



# INTERNATIONAL SERUM INDUSTRY ASSOCIATION

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PAA Laboratories GmbH

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The International Serum Industry Association (ISIA) has been working closely with GE Healthcare to understand the depth and complexity of the issues that resulted in the recall of fetal bovine serum and associated products previously manufactured by PAA Laboratories GmbH, now owned by GE Healthcare. The Association deplores the reported actions, which have raised serious concerns and questions as to the credibility of our industry in the marketplace. ISIA fully supports the open and proactive stance taken by GE Healthcare in dealing with the issue

ISIA was founded with the traceability of product to geographic origin as a primary focus. The Association has notified its members that they must always verify the sources of materials, and that they may need to re-verify sources with specific reference to the PAA situation. In addition, the Association has stressed to the Membership that they, as members of the ISIA, have a duty to rigorously investigate any PAA sourced materials that have passed through their hands and notify customers of any concerns. Such investigations and actions should cover the dates stated by GE Healthcare in being retroactive to 2008. The Association has also stated to its Membership that failure to act in a rigorous manner with regard to PAA produced product could have significant impact on the ability of a company to be traceability certified

ISIA remains committed to ensuring product quality through aggressive implementation of traceability certification and standardization of testing methods. After in depth discussions with GE Healthcare, we are confident that the ISIA Traceability Certification audit would have identified the issues that existed at PAA. We continue to work with GE Healthcare and others to strengthen the ISIA Traceability Certification program.