21 CFR Part 11 Compliance:

5 Key Factors Every FDA Regulated Company Should Know

Wednesday, October 12, 2022

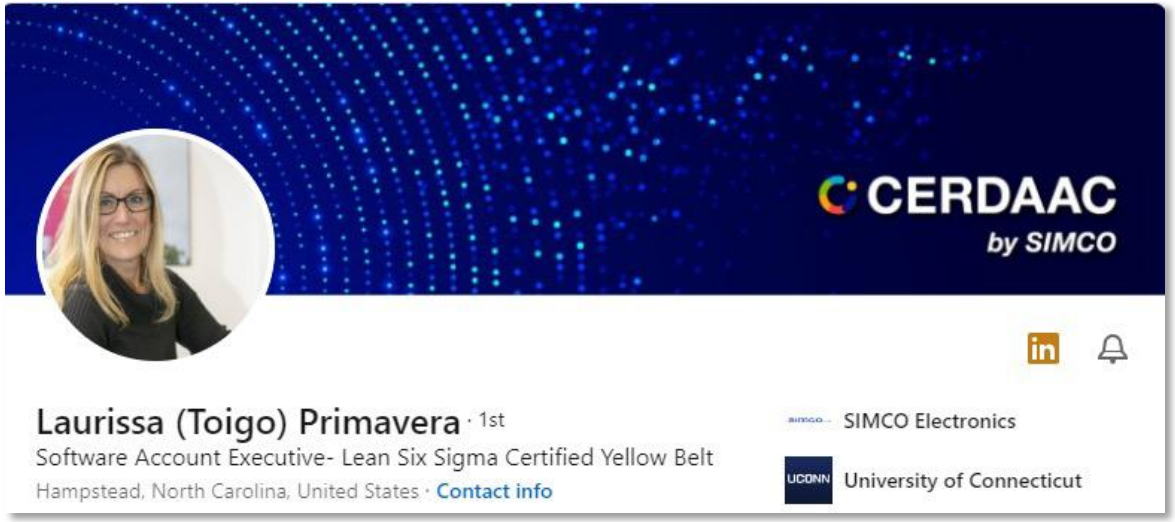
CERDAAC

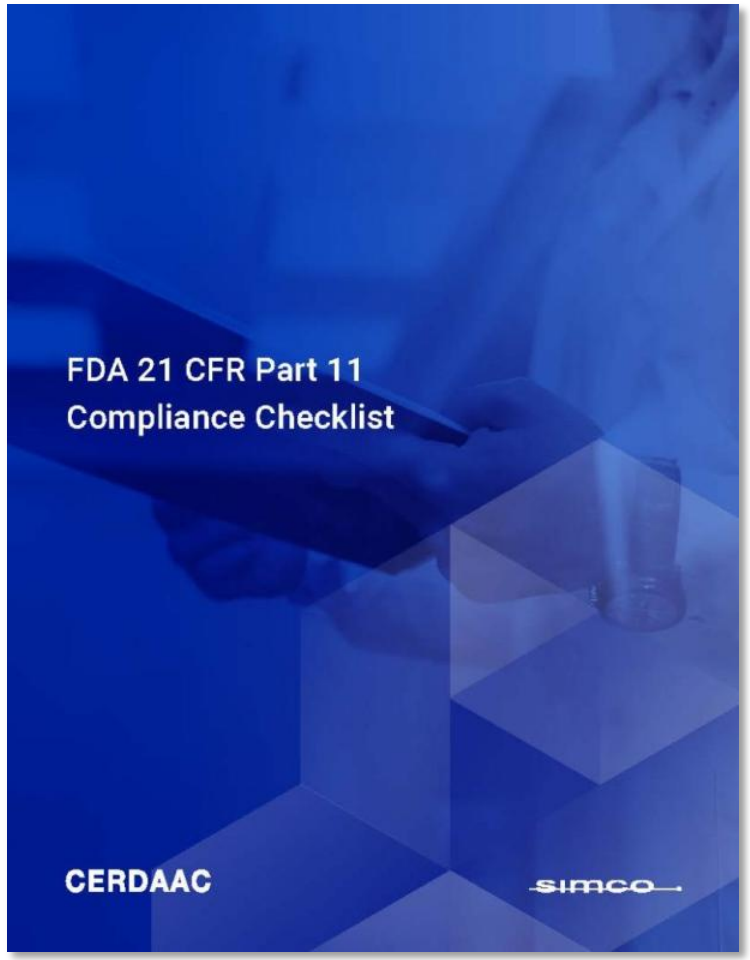
About This Webinar

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_krUS55OeQdi-xTHaHZIIlg
- 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?

