

VALICOM

Serving the Regulated Medical Industries

SUMMARY OF QUALIFICATIONS

Valicom, Inc.

(866) 730-9298

es @ valicom.com www.valicom.com

Mission and Philosophy

Our mission is to provide a standard of performance unmatched in the validation and GxP service industry. Our dedication to quality work and personalized support has earned us an exceptional track record in serving Southern California's regulated medical industries.

Why We Are Unique

Valicom's success has been built upon the personal relationships and hands-on, specialized service that we give our customers.

We carefully choose our staff based on their proven track record of successes. Unlike many of the larger validation firms, we never roll out top-notch staff when scoping a project, only to substitute inexperienced, junior personnel at the inception of work.

Our staff has the balanced combination of regulatory knowledge and technical expertise that ensures the success of your validation project. Our staff's background not only comes from our experience as chemists, microbiologists, quality engineers, and IT professionals, we're also noted speakers in the validation field, and have defended validation work in front of FDA. This is another reason for our very high rate of repeat and referral business.

It costs you less to use Valicom than other validation service firms. Valicom has low overhead costs. We do without the sales staff and expensive corporate headquarters that are the hallmarks of larger firms, allowing us to pass along substantial savings to our clients. Our base in Carlsbad, CA lends us easy access to your Southern California facility without the need for substantial, supplemental travel costs.

Description of Services

Valicom is pleased to offer services in the following areas:

- Computer System Validation, including laboratory equipment validation
- Manufacturing Equipment Validation
- 21 CFR § 11 Compliance
- Facility Validation
- Cleaning Validation
- Process Validation
- Quality System Implementation
- Technical Writing: Procedure and Policy Development
- Auditing and other compliance services

*Description of Services, cont'd***Computer System Validation**

Valicom is experienced with validation of computer systems, including information systems, test equipment, laboratory instrumentation, automated manufacturing systems, and medical devices. Some of our areas of expertise include:

- **Validation of Laboratory Information Management Systems (LIMS)**, including design. We specialize in Applied Biosystems' SQL*LIMS product. We're familiar with the vendor's validation protocols, as well as validation of customizations, such as reports, PL-SQL code, custom tables and forms, custom labels and barcodes, and laboratory instrument interfaces. We're also familiar with a number of applications of SQL*LIMS, including uses for QC testing, environmental monitoring, stability testing, and clinical trial management.
- **Validation of Electronic Document Management Systems (EDMS)**, including system design and development of requirement documentation.
- **Design and validation of custom databases and spreadsheets**, including validation of embedded macros and Visual Basic script.
- **Configuration and validation of chromatography equipment (HPLC, GC, and CE)**, including validation of networked data systems (e.g. Agilent's ChemStation/ChemStore and Waters' Millennium).
- **Validation of other testing equipment**, such as spectrophotometers and spectrometers, and automated in-process testers.
- **Development and maintenance of GAMP documentation**, including requirement specifications, functional specifications, validation master plans, design documents, and traceability matrices.
- **Preparation of gap analyses and risk assessments.**

*Description of Services, cont'd***Manufacturing Equipment Validation**

Valicom is experienced with validation of process control systems and manufacturing equipment found in a variety of facilities. Our staff's experience includes IQ, OQ, and PQ of:

- Filling lines, including sterile filling operations,
- Mixing and compounding equipment,
- Tablet presses,
- Packaging systems,
- Autoclaves and sterilizers,
- Incubators, refrigerators, freezers, and related equipment requiring thermal validation,
- Bioreactors and fermentors, including control systems,
- Labeling and barcode reading equipment,
- Organic synthesis equipment,
- Fluid bed dryers,
- Molding equipment, including blow molding, injection molding, and sterile blow-fill-seal operations.

*Description of Services, cont'd***21 CFR § 11 Compliance**

Valicom is experienced with the thought process behind and the practical application of the Electronic Records / Electronic Signatures rule. We understand the way to get your systems compliant in a practical manner, with consideration of FDA's recent guidance documents.

