

# Paul A. Labas

19 Mack Drive  
Hillsborough, NJ 08844

(908) 431-3090  
paul.labas@gmail.com

[www.PaulLabas.com](http://www.PaulLabas.com)

---

## EXPERIENCE

- 8+ years of Pharmaceutical Quality Assurance and Validation. List of clients includes Bristol-Myers Squibb, Novartis, Schering-Plough and Johnson & Johnson.
- 3+ years of Quality and Validation teams leadership.
- 4+ years of software development and technical training delivery.
- Proven expertise with 21 CFR Part 11 and 820; cGMP and GLP; GAMP5; FDA and EMEA guidance documents; IEEE and ISO Standards; VLC and SDLC; HP (former Mercury) Quality Center; etc.

### Quality Assurance / Control

- Fully executing complex and high risk computerized system validation efforts in regulated domains.
- Establishing, documenting and implementing system quality assurance and validation strategies based on applicable health authority, company and departmental regulations and policies.
- Involving in project management efforts to ensure successful correlation of VLC and SDLC.
- Providing the regulatory and quality subject matter expertise and training to project teams.
- Continuously improving existing quality systems through risk-based evaluating of existing environments, identification of compliance gaps and optimal remediation strategies (CAPA activities), introduction of Validation and Quality uniformity standards, leading the development, implementation and adherence to Standard Operating Procedures, etc.

### Validation Documentation

- Authoring, reviewing or approving key validation deliverables such as Regulatory, Security and Business Risk Assessments; Vendor Audit Reports; Validation Plans and Summaries; Requirement, Functional and Design Specifications; Test Plans, Summaries and Scripts covering Unit, Integration, IQ, OQ (ST), PQ (UAT) testing; Phase Completion Reports, Deployment and Training Plans, SOP; etc.
- Establishing and directing Validation documentation development and approval processes.

### Testing

- Owning responsibility for extensive multi-site and international system testing efforts from establishing and communicating quality expectations, to identifying test data and environment, to participating in testing flow management, to reporting and acting on testing results.
- Establishing, implementing and managing testing support systems that ensure the highest level of quality and control over the test documentation flow, issues reporting and resolution, system and documentation change management, resources allocation, testing progression tracking, etc.

---

## EMPLOYMENT

### Manager – Validation / Quality Assurance

8/2009 – Present

Bristol-Myers Squibb, Hopewell, NJ

Managing Validation and Quality Assurance of numerous system implementations, including eCTD submission creation and management system, adverse event reporting system, etc.

- eCTD submission system was deployed internationally in FDA, EMEA and Health Canada domains and is in scope of 17 highly technical regulatory documents.
- Representing IT Quality during internal and external audit activities.
- Overseeing numerous projects in Quality Assurance and Validation advisor and support role.

**Manager – Project and Operational Quality****10/2008 – 8/2009**

Novartis, East Hanover, NJ

Was responsible for Validation and Quality of internationally deployed GxP and 21 CFR Part 11 regulated systems, including a system responsible for automated adverse event signal detection, management and reporting; and a system responsible for clinical trials data storage and management.

- Simultaneously supported four projects.
- Championed and implemented a system of tracking audit findings and CAPA status for 50+ operational systems. Fully executed numerous internal audits and directed CAPA efforts.

**Project Lead – Validation / Quality Assurance****10/2006 – 10/2008**

Bristol-Myers Squibb, Lawrenceville, NJ

Led all Validation and Quality Assurance activities during multiple major releases of a 21 CFR Part 11 and GLP regulated Common Technical Document generator application developed overseas and used by BMS organizations throughout the North America.

- Directed numerous complex multi-site testing efforts.
- Successfully collaborated with all levels of IT, Quality and Business personnel.

**Team Lead – Validation / Quality Assurance****08/2003 – 10/2006**

Schering-Plough, Cranford and Springfield, NJ

Managed a team of four Validation / Quality Assurance professionals assembled to support the Schering-Plough Consent Decree Management Program.

- Managed the team workload pipeline, task assignments, resource allocation, interaction with other business areas, output and performance reviews, open expertise sharing, etc.
- Provided subject matter expertise to numerous Consent Decree management activities.
- Implemented sufficient and unique quality control model for a 21 CFR Part 11 and GMP regulated clinical adverse event control and reporting system production environment. The system underwent two EMEA and one FDA audits resulting in only few minor findings.

**Sr. Specialist – Systems Compliance and Validation****10/2002 – 08/2003**

Johnson &amp; Johnson, Raritan, NJ

Provided hands-on technical leadership of Computer Systems Validation and Remediation projects within 21 CFR Part 11 and GMP regulated environments.

- Introduced and implemented a validation strategy that resulted in \$0.5 million budget saving.
- Lead a team of specialists through development and approval of 1,700+ pages of OQ/PQ scripts.

**Sr. Specialist – Systems Compliance and Software Development****10/2001 – 03/2002**

ModusArt, Inc., East Windsor, NJ

**Sr. Technical Trainer and Software Developer****03/2000 – 04/2001**

ADC Telecommunications Corporation, Cranbury, NJ

**Programmer/Analyst****10/1998 – 03/2000**

PERQ/HCI Corporation (Division of VNU USA), Princeton, NJ

---

**EDUCATION****Bachelor's Degree; Computer Science****2002**

Rutgers University, New Brunswick, NJ

**Associate's Degree; Computer Information Systems****1998**

DeVRY University, North Brunswick, NJ