

Erik C. Staley

300 Carlsbad Village Dr.
Suite 108A, PMB 107
Carlsbad, CA 92008

Phone: (760) 720-0154
Fax: (760) 720-0144
es@valicom.com

PROFESSIONAL SUMMARY

Results-driven validation and FDA compliance specialist with over 17 years of experience in the regulated life science industries.

- Extensive project management and hands-on experience in the validation field, with a focus on validation of computer systems and laboratory instrumentation,
- 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 computer validation and FDA compliance. Accomplishments have included:

- Validating Laboratory Information Management Systems (LIMS), such as Applied Biosystems' SQL*LIMS. Responsibilities have included development of Validation Master Plans and validation of LIMS applications and customizations, including database tables and reports, labeling and barcode systems, and interfacing with laboratory instruments,
- Development of comprehensive validation plans and protocols for laboratory equipment vendors,
- Designing, reviewing, and revising corporate quality policies,
- Developing a QSR-compliant quality system for device / diagnostic manufacturer, and submission of regulatory filings,
- Preparing SOPs for validation, change control, equipment operation, and system administration,
- Validating an Electronic Document Management System (EDMS), Open Text's LiveLink,
- Designing and validating custom databases and spreadsheets, including validation of embedded macros and Visual Basic script,
- Configuring and validating networked chromatography equipment (HPLC, GC, and CE), including upgrading and validation of data systems, such as Agilent's ChemStation / ChemStore and Waters' Empower,
- Performing risk assessments, gap analyses, and compliance assessments,
- Developing and maintaining GAMP lifecycle documentation, including user requirement specifications, functional specifications, validation master plans, design documents, and traceability matrices,
- Auditing vendors and suppliers, including software vendors and hosting services,
- Training clients on contemporary GxP topics,
- Selecting and managing staff.

Valicom's clients have included **Genentech, Biogen Idec, Abbott Laboratories, SkyePharma, Anadys Pharmaceuticals, De Novo Software, Aperio Technologies, and Innovative Cell Technologies**

**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 configuration, remediation, and validation of deficient systems,
- Presented validation work to FDA inspectors during PAIs and GMP inspections,
- Completed process validations: Characterized critical process parameters, designed and reviewed protocols, supervised sampling activities and analyses, and prepared summary reports,
- Completed IQ, OQ, and PQ of manufacturing equipment, such as tablet presses, sterile filling lines, mixing equipment, packaging lines, autoclaves, incubators, labeling and barcoding systems, and organic synthesis equipment,
- Developed and validated custom spreadsheets,
- 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,
- Prepared SOPs describing validation policies, change control procedures, and equipment operation.

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 plans for a manufacturer of medical devices and injectable drug products.

- Developed Validation Master Plans, IQs, OQs, PQs, and summary reports,
- Validated new manufacturing facilities, process utilities, manufacturing equipment, and computerized test systems,
- Coordinated the activities of Engineering, Quality, and contract staff,
- Selected and managed 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 an ISO-9000 compliant document control and specification management system.

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

1994

Managed QC Chemistry and QC Microbiology laboratories for an IND-phase 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 the instruments, interfaces, hardware, and software components of a computerized chromatography network,
- Validated cleaning processes and manufacturing equipment,
- Investigated manufacturing deviations, recommended corrective actions, and prepared related technical reports,
- Selected a LIMS for use with the Quality Control and Development laboratories; completed SQL*LIMS Key User training,
- Assisted with 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 testing on lead-acid battery components as part of a university work-study program.

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, September 2007.
- Presented **Successfully Designing and Validating LIMS for the Regulated Medical Industries** at the *6th Annual Laboratory Instrumentation Validation and Qualification Conference*, Chicago, IL, April 2003. Panelist in the **Attaining FDA Compliance with Your Validation and Qualification Program** session.
- Chaired the *5th Annual Laboratory Instrumentation Validation and Qualification Management Conference*, April 2002, 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, January 1999.

ADDITIONAL CAPABILITIES

- Familiar with implementation and use of database applications, including some SQL and HTML programming.
- Language skills:
 - Spanish, moderate capability, spoken and written.
 - Portuguese, moderate capability written, basic capability spoken.
- Attained ASQ Certified Quality Engineer (CQE) certification in 1997.