GxP compliance: electronic records and signatures guide

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What is GxP?

A collection of quality guidelines and regulations designed to ensure your products and projects are safe, meet their intended use, and adhere to quality processes throughout the manufacturing, control, storage and distribution stages

GxP guidelines represent the minimum requirements your business needs to meet

GxP compliance is essential for life science organizations and any regulated business which supplies products and services to the U.S. and E.U.

Represented through 2 major pieces of legislation:

- EudraLex Volume 4 Good Manufacturing Practice (Annex 11: Computerised Systems)
- FDA 21 CFR Part 11 cGMP guidelines

FDA 21 CFR Part 11 vs. EU Annex 11

	FDA 21 CFR Part 11	EU Annex 11
Context	Context may seem similar but both regulations are based on different regulatory structures and intentions	
Objective	The final objectives of both Part 11 and Annex 11 are mirrored: a modern and effective validation approach will normally unlock compliance with both regulations	
Timeline	Finalised in March 1997	Finalised in June 2011
Relevance	Based on the basic prerequisite that systems are validated according to Good Manufacturing Practice (GMP), but also relevant for GDP, GLP, GCP and medical device organizations	Annex 11 is relevant for GMP requirements, but is also referenced in other areas
Validation	Validation of systems to ensure accuracy, reliability, consistent intended performance and ability to discern invalid or altered records	On top of the V-model approach, it combines elements like risk, project, data, IT service/security, suppliers and contracts, release, requirements, test, development lifecycle and documentation management

What is FDA 21 CFR Part 11?

Part 11 is designed to give your business the framework to ensure that:

1. Data integrity and reliability is maintained for all electronic records that are created, modified, maintained, archived, retrieved or transmitted
2. The software and systems your business uses in its day-to-day activity are **validated** as appropriate and compliant
3. Your data is maintained safely and securely
4. Electronic signatures are non-disputable
5. Data changes can be tracked
6. Falsification of records is prevented and/or easily detected
7. Your electronic records are as trustworthy as a paper record
8. Your electronic signatures are as valid and legally binding as a wet signature

- **‘21’:** Chapter of US Federal Law, Food & Drug Act c. 1906
- **‘CFR’:** Code of Federal Regulation
- **‘Part 11’:** The section of the CFR dealing with electronic records and electronic signatures — a crucial component of GxP

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Does FDA 21 CFR Part 11 apply to me?

Some key questions:

- What do you class as your master record?
- Are you using a closed or open system?
- Do you upload documents or scan documents to a shared file? (This could be prior to uploading into a computerized system.)
- Do you use printouts, while still relying on electronic records in the computerized system to perform your regulated activities?
- Do your personnel require a username and password to log into a computerized system?
- Do you work within a regulated industry that provides products and/or services to the U.S.?

You are subject to compliance with Part 11 as soon as an electronic document is uploaded

Section 11.3: Definitions

- **Electronic record:** Any combination of text, graphics, data, audio, pictorial or other information representation in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system
- **Electronic signature:** A computer data compilation of any symbol or series of symbols executed, adopted or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature

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Digital and data security considerations

Digital security: how will you access your system?

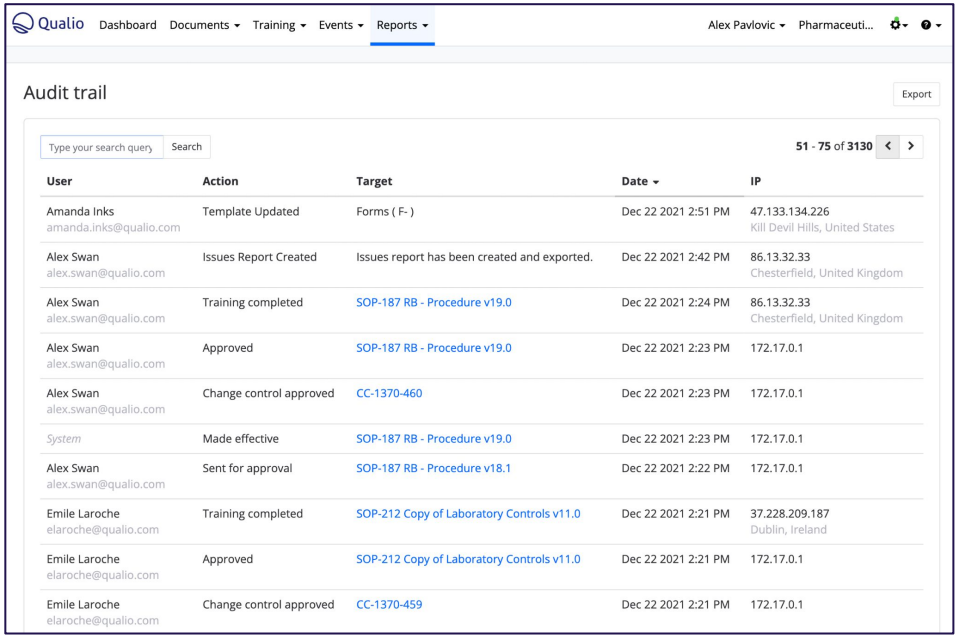
- Passwords are a major component
- Security is the major area of concern for FDA 21 CFR Part 11
- User accounts with relevant permissions should be set up so not just anyone can log in
- Account sharing should be forbidden. User accounts should be connected to individuals
- Password best practice should apply
- *Look to ISO 27001:2013 for guidance on good information security practice*

Data security: who can view your electronic data?

