21 CFR Part 11 Compliance:

5 Key Factors Every FDA Regulated Company Should Know

Tuesday, September 27, 2022

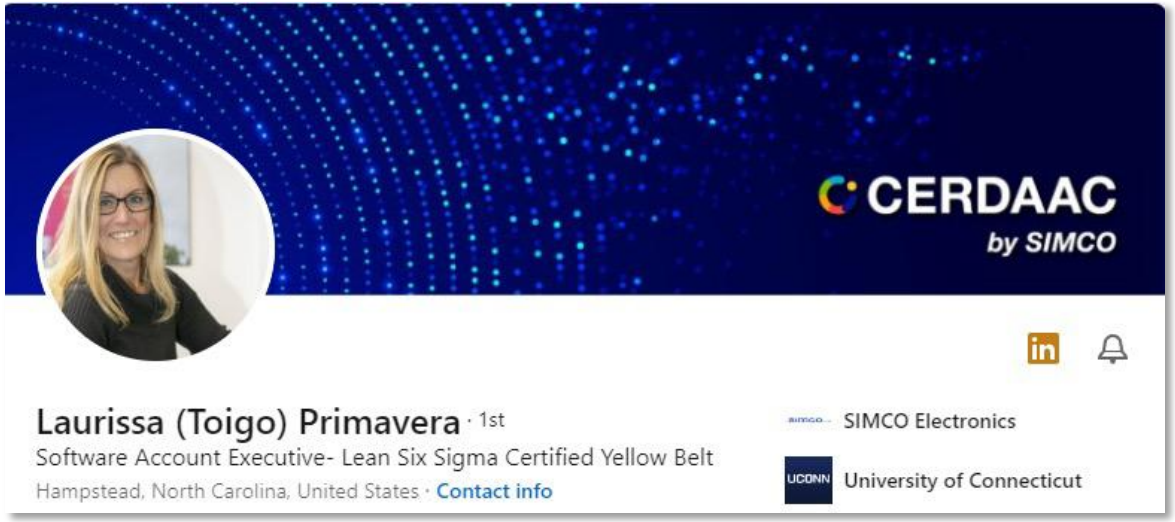
CERDAAC

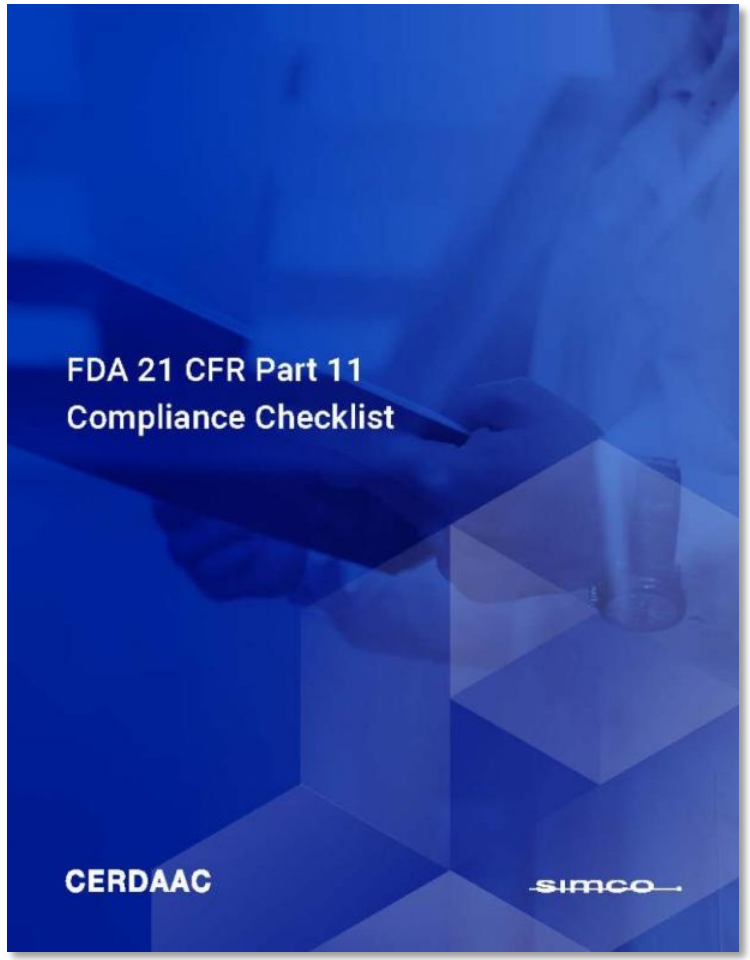
About This Webinar

FDA 21 CFR Part 11 Compliance Regulation

- What it is, Why it Matters
- 5 Main Areas of Regulation Review
- How to Ensure Compliance without Increasing Costs
- Detailed compliance checklist to be emailed to participants after the webinar
- Q&A

Our Presenter:





We'll email you the compliance checklist after the webinar.

Housekeeping

- Webinar Link: https://simco.zoom.us/webinar/register/WN_gQkxHAxPQoq3fvP6qYjaGQ
- Topic: FDA 21 CFR Part 11 Compliance: 5 Key Factors Every Regulated Company Should Know
- Duration: 25 minutes + 5 Minute Q&A
- Hashtag: #simcowebinar
- All attendees will be on mute during the presentation and Q&A
- Q&A: submit your questions at any time during the webinar in the Q&A window, and we will answer your questions at the end of the presentation. Any questions we don't get to we will follow up by email to answer.
- The webinar will be recorded and the link to the recording emailed to all registrants within 1 week after the webinar.
- For support, email: rebecca.macdonald@simco.com.

About 21 CFR Part 11 Compliance

What is FDA 21 CFR Part 11?

- FDA Regulation governing the use of electronic records and digital signatures to store, track and transfer records pertaining to the manufacture of products
- Defines the criteria under which electronic records and e-signatures are considered trustworthy, reliable, and equivalent to paper records
- Electronic systems are not required, but increasingly used by manufacturers to improve compliance faster and at lower cost

