



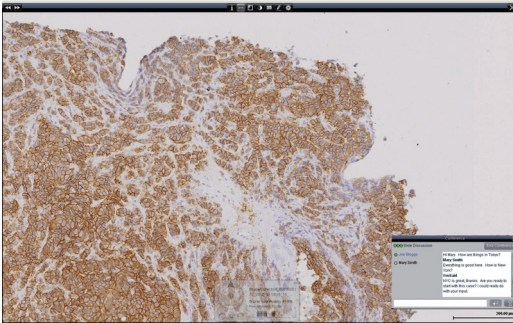
Regulatory Compliant Research

Bringing Virtual Microscopy into the regulated laboratory environment with the Leica SCN400 and SlidePath software solutions.

Living up to Life



Flexible Solutions, Enabling Virtual Microscopy in Regulatory Compliant Research



Use SlidePath's conferencing module for simultaneous slide discussion online with your colleagues worldwide.

Your Benefits:

- Support multi-site collaboration through a single online solution
- Full technical controls for achieving 21CFR part 11 compliance
- Review multiple images in a single window for side-by-side viewing and improved slide comparison
- Integrate with 3rd party systems using flexible XML and SOAP communication specifications
- Conferencing tool simulates a multi-head microscope environment for rapid slide discussion and peer review
- Integrate searchable 1D and 2D barcode information
- Create a complete peer discussion platform for all users with slide observations and comments

SlidePath applications are not cleared by the FDA, Health Canada or in the EU for diagnostic or clinical use. All applications are intended solely for use in the research or educational setting, such as university or pharmaceutical development. These applications are described as Research Applications or Research Use Only.

No vendor can claim their software products are certified Part 11 compliant. A vendor can only say they have all of the Technical Controls for 21 CFR Part 11 compliance built into their product. It is the responsibility of the customer to implement the Procedural and Administrative Controls along with using products with the correct Technical Controls for overall Part 11 compliance.

Auditing, Security and Compliance

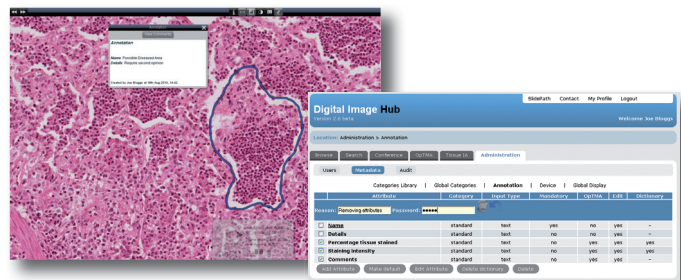
Carrying out research under the guidelines of regulatory bodies requires conformation to standards and compliance in both work practices and systems utilised. Digital Image Hub enables users in these environments to implement high-resolution slide scans from the Leica SCN400 and modernise research practices and workflows. With technical controls for FDA 21CFR Part 11 compliance coupled with comprehensive audit trails and tightly controlled user access, Leica provides the complete Virtual Microscopy solution for these users.

Standardisation and Access

Readily facilitate multi-user collaboration with secure and safe online access to high-resolution slide scans and associated study information. Reviewers are no longer tied to the microscope and can access whole slide scans through a web-based system. User-defined dictionaries and glossaries ensure standardisation of nomenclature throughout a study, or indeed organisation, thus resulting in accurate data and reducing analysis time.

Faster Studies

Complete non-diagnostic, confirmatory review of tissue for clinical trials online, thus removing the cost and time associated with transporting slides or samples. High throughput workflows, designed for the specific needs of preclinical research and toxicological studies, enable rapid study completion. Seamlessly integrate SlidePath's Conferencing module for multi-site peer review and slide discussions.



Screenshots from Digital Image Hub showing audit trails and time/date stamps.