Mari Pigott
Validation Engineer - GxP Systems/Boston Scientific

Campbell, CA - Email me on Indeed: indeed.com/r/Mari-Pigott/eda924ee94b35188

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• Computer Systems Validation engineer with 7 years experience in Medical devices sector.

• Highly trained and motivated professional with 5 years test management experience

• Detailed understanding of GAMP and FDA Regulations- 21 CFR Part11 and 21 CFR 820

• Experience of testing with various environments (mainframe, client/server, web-based) and various programming languages, (PL1, Java, Visual Basic) and databases (e.g., SQL, Oracle, DB2, MS Access).

• Excellent knowledge of Windows, Word, Excel, PowerPoint, Outlook, Access, Microsoft Project, Adobe Acrobat, Photoshop, GIS (Geographic Information Systems).
Willing to relocate: Anywhere
Authorized to work in the US for any employer

WORK EXPERIENCE

Validation Engineer
GxP Systems/Boston Scientific - Los Gatos, CA - May 2013 to Present

Execution of IQ/OT protocols for R&D systems.
• Review of validation documentation to ensure compliance and audit readiness

Senior Validation Engineer
Boston Scientific - Boston, MA - May 2009 to 2013

Writing, execution and review of protocols (IQ/OT) including generation of database scripts in AGILE environment
• Co-ordination of validation engineers and requirements for rollout of production lines.
• Support and collation of PQ execution.
• Responsible for issue tracking and support and execution of system enhancements.
• Establishment of complete suite of validation documents and reporting for facilities Building Management System.

Audit Readiness Validation Engineer
GxP Systems/Boston Scientific - Spencer, IN - January 2009 to April 2009

Cell lead (Galway team) for audit readiness - review of executed IQ and OQ protocols.
• Document and review non-conformances
• In software quality engineer role, reviewed documentation including Software Development Plan, Test Plan and validation protocols.

Cell Lead Validation Engineer
GxP Systems, Galway, Ireland - Boston, MA - 2007 to 2009

As part of the software development team, rollout of new Equipment and Automated Systems Development lifecycle document set (user requirement specification, functional specification, software development plan, system test plan, system design specification, unit testing, risk analysis, SFMEA etc).
• Co-ordination of teams (e.g. Quality Engineer, Mechanical Engineer, Software Quality Engineer) to ensure project deadlines are met.
• Co-ordination, writing and execution of validation protocols (IV/OT) and reports (IVR) and S88 control modules.
• Review of validation engineers' protocols and executions.

Validation Engineer
GxP Systems   -   Galway, NY   -   2006 to 2007

Responsible for validation of computerized production tracking system (Xience).
• Writing and execution of Installation and Operational Qualification protocols and reports for back-end of line (Promus DV).
• Writing and execution of PQ protocol (Promus DV).

Volunteer
Global Service Corp   -   2005 to 2006

Volunteer in Tanzania teaching local farmers about Sustainable Agriculture in order to increase their income and provide more nutritious crops.
• Organized and updated literature provided to farmers and volunteers.

Geographic Information Systems Internship (final College year)
Urban Harbors Institute   -   Boston, MA   -   2004 to 2004

Researched and analyzed natural resource and land use data and information for Boston Harbor watershed. Summarized pattern of existing land use and land use trends using Geographic Information Systems.

Software Testing/Helpdesk Manager (Officer)
State Street Corporation   -   Quincy, MA   -   1998 to 2003

Managed software testing team in order to ensure quality of new software; monitored test plans; reviewed and recorded testing progress.
• Managed testing and implementation of system upgrades and critical bug fixes.
• Create and/or proof read documentation outlining system changes and bug fixes for international user community.
• Managed team of analysts who provided support for numerous financial systems.
• Management of staffing resources, including cross training, reviews, hiring new employees, etc.
• In order to increase efficiency and knowledge of Helpdesk staff, created Helpdesk information point and implemented helpdesk query system.
• Coordinated Business Recovery exercises for Securities Services unit

Software Tester/Help Desk Analyst
State Street Corporation   -   Quincy, MA   -   1997 to 1998

Testing of critical bugs fixes on mainframe, client/server and web environments.
• Developed documentation to communicate software changes to user community.
• Due to expertise, analyzed complex time critical queries on numerous custodial banking systems.
• Worked with business analysts, programmers, technical staff and business representatives to resolve time critical issues and/or determine workarounds, in order to meet strict deadlines.

Software Tester

State Street Corporation   -   Quincy, MA - 1994 to 1997

Produced complex test plans for various business projects.
• Testing of new software and documentation of bugs for various banking systems, (e.g. Custody, Income, SWIFT, Corporate Actions) to strict deadlines.

Experience

EDUCATION

B.A. in Earth Science and Geography
University of Massachusetts   -   Boston, MA
2004