Richard L. Streeton, Jr
Principal

Summary. 24 plus years of experience in the Pharmaceutical/Biotechnology/Medical Device industry with a focus on Quality Assurance and Compliance. Areas of experience and expertise include:

- Lead more than two dozen FDA regulated inspections for both GLP and cGMP.
- Responsible for developing and setting strategic regulatory visions for major CROs and industry corporations. In a number of these cases this included the development of entirely new regulatory systems within the company.
- Expertise in developing 21 CFR Part 11 programs which included the development of a Validation team and setting validation standards for the Quality Assurance groups.
- Working with Venture firms as part of the due diligence process to review Quality programs and regulatory risk.
- Experience in developing programs for Document Control, Quality Metrics, Training and Supplier Programs.

Professional Experience

RLS Consulting
Principal: 2007-2010

Charles River Laboratories, Inc.
Corporate Director Quality and Compliance: 2001-2006

Primedica Corporation
Director, Regulatory Compliance: 1998-2000

Pharmaceutical Quality Consultant
Consultant: 1996-1998

Pharmaco LSR, Inc.
Director, Quality Assurance: 1994-1996

Bio/Dynamics, Inc.
Quality Assurance: 1986-1994

Education/Certification

1986; B.S., Biology, Mount Saint Mary's College, Emmitsburg, MD.

Selected Publications

Quality Assurance: Good Practice, Regulation, and Law.
1993 Training the Quality Assurance Professional

1994 Analytical Data Capture Systems Validation in Preclinical/Clinical Laboratory

1995 A QA Managers Perspective on In-Life Audits. (Accepted publication)

Presentations

1991 SQA Meeting, Kansas City, MO
Visions for the 90's: A Focus on Training (Poster)
1992 SQA Meeting, Atlanta, GA
Training the Quality Assurance Professional
1993 SQA Meeting, San Francisco, CA
Analytical Data Capture System Validation in Preclinical/Clinical Laboratory (Poster)
1994 SQA Meeting, New Orleans, LA
A QA Manager's Perspective on In-Life Audits
Nov. 1995, May 1996, Nov. 1996, and May 1997
MARSQA Training Seminar, Lahaska, PA
Interactive GLP Training
November 1999 NERCSQA Meeting, Worcester MA
Roundtable Chair: "Protocol Deviations/Amendments in a GLP/GCP/cGMP environment"
April 2001 Society for Biomaterials "GLP Training for Sponsors of Pre-clinical Trials"
June 2003 Data/Document Archiving, Migration and Management Summit
"Challenges of Archiving Electronic Data in a 21 CFR part 58
Environment to meet Predict Rule Requirements"
October 2003 Society of Quality Assurance Meeting "Moving a facility from non-GLP to GLP"
May 2004 American Society for Mass Spectrometry "Cohesive Aria Systems used in GLP Environments"
June 2004 NERCSQA "Risk Assessment from a GLP Perspective"
September 2005 Academy of Surgical Research "CRO Regulatory Challenges in running Studies with Surgical Components."
August 2005, 2006 Charles River Laboratories Client LAL Workshop "Regulatory Update and Trends"