Erik C. Staley

2630 Lewis Ln (760) 720-0154
Carlsbad CA 92008 es@valicom.com

PROFESSIONAL SUMMARY

Results-driven validation and compliance specialist with over 25 years of experience in the life science industries.

- Extensive project management and hands-on experience in the validation and regulatory compliance fields
- Noted speaker and contributor to industry, excellent communicator, and strong technical writer
- As the leader of two contract consulting firms, effectively managed staff, applied technical expertise, and drew upon regulatory knowledge so that clients consistently met objectives, such as obtaining FDA approvals and overcoming regulatory hurdles.

EMPLOYMENT SUMMARY

President / Principal Consultant
Valicom, Inc.
Carlsbad, CA **2002 - present**

Presently directing operation of a consulting firm specializing in validation and compliance.
Accomplishments include:

- Implementing efficient and effective quality systems for manufacturers of drugs, devices, biologics, and combination products, including developing comprehensive suites of policies and procedures for start-ups
- Configuring and validating LIMS, LIS, and related data systems for QC (GMP), preclinical (GLP), and clinical (GCP and CLIA) operations
- Leading gap analyses and risk assessments (GMP, QSRs / ISO-13485, GLP, GCP, 21 CFR Part 11, and HIPAA), and remediation of deficient operations
- Developing comprehensive computer system and instrumentation validation packages that lab equipment and software vendors sell to customers
- Developing and maintaining SDLC lifecycle documentation, including policies for management of information in environments subject to GxP and QSRs
- Validating Electronic Document Management Systems (EDMS), such as Open Text's Livelink,
- Upgrading, configuring and validating networked chromatography equipment (HPLC, GC, and CE), such as Agilent and Waters systems
- Auditing vendors for compliance, including conducting audits of:
    - Providers of clinical and nonclinical services, including comprehensive technical and compliance audits of software vendors, datacenters, and application service providers
    - Manufacturers of drug and device components, including APIs
    - Contract laboratories for GxP testing purposes and drug stability
- Representing clients during regulatory and compliance inspections, including those conducted by FDA, California FDB, and customers
- IND preparation
- Selecting, managing, and training staff.

Valicom's clients have included **Abbott Laboratories, Aeolus Pharmaceuticals, Ambry Genetics, Anadys Pharmaceuticals, Aperio Technologies, Biogen Idec, Dart Neuroscience, De Novo Software, Dose Medical/Glaukos, Genentech/Roche, Innovative Cell Technologies, John Wayne Cancer Institute,** and **SkyePharma.** Many of these companies are long-term and returning clients.

Principal Consultant / Co-Owner
CPK Validation Services
Lake Forest, CA **1998 – 2002**

Directed operation of a validation consulting firm.

- Configured and validated networked chromatography data systems
- Validated other computerized laboratory equipment, such as spectrophotometers, spectrometers, and automated in-process test equipment
- Completed 21 CFR Part 11 compliance assessments of laboratory and manufacturing systems, including remediation and validation of deficient systems
- Presented validation work to FDA inspectors during PAIs and GMP inspections
- Developed and validated custom Excel spreadsheets and applications for laboratories
- Completed IQ, OQ, and PQ of manufacturing equipment, such as tablet presses, mixing and filling equipment, packaging lines, autoclaves, incubators, labeling and barcoding systems, and organic synthesis equipment
- Directed cleaning validation studies, including development of sampling techniques, validation of trace level analytical methodology, preparation of SOPs, assignment of limits, and presentation of results
- Completed process validations: Characterized critical process parameters, designed and reviewed protocols, supervised sampling activities and analyses, and prepared summary reports
- Prepared validation policies, change control procedures, and equipment operation SOPs.

CPK's clients included **IDEC Pharmaceuticals** and **Celltech Pharmaceuticals** (formerly **Medeva Pharmaceuticals CA**).

Sr. Quality Engineer
B. Braun McGaw
Irvine, CA **1995 – 1998**

Completed validation projects and developed quality systems for a manufacturer of medical devices and injectable drug products.

- Developed validation master plans, IQ, OQ, and PQ protocols, and summary reports
- Validated computerized test systems, manufacturing facilities, process utilities, and manufacturing equipment
- Selected and managed consultants; coordinated teams of engineering, QA, QC, and consultants
- Designed studies to troubleshoot and improve manufacturing processes
- Developed sampling plans, specifications, and SOPs
- Audited suppliers and presented findings.

Process Engineer
Canon Business Machines
Costa Mesa, CA **1994 – 1995**

Responsible for implementation of quality plans for new products and improvement of existing processes.

- Developed chemical test methods and established material and process specifications
- Implemented statistical process control (SPC) techniques to monitor operations, and employed design-of-experiment (DOE) techniques to optimize operations
- Established ISO-9000 series compliant systems, such as for document control

Quality Control Supervisor
Techniclone International
Tustin, CA **1994**

Managed QC Chemistry and QC Microbiology laboratories for a monoclonal antibody manufacturer.

- Audited laboratory operations and brought laboratories into compliance with GLP
- Supervised laboratory staff
- Developed and validated analytical testing methods and prepared related SOPs.

Analytical Chemist
Gensia Laboratories, Ltd.
Irvine, CA **1991 – 1993**

Fulfilled technical service and validation support functions for a manufacturer of small-volume injectable drug products.

- Validated computerized chromatography network
- Developed cleaning validation techniques; validated cleaning processes
- Investigated manufacturing deviations, recommended corrective actions, and prepared related technical reports
- Selected a LIMS for use with QC and development laboratories; completed SQL*LIMS Key User training
- Validated analytical test methods
- ANDA preparation.

Research Associate
Kendall - McGaw
Irvine, CA **1990 – 1991**

- Performed analytical chemical testing to support the development of new injectable drug products and medical devices.

Quality Control Technician
Teledyne Battery Products
Redlands, CA **1988 – 1989**

- Performed chemical QC testing on lead-acid battery components.

EDUCATION

BS Chemistry, BS Biology, University of Redlands, Redlands, CA, 1990.
Additional coursework in computer science and electrical engineering.

INDUSTRY CONTRIBUTIONS

- Presented **Strategies for Efficient and Economical Validation of Laboratory Equipment** and **Current FDA Inspection Trends for the Analytical Laboratory** at the *Laboratory Equipment Qualification & System Validation Conference*, Boston, MA.

- Presented **Successfully Designing and Validating LIMS for the Regulated Medical Industries** at the *6th Annual Laboratory Instrumentation Validation and Qualification Conference*, Chicago, IL. Panelist in the **Attaining FDA Compliance with Your Validation and Qualification Program** session.

- Chaired the *5th Annual Laboratory Instrumentation Validation and Qualification Management Conference*, Philadelphia, PA. Taught **Validation of Laboratory Spreadsheets** course.

- Presented **Validation of Steam and Process Gases for Biotech Products** at the *Validating Utilities* conference, Philadelphia, PA.

ADDITIONAL CAPABILITIES

- Familiar with implementation, use and administration of database applications.

- Experienced with website development, deployment, and management.

- Proficient with advanced uses of the MS Office application suite for management of validation, development life cycle, inventory, training, and compliance records.

- Languages:
  Spanish, moderate capability, spoken and written,
  Portuguese, moderate capability written, basic capability spoken.

- Attained ASQ Certified Quality Engineer (CQE) certification.