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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 include:

- Configuring and validating Laboratory Information Management Systems (LIMS), such as Applied Biosystems' SQL*LIMS:
 - Developing validation master plans and validating LIMS implementations,
 - Validating custom configurations, including database tables and reports, labeling and barcode systems, and laboratory instrument interfaces,
 - Configuring and validating LIMS for QC (GMP) and Clinical (GLP/GCP) laboratories,
- Performing gap analyses and risk assessments (GMP, GLP, GCP, 21 CFR Part 11, and HIPAA),
- Developing and maintaining GAMP lifecycle documentation, including user requirement specifications, functional specifications, risk assessments, and traceability matrices,
- Developing a comprehensive computer system and instrumentation validation package that a laboratory equipment vendor sells to its customers,
- Validating Electronic Document Management Systems (EDMS), such as Open Text's LiveLink,
- Designing and validating custom applications, databases, and spreadsheets,
- Upgrading, configuring and validating networked chromatography equipment (HPLC, GC, and CE), such as Agilent's ChemStation / ChemStore and Waters' Empower,
- Auditing vendors and suppliers for GxP and HIPAA compliance, including comprehensive technical and compliance audits of software vendors, datacenters, and ASPs,
- Developing QSR-compliant quality systems for device / diagnostic manufacturers, and submission of regulatory filings,
- Establishing clients' compliance with HIPAA, including crafting security and privacy policies and procedures, and development of business associate agreements,
- Selecting and managing staff.

Valicom's clients have included **Genentech, Biogen Idec, Abbott Laboratories, Aperio Technologies, SkyePharma, Anadys Pharmaceuticals, De Novo Software, 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 remediation and validation of deficient systems,
- Presented validation work to FDA inspectors during PAIs and GMP inspections,
- 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,
- 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,
- 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, IQ, OQ, and PQ protocols, and summary reports,
- Validated computerized test systems, manufacturing facilities, process utilities, and manufacturing equipment,
- Coordinated the activities of engineering, QA, QC, 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 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 a 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 the Quality Control and Development laboratories; completed SQL*LIMS Key User training,
- Validated analytical test methods,
- 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.
- Proficient with the Microsoft Office application suite (Access, Word, Excel, PowerPoint, Visio) and advanced uses of these applications for development and maintenance of validation and compliance documentation.
- Language skills:
 - Spanish, moderate capability, spoken and written.
 - Portuguese, moderate capability written, basic capability spoken.
- Attained ASQ Certified Quality Engineer (CQE) certification in 1997.