Sr. Computer Systems Validation (CSV) Lead/ Consultant Sr. Computer Systems Validation (CSV) Lead/ Consultant Raleigh, NC Work Experience Sr. Computer Systems Validation (CSV) Lead/ Consultant November 2018 to Present Responsibilities: Support all CSV activities at multiple sites and ensure procedural consistency Manage tasks, schedules, and deliverables associated with the overall initiatives related to Laboratory, Manufacturing, Engineering, and Enterprise Systems Create, review, and/ or approve all CSV Validation Plans, User Requirements (URS), Functional and Design Specifications, Testing Protocols (IQ/OQ/PQ), Requirements Traceability Matrix (RTM), Validation Reports, SOPs, Change Control Documentation, Risk Assessments, and Validation Summary Reports Build and maintain trusting, collaborative relationships and partnerships with internal stakeholders to ensure key business objectives are satisfied Sr. Consultant Computer Systems Validation (CSV) November 2018 to Present KBI July 2016 to Present Director, Computer Systems Validation (CSV) and Lab Support Computer Systems Validation (CSV) - Durham, NC July 2016 to November 2018 7/2016 - 11/2018 Responsibilities: Support and oversee all CSV activities at multiple sites (Durham, NC, Boulder, CO, Houston, TX, and Leuven, Belgium) and ensure procedural consistency Manage cost, tasks, schedules, and resources associated with the overall initiatives related to Laboratory, Manufacturing, Engineering, and Enterprise CSV and Lab Support efforts Review and approve all CSV Validation Plans, User Requirements (URS), Functional and Design Specifications, Testing Protocols (IQ/OQ/PQ), Requirements Traceability Matrix (RTM), Validation Reports, SOPs, Change Control Documentation, Risk Assessments, Periodic Compliance Reviews and Validation Summary Reports Ensure a high degree of Inspection Readiness for Systems/Infrastructure and support internal and external customer and regulatory audits Build and maintain trusting, collaborative relationships and partnerships with internal stakeholders to ensure key business objectives are satisfied Initiate and manage all data integrity and Part 11 compliance gap assessments and remediation projects for approximately 60+ existing systems Sr. IT Validation/ Project Lead Novartis November 2014 to July 2016 Responsibilities: Manage change requests related to the GLIMS system; determine validation approach, and work with the business to ensure accuracy and timeliness Track and report on project milestones/ deliverable to the System Owner

and Management  Manage validation efforts for multiple Divestiture Projects (Vaccine Division was sold to GSK and CSL)  Facilitate project meetings and communicate daily with the project teams in Germany, Italy, and Liverpool QC LIMS Sr. Project Manager Biogen Idec February 2014 to August 2014 Responsibilities:  Managed cost, tasks, schedules, and resources associated with the overall initiatives related to the LIMS Project  Proposed and implemented a QC LIMS support model to include a Change Management Process  Managed the LIMS Support Team; assigned resources, tracked progress, and reported status  Provided guidance/ support to QC to understand the business needs and work with IT to define the best approach  Attended/ facilitated project and stake holder meetings Sr. IT Validation Lead Novartis October 2013 to March 2014 Responsibilities:  Project Lead tasked with determining overall validation approach for QC e-Lab Project  Authored validation documentation as needed  Tracked and reported on project milestones/ deliverable to the System Owner and Management Sr. Validation Lead/ Project Manager Hospira July 2012 to August 2013 Responsibilities:  Project Lead tasked with determining overall validation approach for IT/ QC systems  Provided guidance/ support to IT employees with regards to Computerized System Validation requirements  Created and maintained change controls and validation deliverables for IT and QC systems  Coordinated documentation, testing, and change management activities  Member of the IT Change Control board; provided quality assurance oversight for all IT Infrastructure projects Sr. Project Manager, IT Quality GlaxoSmithKline January 2012 to June 2012 Responsibilities:  Project Lead tasked with determining overall validation approach for IT/ QC systems  Reviewed and approved project validation documentation to ensure consistency with quality standards  Initiated all project IT and QC change controls  Provided weekly updates to Project Stakeholders / System Owners Sr. IT Project Manager Biogen Idec June 2011 to December 2011 Responsibilities:  Managed cost, tasks, schedules, and resources related to the LIMS (Labware) Optimization Project and the MyQUMAS (Documentum) Interface Project  Reviewed and approved system documentation to ensure consistency with quality standards and quality of deliverables  Built credibility, established rapport, and maintained communication with stakeholders at multiple levels, including those external to the organization Sr. Validation Consultant (Assigned

