IT Lead IT Lead Pharmaceutical IT Lead Philadelphia, PA A Senior IT Position where extensive system implementation, application support, and project management (Waterfall/Agile) experience can be best utilized. Work Experience IT Lead Johnson & Johnson May 2015 to April 2019 Remote Responsible for implementation and support for Laboratory IT systems in support of medical devices manufacturing. Contractor Merck - West Point, PA September 2014 to January 2015 Responsible for support for Waters NuGenesis SDMS enterprise system at Merck Manufacturing Division. Sr. IS Specialist/ Project Manager Sanofi Aventis R&D - Bridgewater, NJ June 2001 to March 2014 Responsible for full life cycle project management, implementation, and support for IT systems deployed in Pharmaceutical R&D. Also responsible for overall liaison responsibilities between CMC business units and other groups within R&D IS to facilitate current and proposed projects as well as providing general IT professional support to meet client needs. Transitioned to Project Management Competency Center in 2/10 where acquired specialized skills in Agile Scrum Project Management being currently leveraged. Scrum Master Certified 8/09. Specific accomplishments include: Service Manager for outsourced application support by Cognizant service. PM for Platform and Services implementation of Appian's BPM solution. PM for Compound Library System expansion to Genzyme Boston Hub following company acquisition. PM for PK Data Management System implementation. PM for Document and Laboratory Data electronic archiving system employing use of EMC Documentum software tools. Project being conducted as first regulated Agile Pilot Project in R&D IS. PM for MPK Watson LIMS reporting system to extract and publish reports for inclusion in FDA submissions. Scrum Master PM for Web Portal application enhancements project used by CMC business units for Drug Development Project Tracking. Project conducted as first pilot of Agile Scrum methodology in R&D IS. IS Lead for BW GxP Empower 2 CDS upgrade from Millenium32 4.0. Co-developed validation strategy with user leads. PM for BW GxP Amegaview CMS environmental monitoring system upgrade and implementation. Quality audited by both FDA and EU Health Agencies with no reported findings. Appointed Site IS representative for GxP equipment metrology/qualification advisory group. Provided on-going Laboratory application and instrument support in GxP areas across all preclinical functions

continually maintaining GxP compliance. System Administrator for Waters Empower CDS.   PM for CDS system upgrade of Waters Millennium32 GxP CDS to Version 4.0 with integrated NuGenesis Archive SDMS system.   IS Representative on multiple Vendor Quality Audits including Waters, NuGenesis. Project Manager Merck - Kenilworth, NJ June 1992 to June 2001 Responsible for design, implementation, and overall project coordination of IT projects in the Development Operations areas within Schering-Plough Research. Specific accomplishments include: PM for CDS system upgrade of Waters ExpertEase to Millennium32 for Biotech and Chemical Development Analytical Labs. Managed and coordinated project including infrastructure upgrades, NT server acquisition, software implementation, and GxP validation of system. System implemented on NT Workstation and Server.   PM for POMS clinical supplies implementation for Schering Research Clinical Supplies department. System is targeted to streamline the tracking and management of the clinical supplies in phase I. Phase II will expand the system to include electronic batch record implementation in clinical manufacturing. Phase III will target the overall expansion of the system to the Chemical Development and Biotech business units of Development Operations.   IS Lead for Base 10 FlowStream MES implementation team at Schering-Plough Research Chemical Development business unit. Developed approximately 100 FlowStream Scripts. Implemented PVCS Version Control to manage script development and change control. Developed over 50 reports and queries against the FlowStream Oracle database including a Compliance Batch Record report. Developed a solution to the issue of Documentum review of the FlowStream EBR (paper presented at 1997 FlowStream User Conference).   Project Lead on upgrade project to convert Union Site Chemical Development LAN from AppleTalk to Ethernet to support FlowStream MES implementation. This included management of hazardous area networking and install of XP-rated X-Terminals in Chemical Development plant locations.   Developed a database loader application that transferred Discovery Research biological test result data from Excel spreadsheets to an Rdb database. Developed in OMNIS 7 on Macintosh OS. This application was the first client/server application to be developed in Research Information Systems.   Assigned to client/server development task force. This group evaluated a suite of client/server development and reporting

tools to make recommendations on and launch client/server development in Research Information Systems. Tools evaluated included OMNIS 7, PowerBuilder, Access, BI Query, and Business Objects. Senior member of implementation team for system to automate the submission of compounds developed by Discovery Research for testing as viable drugs. System tracked sample inventory, testing submission, and results of biological tests. Developed in Fortran, C, SQL, and Rdb on DEC/VAX. Education B.S. in Computer Science SETON HALL UNIVERSITY - South Orange, NJ

Name: Amanda Schroeder

Email: tinabooker@example.net

Phone: 001-503-498-1996