5 Successful Tips for

21 CFR Part 11 Compliance

01 Data Security

Data security is critical for 21 CFR compliance. Providing multiple user roles and access levels with appropriate permissions will help ensure your data is secure and you are in compliance. Make sure to check permissions and ensure users have appropriate access for their role

02 Password Protection

Passwords play a major role in digital security and 21 CFR compliance. Follow password best practices when creating them, including periodic password updates, automatic logging out of inactive users, and system lock outs for multiple failed password attempts

03 Establish Audit Trails

Audit Trails must be established to track all electronic record modifications. It is your responsibility to track what user performed any modifications, along with the exact date and time the modifications were made. This includes record creation, modification, and deletion. You should also track when users accessed records even if no modifications were made

04 Electronic Signatures

If you are using electronic signatures, you must first notify the FDA. To comply with 21 CFR Part 11 guidelines, each person signing the document should have separate access to the document, and the documents should not be editable once in the approval process. If edits are needed the approval process should begin again one edits are made.

05 Validate for IQ, OQ & PQ

IQ (installation qualification), OQ (operational qualification), and PQ (performance qualification) are all qualifications you need to validate to confirm 21 CFR Part 11 compliance. IQ validates that your software is installed correctly. OQ validates that your software is capable of meeting regulatory requirements. PQ validates that your browsers, operating systems, etc. comply with installation requirements. Establishing reporting and protocols will help you to maintain compliance.