

DPA lauds FDA draft guidance, 5/15

May 2015—The Digital Pathology Association is commending the FDA for developing and releasing draft guidance that provides industry and agency staff with recommendations regarding the technical performance assessment data that should be submitted for regulatory evaluation of a digital whole-slide imaging system.

The draft guidance establishes an approach for characterizing the technical aspects that are relevant to WSI performance for their intended use and that are important in determining their safety and effectiveness. The association said it anticipates that this draft guidance and other yet-to-be published guidance documents will help clarify the agency's expectations for WSI regulatory submissions, enabling increased access and wide-scale adoption of digital pathology for clinical use in the U.S.

The draft guidance describes how manufacturers should characterize their WSI systems for clinical use. The document lists the components of a whole-slide imaging system and goes on to describe each of the components, including slide feeder, light source, imaging optics, mechanical scanner movement, digital imaging sensor, image processing software, scanning methods, image file formats, image review manipulation software, computer hardware, and displays. Another aspect of the guidance is the discussion surrounding a framework of a typical system-level test and the items that a usability validation test report should include. The draft guidance is detailed in listing several critical line items that the vendors should consider when providing data for regulatory evaluation of digital WSI systems.

The association said the document sends important signals to the public about the FDA's willingness to establish a more defined and predictable regulatory path, and demonstrates their ability to align toward such goals. The DPA said it intends to submit detailed and specific comments to the FDA related to the content of the draft guidance by the May 26 deadline.