Christopher Bentsen, M.S., RAC, FRAC is Manager, Regulatory Affairs, Quality Assurance and Clinical Affairs for Bio-Rad Laboratories, Redmond, WA Bio-Rad Laboratories in Redmond, WA is a U.S. licensed manufacturer of HIV and hepatitis blood screening *in vitro* diagnostic test kits. The company performs clinical trials for diagnostic test kits under either IND and/or IDE and submits 510(k), PMA and BLA applications to FDA on *in vitro* diagnostic test kits including HIV and hepatitis products.

Chris received his Masters of Science degree in Clinical Microbiology from Thomas Jefferson University in Philadelphia, Pa. He worked for a number of years as a Clinical Microbiologist before taking an R&D position in the diagnostics industry with Du Pont Medical Products in 1985. He then moved into a Regulatory Affairs Manager position in 1988 and worked on 510(k), PMA and PLA/ELA submissions to the FDA on clinical chemistry and infectious disease products, including hepatitis and HIV. He joined Genetic Systems in 1993 as Director, Regulatory Affairs, Quality Assurance and Clinical Affairs. Bio-Rad Laboratories purchased Genetic Systems in 1999. Chris has been a RAPS member since 1988 and received his RAC certification in 2001 and was awarded a Fellow in Regulatory Affairs by RAPS (FRAPS) in 2012. He was a Board Member of the Association of Medical Diagnostics Manufacturers (AMDM) from 2003-2012 and also serves on a number of regulatory affairs committees for AdvaMed (Advanced Medical Technology Association) in Washington D.C.