



Bridge Associates
International LLC

"Partners for Quality and Manufacturing Excellence"

Roy T. Cherris *Managing Partner*



Roy T. Cherris has over 30 years of Quality Assurance experience, including serving as the head of Microbiology Laboratories for Hoechst Marion Roussel, with a focus on the microbiological aspects of parenteral and solid dose manufacturing, and investigative microscopy. Roy is a well respected expert in the field of investigative microscopy, specializing in the physical characterization of excipients and bulk drug substances as it applies to pharmaceutical development and commercial manufacturing.

Roy's technical expertise includes Visual Inspection, investigative microscopy, aseptic manufacturing, sterilization processes, 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 the validation of parameter monitoring and computer control systems. Roy has worked extensively internationally, including serving organizations in Germany, France, England, Italy, the U.S. and Puerto Rico.

Roy is widely considered an industry expert in the field of visual inspection systems. Besides designing cutting edge programs for companies, Roy serves as a member of the PDA Task Force on Visual Inspection and on the USP committee for Visual Inspection. He and has been key in drafting the current Pharmacopeial Forum changes to USP <1> Injections – Particulate Matter.

Roy's professional activities include various PhRMA and PDA technical committees, ASTM, American Society for Microbiology, Institute of Environmental Sciences, the New Jersey Pharmaceutical Quality Control Association, ISPE, and the American Society for Quality. 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, and regulatory problems for pharmaceutical/food ingredient 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, aseptic manufacturing, sterilization processes, environmental monitoring, microbiological testing, laboratory and process development, as well as the qualification of equipment, facilities, and instrumentation and general cGMP.

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 various PMA, PDA technical committees including the PMA-USP <788> Revision Task Group and PDA Visual Inspection Task Force, ISPE, ASTM, American Society for Microbiology, Institute for Environmental Sciences and the American Society for Quality.

PUBLICATIONS AND REFERENCES: Available upon request.

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