

Pharmaceutical Companies under the Microscope



Achieve FDA 21 CFR Part 11 compliance for your Microscopy Software with PAX-it!

PAX-it! Extended Security Features

A secure set of tools for tracking and locking down images, reports, and other digital assets, as well as Administration tools for setting up permissions within the software, verification of asset integrity, and audit trails.

Administrative tools

- Assign unique logins to users
- Windows authentication (active directory)
- Administrator assigned permissions for groups or individuals

Electronic Records/Electronic Signatures (ER/ES)

- Digital signatures are applied by user credentials
- Multi-level digital signatures
- Flexible pass/fail notes may be applied to each signature

Audit trails

- Activity tracked to image manipulation, deleting, adjusting etc.
- Creation and modification of file types
- User activity and more



PAX-it!





IQ/OQ Documentation Service

Trained software technicians are available to help execute standard IQ/OQ documentation as part of the FDA 21 CFR Part 11 procedural requirement.

Summary of PAX-it! Features

- Supports Windows Authentication (Active Directory) or SQL / Oracle Authentication for unique software logins
- User lockout after three failed login attempts
- Stringent authentication algorithms for data integrity from file creation to final reporting and presentation
- Authenticity can be verified for any image or file at any time
- Annotations, measurements, and analysis results are stored in separate files to maintain image integrity
- Multi-level digital signatures accommodate reviewer roles, defined by your lab
- User credentials are required upon signing
- User creation and assignment of customised Pass/Fail and Reason criteria for each digital signature
- Details of digital signature are applied to any human-readable output, the original file remains unaltered
- Tracking of parent image(s) or original image source
- Comprehensive log reports including user activity, document activity, and metadata edits
- IQ/OQ documentation service available



PAX-it!

For more information

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