A STATEMENT CONCERNING USE OF AUGMENTIQS LIVE TELEPATHOLOGY TECHNOLOGY FOR PEER REVIEW IN GLP STUDIES

The histopathology primary evaluation and peer review are evaluated using the appropriate Standard Operating Procedures (SOP), respecting the GLP regulations. The study pathologist (SP) and peer review pathologist (PRP) evaluate the glass slide specimens which provides the basis for data entry, the pathology report, and peer review statement (Morton et al, 2010).

The use of the Augmentiqs system for live histopathology sessions by the SP and PRP serves for illustrative purposes, without any QA audit or regulatory issues. Digital images may be taken for illustrative purposes (Tuomari et. al, 2007). These images are not used for data generation or interpretation, and will not be archived or included in the final report.

If in their professional judgement the SP and PRP conclude that digital images shared by any means are not sufficient for Peer Review consensus, then they would request consensus by other means such as a face to face review of glass slides (Morton et. Al, 2010).

References:

Morton D, Sellers RS, Barale-Thomas E, Bolon B, George C, Hardisty JF, Irizarry A, McKay JS, Odin M, Teranishi M (2010). Recommendations for pathology peer review. Toxicol Pathol. 38:1118-27.

Tuomari DL, Kemp RK, Sellers R, Yarrington JT, Geoly FJ, Fouillet XL, Dybdal N, Perry R(2007). Society of Toxicologic Pathology. Society of Toxicologic Pathology position paper on pathology image data: compliance with 21 CFR Parts 58 and 11. Toxicol Pathol. 35(3):450-5.