- All users with access need the right roles and permissions
- Data viewing permissions should be locked down to relevant users and groups
- This requirement is relevant for computerized systems and simple digital folder structures on your organization's drives

Traceability of your system and records

- Audit trails! Who, where and when?
- All system actions and events should be recorded with the exact user, date and time
- Change logs should be complete and easily accessible
- Know when and IF your users are logging in
- Housekeep your systems and records with automatic review periods
- Access information for regulatory audits and inspections quickly and easily



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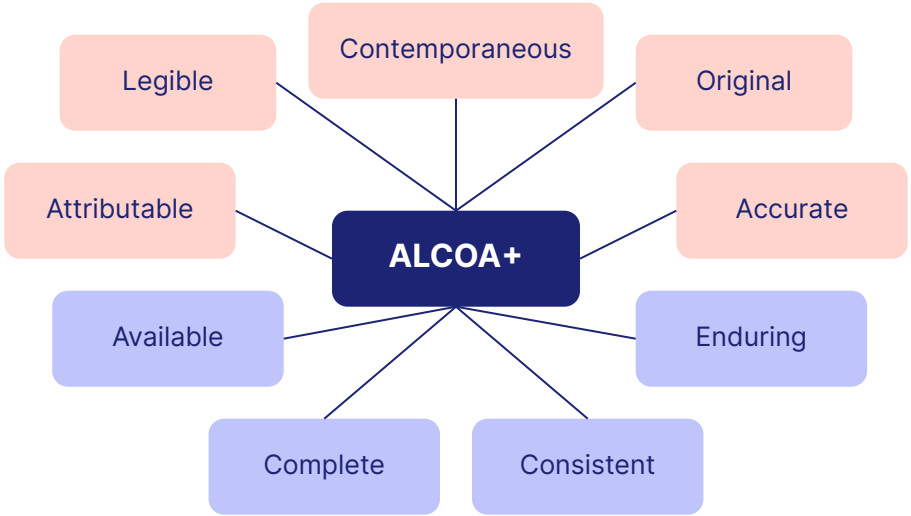
9 best practice tips

1. Control access to your electronic records with a unique login (username + password combination)
2. When setting a generic password for a new user, ensure the user is forced to change to their own unique password
3. Consider an inactivity timeout on your system
4. Disallow previous passwords or set a minimum time before they can be reused
5. Lock users out after a defined amount of incorrect passwords
6. Ensure passwords are updated periodically
7. Use *operational system checks* to enforce permitted sequencing of steps and events
8. Use *authority checks* to ensure only authorized users can access the system
9. Use *device checks* (if relevant) to determine the validity of the source of data input or operational instruction

ALCOA+

ALCOA+ provides 9 data integrity benchmarks you must fulfil for GxP compliance. Your electronic records and signatures should be:



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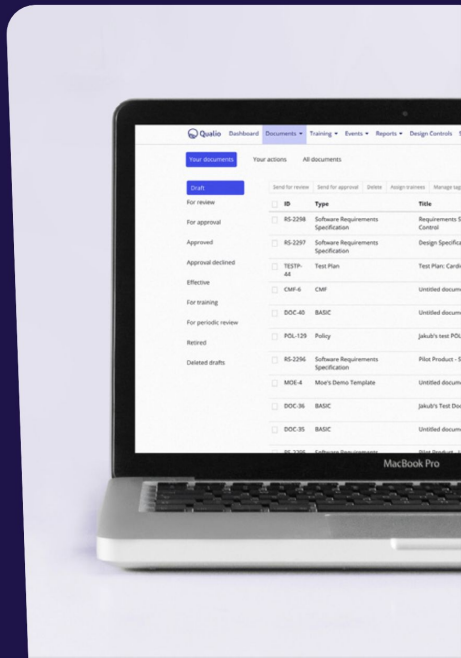
Summary: how do I comply?

1. Documented procedures (SOPs)
2. Trained and qualified individuals
3. Limited role-based access with security controls
4. Password policies
5. Linking of electronic signatures to records
6. Keep accurate and complete records (ALCOA+)
7. Protect and easily retrieve records throughout the retention period (ALCOA+)
8. Audit trails (ALCOA+)
9. Invest in an appropriate and validated electronic quality system that automates these processes and benchmarks for you

See our GxP quality management software in action

qualio.com/demo



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