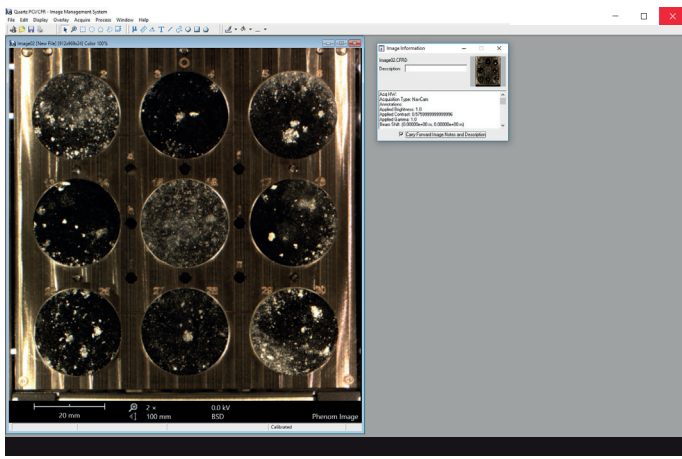


Phenom SEM and Quartz PCI/CFR

SEM imaging traceability compliant with
21 CFR Part 11





Quartz PCI/CFR user interface showing the acquired NavCam image.

Quartz PCI/CFR for the Phenom XL

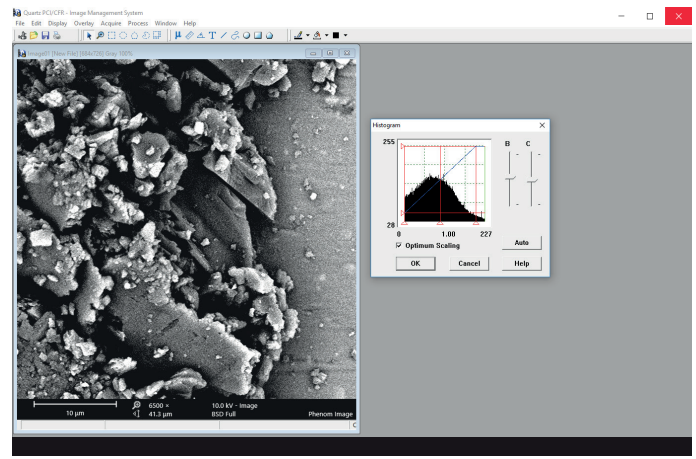
The Thermo Scientific™ Phenom XL™, equipped with Quartz PCI/CFR, helps you to meet the requirements of 21 CFR Part 11. The integration of the Phenom SEM with the Quartz PCI/CFR software allows direct acquisition of both the NavCAM and SEM images. This significantly reduces the complexity of standard operating procedures (SOPs), ensuring compliance with data integrity requirements.

After selecting the region of interest and the imaging parameters required on the Phenom UI, the user acquires the image using Quartz PCI/CFR.

Various post-acquisition image processing tools are available with Quartz PCI/CFR. These include adjusting the brightness and contrast, local smoothing and sharpening tools, and annotation and drawing tools. Furthermore, sizes and distances are easily measured with the built-in tool.

All changes that are applied to images are logged in an audit trail system that can be opened and viewed using Quartz. Images can be signed electronically and PDF reports can be exported to finalize the analysis.

Note: Element identification and the Phenom ProSuite software package are not included in the 21 CFR compliant solution.



Quartz PCI/CFR user interface showing the acquired SEM image and the adjustment for brightness and contrast.

Part 11 of Title 21 of the “Code of Federal Regulations; Electronic Records; Electronic Signatures” (21 CFR Part 11) ensures the reliability and authenticity of electronic records. This regulation includes guidelines on the storage and protection of electronic data and the application of electronic signatures.

Specifications

Software solution providing 21 CFR Part 11 compliance for the Phenom XL or Phenom Pro

Compatible with the Phenom XL and Phenom Pro desktop SEMs

Phenom ProSuite including mini PC and monitor

Windows 10 64-bit operating system support

Direct image acquisition from the Phenom SEM:

- NavCam image acquisition
- BSD or SED image acquisition

Configurable user rights and roles

User-specific audit trail

Electronic signatures

Find out more at thermofisher.com/phenomworld

ThermoFisher
SCIENTIFIC

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