QUARTZPCI-CFR
VERSION 6.0

What's New in PCI/CFR Version 6.0

- ▲ "Secure Repository" can save any kind of file (EDX, spreadsheet etc.) with CFR Part 11 support
- ▲ Workstation log records all access to system and files (even reading file)
- ▲ Can retrieve raw data file exactly as it came from instrument for further analysis
- ▲ Virtual printer driver can record multipage documents as single file
- ▲ Rules can be applied to signatures (e.g., order of signatures, only applied once etc.)
- ▲ Spider function can operate without deleting original file
- ▲ Improved image format support (DICOM)
- ▲ Windows 11 support

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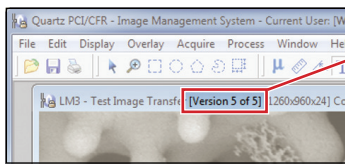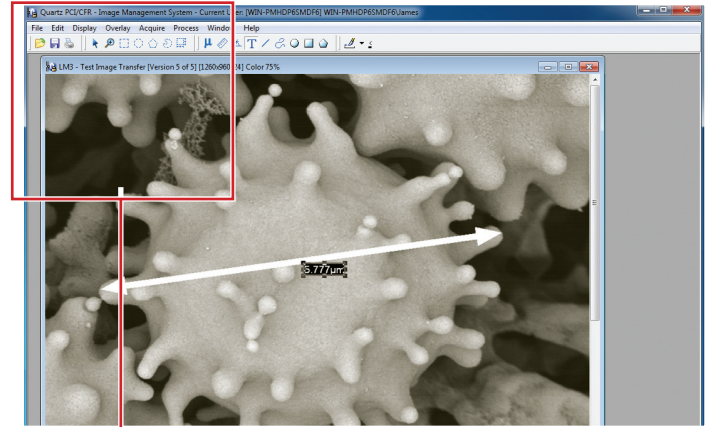
All versions of each image are retained by the system. It is always possible to retrieve earlier versions.

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.

**Ask about access to a recorded demo of
PCI/CFR Version 6.0**

Technical Features

CFR Compliance

- Acquires images and stores them in accordance to 21 CFR Part 11.
- Maintains an audit trail that records all changes that take place in our software to each image.
- Retention of copies of all versions of each image.
- Use of encryption and digests to ensure data integrity.
- Apply digital signatures to images.
- Export data as digitally signed PDF files, including audit trail.
- User rights and roles.
- Works with Windows security system to provide password protection, permissions and user roles.

Image Acquisition

- PCI/CFR can work with any electron or light microscope.
- PCI/CFR reads the calibration information from most digital SEMs.
- Integrated versions of the software for some electron microscopes.
- TWAIN interface for digital still camera with TWAIN driver.
- Spider versions monitors a "hot folder" for non-integrated electron microscopes and light microscopes that do not have a TWAIN driver.
- Virtual Printer Driver version to "print" files, such as EDX data, from other applications to PCI/CFR as an image.
- We use our passive slow scan system with USB computer interface for analog SEMs.

Image Processing

- Histogram functions for contrast, brightness and gamma adjustment.
- Display functions for zooming, panning, false coloring and slide show display.
- Image rotate and resize.
- Color correction.
- Color variations.
- Hue and saturation adjustment.
- Local contrast, sharpen and median filter tools.

Measuring and Drawing Tools

- Line measurement tool.
- Angle measurement tool.
- Line drawing tool.
- Freehand drawing tool.
- Circle/Ellipse drawing tool.
- Square/Rectangle drawing tool.
- Polygon drawing tool.
- Text tool.
- Line width tool.
- Color picker tool.
- Drawing tools operate on a separate overlay layer.
- Image Overlay functions including ordering, duplicating and applying.
- Default Overlay function eg.) Confidential, Company name, etc. for all images.

Reporting

- Export image as a digitally signed PDF including audit trail information.

General

- Supports Windows 11. It also works on Windows 7, 8 and 10.
- Runs on 32-bit and 64-bit operating systems.
- Support for 24-bit color and 8- and 16-bit grayscale images.
- Images can be exported to most popular file formats.
- Output to any Windows supported printer.
- Micron marker function for adding micron marker to images, such as from light microscope, that do not contain a micron marker.
- Slide show function.
- Common user interface for all image sources.
- Dual monitor and widescreen support.