Most of you answered you are using paper-based processes with the next greatest being a combination of spreadsheets, paper-based processes & software. Then a combination of paper-based and software and paper-based and Excel. Some already using software.

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

Paper-based processes (manual records retrieval), traceability, talent, tracking changes (audit trail), validation and keeping up to date

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

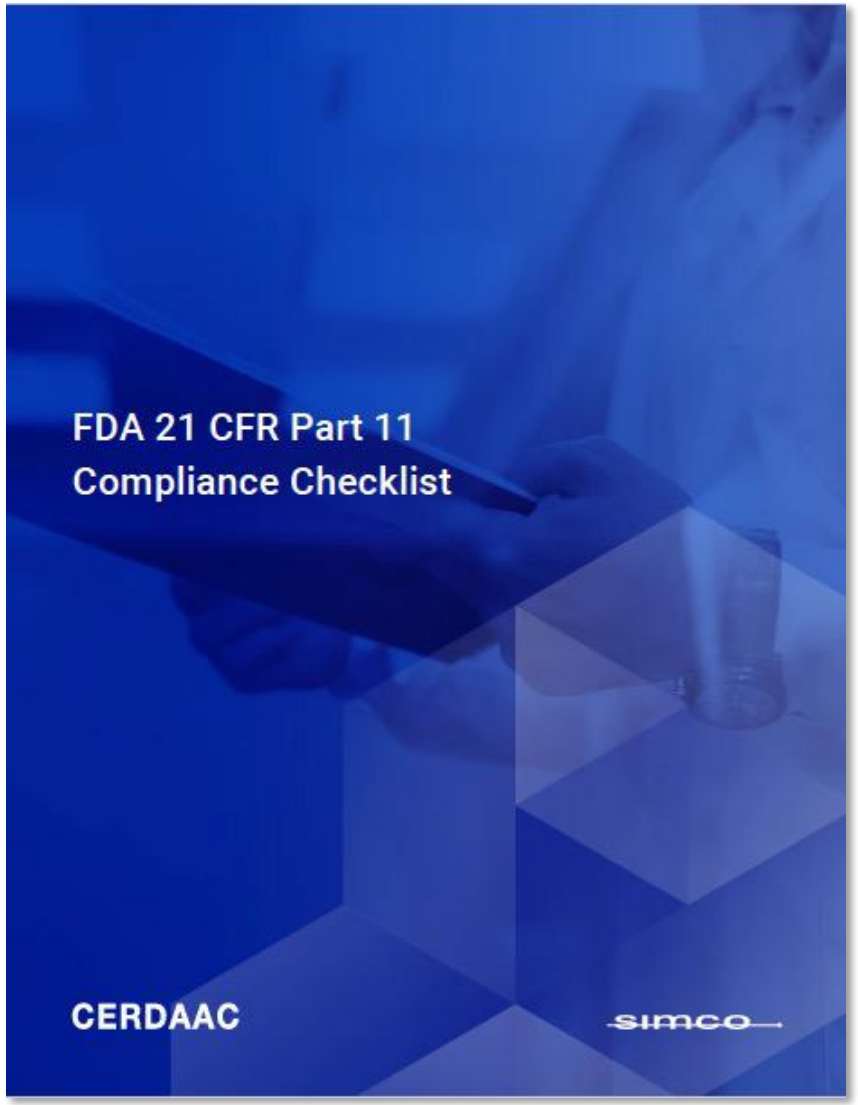
Majority of you answered several days, then months, then weeks and days

Have you had a recent audit or CAPA finding?