Services that we offer include:

- **Compliance assessment** of laboratory, manufacturing, and support systems: we can tell you what systems require redesign, which require simple remediation, and which are compliant.
- **Configuration, remediation, and validation of deficient systems.**

Facility and Utility Validation

Valicom's staff is familiar with validation of a variety of types of facilities found in the medical industries. We've validated cleanrooms and laminar flow hoods, including subsequent development of routine monitoring programs for monitoring viable and non-viable particulate matter. We've also characterized and validated stability storage areas and warehouses, including performance of temperature and humidity mapping studies.

We've validated utilities used in the pharmaceutical and biotech industries, including:

- **Process gases** (e.g. compressed air, nitrogen, carbon dioxide),
- **Steam systems**, including process steam and clean steam systems,
- **Water systems**, including DI and WFI systems,

*Description of Services, cont'd***Cleaning Validation**

Valicom's staff is well-versed in the field of cleaning validation. Our experience in the analytical laboratory as well as on the manufacturing floor gives us a unique edge in this discipline.

Some of our areas of expertise include:

- Determination of cleanliness limits, and answering that nagging question of "how clean is clean?"
- Development of test methods for detection and quantification of trace levels of contaminants,
- Development of sampling techniques for detection of chemical and microbiological residues,
- Development and optimization of cleaning cycles for process equipment,
- Preparation of analytical method validation protocols, and performance of analytical testing as needed,
- Preparation of cleaning validation protocols, and execution of them,
- Preparation of summary reports.

Process Validation

Valicom's process validation capabilities include:

- Characterization of critical process parameters,
- Design of validation protocols,
- Supervision of sampling activities and analyses,
- Preparation and presentation of reports.

Our experience provides us with the ability to diagnose problems in existing processes and guide you toward rapid validation of your systems... the first time.

*Description of Services, cont'd***Quality System Implementation**

Valicom has assisted device and diagnostic manufacturers with implementation of FDA's Quality System Regulations (QSRs / 21 CFR § 820). We've developed and established:

- Quality Policies,
- Auditing Programs,
- Training Programs,
- Purchasing Control Systems,
- Document Control Systems,
- Device Master Record (DMR) Procedures,
- Device History Record (DHR) Documentation Framework.

We've also guided the filing of FDA documentation to register manufacturing sites and products.

Find out how Valicom can get your facility and device/diagnostic product in compliance with the QSRs.

*Description of Services, cont'd***Technical Writing: Procedure and Policy Development**

Valicom's technical writing capabilities extend well beyond preparation of validation protocols. We've proven our ability to:

- Design, review, and revise corporate quality policies and validation policies, including those for computer system life-cycle management,
- Prepare procedures for the operation and administration of computerized systems,
- Develop change control policies and procedures, and administer change control programs,
- Develop SOPs for operation of laboratory equipment and manufacturing equipment.

We also can provide critical review of existing validation protocols, SOPs, and policies. We can either directly approve such documents for your company's quality group, or advise whether approval is appropriate.

We also can train your staff on new and existing SOPs, as well as on general GxP / QSR topics.

Auditing and Other Compliance Services

Valicom can provide you with cost-effective auditing services, such as:

- Audits of vendors and suppliers,
- Mock FDA PAI and GMP inspections,
- Inspections for "due diligence" prior to company acquisitions,
- Review and critique of facility designs and computer system designs.

We've presented and defended materials to FDA inspectors, and have contacts within FDA. This background permits us to focus audits on known "hot topic" areas.

Professional Background

Erik Staley, President and Principal Consultant

Summary of Qualifications

Mr. Staley has over 15 years of experience in the regulated medical industries. This includes eight years of day-to-day management of Valicom, and of Valicom's predecessor, CPK Validation Services. Mr. Staley's background includes validation of computer systems, laboratory equipment, manufacturing equipment, manufacturing processes, facilities, utilities, and cleaning regimens for the biotech, pharmaceutical, device, and API industries. He has also performed audits, prepared policies, and presented GxP compliance topics. Prior to entering the field of validation, Mr. Staley was an analytical chemist in the pharmaceutical industry.

