PAUL H. JOHNSON

Moorpark, CA 93021 805-558-6441 (cell) phjohnson@yahoo.com

BUSINESS ANALYST, VALIDATION ENGINEER, and PROJECT MANAGER

for COMPUTERIZED SYSTEMS

Business Analyst, Validation Engineer and Project Manager for computerized systems with twenty years of experience in the development, validation, implementation and administration of software applications and computerized systems including enterprise-wide business information systems, quality management systems, device master records and batch records, clinical trial management, adverse event management, automated manufacturing equipment (with PLC), control and monitoring systems (SCADA), manufacturing execution systems (MES), enterprise resource planning (ERP), analytical instruments, data management systems, IT infrastructure and web-based applications.

- Performed business process analysis and constructed business process maps
- Conducted meetings to define system requirements and data flows
- Wrote/Reviewed/Approved validation documentation
- Executed validation protocols
- Conducted data migration validation
- Conducted internal audits for 21CFR Part 11 compliance
- Performed validated state reviews
- Performed data integrity assessments
- Initiated, investigated, and closed CAPAs
- Performed IT supplier qualification
- Conducted QA review of CSV documentation
- Performed change control for documents and computerized systems
- Wrote procedures for use, administration and maintenance of computerized systems
- Created and improved computerized system validation policies, procedures and templates
- Project manager for validation and often the entire computerized system implementation

Key strengths:

- Thorough knowledge of the system development life cycle, computer technology and project management
- Experienced implementing companywide systems and working with globally dispersed project teams
- Familiar with GAMP-5, 21CFR 11, 21CFR 820, 21CFR 58, ISO 13485, ISO 14971, and 21CFR 210/211
- Certified Project Management Professional (Project Management Institute)
- Certified Software Quality Engineer (American Society for Quality)
- Certified Manager of Quality and Organizational Excellence (American Society for Quality)
- Excellent technical writing skills and ability with MS Office (Word, Excel, PowerPoint, Outlook and Visio)
- Expertise with project management tools (MS Project, Jira, SmartSheet)
- Skilled at business process analysis
- Eight years work experience managing projects and project teams

PAUL H. JOHNSON

Moorpark, CA 93021 805-558-6441 (cell) phjohnson@yahoo.com

PROFESSIONAL EXPERIENCE

STERLING DEVELOPMENT LLC Moorpark, CA (12/2017 – current)
Computerized System Validation and Project Management services for various clients, including*:

SaniSure Camarillo, CA 11/2023 to 3/2024

- Computerized system validation and project management (Infor SyteLine ERP)
- IT Supplier Qualification of Infor as supplier of SyteLine ERP software
- Wrote procedures for administration and maintenance of SyteLine ERP
- Data Integrity Assessment for batch records

Azurity Pharmaceuticals (Remote) 10/2022 to 1/2023

- Computerized system validation and project management (SphereWMS)

SmileDirectClub (Remote) 7/2022 to 9/2022

- Audits of computerized system validations and procedures

Arcutis (Remote) 10/2021 to 3/2022

- Wrote the company computerized system validation program, created validation procedures and forms
- Computerized system validation (SAS validation)

Abbott (Remote) 10/2021 to 3/2022

- Project Management for computerized system validation quality management system harmonization

Amgen (Remote) 3/2020 to 10/2020

- Business analysis for computerized systems (OSIsoft PI), Computerized system validation (laboratory)

Clinical Innovations Salt Lake City, UT 9/2019 to 1/2020

- GxP validation of enterprise resource planning software (Visual ERP)

Stryker Medical Redmond, WA 3/2019 to 8/2019

- Process improvements for GxP computerized system validation and quality systems
- Revised / rewrote / created computerized system validation procedures
- Updated the Computerized System Inventory List
- Wrote, reviewed and approved computerized system validation documents
- Trained staff on computerized system methodology, philosophy and established procedures

Medtronic Northridge, CA 3/2018 to 7/2018

- Validation Review and Re-Validation of GxP custom automated test systems

*(Plus other projects, for clients and personal, in the spaces between and concurrent with those listed above)

STAAR SURGICAL Monrovia, CA (11/2015 to 10/2017)
GxP Computerized System Validation and Project Management