Majority of you answered no with an answer of yes right behind. Several were not sure

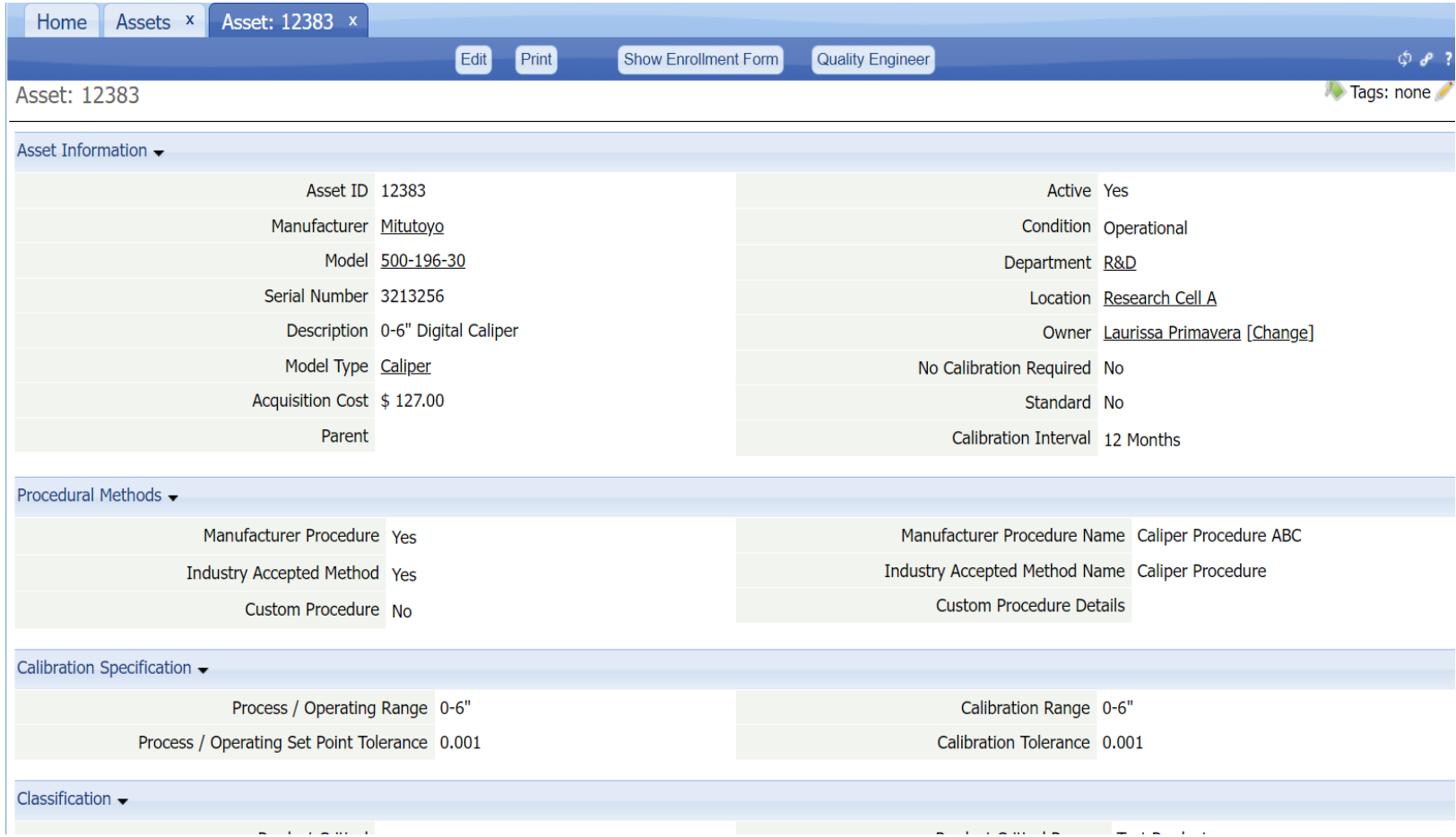
Five Key Areas of the Regulation

- 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



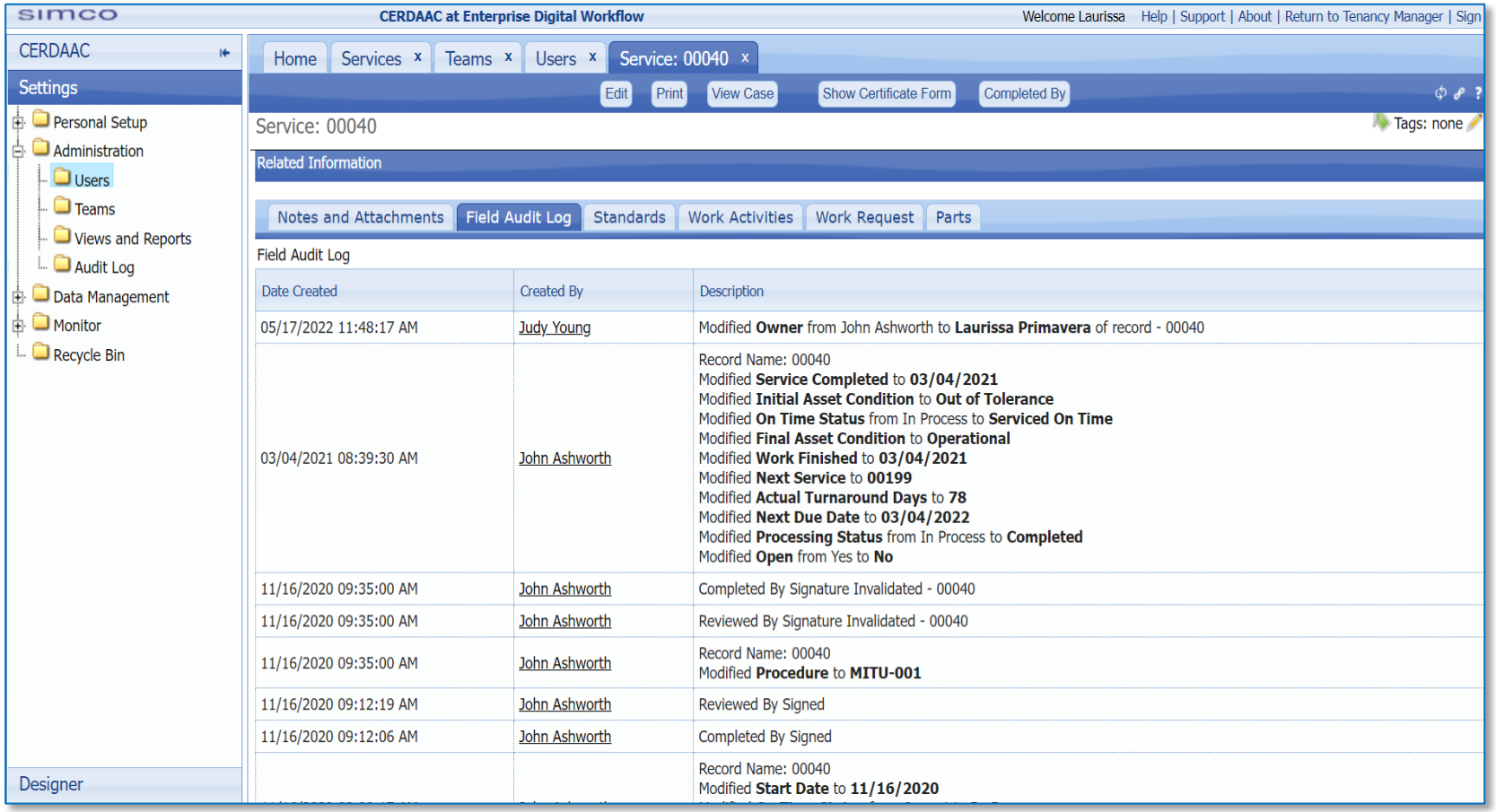