Benefits of using electronic systems for 21 CFR Part 11 compliance:

- Reduced errors
- Increased data confidentiality, integrity, and accessibility
- Faster information exchange
- Increased cost savings

Penalties for non-compliance can include:

- FDA Form 483, a warning letter, an injunction (which can include a market recall or ban on importation), or a consent decree.
- Criminal penalties, fines, etc.

Maintaining FDA Compliance is a Top Industry Challenge

90% of Quality Leaders say maintaining compliance is their top challenge

Recent Inspection Citations Manufacturers Received from the FDA:

- ”Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.”
- ”The calibration of instruments and apparatus is not done at suitable intervals.”
- ”Electronic records are used, but they do not meet systems validation, system access limitation, audit trail, operational system check, authority check, device check, personnel qualifications, employee accountability/responsibility policy, systems documentation control, open systems control, signature manifestation and signature to record linking requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.”

Your Top Compliance Challenges

We asked, you answered: results of our informal survey prior to this webinar

How are you currently managing your FDA processes?

Majority of you answered you are using a combination of spreadsheets, paper-based processes & software. Some just using paper-based processes or a software

What is your biggest challenge in meeting FDA 21 CFR Part 11 compliance requirements?

Paper-based processes (Electronic signature, audit trails), retrieval of paper, and consistency across locations

How long would it take for you to prepare for an upcoming FDA audit?

