



## Guest Commentary

# FDA Advisory Panel Convenes To Assess Whole Slide Imaging

By Martin Perry

*Editor's Note: Guest writer Martin Perry attended the FDA's advisory panel on digital pathology conducted earlier this month. He is CEO of The Perry Group and has extensive experience in imaging and healthcare. He offers his insights from the FDA proceedings on digital pathology imaging.*

**D**IGITAL PATHOLOGY CONTINUES to gain acceptance at a steady but measured pace. The **Food and Drug Administration** (FDA) acknowledges these developments and is prepared to regulate emerging digital pathology technologies.

This FDA message was clear at the two-day Advisory Panel meeting, which took place on October 22-23 in Gaithersburg, Maryland. The meeting was conducted by the Panel for Hematology and Pathology Devices, which is part of the Medical Devices Advisory Committee.

The objective of the two-day meeting was to provide input to the FDA panel about the current status of the industry and its expectations of the future. The panel also reviewed how digital pathology imaging is being used by pathologists alongside conventional light microscopy, along with the challenges of bringing digital whole slide images (WSI) into mainstream use.

### ► Digital Pathology Images

There was discussion about the hardware and computer monitors used to view digital pathology images and the ability of these devices to support an accurate diagnosis. The advisory panel consisted of well-known physicians and scientists currently engaged in some aspect of digital imaging, as well as an industry representative.

Presenting to the panel were FDA scientists, physicians with practical experience in the technology, and executives from companies developing and selling digital scanning products and digital pathology systems.

At the outset, FDA officials stated—in no uncertain terms—that it intended to regulate the use of digital pathology devices and it would not classify them as exempt under 21 CFR864.9 rules. While there have been no known instances of a negative impact on patient care to date, the FDA is wary that incorrect use of this new technology could result in serious consequences to patient care and outcomes.

### ► “Gold Standard” Microscope

While the many advantages of digital pathology were described by the experts who spoke at the meeting, these speakers also emphasized several common points. For example, it was noted that the microscope has been the “gold standard” for use in rendering a diagnosis for the past 100 years. However, the microscope is not subject to a standard itself.

As noted by one presenter, the standards used today may be considered an “artisan standard” at best, subject to the preferences of the user. How then does a valid comparison of performance come about, given the variability inherent to the configuration of a microscope, i.e. optics, illumination, centrations, etc.?

Even maintenance and day-to-day adjustments of the standard microscope come into play. There was discussion about the need to develop a microscope slide “phantom” to test microscope performance. This phantom would be trans-

latable to whole slide pathology imaging applications, as was done in radiology.

In developing this new “gold standard,” what considerations should be given to the definition of the pathologist’s role as an integral part of the standard? Towards this end, the participation of the **College of American Pathologists (CAP)** was mentioned by at least one presenter during the discussions and, in conversation, seemed to be a point of agreement.

### ► Performance Characteristics

There was discussion among the speakers and the panel about the need to establish performance characteristics for monitors, image sensors, and the basic optics used in digital imaging systems. The types of training to be provided by the manufacturers and interoperability between different systems were also recognized as issues. Several speakers recommended that DICOM might be part of the solution.

One insight that emerged was that the FDA appears to be studying the lessons learned in radiology as that specialty adopted digital mammography systems and made the transition away from film. At that time, radiology had well-established and detailed standards to guide the transition from film-based images to digital images. Currently, pathology lacks a comparable set of standards as existed in radiology.

### ► Integrated Work Flow

Productivity and workflow issues were considered during this FDA meeting. It was recognized that digital systems would not go mainstream unless they are designed to integrate easily into the daily workflow of the pathology laboratory. Both manufacturers and users acknowledged the necessity of making digital technology convenient, reliable, and cost effective for the long term. For example, one obstacle to widespread adoption has been the time required to scan a slide. However, scan times have decreased dramatically in recent years.

On the supply side, manufacturers of current and future digital pathology products were well represented. They expressed their views and expectations to the panel quite clearly. For now, only the FDA knows what course it will ultimately follow in regulating digital pathology products and systems.

Some industry experts point out that the less stringent 510(k) approval process, rather than the more stringent PMA (Pre-Market Approval), would allow faster implementation. However, FDA officials offered no comments on their thinking on this matter. Industry expressed its willingness to work with the FDA. Many would prefer that industry and users, not governmental regulation, should control the process.

### ► Pathology Globalization

Of course, globalization of pathology testing services was not overlooked. In that count, one presenter remarked that the United States lags behind other countries, notably Sweden, in the implementation of whole slide imaging. The attendance of suppliers from Europe, Canada, and Asia indicates the keen interest to participate in the growth of the U.S. market. Some speakers urged the FDA to help the industry grow by adopting a regulatory approval path that would be less stringent.

By itself, this first public meeting of an advisory panel to evaluate whole slide imaging in pathology confirms its growing presence in the clinical marketplace. It is expected the FDA Advisory Panel will schedule future meetings to explore other issues, including image analysis and its use in whole slide imaging, standards for data storage of images, and validation studies.

Interested parties can visit the FDA website to obtain transcripts and audio recordings of the proceedings. The URL is [www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm](http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm). **TDR**

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