Systems Compliance

- 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

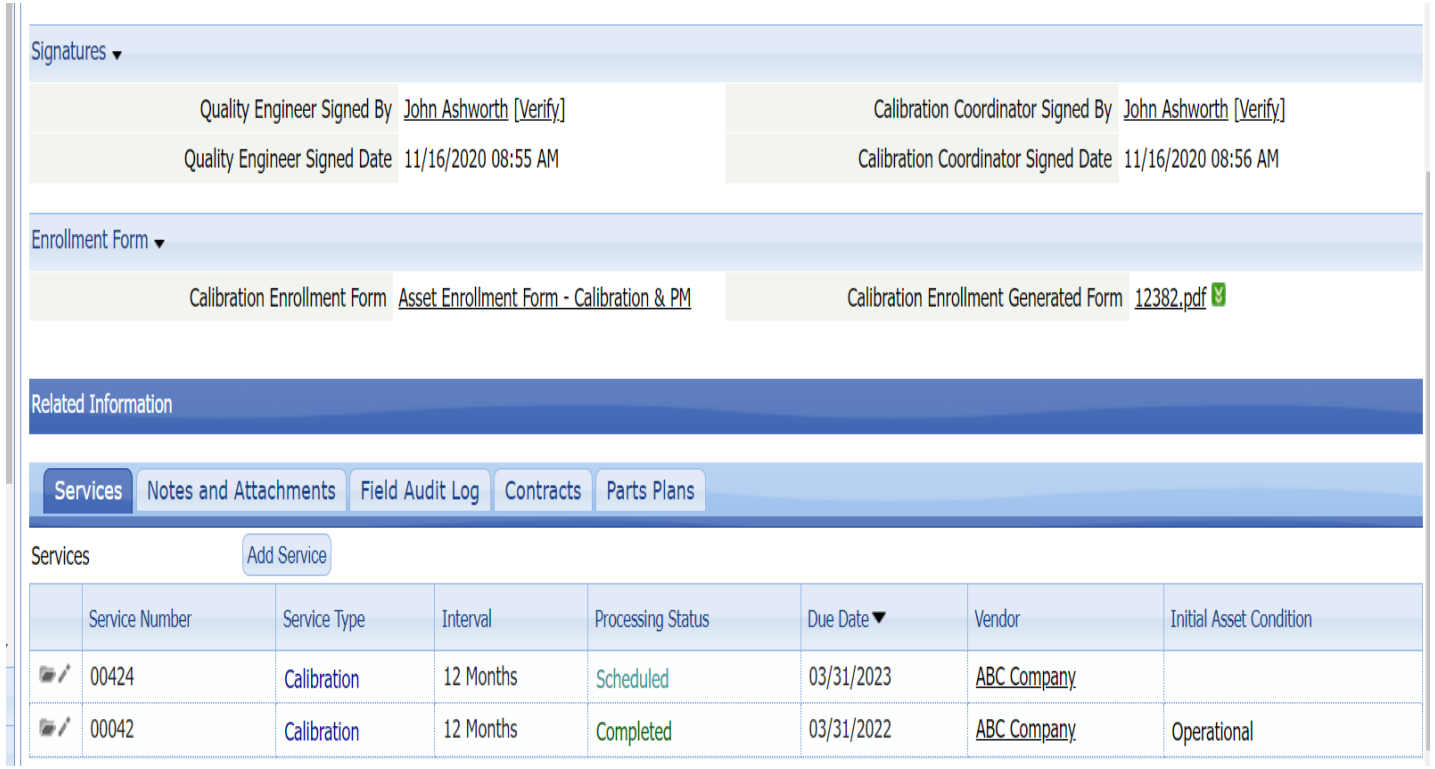
- Time stamped audit trails with complete histories?
- Are change histories available, and previous versions stored?
- Audit trails retrievable and available for review?
- Device checks to confirm source data validity?
- Evidence of system checks?
- Written policies that deter record and/or e-signature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