Frequently Asked Questions

1. Who is Quartz Imaging?

Quartz Imaging was founded in 1993 with the launch of our first PCI software that combined with a computer board that we developed to acquire digital images from analog microscopes.

2. When did you first introduce your PCI/CFR software?

We developed the first version of our PCI/CFR software about 20 years ago and have worked with many of the biggest names in the pharmaceutical sector, such as Pfizer, J&J, Roche, Merck, Novartis, Bayer, Sanofi, Bristol Myers Squibb, Abbott Labs, GSK, Takeda, Amgen, Novo Nordisk, Boehringer Ingelheim, Viatris, Baxter, Teva Canada, etc.. We are currently shipping version 6.

3. What microscopes are you compatible with?

Through the use of different 'flavors' of our software we can work with any make and model of electron and light microscope. We have been contracted by a number of microscope manufacturers to provide some level of integration between our PCI/CFR software and their microscopes and are now their source of PCI/CFR software for their customers. For use of PCI/CFR with microscopes where we are integrated with the microscope we have a specific 'flavor' for each manufacturer. For other instruments you would use either our Spider version which monitors the folder where images are saved to and the images are then automatically available in PCI/CFR or you could use our TWAIN version with a microscope whose camera has a TWAIN driver (or you could use the Spider version).

4. How does your software work with the microscope and the microscope software?

PCI/CFR software is passive in that it does not interfere with the operation of the microscope in any way. Our software works on its own and does not interfere with the use of other microscope software.

5. What about the calibration information from the microscope?

We have worked with many of the microscope manufacturers so that their images arrive in our software already calibrated and ready to measure. These include Hitachi, Zeiss, JEOL, Phenom, Tescan and FEI/Thermo. We are happy to work with other electron and light microscope manufacturers in order to provide you with the same calibration feature. If the images do not arrive already calibrated you can easily and quickly calibrate the image with a few clicks.

6. We have other software to perform specialized functions on our images. How does that work?

A number of our customers have this same workflow issue and it was resolved by writing Standard Operating Procedures that allow them to take the image into the other software and then into PCI/CFR while maintaining CFR compliance.

7. What if I need an IQ/OQ done on PCI/CFR software?

If you would like us to conduct the IQ/OQ we would complete this over a web meeting that typically takes about 2 to 3 hours. We use Teams and GoToMeeting or we can use another web meeting tool if you prefer. (Please see the IQ/OQ web meeting requirements below.)

If, for example, your microscopes cannot be connected to the internet we offer the option to purchase a license to use our protocol and report template. This is a license per instrument and if for some reason you have to redo the IQ/OQ on that microscope there is no additional cost.

Customer Requirements for web meeting IQ/OQ:

▲ Instrument support PC needs to be connected to your corporate network/domain for authentication.
▲ Any driver software required (such as a TWAIN driver for light microscope cameras) needs to be installed and tested on the support PC before our meeting.
▲ A local Administrator log-in is required to install the PCI/CFR software (i.e., someone with an Administrator account will need to log in before the software installation).
▲ Log-ins to both Administrator and Non-Administrator accounts are required during the IQ/OQ. During the IQ/OQ, we will need to add users to local groups on the machine.
▲ If SEM, need a sample that has known dimensions. If possible, sample should be in the SEM and pumped down before the meeting.
▲ If Light microscope, need a stage micrometer.
▲ The instrument should be checked to ensure that it is fully operational before we start, and an experienced operator needs to be on hand to operate the instrument.
▲ Session should take approximately 2 to 3 hours

8. Can we install the software ourselves?

Yes, PCI/CFR utilizes a standard Windows installer and we provide you with detailed information on the options to ensure it is set up for your specific needs. If you want us to conduct the IQ/OQ we can do the software installation for you.

9. What if we have any problems after installing the software?

If you run into any issues we available by phone, email and web meeting to help you out. We support our over 2,500 customers in 41 countries around the world from our offices in Vancouver Canada.

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