

21 CFR Part 11 Compliance: 5 Key Factors Every FDA Regulated Company Should Know

Wednesday, October 12, 2022

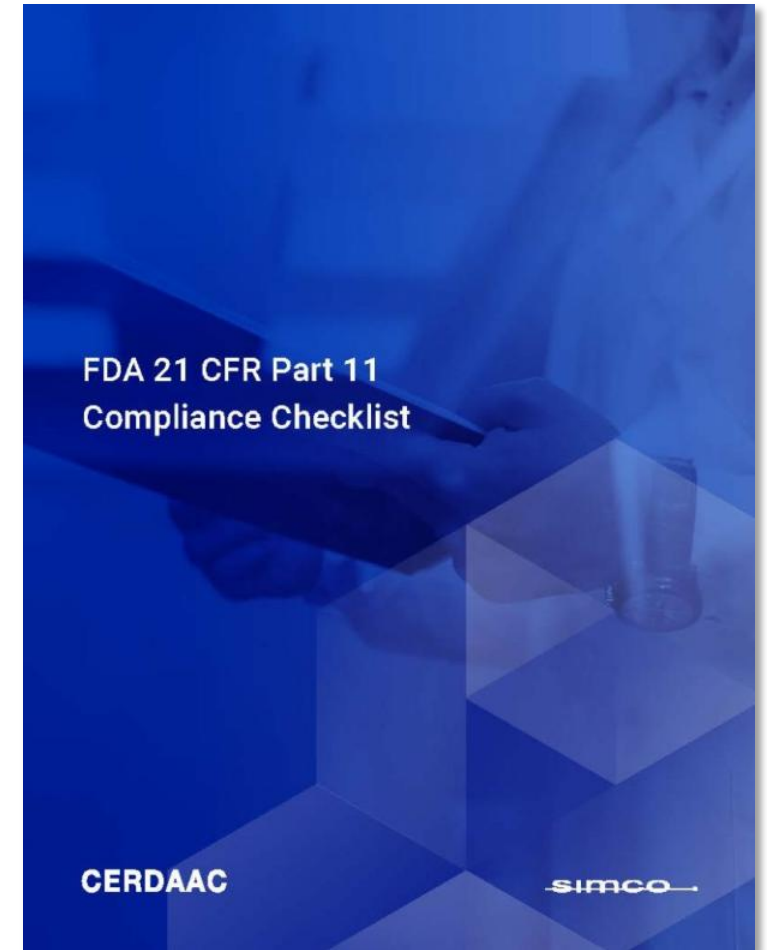
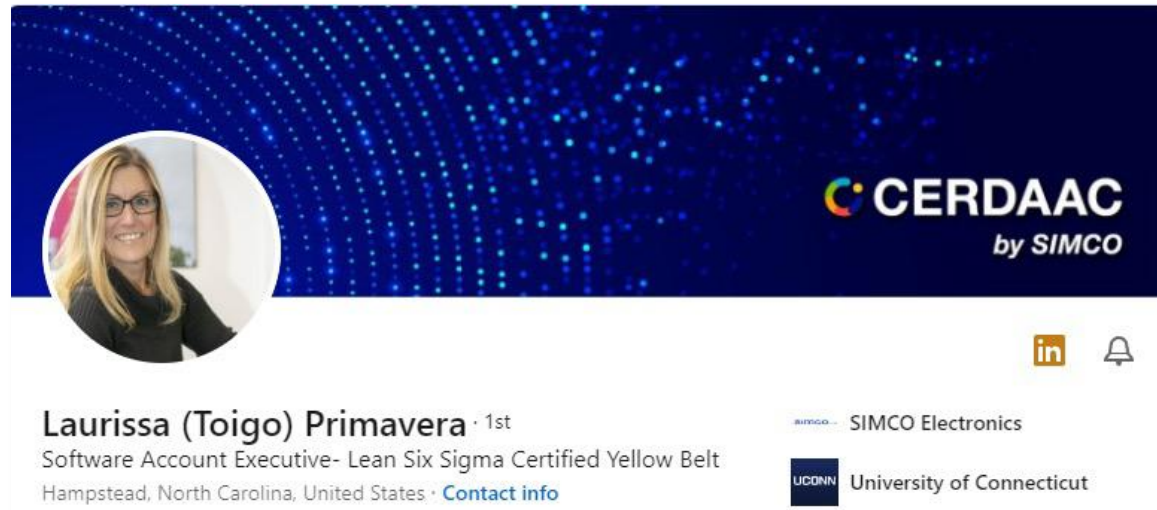


About This Webinar

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-xTHaHZIllg
- 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?