- Conducted company-wide audit of the validated state of computerized systems and updated validation master plan
- Validation and implementation of InfoFlo ERP for host environment upgrade including data migration
- Validation and implementation of JCI Metasys for facility monitoring and alarming
- Wrote standard operating procedures for the use and the administration of TrendManager, Japan Product Label Printing System, Minitab, and JCI Metasys
- Validation of MasterControl including data migration from legacy system: Worked with third-party consultants, STAAR IT and MasterControl to construct and validate the on-site host environment, verify the installation of application software, and review/approve/execute validation documents prepared in-house or prepared by third-party contractors
- Initiated product labelling quality system improvements
- Project manager for product label changes for regulatory compliance and product label printing systems
- Project Manager for the implementation and validation of TrendManager with Honeywell Electronic Data Recorder for steam sterilization batch records
- Project Manager for the implementation of Minitab for process monitoring and process improvement

PAUL H. JOHNSON

Moorpark, CA 93021 805-558-6441 (cell) phjohnson@yahoo.com

PACIFIC BIOSCIENCES Menlo Park, CA (4/2015 to 10/2015)
GxP Computerized System Validation

- Validation Master Plan writing for computerized systems
- Validation of Salesforce.com upgrade with SAP interface
- Camstar MES implementation
- Wrote/revised standard operating procedures for computerized system validation and Oracle Agile PLM
- Project Manager for the validation of site-wide equipment monitoring system

BAXTER HEALTHCARE Westlake Village, CA (5/2014 to 11/2014)
GxP Computerized System Validation

- Implementation and validation of Emerson Delta V and OSIsoft PI Historian
- Validation and change control of Accelrys Discoverant
- Tibco Spotfire query validation (business analytics reports)
- Used Trackwise, Documentum, SharePoint and HP Quality Center

ADVANCED BIONICS Valencia, CA (4/2011 to 1/2014)
GxP Computerized System Validation

Managed the computer system validation program at Advanced Bionics, trained and mentored staff, developed and validated computer systems, initiated and closed CAPAs, audited software vendors.

- Validation gap analysis and remediation of computerized quality systems related to the physical relocation of those computerized systems
- Database analysis for the migration of product complaint tracking from NetRegulus to SAP
- Revised the computer system validation program to be consistent with GAMP-5, revised procedures and templates
- Validated Camstar MES, DataFlo ERP, Oracle Agile PLM and custom software
- Created forms and processes for device history records
- Validated automated test equipment
- Validation Lead and Project Manager of BarTender Label Printing System upgrade for Receiving Inspection
- Validation Lead and Project manager for Merge Evolve for clinical trial management (now IBM eClinical)

ARROW INTERNATIONAL Czech Republic (through Judge Research) (6/2008 to 1/2009)
Validation Consultant, Medical Device Manufacturing

- Validated GxP automated manufacturing equipment used to produce spring wire guides for catheters for FDA compliance (coiling, cutting, grinding, stamping, welding, ultrasonic cleaning, and bending machines)
- Trained staff on computerized system methodology, philosophy and established procedures

B.BRAUN MEDICAL Irvine, CA (12/2006 to 5/2008)
Quality Assurance Specialist, GxP Computerized System Validation

Validated automated equipment and facilities, laboratory analytical instruments, IT infrastructure, custom software applications and Excel spreadsheets.

- Computer system validation lead for the installation of eight PLC-controlled packing lines and associated HMIs that reduced labor costs and increased throughput by using four robots to stack cases onto pallets
- Validated analytical instrumentation, including chromatography systems with Waters Millennium/Empower LIMS
- Project Manager for the migration of software applications and files from two servers running obsolete Novell software to two servers running Windows, which reduced the business risks arising from depending on obsolete technology for critical business applications

PAUL H. JOHNSON

Moorpark, CA 93021 805-558-6441 (cell) phjohnson@yahoo.com

METROPOLITAN WATER DISTRICT Los Angeles, CA (through P. Murphy) (3/2006 to 12/2007)
Software Quality Analyst Consultant

Project Manager for the development, validation and implementation of custom software to control and manage water distribution in Southern California:

- Automated process control software written in C that controls the flow of water through the Irvine Regulating Structure, which improved system reliability and reduced costs by eliminating the need for continuous operator attention and intervention
- Web-based application used to manage the purchase, accounting, and reporting of electric power used to pump water through the Colorado River Aqueduct, which reduced costs by automating labor-intensive manual business processes