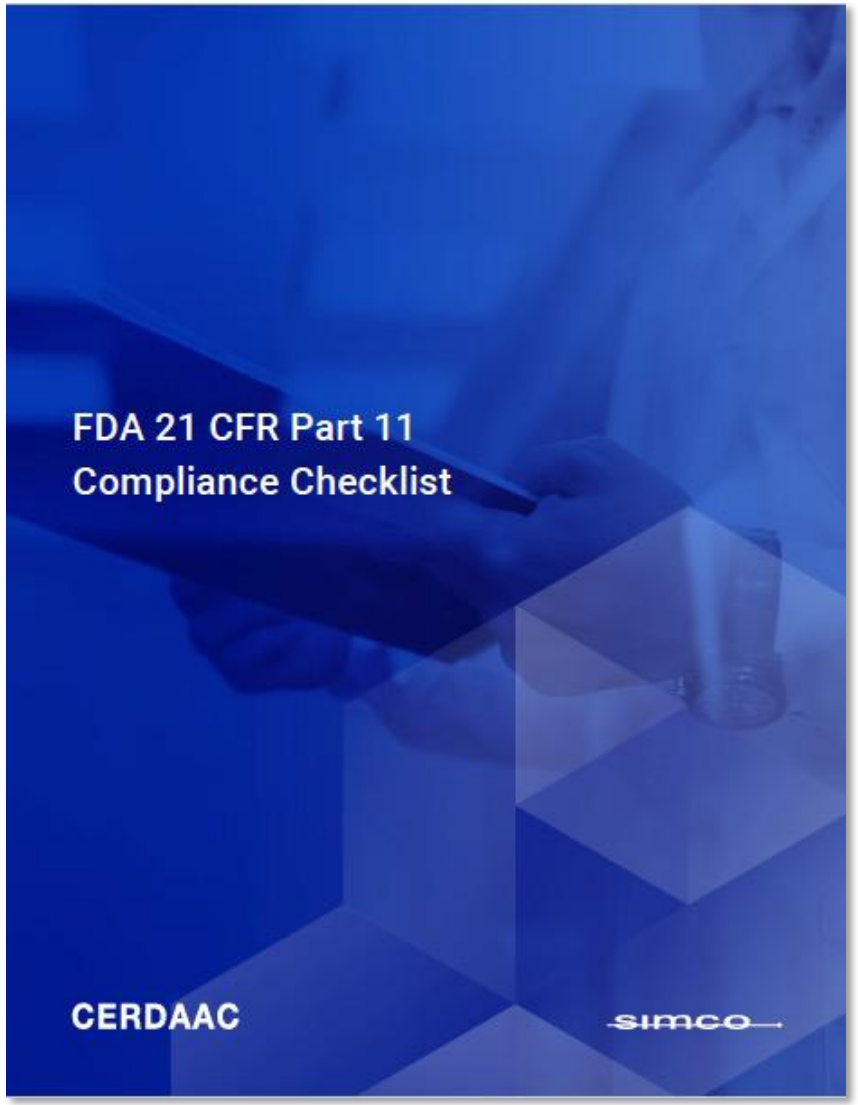
Majority of you answered several days, then weeks, two one day and one advised one month

Have you had a recent audit or CAPA finding?

