements (to facilitate user adoption)

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