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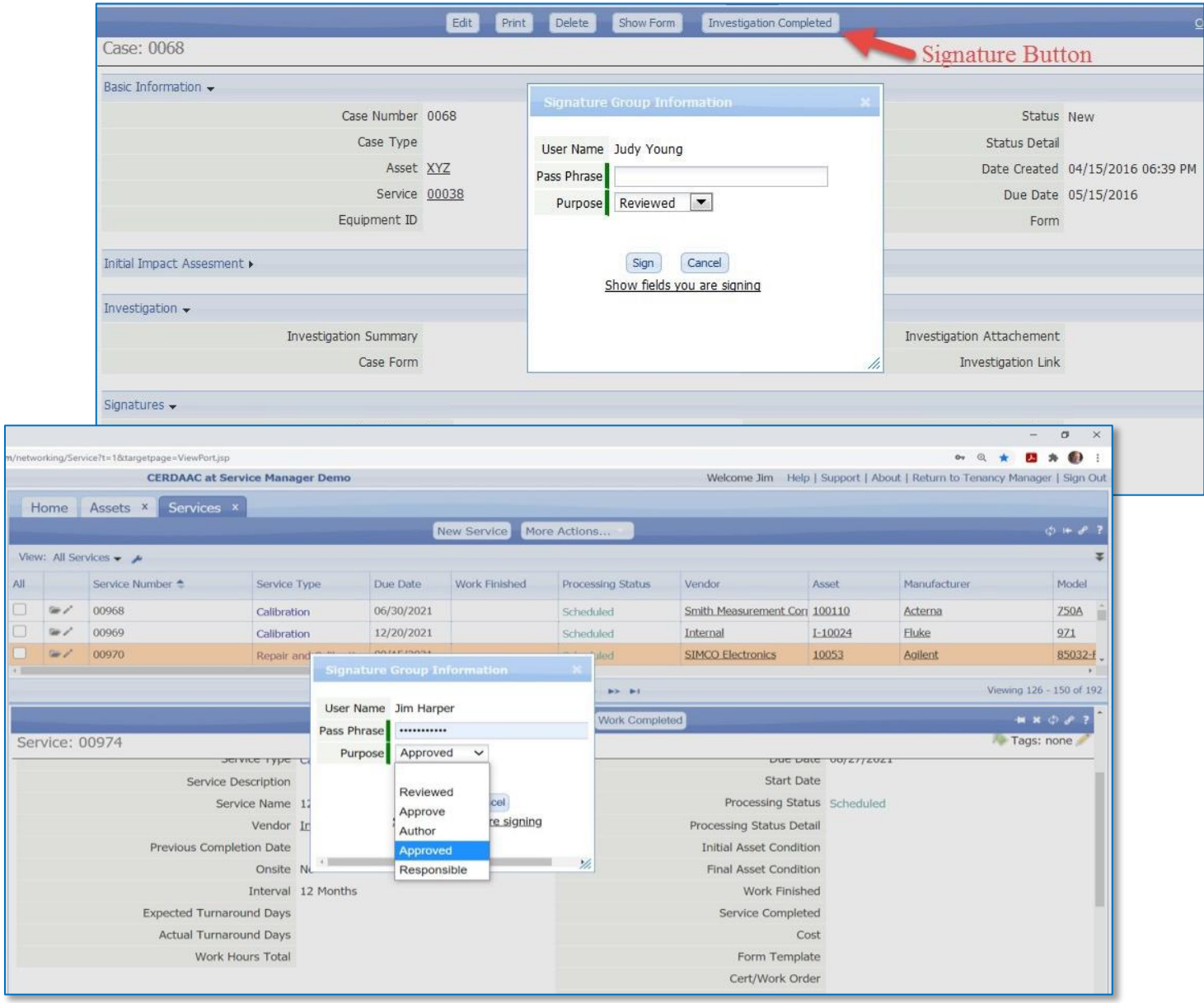
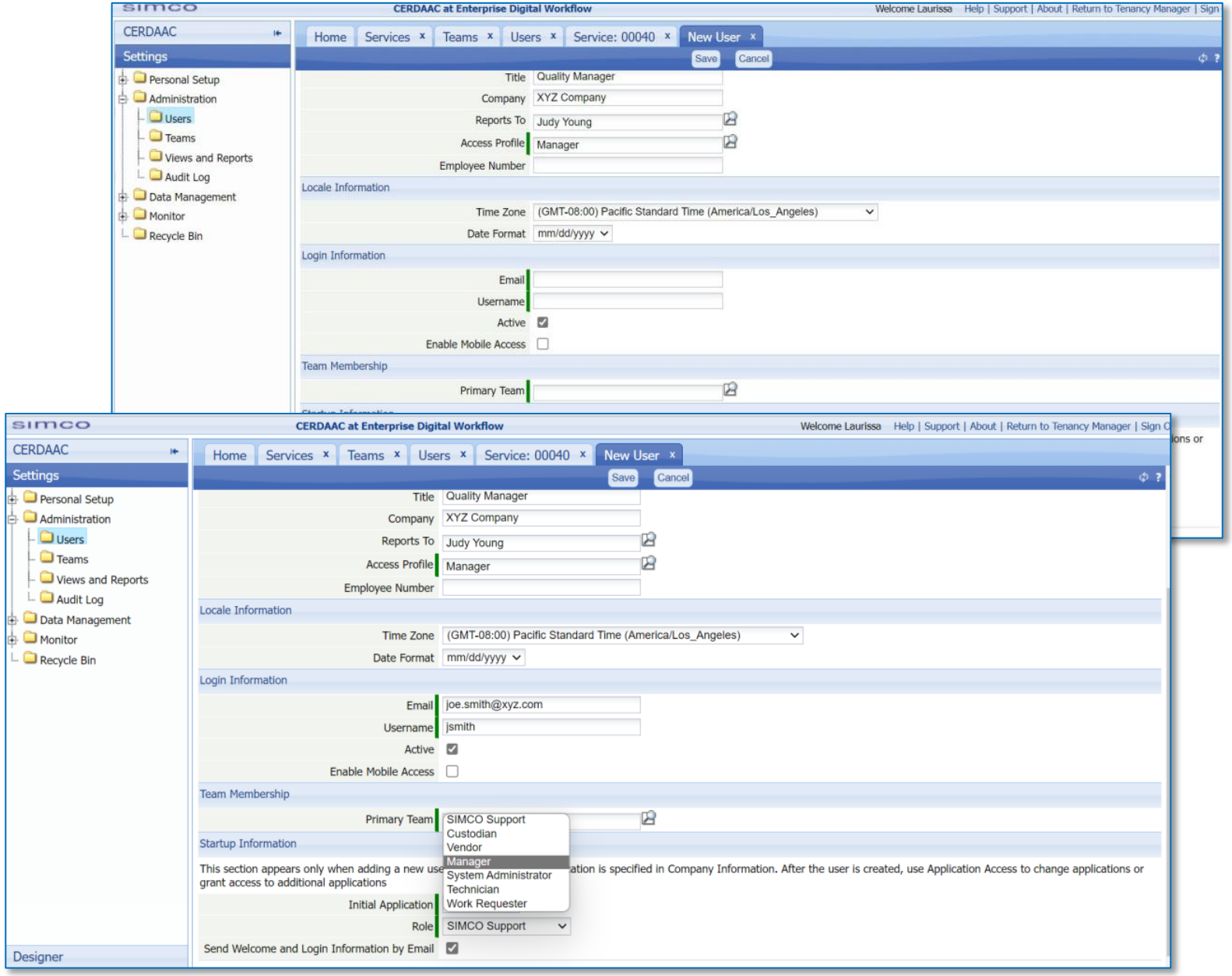