Many of you answered no, there were equal numbers of yes and not sure

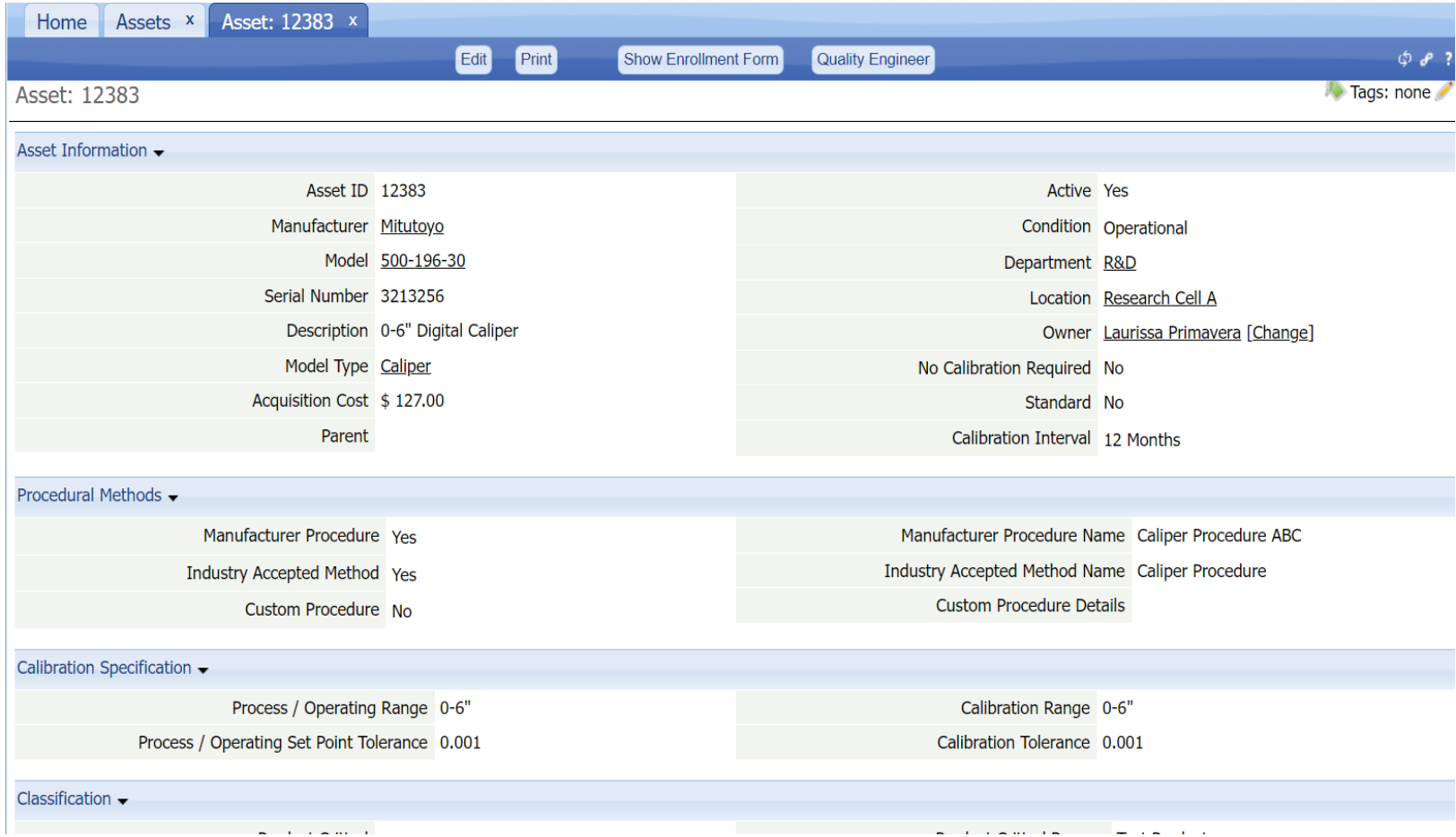
Five Key Areas of the Regulation

- Systems: are the electronic systems being used to store records in compliance
- Audit Trails: are records kept of alterations and changes, with previous versions stored and available?
- Electronic Signatures: who can sign, are signatures validated?
- Access and Control: are roles and permissions properly defined and controlled?
- System Validation: the difference between “validatable” and prevalidated, and key requirements