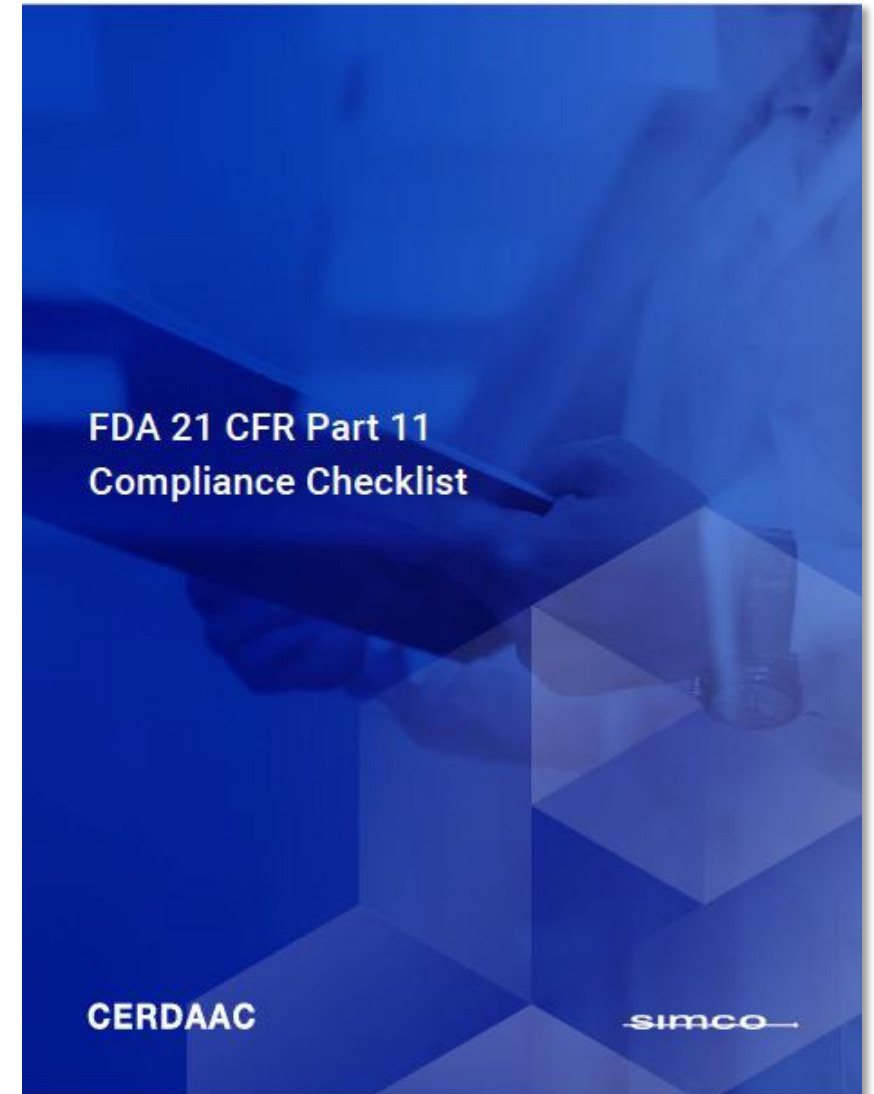
Majority of you answered several days, then months, then weeks and days

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?

Home Assets x Asset: 12383 x

Edit Print Show Enrollment Form Quality Engineer

Asset: 12383 Tags: none

Asset Information ▼

Asset ID	12383	Active	Yes
Manufacturer	Mitutoyo	Condition	Operational
Model	500-196-30	Department	R&D
Serial Number	3213256	Location	Research Cell A
Description	0-6" Digital Caliper	Owner	Laurissa Primavera [Change]
Model Type	Caliper	No Calibration Required	No
Acquisition Cost	\$ 127.00	Standard	No
Parent		Calibration Interval	12 Months

Procedural Methods ▼

Manufacturer Procedure	Yes	Manufacturer Procedure Name	Caliper Procedure ABC
Industry Accepted Method	Yes	Industry Accepted Method Name	Caliper Procedure
Custom Procedure	No	Custom Procedure Details	

Calibration Specification ▼

Process / Operating Range	0-6"	Calibration Range	0-6"
Process / Operating Set Point Tolerance	0.001	Calibration Tolerance	0.001

Classification ▼

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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?

simco CERDAAC at Enterprise Digital Workflow Welcome Laurissa Help | Support | About | Return to Tenancy Manager | Sign

CERDAAC Home Services x Teams x Users x Service: 00040 x

Settings Edit Print View Case Show Certificate Form Completed By

Personal Setup
Administration
Users
Teams
Views and Reports
Audit Log
Data Management
Monitor
Recycle Bin

Service: 00040 Tags: none

Related Information

Notes and Attachments **Field Audit Log** Standards Work Activities Work Request Parts

