Joshua Sharlin, Ph.D.

Washington, D.C. ♦ C: 410-231-8900 ♦ jsharlin@pipeline.com

DATA INTEGRITY AND SOFTWARE VALIDATION EXPERT: SUMMARY

Expert in software validation and identifying, preventing and solving data integrity problems. Evaluate FDA compliance of study data, the transfer of study data, IT infrastructure, software development processes, and software applications whether purchased, provided by a contract research organization (CRO), or built in-house. Evaluate legacy systems and data bases for FDA compliance. Investigate and solve chain of custody problems for study data.

KEY SKILLS, EXPERIENCE & QUALIFICATIONS

• Former FDA reviewer, FDA statistician	• Taught software development to staff in FDA regulated companies
• Managed a team of 25 programmers responsible for building the software systems supporting Marriott International's hotel rewards program	• Conduct software validation audits of lab equipment, clinical sites, contract research organizations (CROs), sponsors and software vendors
• Expert at producing documentation and creating processes that demonstrate compliance with FDA's software development requirements	• Evaluate data integrity and data quality of study data collection, database creation and storage, data transfer and statistical analysis
• Identify and close FDA compliance gaps in software development & validation practices and documentation	• Write and improve standard operating procedures and documentation demonstrating FDA software validation compliance
• Develop and teach classes in meeting FDA's requirements for software validation	• Identify, prevent & solve FDA compliance problems in data integrity and software validation for current and legacy systems

WORK HISTORY

Consultant & Principal, 06/1994 to Current

Sharlin Consulting – Washington, D.C.

- Evaluate and Document Software Compliance. Evaluate purchased software, software used in the cloud, software provided by a CRO, software developed in-house, and software intended for sale to FDA-regulated companies for compliance with all regulatory requirements including 21 CFR Part 11.

WORK HISTORY (continued)

- Standard Operating Procedures. Write IT-related SOPs, solve compliance problems and produce needed documentation.
- Legacy Systems. Perform regulatory assessments of legacy software systems and databases. Evaluate data migration processes from retired software to new software systems. Create the necessary compliance documentation.
- Analyze Compliance of Software Development Processes. Evaluate the quality, efficiency and compliance of software development practices of sponsors, CROs and software vendors. Appraise the compliance and quality of methods used to design and populate databases. Recommend methods to close compliance gaps.
- Develop and Implement Company-Wide 21 CFR 11 Compliance Processes. Analyze a company's software, software use and IT infrastructure to develop a customized risk assessment process. Create a 21 CFR 11 compliance strategy that meets a company's specific needs and risks. Write the necessary SOPs and create the needed documentation.
- Reverse Engineer 21 CFR 11 Compliance. Develop solutions to retrospectively demonstrate FDA compliance of software applications, software development processes and data. Create evidence of compliance by examining all sources of information including archived material, old testing results and interim database versions.
- Conduct Audits. Conduct 21 CFR 11 audits of CROs for sponsor companies. Perform mock 21 CFR 11 audits of sponsor companies and clinical sites to provide assurance of passing an FDA audit. Evaluate CRO compliance in advance of customer audits. Evaluate content and quality of 21 CFR 11 compliance SOPs. Write needed SOPs and create missing 21 CFR 11compliance documentation.
- Improve Data Quality. Develop methods and write software programs to evaluate data quality. Identify root causes of poor data quality. Develop processes to improve data quality and prevent problems from occurring.
- Conduct Training on how to Pass a 21 CFR 11 Compliance Audit. Develop and deliver training classes on preparing for a compliance audit of 21 CFR 11 regulations and predicate rules.
- Audit Purchased Software and Software Used in the Cloud. Apply risk assessment to evaluate compliance of purchased software and software used in the cloud. Evaluate controls and processes used to mitigate risk. Determine if adequate documentation exists to meet FDA requirements for data integrity.
- Verify Quality and FDA Compliance of Work Performed by CROs. Use skills as a SAS programmer, experience as an FDA reviewer and understanding of submission complexities to review and evaluate the work performed by CROs. Identify FDA compliance gaps in; (1) Implementing document and data requirements, (2) Study execution and, (3) SAS programs and database structures
- Confirm Data Integrity and Chain of Custody. Write SOPs and implement procedures to use MD5 checksums to create documentation proving there were no accidental or deliberate erroneous database changes during or after a clinical trial.

WORK HISTORY (continued)

Drug Reviewer, 05/1992 to 06/1994

Food and Drug Administration (FDA) – Rockville, MD

Manage the drug review process. Instruct firms on how to proceed with drug approval. Summarize outstanding problems and issues with protocols and studies. Determine if deficiencies were adequately addressed. Review statistical methodology of studies. Author all written communication to the sponsoring firm and integrate comments from other reviewers.

EDUCATION

Ph.D. - Physiology, **University of Georgia** – Athens, GA

M.S. - Physiology **University of Maryland** – College Park, MD

B.A. - Biology, **University of Iowa** – Iowa City, IA