Section 3

How to Configure Electronic Signatures for GxP Compliance

Before reading the document please note that the key takeaways that we provide represent our advice in regards to the regulations and how you can implement your electronic signatures to help compliance with 21 CFR Part 11 regulations. We do not represent any government agency and nothing in the in this guide should be taken as fact. The regulations we provide are true to the publishing date.

All the key takeaways

- Maintain a historical list of electronic signatures.
- Ensure electronic signatures are historically unique.
- Keep an account of electronic signatures to ensure that a name is not duplicated.
- Maintain a historical list of current and historical users with access privileges.
- Periodically review current and historical list of users with access privileges to find users who have changed roles or jobs but still retain access.
- Each individual who will be using an electronic signature must have their identity confirmed.
- Organisations that wish to use electronic signatures must inform the FDA in writing prior to making the switch.
- Tips for setting up an electronic signature, see sectiion 4.
- Every individual must have two components to their signature (username and password).
- Finger print, retinol scans etc. cannot be overwritten by any individual and can only be used by the individuals whom they are assigned.
- Ensure that no two users have the same combination of username and password.
- Periodically check and change usernames and passwords.
- If a username and password is stolen or lost, it must be deauthorized and the individual must be given a secure replacement.
- Configure user accounts so that any attempts to gain access to unauthorised accounts is detected and reported to the appropriate person in an organisation.
- How to configure these settings in windows.
- Before electronic signatures are used they must be tested to make sure they are functioning correctly.

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Additional information

- Check that you systems can't be accessed by a public password.
- For additional 21 CFR Part 11 implementation see Version Control Compliance Guide the document presents the technical features of Version Control in regards to FDA 21 CFR Part 11 and how these individual regulations can be satisfied with Version Control to help your organisation comply with the Food and Drug Administration's FDA 21 CFR 11 regulations.