



What's New in PCI/CFR Version 4.0

- Windows 10 support
- 64-bit operating system support
- User authentication required before software starts
- Re-authentication required after period of inactivity
- Configurable user rights and roles
- Built-in digital signature function
- Reads calibration information from most EM images

Meeting the challenge of CFR 21 Part 11 compliance for microscopy

Maintaining CFR compliance for your digital images is challenging. Unlike text documents, where it is a simple matter to compare old and new versions to determine how they have been changed, it is usually not possible, when looking at two versions of an image, to determine the processing steps that have led to the changed image. Therefore, specialized software is required to audit every processing step and to keep read-only copies of every predecessor version of each image.

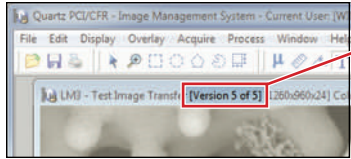
Whether you use light or electron microscopes, Quartz PCI/CFR helps you meet this challenge. After data capture, every processing and annotation operation that is carried out on the image is recorded in a secure audit trail. The raw data and each subsequent version of the image are saved in read-only, encrypted files so that you can always retrieve earlier versions of processed images and you can be sure they have not been tampered with. Members of your organization can apply digital signatures to the data. Finally, you can export your data as digitally signed, industry standard PDF files for regulatory submission or sharing with colleagues.

CFR 21 Part 11 Image Capture

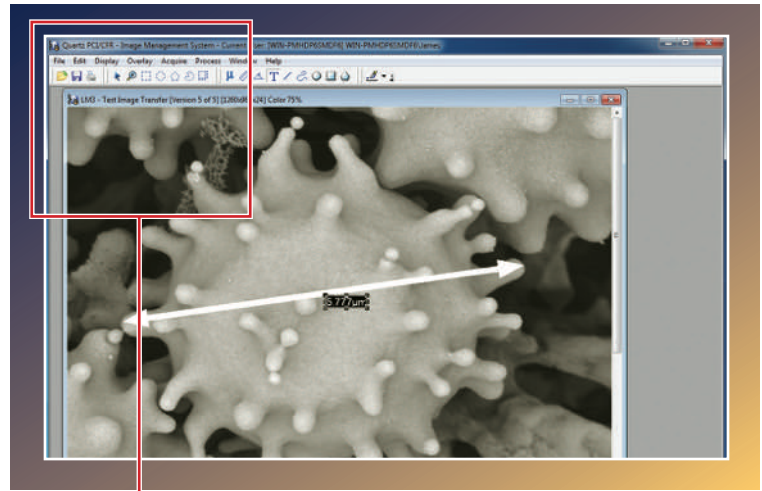
Images are captured directly from light and electron microscopes. Packages are available for direct image transfer from PC-based SEMs or slow scan capture from other SEMs. For light microscopes, images can be acquired from video or digital still cameras.

Retention of Original Data

Original data transferred from the instrument is saved by the system prior to any changes by the operator. Thereafter, each version of the data is also stored as changes are made. It is always possible to retrieve predecessor versions of the data.

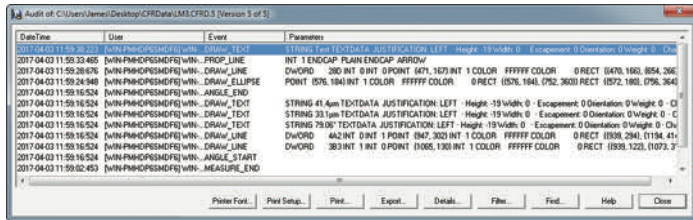


All versions of each image are retained by the system. It is always possible to retrieve earlier versions.



21 CFR Part 11 Audit Trail

Every user action is retained in an audit trail which includes the date and time, user name, computer name and specific details of the action.



Data Encryption

All data is encrypted to make unauthorized changes virtually impossible while, at the same time, digital signature technology makes tampering easily detectable.

21 CFR Part 11 Electronic Signatures

Images stored as electronic records can be digitally signed by authorized users. Signature information includes the name of the signer, the date and time of signature execution and the meaning of the signature, such as review, approval, responsibility or authorship. Applying a digital signature requires entry of two distinct identification components (user name and password). These signatures are embedded within their respective electronic records and cannot be excised from them.

Technical Features

PCI/CFR Standard Features

- Secure audit trail.
- Retains copies of all versions of data.
- Use of encryption and digests to ensure data integrity.
- PDF file export, with digital signatures.
- Runs on Windows XP, Windows Vista or Windows 7, 8 and 10. (32 and 64 bit)
- Works with the Windows security system to provide password protection, permission and user roles.
- Common user interface for all image sources.
- Images can be exported to most popular file formats.
- Image manipulation functions include contrast, brightness and gamma adjustment, color correction, histogram adjustments, zooming, smoothing, sharpening, median filtering, rotating and resizing.
- Support for 24-bit color and 8- and 16-bit grayscale images.
- Length and angle measurements.

- Micron marker function for adding micron marker to images, such as from light microscope, that do not contain a micron marker.
- Drawing tools operate on separate overlay layer. Overlay elements can be moved or deleted without interfering with each other or the underlying image.
- Slide show function.

Image Acquisition

SEM

- PCI/CFR reads the calibration information from most digital SEMs.
- We use our passive slow scan system with USB computer interface for analog SEMs.

Light Microscope

- TWAIN interface for digital still camera.
- RGB frame grabber for video capture.

Ask about access to a recorded demo of
PCI/CFR Version 4.0

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