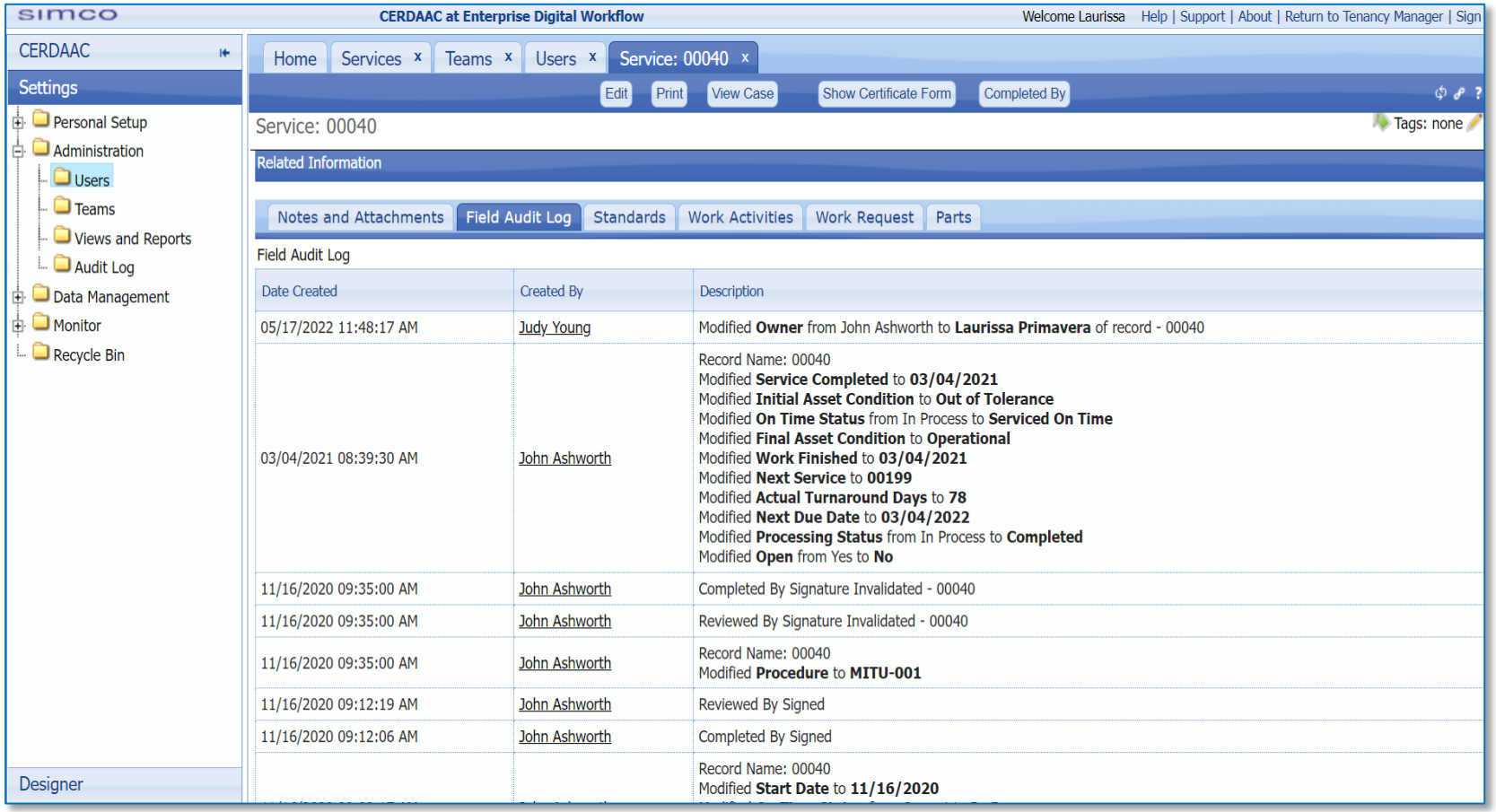
Systems Compliance

- Does the system include workflows that enforce compliance?
- Control and limit delete capabilities included?
- Are proper sequence of steps and processes enforced?
- Are roles and permissions properly controlled?
- Can results be altered, and if so, are changes easily tracked and identified?
- Is training provided and documented?



