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Dr. Muhvich is the Principal Consultant for Micro-Reliance LLC, which specializes in Microbiology and Regulatory Compliance Consulting. He has conducted numerous mock Prior-approval audits of sterile manufacturing facilities, including their microbiology laboratories. He is frequently involved in guiding companies in sterile process design and validation. He is often called upon to help lead investigations into batch sterility failures and/or to review completed sterility failure investigations. From 1992 to 1997 Ken was a Review Microbiologist at the U.S. Food & Drug Administration's Office of Generic Drugs. He is a recognized expert in aseptic processing of sterile drug products. He holds a Masters degree in Medical Microbiology from West Virginia University and a Doctor of Philosophy degree in Experimental Pathology from the University of Maryland.