Bridge Associates International Pharmaceutical Consulting

InQuest Science

Roy T. Cherris
Senior Advisor

Roy T. Cherris has over 45 years of Quality Assurance experience. He is a founder and Senior Advisor of Bridge Associates International Pharmaceutical Consultancy focused on GXP pharmaceutical manufacturing and quality excellence. He is also Chief Science Officer and founder of InQuest Science which provides expert monitoring and control database systems that troubleshoot product defect issues providing training and guidance on particulate matter control, inspection qualification, optimized inspection processes and defect monitoring. InQuest Science premium digital tools continuously track the Visual Inspection, Particulate and Physical Defect Lifecycle of Parenteral Products.

Roy formerly served as the head of Microbiology Laboratories for Hoechst Marion Roussel and Aventis Pharmaceuticals with a focus on the microbiological aspects of parenteral, topical, ophthalmic, liquid and solid dose manufacturing. He is a well respected expert in the field of visual inspection systems and investigative microscopy for particle source identification and mitigation. He also specializes in the physical characterization of excipients, bulk drug substances and primary packaging components as they apply to pharmaceutical development, clinical and commercial manufacturing. His technical expertise includes visual Inspection, investigative microscopy, aseptic manufacturing, sterilization processes, environmental monitoring, microbiological testing, medical devices, laboratory and process development, as well as the qualification of equipment, facilities, and instrumentation. He has been certified by the New Jersey Pharmaceutical Quality Control Association in GxP, Good Manufacturing Practices. He has extensive experience with the validation of software, computerized control systems and metrology systems. Roy has worked internationally throughout the Americas, Australia, Europe and Asia.

Roy has a B.S.c. degree in Life Sciences with concentration in Microbiology and has studied forensic microscopy extensively at the McCrone Research Institute in Chicago. His current publication is the technical book titled “Visual Inspection and Particulate Control” 2016, Davis Healthcare International Publishing, LLC, ISBN: 1-933722-93-2, PDA Bethesda, MD.

Roy served as a member of the PDA task force on Visual Inspection since 1998. He chaired the PDA task force for evaluating particulate matter in Difficult to Inspect Parenteral products which published PDA Technical Report TR-79 in 2018.

Roy is an active member of the **USP Expert Panel** for Visual Inspection of parenterals (2009-present). His expertise has been key in drafting guidance which lead to the establishment of USP <790> (2015) Particulate Matter in Parenterals and General Guidance Chapter USP<1790> (2017) for best practices in inspection, particulate matter and defect life-cycle management.

Roy's professional activities have included various technical committees in ACS, ASQ, ASTM, ISPE, PhRMA(PMA), PDA, ASPS, American Society for Microbiology, Institute of Environmental Sciences, and the United States Pharmacopeia.

Roy T. Cherris

EXPERIENCE: **BRIDGE ASSOCIATES INTERNATIONAL PHARMACEUTICAL CONSULTING LLC.**
Medford and Princeton, NJ USA
"Advisors for Manufacturing and Quality Excellence"
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 for companies of all sizes.

1998 to present **MANAGING PARTNER/SENIOR ADVISOR**

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 guidance.

EXPERIENCE: **INQUEST SCIENCE**
Princeton & Medford, NJ USA

InQuest Science has developed a cutting-edge expert data management system for evaluating product defect issues along with providing training and guidance on particulate matter control, optimized inspection and 21CFR part 11 compliant electronic particulate and physical container/closure defect tracking systems. Focusing on Parenteral, Ophthalmic and Medical Device manufacturing to achieve a robust product lifecycle knowledge and control basis. These modular based data management and monitoring systems are designed to assure routine particulate and defect control compliance for raw materials, API, incoming single use materials, primary components, 100% in-process inspection and AQL inspection meeting USP<1790>, USP<790>, USP<771, USP<787>, USP<788> and USP<789> requirements. In Addition, we have developed logical control processes for inspector training and qualification standards management which is unsurpassed in the industry. All this, in conjunction with the appropriate forensics for defect identification and CAPA remediation leads to a high degree of sophistication in day to day process monitoring for companies of all sizes.

2015 to present **CHIEF SCIENCE OFFICER**

Responsible for defect control solution development, product quality/cGMP, educational workshops on the lifecycle of particulate/defect management, manufacturing-quality assurance and management projects for global firms world-wide, specializing in visual inspection, investigative forensic microscopy, process optimization, aseptic processing and CAPA initiatives.

PAST 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

Thomas Edison University 1976-1982

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 , Flow Imaging Microscopy and Particulate Matter on Single Use Process Materials. Also American Society for Microbiology, American Society for Quality, Institute for Environmental Sciences and ISPE.

PUBLICATIONS AND REFERENCES: Further available upon request.

Brief Summary:
Technical book titled “Visual Inspection and Particulate Control” 2016, Davis Healthcare International Publishing, LLC, ISBN: 1-933722-93-2, PDA Bethesda, MD.

Chaired the PDA task force for evaluating particulate matter in Difficult to Inspect Parenteral products which published PDA Technical Report TR-79 (2018).

Drafting guidance which lead to the establishment of USP <790> (2015) Particulate Matter in Parenterals and General Guidance Chapter USP<1790> (2017) for best practices in particulate matter inspection programs.