Audit Trails

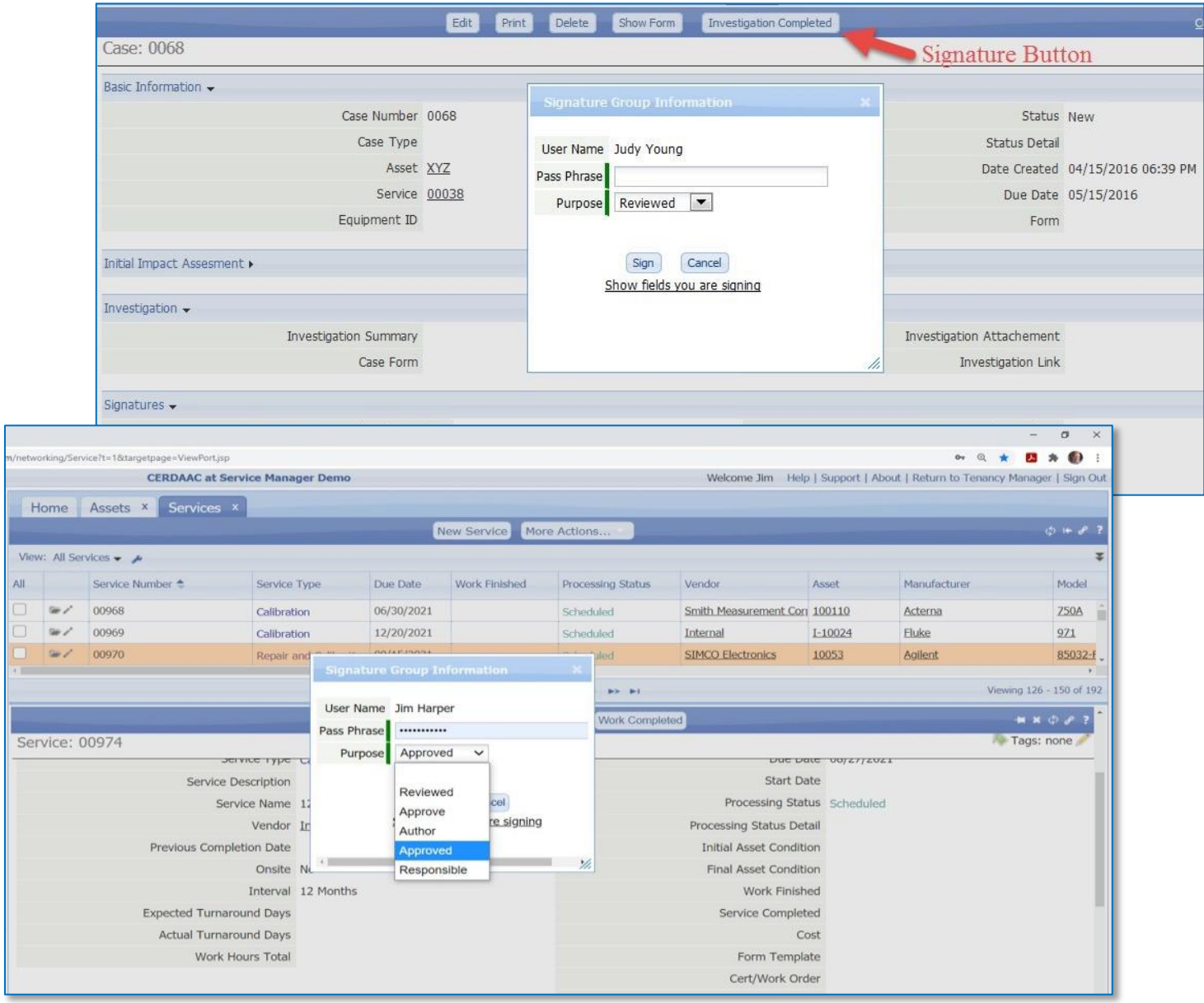
- Time stamped audit trails with complete histories?
- Are change histories available, and previous versions stored?
- Audit trails retrievable and available for review?
- Device checks to confirm source data validity?
- Evidence of system checks?
- Written policies that deter record and/or e-signature falsification?