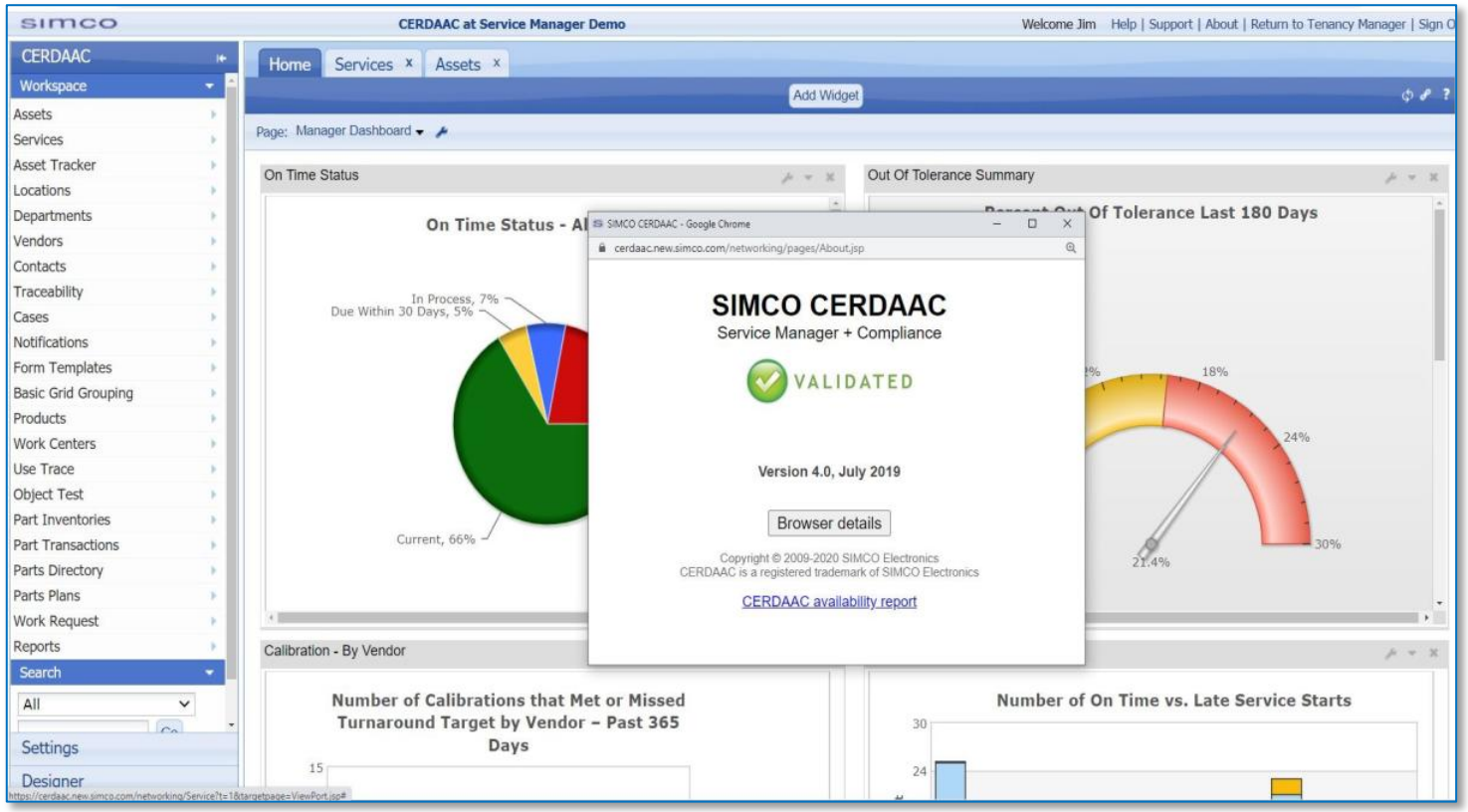
Access and Control

- 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

WuXi AppTec Case Study

The Challenge: Prior to implementing SIMCO CERDAAC, WuXi AppTec was using a combination of manual, paper-based processes, spreadsheets and a software system from Blue Mountain to schedule its calibration and preventive maintenance services. The result was
a lot of redundant data entry and processes that were prone to error.

Before CERDAAC

"The reporting of KPIs and other metrics out of our previous system was practically impossible. It was like driving down the highway without being able to see how fast you're going, or if your check engine light is on."

After CERDAAC

"CERDAAC really allowed us to customize or configure the options we needed very easily. It's very intuitive, as well as very easy to learn and use."

PHARMA CASE STUDY

OVERVIEW: Pharmaceutical leader with large network of PET radio-pharmacies uses CERDAAC to transform its operations in compliance with new FDA regulations.

The Challenge: By 2012, the FDA had published CGMP 212, the new regulatory requirement for PET manufacturing. Suddenly, the company was faced with the need to undergo a complete transformation of its manufacturing process controls and reporting requirements in order to meet the compliance requirements of the new standard.

Before CERDAAC

"With the change in FDA regulatory requirements, we realized we did not have the right controls in place for tracking the calibration and the maintenance of the equipment used in the manufacturing process to meet these new requirements."

With CERDAAC

"After our initial evaluation of CERDAAC, we realized it was the only solution we had found on the market that would help us meet our needs and the new, more stringent FDA requirements."

Q&A

Type your questions into the Q&A window.

Thank You

Questions?

Visit: cerdaac.com