AMGEN Thousand Oaks, CA (5/2002 to 11/2005)
Validation Engineer, GxP Computerized Systems

Supervised validation contractors, and provided QA review and approval of the validation deliverables, for the work listed below:

- Managed a team of validation engineers to implement and validate laboratory analytical instrument systems for 21CFR Part 11 compliance, including HP/Agilent chromatography systems with Chemstation LIMS
- Validation of automation control systems and the associated HMIs (PLC, DCS, SCADA), laboratory instruments, controlled-temperature chambers and data systems used in a biologics manufacturing environment
- Conducted internal audit for 21CFR 11 compliance of Process Control Department computerized systems
- Led the validation of an Emerson DeltaV Process Control System in a biotech manufacturing facility designed for the production of a billion-dollar biologic drug
- Led the validation of a GE Fanuc Cimplicity Manager software version control system, which reduced the engineering costs for maintaining software backups and installing software upgrades (Completed the validation in five months by proactively scheduling QA resources for quick document turnaround)
- Project Manager for the 21 CFR Part 11 compliance project for the metrology department. Managed the upgrade and validation of all metrology equipment, which brought the department into compliance with 21CFR Part 11.

MERCK West Point, PA (through Kelly Services) (9/1999 to 4/2002)
IT Consultant for GxP computerized systems – Various IT tasks as assigned

- Managed an Oracle database of drug stability data (Used SQL scripts to load data and create reports)
- Participated in the upgrade and revalidation of a Beckman Laboratory Information Management System (LIMS)
- Created and validated Excel spreadsheets with VBA macros used to process and report laboratory data
- Used Blue Mountain RAM software to manage equipment, equipment maintenance and equipment calibration

HEWLETT-PACKARD/MICROSENSOR TECHNOLOGY Little Falls, DE (3/1991 to 1/1999)
Hardware Engineer, Research & Development

Developed miniature gas chromatography devices based on silicon micro-machined components.

- Created new products that tripled miniature gas chromatography sales, and patented the key technologies (US Patents: 5,487,313; 5,544,276; 5,652,398; and 6,056,269)
- Invented the fluid-lock fixed-volume injector, which improved the precision and accuracy of miniature gas chromatograph analytical results and increased sales
- Invented the fixed-volume injector with backflush capability, which expanded the market for the miniature gas chromatograph and increased sales
- Manufacturing process development including test fixtures

PAUL H. JOHNSON

Moorpark, CA 93021 805-558-6441 (cell) phjohnson@yahoo.com

ECOLOGY AND ENVIRONMENT San Francisco, CA (9/1985 to 10/1990)
Environmental Chemist – Conducted hazardous waste site investigations for US EPA Superfund

- Performed quality assurance reviews of environmental sample analytical data
- Conducted hazardous waste site investigations
- Setup and managed a mobile environmental laboratory and base station lab facility
- Performed on-site and near-site analysis of soil, water and air samples and developed custom testing methods
- Managed hazardous waste site field investigation teams
- Supervised subcontractors performing hazardous waste site investigations

PROFESSIONAL ACTIVITIES

Project Management Institute
American Chemical Society
American Society for Quality
Presented at four professional conferences for computer system validation in FDA-regulated industries

CERTIFICATIONS

Project Management Institute, Certified Project Management Professional (PMP 1459468 since 31Aug2011)
American Society for Quality, Certified Software Quality Engineer
American Society for Quality, Certified Manager of Quality and Organizational Excellence

ACADEMIC TRAINING

MS Chemistry, University of California, Berkeley
BS Chemistry, Pennsylvania State University, University Park
Business Supervision and Management Certificate, Ohlone College in Fremont, CA
Client/Server and Database Technology Certificate, Pennsylvania State University

ONLINE LINKS

https://www.SterlingDevelopment.biz
https://www.linkedin.com/in/paul-h-johnson-2414bb5/
https://image-ppubs.uspto.gov/dirsearch-public/print/downloadPdf/5487313
https://image-ppubs.uspto.gov/dirsearch-public/print/downloadPdf/5652398
https://image-ppubs.uspto.gov/dirsearch-public/print/downloadPdf/6056269