Field Audit Log

Date Created	Created By	Description
05/17/2022 11:48:17 AM	Judy Young	Modified Owner from John Ashworth to Laurissa Primavera of record - 00040
03/04/2021 08:39:30 AM	John Ashworth	Record Name: 00040 Modified Service Completed to 03/04/2021 Modified Initial Asset Condition to Out of Tolerance Modified On Time Status from In Process to Serviced On Time Modified Final Asset Condition to Operational Modified Work Finished to 03/04/2021 Modified Next Service to 00199 Modified Actual Turnaround Days to 78 Modified Next Due Date to 03/04/2022 Modified Processing Status from In Process to Completed Modified Open from Yes to No
11/16/2020 09:35:00 AM	John Ashworth	Completed By Signature Invalidated - 00040
11/16/2020 09:35:00 AM	John Ashworth	Reviewed By Signature Invalidated - 00040
11/16/2020 09:35:00 AM	John Ashworth	Record Name: 00040 Modified Procedure to MITU-001
11/16/2020 09:12:19 AM	John Ashworth	Reviewed By Signed
11/16/2020 09:12:06 AM	John Ashworth	Completed By Signed
		Record Name: 00040 Modified Start Date to 11/16/2020

Designer

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?

The screenshot displays a software interface with several sections:

- Signatures**: A section with two rows of signature data.

Quality Engineer Signed By	John Ashworth [Verify]	Calibration Coordinator Signed By	John Ashworth [Verify]
Quality Engineer Signed Date	11/16/2020 08:55 AM	Calibration Coordinator Signed Date	11/16/2020 08:56 AM
- Enrollment Form**: A section with two rows of enrollment data.

Calibration Enrollment Form	Asset Enrollment Form - Calibration & PM	Calibration Enrollment Generated Form	12382.pdf
- Related Information**: A section with a tabbed interface. The 'Services' tab is active, showing a table of service records.

Services Table:

	Service Number	Service Type	Interval	Processing Status	Due Date	Vendor	Initial Asset Condition
	00424	Calibration	12 Months	Scheduled	03/31/2023	ABC Company	
	00042	Calibration	12 Months	Completed	03/31/2022	ABC Company	Operational

Electronic Signatures

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The top screenshot shows a software interface for Case 0068. A red arrow points to the 'Investigation Completed' button, which is labeled 'Signature Button'. A 'Signature Group Information' dialog box is open, showing 'User Name: Judy Young', 'Pass Phrase' (masked), and 'Purpose: Reviewed'. The dialog box has 'Sign' and 'Cancel' buttons, and a link 'Show fields you are signing'.

The bottom screenshot shows a software interface for Service 00974. A 'Signature Group Information' dialog box is open, showing 'User Name: Jim Harper', 'Pass Phrase' (masked), and 'Purpose: Approved'. The dialog box has a dropdown menu for 'Purpose' with options: Reviewed, Approve, Author, Approved, and Responsible. The 'Approved' option is selected.

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

The image displays two screenshots of the SIMCO CERDAAC at Enterprise Digital Workflow interface, showing the 'New User' form.

Top Screenshot: The form is titled 'New User' and includes fields for Title (Quality Manager), Company (XYZ Company), Reports To (Judy Young), Access Profile (Manager), and Employee Number. The Locale Information section shows Time Zone (GMT-08:00) Pacific Standard Time (America/Los_Angeles) and Date Format (mm/dd/yyyy). The Login Information section includes Email, Username, Active (checked), and Enable Mobile Access (unchecked). The Team Membership section shows Primary Team.

Bottom Screenshot: The form is titled 'New User' and includes fields for Title (Quality Manager), Company (XYZ Company), Reports To (Judy Young), Access Profile (Manager), and Employee Number. The Locale Information section shows Time Zone (GMT-08:00) Pacific Standard Time (America/Los_Angeles) and Date Format (mm/dd/yyyy). The Login Information section includes Email (joe.smith@xyz.com), Username (jsmith), Active (checked), and Enable Mobile Access (unchecked). The Team Membership section shows Primary Team (SIMCO Support). The Startup Information section includes Initial Application (Work Requester), Role (SIMCO Support), and a checkbox for Send Welcome and Login Information by Email (checked).

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, records, data, etc.
- **Prevalidated** system saves you time and money
- Manage quality and compliance of assets, people and processes
- 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.”

477% ROI
\$148,550 savings
annually
~1,000 hours
saved in audit
support

Download case study:
www.simco.com/wuxi-case-study

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.”

- 400 users
- 43 sites
- 5,000 assets tracked
- Staff training and certifications also tracked in CERDAAC



Q&A

Type your questions into the Q&A window.



Thank You

Questions?

Visit: cerdaac.com