



Resume of Verdad Systems Consultant Ben Larson – FDA Validation Specialist

QUALIFICATION SUMMARY

Accomplished quality assurance/validation professional and contract project manager with diverse background in pharmaceutical manufacturing, clinical studies and laboratory technology. Extensive experience interpreting and applying GMP, GLP, GCP and Quality System regulations, especially as they relate to electronic records and signatures. Proficient in the development and application of systems development life cycle policies and procedures. Broad experience with a diversity of systems from tabletop lab instruments to enterprise-wide systems. Works well under pressure and with users of varying skill levels.

MANAGEMENT & TECHNICAL EXPERIENCE

- As Project Manager, directed a long-term, high-profile initiative to redefine quality system policies and procedures for the computer systems validation unit at major non-clinical research facility. The project established the regulatory obligations of the unit, defined internal compliance standards and codified those standards in a set of integrated, cross-referential SOPs.
- Directed a global validation project for a major pharmaceutical client comprising 4 countries, 7 sites and 95 GxP-regulated systems.
- Developed and launched a Part 11 Assessment & Remediation service for cGxP computer systems. The assessment includes a comprehensive evaluation of software functionality, procedural controls and Standard Operating Procedures. The results of the assessment are summarized in a final report that serves as a guide for future cGxP remediation efforts. This process was successfully applied to over 100 systems and served as the foundation for enterprise-wide remediation plans at several large pharmaceutical companies.
- Developed a complete set of Quality Assurance policies and procedures for a five-year, \$7MM software development project for an EPA-regulated client. The quality assurance system covered all phases of software development and defined QA measures for project management, product metrics, risk management, configuration management and formal validation.
- As a Validation Project Manager, directed a staff of four senior consultants and three junior consultants in the execution of validation projects. Responsibilities included providing technical support to sales staff, project planning, budget and schedule estimates and resource management.
- Developed and launched a software vendor audit service and executed vendor audits on behalf of clients. Audits encompassed the full software development life cycle, as well as standard operating procedures, support policies, employee training, configuration management, quality assurance and source code escrow policies.
- Designed and developed a Part 11-compliant Microsoft Access application to track change control processes for a sterile fluid manufacturing facility. This application, developed in response to an FDA 483, was designed, developed and deployed with full systems documentation and comprehensive validation package and exceeded the clients expectations.

- Led the development and launch of a nationally-deployed, database-driven intranet that streamlined collaboration between clinical research associates located in offices throughout the United States.

TECHNOLOGY EXPOSURE

LABORATORY: BioWhittaker Kinetic Plate Reader; Biocad 60, ProChrom and Unicorn Chromatography software; TurboChrom, TotalChrom and Biotage chromatography systems; Biacore Surface Plasmon Resonance Analyzer; Varian/Cary 3E, Perkin-Elmer, MicroQuant and Shimadzu Spectroscopy systems; HP Chemstation/Chemserver system; OligoPilot & OligoPilot II DNA Synthesizer; Datafax Clinical Trial Data Management System; Clintrial, Clintrace, SAS, Nugensis Laboratory Data Archiving system, Blue Mountain Calibration Manager; Qumas DocCompliance; Proflux A60 Tangential Flow Filtration System; Sympatec Helos and Malvern Mastersizer 2000 Particle Size Analyzers; SOTAX Dissolution Testing System; Shimadzu XRD-6000 X-Ray Defractometer.

MANUFACTURING: Wonderware; Metasys and RSView32 SCADA systems; Johnson, Seimans, and Allen-Bradley HVAC controls; BPO Autoclave System; Rees Environmental Monitoring System; Sartocheck Filter Integrity System

ENTERPRISE-LEVEL SYSTEMS: Documentum, QUMAS, Livelink and Hummingbird document management systems.

APPLICATION DEVELOPMENT: Visual Basic, Visual Interdev, VBScript, JavaScript, HTML, SQL Server, Oracle, ODBC, ErWin, Crystal Reports, Delphi, Lotus Notes & Domino, Remote Data Service, Active Server Pages, Internet Information Server, Microsoft Access, Microsoft FrontPage, ReportSmith

EMPLOYMENT HISTORY

2004 – Present	Independent Software Development & Validation Project Manager
2003 - 2004	Validation Project Manager, Digital Consulting & Software Services, Inc.
2001 – 2003	Validation Project Manager, Cetan Technologies
1995 – 2000	Software Project Manager, Quintiles Pacific, Inc.
1990 – 1995	Independent Software Developer
1987 – 1990	Computer Operations Manager, Reseal Pharmaceutical Systems, Inc.
1980 – 1987	U.S. Navy (Medical Laboratory Technologist)

EDUCATION

Bachelors of Science in Business Mgmt., University of Maryland
 U.S. Navy School of Advanced Laboratory Technology
 U.S. Navy Hospital Corps School

PROFESSIONAL TRAINING

- Java Development, Level II – UCSD Extensions – July 2001
- Object-Oriented Analysis & Design – UCSD Extensions – April 2001
- Oracle II – UCSD Extensions – November 1999
- Oracle I – UCSD Extensions – August 1999
- SQL Server Data Warehousing – Microsoft – May 1999
- Web-Site Design Using HTML – Ted Blue Training – April 1999
- PeopleTools I – Peoplesoft – March 1999
- Principles of Client/Server Architectures – UCSD Extensions – October 1998
- Management Skills Training – Quintiles Pacific – June 1998
- SQL Query Language – UCSD Extensions – April 1998

PRESENTATIONS DELIVERED

- The Implications of Part 11 on Sharing Clinical Data – DIA Conference
- The FDA's New Approach to Computer System Validation – Pittcon Conference
- Keeping the Lid on Validation Costs – Labware Users' Conference
- Fundamentals of Validation – University of California, San Diego
- A Primer on Digital Signatures - Cetan Project Management Seminar
- Executing Part 11 Assessments - Various clients
- Defining and Executing a Validation Plan – Various clients
- Requirements Engineering from Concept to Approval – Various clients