

# ERIK C. STALEY

San Diego, CA | (760) 720-0154 | es@valicom.com | [www.valicom.com](http://www.valicom.com)

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## **SENIOR CSV / GxP COMPLIANCE LEAD | PHARMA, BIOTECH, DEVICE, DIAGNOSTICS** **Technical expertise, regulatory knowledge, and leadership yield efficient compliance**

Senior validation and compliance consultant with 30+ years in FDA and ex-USA regulated environments supporting drugs, biologics, medical devices, diagnostics, and combination products. Specialized in risk-based computer system validation (CSV) / computer software assurance (CSA), data integrity, and implementing contemporary, practical, efficient quality systems for GxP operations. Proven record leading validations, gap and risk assessments, remediations, and audits.

## **CORE COMPETENCIES**

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GxP (GMP, GLP, GCP) | 21 CFR Part 11 / 210 / 211 / 820 (QMSR) | EU Annex 11 | ISO 13485 / 14971 / 27001 | Data Integrity (ALCOA+) | CSV / CSA | SDLC | URS / FRS | Compliance Gap Analysis | Risk Assessment | Remediation | Qualification / Validation | Deviation / CAPA | System Configuration and Change Control | GxP Auditing and Vendor / CRO / Cloud / SaaS Assessments | LIMS | CDS (HPLC / UPLC / GC / CE) | EDMS | QMS Inspection readiness | BLA / NDA / ANDA / IND preparation | Client Training

## **PROFESSIONAL EXPERIENCE**

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### **PRESIDENT / PRINCIPAL CONSULTANT, Valicom, Inc., San Diego, CA | 2002 – Present**

Founder of a GxP validation and compliance firm serving pharma, biotech, device, diagnostics, and research organizations.

- Lead CSV/CSA for LIMS, CDS, EDMS, eQMS, manufacturing, testing, and cloud/SaaS systems across GMP, GLP, GCP, and CAP/CLIA; author, implement, and execute risk-based SDLC/SLC validation packages (URS/FRS, risk assessment, configuration management, validation, traceability, reports).
- Perform Part 11 / Annex 11 / data integrity / QMS gap assessments and implement remediation plans for legacy and new systems.
- Implement contemporary SDLC/SLC systems based on current FDA, ICH, and GAMP 5 2<sup>nd</sup> ed guidance, and Agile approaches.
- Build and refine quality systems (QMS, policies, SOPs) for start-ups (preclinical), growing companies (clinical) and established organizations (commercial manufacture) to achieve and maintain inspection-ready status.
- Develop validation toolkits and templates for lab instrument and software vendors to sell to regulated markets.
- Conduct vendor (contract manufacturer/service/hosting/CRO) audits focused on GxP, security, and data integrity; conduct client mock-PAI / PLI and due diligence; provide prioritized remediation guidance.
- Support response to FDA, state (e.g., CA FDB), and client audits by presenting QMS, validation strategies, evidence, and risk justifications.
- Contribute to regulatory submissions and inspection responses.
- Train client teams on CSV/CSA and data integrity; mentor internal staff to sustain risk-based compliance without over-testing.

- Clients have included Abbott, Aeolus Pharmaceuticals, Ambry Genetics, Aperio/Leica, Biogen Idec, Dart Neuroscience, De Novo Software, Genentech/Roche, Genopis/Wacker, Glaukos/Dose, Innovative Cell Technologies, La Jolla Pharmaceutical, SkyePharma, and others.

### **PRINCIPAL CONSULTANT / CO-OWNER, CPK Validation Services, Lake Forest, CA | 1998 – 2002**

- Delivered CSV and equipment validation for pharma and biotech manufacturers, including chromatography data systems, lab instruments, and manufacturing systems.
- Led Part 11 assessments and remediation; authored validation master plans, protocols, and summary reports.
- Executed IQ/OQ/PQ for process and packaging equipment; supported cleaning and process validation programs.
- Supported FDA inspections and customer audits on validation and documentation.

### **SENIOR QUALITY ENGINEER B. Braun McGaw, Irvine, CA | 1995 – 1998**

- Developed and managed validation programs for devices and sterile drug products (facilities, utilities, equipment, computerized systems).
- Led cross-functional teams; improved processes using SPC and DOE.
- Strengthened QMS procedures and supplier controls.

### **EARLY CAREER SUMMARY**

Engineering, QC, and analytical roles with Gensia Laboratories, Techniclone, Kendall-McGaw, Canon, and Teledyne, building foundation in analytical methods, process control, computerized lab systems, validation, technical writing, and ISO- and GMP-aligned quality systems.

### **EDUCATION**

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**B.S. Chemistry**, University of Redlands, 1990

**B.S. Biology**, University of Redlands, 1990

Additional coursework in Computer Science and Electrical Engineering.

### **INDUSTRY CONTRIBUTIONS**

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Speaker and trainer on validation of lab systems, utilities, spreadsheets, custom applications, LIMS, and compliance with data integrity requirements.

### **CERTIFICATIONS & ADDITIONAL SKILLS**

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- Attained ASQ Certified Quality Engineer (CQE).
- Advanced MS Office (VBA / macros / templates / scripting) for GxP.
- Database administration and web application development/configuration for GxP.
- Automated testing tools (Selenium, Python).
- OS: Linux / Ubuntu, Windows 10 / 11 / Server.
- eQMS, LIMS: Veeva, Documentum, Master Control, custom-designed.
- LIMS: LabVantage, custom-designed.
- CDS: OpenLab / Chemstation / Chemstore, Chromeleon.
- Analytical Chemistry: method development and validation; familiar with HPLC, UPLC, CE, GC, FTIR, UV/Vis, TOC, ELISA, imaging systems, sequencers, PCR, lab automation, instrument interfacing.
- Spanish: moderate; Portuguese: reading moderate, spoken basic.