

Developing a Global Digital Image Database for Toxicologic Pathology

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Traditionally, toxicologic histopathology assessments have been performed by veterinary pathologists using glass tissue slides and light microscopes fitted with a number of objective lenses ranging from 1x or 2x to 60x or 100x. Standard light microscopes have inherent limitations, such as the inability to view the entire tissue content of the slide when large organs or multiple organs are present in the same tissue block, or the inability to view more than one slide at a time for comparison. In addition, stacks of slide trays or racks are delivered to the pathologist, with the risk that some of the glass may be lost or broken. Digital pathology provides an alternative to traditional methods, allowing the user to view images of entire slides, or selected fields at increasing magnifications, and to compare multiple slide images simultaneously. The technology also allows both the use of digital slide images for teleconsulting and the use of robust image databases with metadata and search & retrieval capabilities.

The Pathology department within Safety Assessment at GSK operates on multiple sites worldwide. Collaboration has often been conducted by shipping glass slides, capturing images using cameras mounted on light microscopes or cross-site travel by pathologists. This is costly, both in terms of shipping glass and potential delays in product development. In order to mitigate these costs and meet the need to streamline processes, a decision was made to find and implement an appropriate global solution. This solution is envisioned to allow both internal and external collaboration, with appropriate security controls.

The initial step was to identify vendors with a product that could be implemented in a global network and be compliant with US Federal regulations 21CFR58 (Good Laboratory Practice for Nonclinical Laboratory Studies) and 21CFR11 (Electronic Records; Electronic Signatures) [1]. Then, due diligence was conducted using a series of questions provided to each vendor. The subjects of the questions included cost, IT capabilities (platform, software), after-sale service and technical support. Questions and responses were assigned to ranked categories and the responses in each category were tallied. Follow-up questions were asked where necessary. A subset of vendors was invited to demonstrate their products based on the combination of the highest number of highly-ranked scores and fewest least-ranked scores. A final decision was made using a combination of questionnaire scores and evaluation of product demonstrations.

Using the vendor-specific information gathered, plans for multi-site hardware infrastructure design and software integration within the GSK existing network were designed and reviewed. The vendor was consulted at several points in the development process to ensure that installation and implementation of the product would occur seamlessly within the network.

Initial implementation has proceeded in a development environment, which has safely allowed for hardware and software testing, building metadata fields and pick lists, training of staff conducting data input and pathologists accessing digital slide data, development of documentation and

troubleshooting. As a result of these initial rounds of testing, we can already demonstrate a clear return on investment as evidenced by increased awareness and acceptance of digital pathology imaging as a viable platform and improved collaboration within and between geographic sites.

References

- [1] Code of Federal Regulations, United States Government.
- [2] There is no commercial endorsement stated or implied by the content of this abstract.
- [3] The authors acknowledge the support of Safety Assessment and IT management and the technical support of Aperio Technologies, Inc. during the development phase of this project.

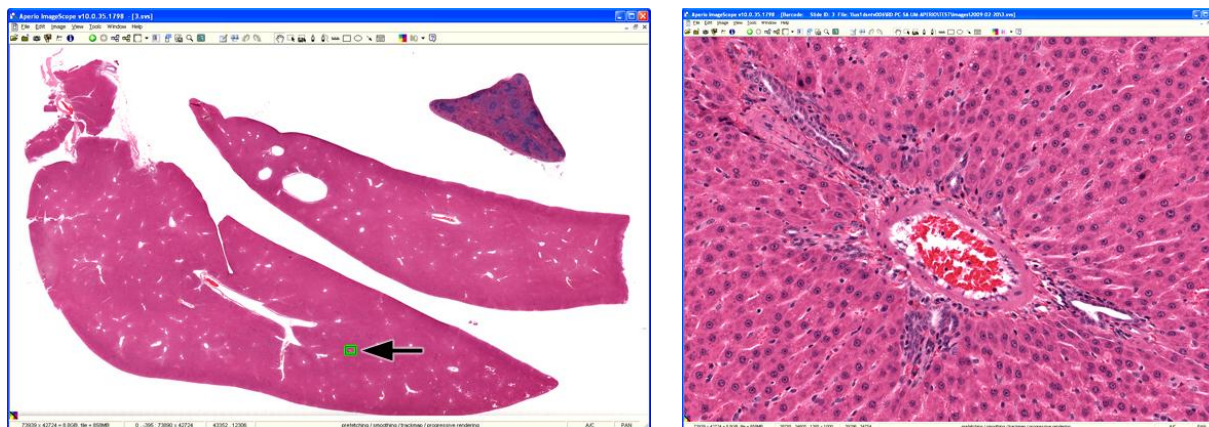


Figure 1. Sample digital histopathology images of a hematoxylin & eosin-stained section of rat liver and spleen used for data review and teleconsultation. Left, entire scanned tissue content of slide, 0.4x original magnification. Right, digital 20x magnification of area indicated by green rectangle (arrow).

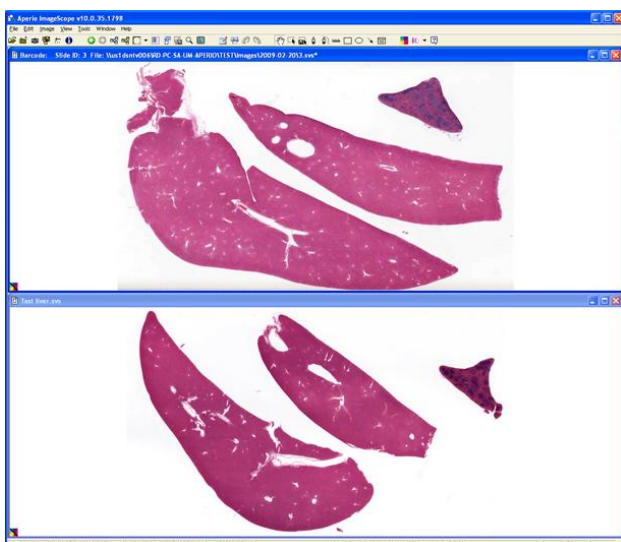


Figure 2. Side-by-side comparison of two digital slides containing hematoxylin & eosin-stained sections of rat liver and spleen are possible using the image viewer application in the vendor's suite of tools.