



## Resume of Verdad Systems Consultant Glenn Walker – FDA Validation Specialist

### PROFILE

Provide validation and product transfer services for the pharmaceutical, biotechnology and medical device industries.

A results oriented technical professional who provides high quality services on time and under budget. Completion of more than 200 software validation projects; 100 manufacturing process validations; 400 equipment validations as well as numerous analytical test systems. Successful development and implementation of compliant, cost effective and efficient validation efforts.

### ACCOMPLISHMENTS

- Management of validation and product transfer consulting projects for pharmaceutical, biotech and device companies including: Allergan, Introgen Therapeutics, B|Braun, Medtronics, Johnson & Johnson, Nanogen, Cephalon, Guidant, and Isis Pharmaceuticals
- Successfully managed projects to develop integrated analytical and diagnostic systems from concept to market introduction
- Managed the product transfer and scale up of manufacturing processes for clinical, biotech, and IVD chemistries, as well as tablet, lyophilization and powder operations
- Developed, characterized, transferred, validated and scaled up analytical instrument manufacturing processes
- Provided support for regulatory submissions
- Provided project management and validation support for systems and software including:
  - Manufacturing Process Systems
    - Facilities and engineering
    - Utilities, environmental, cleaning
    - Manufacturing and test equipment
    - PLC/SCADA systems
    - Manufacturing processes
  - Laboratory Test Methods and Analytical Systems
    - Chromatography/LC/GCMS systems
    - Spectrophotometers/Densitometers/Instrons
    - Biotage, Agilent and Turbochem systems
    - Microchip array systems for genomic analysis
  - Business systems
    - ERP/MRP
    - LIMS
    - Electronic data management
    - Document management
    - Clinical systems
- Carried out system audits, SOP creation and developed validation systems
- Skilled in the utilization of DOE (Design of Experiment), SPC (Statistical Process Control), and SQC (Statistical Quality Control)
- Experienced in the usage of FMEA (Failure Mode Effects Analysis), FMECA (Failure Mode Effects and Cause Analysis) FTA (Fault Tree Analysis), hazard analysis and risk analysis techniques
- Accomplished in the employment of cGMP, design control and validation in medical device or pharmaceutical applications

## **EXPERIENCE**

### **Silver Creek Technical Services**

**April 2004 – Present**

#### **Position: General Manager**

- Evaluation of client systems for compliance with regulatory requirements.
- Planning and execution of validation and product transfer/scale-up projects.
- Provide project management and support for CMC technology transfer for pharmaceutical, medical device and biotech processes.
- Preparation of project timelines and budgets, with milestones and deliverables.
- Alignment of project milestones to meet company objectives and facilitate timely completion of deliverables within budget.

### **Aviva Biosciences Corporation**

**January 2003 – April 2004**

#### **Position: Director of Manufacturing**

- Direct and manage Manufacturing, Material Control, and Quality Assurance functions.
- Responsible for transfer and scale-up of manufacturing processes for Biochip, micro-bead, reagent and analytical platform production.
- Provided oversight in product development production teams.
- Management of validation projects.

### **Cetan Technologies, Inc.**

**October 2001 – January 2003**

#### **Position: Project Manager**

- Management of Pharmaceutical and Medical Device Consulting Projects.
- Planned, managed and executed process, test methods, software and equipment validation activities for clients.
- Evaluation of client systems for compliance with regulatory requirements.
- Identify potential issues and manage cross-functional teams in the resolution of technical and organization problems to keep projects within schedule and budget.
- Interface with stakeholders and project champions to ensure continuous alignment of project tasks and milestones to facilitate timely completion of deliverables.
- Software system validation projects including MRP/ERP, LIMS, and analytical systems including Biotage, Agilant, and Turbochem.

### **Time-To-Market Consulting**

**December 2000-October 2001**

#### **Position: Director of Projects**

- Planned and performed validation of manufacturing processes, equipment, software, analytical systems and test methods for medical devices.
- Planned and performed system integration and validation for a genomic analytical system. Characterized and integrated the chemical and instrument components of the system.
- Performed software and system validation projects on numerous analytical test beds including HPLC, immunoassay, chemistry, GCMS and genomic systems.
- Prepared manufacturing system documentation, specifications, SPC, and SQC.

**Qualisys Diagnostics, Inc.****November 1997-December 2000****Position: Vice President of Operations and Manufacturing**

- Directed and managed Operations, Manufacturing, Product Development, and Material Control departments and personnel.
- Responsible for facility design, incorporating immunochemistry production area and instrument production area.
- Developed and implemented manufacturing processes for immunodiagnostic reagent chemistries and analytical platform.
- Created product transfer process and directed the implementation of cost effective manufacturing processes.
- Defined and developed system components and equipment for packaging.
- Responsible for manufacturing support of in-house tooling and on-going production process optimization of semi-automated and fully automated assembly equipment.
- Characterized and validated instrument and chemical manufacturing processes.
- Developed and managed operating budgets for multiple departments.
- Responsible for the identification and implementation of the MRP system.

**Position: Director of Research & Development**

- Directed and managed the efforts of a research team in carrying out feasibility studies for the development of an integrated analytical and immunochemical diagnostic system.
- Planned and directed feasibility, design and development of diagnostic chemistries.
- Oversaw and managed the initial development of analytical platform.
- Co-developed chemical and immunochemical diagnostic processes.
- Developed and met the product requirements for the initial market phase of products.

**Abbott Laboratories****September 1993-October 1997****Position: Group Leader Technical Process Development**

- Management of product development team in projects to transfer, scale up and validate analytical chemical processes.
- Developed and optimized formulations for liquid, powder, lyophilized and solid dose chemical products.
- Defined and implemented raw material and process testing strategies and methods.
- Validation and laboratory representative for all regulatory agency and third body audits.

**Position: Chemical Process Engineer**

- Responsible for the planning and management of projects for chemical process development, characterization and validation.
- Planned and performed test method and process validations; equipment qualification (IQ, OQ, PQ).
- Initiated and implemented product failure investigations.
- Planned and executed process development, transfer and improvement projects.

**Position: Laboratory Manager**

- Operation and management of a clinical screening laboratory handling an annual patient load of over 13,000.
- Managed contract clinical evaluation projects for pharmaceutical and device companies including: Travenol, Baxter Dade, Centocor, Dow Chemical, and Hybritech.
- Designed data management software (LIMS) featuring algorithms and instrument-to-computer data capture systems for clinical, toxicology research, and environmental applications.
- Developed and wrote procedure manuals for clinical and environmental laboratories to ensure compliance with EPA and CLIA regulations.
- Responsible for all analytical and quality evaluations.
- Responsible for laboratory certification/compliance.
- Designed, assembled, and managed contract mobile environmental laboratories for the Army Corps of Engineers, a clinical testing laboratory, and a toxicology research laboratory.
- Co-developed a RIA assay for the detection of neural tube defects.
- Created test methods for gas chromatography, electron microscopy, flame spectrophotometry, RIA, HPLC, spectrophotometry, and Elisa techniques.
- Directed research staff in the design, initiation, and execution of a variety of research projects using a wide range of laboratory instrumentation and techniques.

**EDUCATION**

BS in Biology, with minors in Electrical Engineering and Chemistry  
University of Arkansas Little Rock

Navy Basic Electronics School  
Navy Radio and Radio Electronics School  
Navy UDT/SEAL Basic/Advanced School  
Statistical Quality Control and Statistical Process Control  
Manufacturing Design of Experiment  
Advanced Design of Experiment  
Process and Test Method Validation  
Advanced Project Management

**PATENTS**

FastPac® pouch test system

Biochip Device for Ion Transport