Professional Experience

Prior to founding CPK Validation Services in 1998, which became Valicom, Mr. Staley held several positions with Southern California medical firms. These included:

- Senior Quality Engineer for B. Braun Medical, Irvine, CA, 1995-1998,
- Quality Control Supervisor for Techniclone, Inc. (now known as Peregrine Pharmaceuticals), Tustin, CA, 1994,
- Chemist for Gensia Laboratories (now known as Sicor, Inc.), Irvine, CA, 1991-1993,
- Research Associate and QC Chemist for McGaw, Inc. (now known as B. Braun Medical), Irvine, CA 1990 – 1991.
- QC Technician, Teledyne Battery Products, Redlands, CA, 1989-1990.

Education

Mr. Staley holds a BS in Chemistry and a BS in Biology from the University of Redlands, Redlands, CA, 1990

Industry Contributions

Presented **Successfully Designing and Validating LIMS for the Regulated Medical Industries** at the *6th Annual Laboratory Instrumentation Validation & Qualification Management Conference*, 4/30/03 – 5/2/03, Chicago IL. Mr. Staley also was a panelist in the **Attaining FDA Compliance with Your Validation and Qualification Program** session.

Chaired the *5th Annual Laboratory Instrumentation Validation & Qualification Management Conference*, 4/9/02 – 4/11/02, Philadelphia, PA. Mr. Staley also presented **Validation of Laboratory Spreadsheets**.

Presented **Validation of Steam and Process Gases for Biotech Products** at the *Validating Utilities* conference, 1/21/99 – 1/22/99, Philadelphia, PA.

Professional Background

Giao Pham, Validation Project Manager

Summary of Qualifications

Mr. Pham has over 14 years of experience in the regulated medical industries. This includes four years of validation work with Valicom. Mr. Pham's background includes validation of computer systems, laboratory equipment, manufacturing facilities, process utilities, and cleaning regimens for the biotech, pharmaceutical, device, and API industries. He has also performed audits, managed laboratory operations, developed quality programs, written operating procedures, and conducted training sessions. On several occasions, FDA inspectors have praised Mr. Pham for his direction of laboratory operations.

Professional Experience

Prior to joining Valicom in 2002, Mr. Pham held several positions with Southern California medical firms. These included:

- QC Laboratory Manager for Celltech Pharmaceuticals CA, Santa Ana, CA, 1999-2001,
- QC and Microbiology Laboratory Manager for Stason Pharmaceuticals, Irvine, CA 1994-1999,
- Raw Material Coordinator for Gensia Laboratories (now known as Sicor, Inc.), Irvine, CA, 1991-1994,

Education

Mr. Pham holds a BS in Biology with emphasis in biochemistry and organic chemistry from the University of California, Irvine, 1991.

Client Listing

Valicom has proudly served the following clients:

- **De Novo Software**, Culver City, CA, 2006-current
- **Genentech, Inc.**, Oceanside, CA 2005-current
- **Anadys Pharmaceuticals Inc.**, San Diego, CA, 2004-2005
- **Biogen Idec**, San Diego, CA and Oceanside, CA, 2000-2004
- **SkyePharma, Inc.**, San Diego, CA, 2004
- **KRJ Company**, San Clemente, CA, 2003
- **Celltech Pharmaceuticals California**, Santa Ana, CA, 1998-2000

Services prior to 2002 were conducted under the business name of CPK Validation Services.

We'd be happy to provide you with references.

Thank You!

Valicom looks forward to serving your validation and compliance needs. For further information, please contact:

Erik C. Staley
President and Principal Consultant
Valicom, Inc.

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

Tel: (866) 730-9298

Fax: (760) 720-0144

Cell: (949) 285-5711

es @ valicom.com

Or visit us on the Web at www.valicom.com