Bridge Associates International LLC

"Partners for Quality and Manufacturing Excellence"

Roy T. Cherris

Managing Partner

Roy T. Cherris has over 40 years of Quality Assurance experience, including serving as the head of Microbiology Laboratories for Hoechst Marion Roussel and Aventis, with a focus on the microbiological aspects of parenteral and oral dose manufacturing including supportive investigative microscopy. Roy is a well respected expert in the field of particulate and physical defect control science, forensic microscopy, also specializing in the physical characterization of excipients bulk drug substances (API) and primary packaging components as it applies to pharmaceutical development and commercial manufacturing.

Roy's technical expertise includes Visual Inspection, investigative/forensic microscopy, aseptic/sterile manufacturing, sterilization processes, microbial environmental monitoring, microbiological testing, laboratory and process development, as well as the qualification of equipment, facilities, and instrumentation. He has extensive experience with the validation of software and metrology systems, specializing in developing particulate and physical defect monitoring and computerized parameter control systems. Roy has worked extensively internationally, including serving organizations throughout North America, Europe and Asia. He is widely considered an industry expert in the field of visual inspection systems. Besides designing cutting edge programs for companies, Roy served as a member of the PDA Task Force (TF) on Visual Inspection, PDA TF for Particulates in Oral Doses and the PDA TF for Particulates in Opaque or Difficult to Inspect Parenterals. He is currently on the USP Expert Panel for Visual Inspection and has been key in drafting revision to USP <1> Injections and establishing the new USP <790> for Visible Particulate Matter in Injectable Products. He is currently working on General Guidance Chapter USP<1790> for best practices in particulate matter inspection programs.

Roy's professional and educational activities include various PhRMA and PDA technical committees, ASTM standards guidance committee, American Society for Microbiology, American Society for Quality, Institute of Environmental Sciences, the New Jersey Pharmaceutical Quality Control Association and ISPE. He received his B.Sc. degree in Life Sciences with concentration in Microbiology. Additionally he attended the McCrone Research Institute in Chicago for advanced studies in microscopy.

Roy T. Cherris

EXPERIENCE: **BRIDGE ASSOCIATES INTERNATIONAL LLC.**
Princeton, NJ USA
Pharmaceutical and medical device manufacturing and quality/cGMP consulting firm, working internationally to identify and solve manufacturing, quality or regulatory problems for all finished pharmaceutical dosage forms, APIs, excipients, primary packaging and primary packaging components companies of all sizes.

1998 to present **MANAGING PARTNER**

Responsible for quality/cGMP, manufacturing and management projects for global firms world-wide, specializing in visual inspection, investigative microscopy, particle and physical defect control and monitoring programs, aseptic and sterile manufacturing, sterilization processes, microbial environmental monitoring, microbiological testing, laboratory and process development, as well as the qualification of equipment, facilities, and instrumentation and general cGXP.

EXPERIENCE: **HOECHST MARION ROUSSEL, INC**.
Bridgewater, NJ, USA

1995 - 1998 **GROUP HEAD OF MICROBIOLOGY, MICROSCOPY AND LABORATORY SERVICES**
Ultimately accountable for establishing, maintaining and overseeing quality control and assurance systems for human and veterinary pharmaceuticals in the Microbiology, Microscopy and Laboratory Services groups.

Head of Microbiology and Microscopy Laboratories for Hoechst Marion Roussel, responsible for the microbiological aspects of parenteral and solid dose manufacturing. Established and managed groups responsible for the physical characterization of excipients and bulk drug substances, and investigative microscopy supporting research, development and commercial projects.

Technical expertise includes aseptic manufacturing, sterilization processes, environmental monitoring, microbiological testing, laboratory and process development, validation of equipment, instrumentation and software, cGMP auditing, metrology systems and particulate matter characterization.

1977 - 1998 Positions held with HRPI include Manager of Microscopy and Laboratory Services (1992), Manager of Microscopy (1990), Assistant Manager of Microbiology (1988), Senior Scientist (1981) and Senior Technician (1977).

EXPERIENCE: **UNION CARBIDE CORPORATION**
Bound Brook, NJ USA

1974 - 1975 **LABORATORY TECHNICIAN:** Responsible for conducting physical and chemical quality testing on bulk plastics.

EDUCATION: Trenton State College, Biological Sciences Program, 1973-1976

Pacific Western University, B.Sc. - Life Science with concentration in Microbiology, 1988

Extensive coursework at the McCrone Research Institute in Chicago for advanced studies in Microscopy. 1981-1992

PROFESSIONAL AFFILIATIONS AND INTERESTS: Professional activities have included, the original PMA-USP <788> development Group and several PDA technical committees including PDA Visual Inspection Task Force, Opaque or Difficult to Inspect Parenterals Task Force, Particles in Oral Dose Task Force. Member of the USP Expert Panel for Visual Inspection including USP<790> and USP<1790>. Development ASTM standards guidance for Laser Light Scattering Particle Counting and Flow Imaging Microscopy. Also American Society for Microbiology, American Society for Quality, Institute for Environmental Sciences and ISPE.

PUBLICATIONS AND REFERENCES: Available upon request.