Electronic Signatures

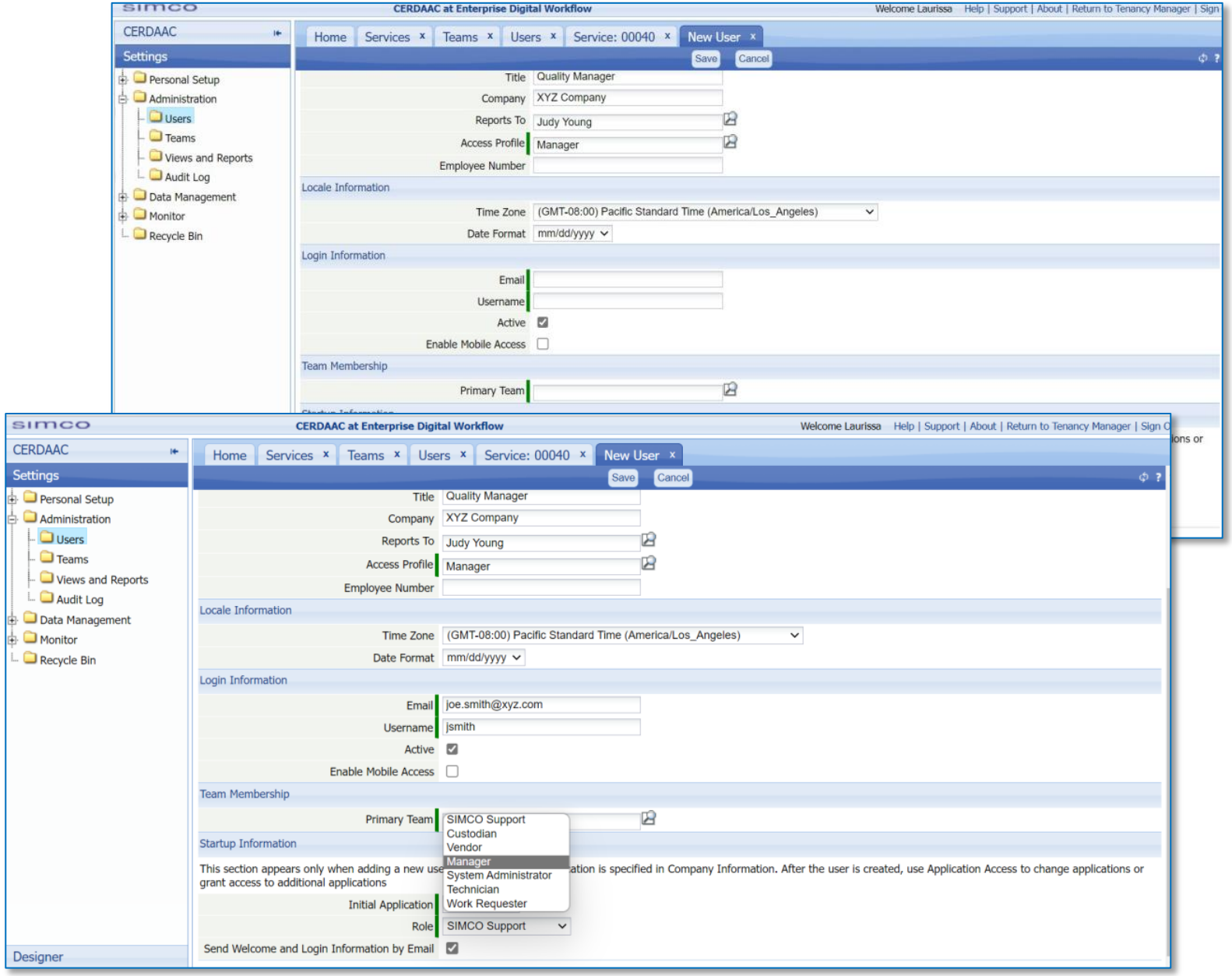
E-signatures can accelerate review and approval processes, BUT there are key requirements for FDA regulated manufacturers to make sure e-signatures are compliant:

- Include printed name and date, as well as signature?
- Meaning of signature included? (review, approval, etc.)
- Are e-signatures linked to their respective electronic records?
- Cannot be cut, copied, falsified?
- Verification of signer's identity?
- Cannot be reused or reassigned?



