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The Impact of digital pathology on the routine workflows and its challenges in a regulatory environment

Elizabeth Neyens

DVM, Toxicological Pathologist & American Board-certified Toxicologists. Consulting Firm: FlandersToxPath-Consulting, Belgium-Canada

Digital pathology has been widely discussed since several years in Societies of Surgical Pathologists. Recently, it's use has been widely increased in additional fields such as in academia for educational purposes, but also in non-clinical drug development research. In 2017, the FDA approved the first Whole Slide Imaging System (WSI) for digital pathology that allows the interpretation of digital surgical pathology slides prepared from biopsied tissue. Its non-binding guidance details with the technical performance assessment of digital pathology of WSI devices. Today, accreditation agencies are actively working to establish comprehensive policies that ensure proper validation towards a global use. The validation of digital pathology systems in the regulated nonclinical environments remains challenging for many R&D facilities due to lack of knowledge, but also due to inefficient multidisciplinary interactions. The Society of Toxicological Pathologists (STP) published a few position papers on the compliance of Pathology Image Data (21Cfr Parts 58 and 11) and its current applications, but many topics in relation to WSI are not yet published. Prospective users need to acquire digital knowledge, but also new skills in order to identify best paths of success. Intra-institutional and inter-institutional collaborations are entering an exciting discipline with far-reaching beneficial effects. This presentation will guide you efficiently towards the paths of success and Summarizes the history and development of WSI; Gives practical overview of the technology (hardware and software); Current WSI status; Describes digital workflows Identifies common pitfalls; Best practices and Regulatory and validation considerations.

Biography

Neyens Elizabeth is graduated from the University of Utrecht in the Netherlands as DVM and Veterinary Pathologist. During her European residency she was rewarded twice for her research in Oncology and was recognized as best Junior lecturer in Pathobiology. She started her career as a Toxicological Pathologist in Charles River Preclinical Services and continued as Preclinical Head of the Pathology department in Baxter, Austria. A few years later, she decided to return back to Canada in order study for her Boards in Toxicology while assuming different roles as Senior Pathologist in various CRO's and she passed successful the American Board in Toxicologist in 2015 and accepted the role of Scientific Advisor for leading CRO in Israel. In 2017, she got certified in Digital Pathology and she decided to build her own Consultancy Firm in Europe with offices in Flanders, Belgium and Vancouver, Canada in order to support her international clients with excellence. Her research interest includes Pre-Clinical ToxPathology.

elizabeth@flanderstoxpath-consulting.com