

#### Bio Narrative for AMDM:

Carol Ryerson, is currently a Senior Principal Advisor at RCRI, Inc. She has 30 years of experience in the medical device and diagnostic industry and has held senior positions in Regulatory and Clinical Affairs at Eastman Kodak, Ortho Clinical Diagnostics, Genzyme Diagnostics and Sekisui Diagnostics. She holds a Bachelor's degree in Chemistry from the College of the Holy Cross, and a Ph. D. in Biochemistry from M.I.T. (Massachusetts Institute of Technology). In her consulting practice, she assists clients with developing regulatory strategies and premarket submissions to the FDA and international authorities. In recent years RCRI has experienced an increase in requests for assistance with Clinical Evaluation Reports to meet EU regulations. In her talk today, Carol will address the "Impact of Upcoming Changes to the IVDR", particularly with respect to "Meeting New Clinical Evidence Requirements".