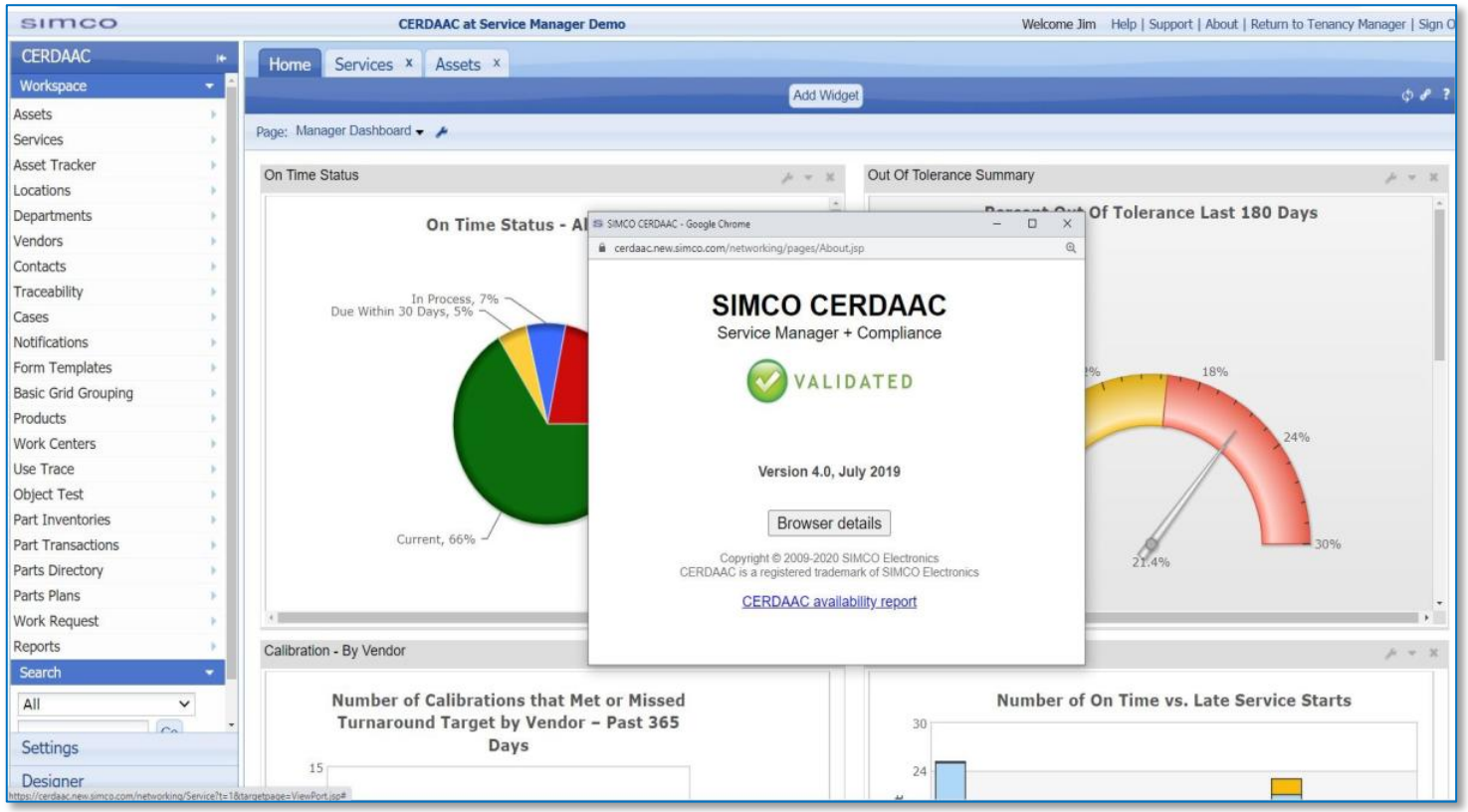
Access and Control

- Individual access control to confirm the identity of the person accessing the system?
- Sophisticated password security measures, frequent password updates, password expirations
- Procedures for recalling passwords
- Unauthorized access attempt notifications
- Loss management procedures for devices
- Controls for testing of devices



System Validation

- Has the system been validated?
- The difference between "*validatable*" or *pre-validated?* The answer can save you considerable time and money!
- Does the system validate for:
  - IQ (Installation Qualification)
  - OQ (Operational Qualification)
  - PQ (Performance Qualification)—"Does This Process Produce the Right Result"? "Is This Process Safe and Consistent?"



CERDAAC: Ensures FDA 21 CFR Part 11 Compliance without Increasing Costs:

Purpose-built for highly regulated industries:

- 16 of the top 20 global life sciences companies
- 14 of the top 20 global aerospace & defense companies
- 60 years in business
- 15M+ services performed

- FDA 21 CFR Part 11 Compliant: e-signatures, workflows, record data, etc.
- **Prevalidated** system saves you time and money
- Manage quality and compliance of assets, people and processe
- Cloud solution makes it easy to access, deploy, and maintain
- Highly configurable to your business needs
- Easy to use
- Secure, controlled access

Q&A

Type your questions into the Q&A window.

Thank You

Questions?

Visit: cerdaac.com