Kymanox, Inc April 2011 to June 2011 Responsibilities: Performed a GxP Gap Assessment on two legacy ERP systems Created a Gap Assessment Report documenting the findings and a proposed path forward to mitigate the gaps Kymanox, Inc September 2010 to June 2011 Sr. Validation Project Lead (Assigned Kymanox, Inc December 2010 to April 2011 Responsibilities: Project Liaison/ Lead between the Business (end-users) and Quality to identify the user/ system requirements and determined overall validation approach (COTS Software) Developed all validation and project related documentation required to meet the project needs Developed/ maintained overall project schedules with critical tasks and milestones Created Computer System Validation Standard Operating Procedures and Forms to be implemented Sr. Validation Project Lead, SAP Project Implementation Team Kymanox, Inc September 2010 to February 2011 Responsibilities: Project Lead between the Business (end-users), Quality, and the Technical teams to identify the user/ system requirements and determined overall validation approach Developed overall project schedules with critical tasks and milestones, and assigned resources to ensure deadlines were met Developed project related documentation required Worked closely with the project team to identify and mitigate all procedural gaps identified Implemented processes/methods to improve efficiency and promote consistency Held weekly status meetings with Project Team/ Stakeholders Sr. IT Manager, Data Management Teleflex Medical January 2008 to March 2010 Responsibilities: Managed (full-time) staff of 5 in accordance with company policies and applicable regulations. Responsibilities included planning, assigning, and directing work; performance appraisals, addressing employee relations issues, and managing cost center budget Effectively communicated and interacted with all levels of associates and management within the organization; worked with external vendors on RFIs and RFPs for data cleansing and data governance efforts Developed, implemented and maintained the data governance structure per the business needs Provided leadership and direction for new site implementation projects, business process improvement and data standardization efforts, data quality and data integrity improvement initiatives, as well as system enhancements/ upgrade efforts Managed the creation of new and maintenance of existing SAP Master Data Standard Operating Procedures (SOPs), Forms, Training Material, and Data

Standards used across all sites (Core SAP Objects: Material, Customer, Vendor and Quality) Developed and implemented the Data Auditing Program and the Data Change Management Process Coordinated and conducted new employee and refresher training for all Master Data Custodians and Stewards on the Data Entry and Data Maintenance Processes (8 active sites) Reviewed and approved all data-related Change Controls and validation/ project documentation; managed all data-related CAPAs and deviations through to resolution Worked closely with the IT functional teams and business owners/ SMEs to identify issues and potential risks related to master data; proactively managed them to resolution and/or mitigation Teleflex Medical July 2007 to March 2010 IT Manager, SAP Project Implementation Team Teleflex Medical July 2007 to December 2007 Responsibilities: Managed (contract and full-time) staff of 12 in accordance with company policies and applicable regulations. Responsibilities included day-to-day management of project staff, including work assignments, staff development, issue tracking and resolution, and monitoring work progress; managed the project budget Worked closely with all levels of associates and management within the organization to introduce and implement the new data governance/ data maintenance policies Created all project related documentation in accordance with the corporate ePMO standards Managed the development and implementation of global processes / procedures related to data management to ensure regulatory compliance and business requirements were met across all functional business units; 70+ SOPs, forms and Data Standards were created for this project Established a data governance structure, defined data ownership and stewardship, and developed, tested, and assigned the security Master Data Roles (currently 40+ security roles exist for Master Data Maintenance) Coordinated and conducted training for Master Data Custodians and Stewards on the new Master Data process Implemented and managed the Dual-Maintenance Program to ensure data residing in the new system was up-to-date until go-live Consolidated and cleansed master data from three (3) legacy ERP systems into SAP Sr. Project Manager, IT Quality GlaxoSmithKline July 2006 to July 2007 Responsibilities: Created, reviewed, and/ or approved IT change control requests and validation-related deliverables Provided weekly project updates to Project Stakeholders / System Owners Assisted in developing functional and technical

requirements for IT systems  Provided GxP-related quality assurance oversight, with an emphasis on software validation IT Business Systems Analyst/ Project Manager Teleflex Medical February 2006 to July 2006 Responsibilities:  Lead the Global Labeling Project  Coordinated all external vendor demos and was the main point of contact during the RFI and RFP process  Liaison between the Users/ Business Owners and Technical Project Leads; analyzed the business process, gathered requirements, provided design solutions and process improvements  Effectively communicated project updates / status to Project Stakeholders / Sponsors LIMS Team Manager/ QC Systems Compliance Project Manager Wyeth Vaccines - Sanford, NC July 2004 to January 2006 Responsibilities / Teams:  LIMS Support Team Manager  Managed the LIMS System support team (8 full-time employees and 2 contractors) in accordance with company policies and applicable regulations. Responsibilities include planning, assigning, and directing work; performance appraisals and addressing employee relations issues  Managed the implementation, validation, and cutover process for the Labware LIMS Enterprise System project  Coordinated system upgrades with the Corporate Support Team; trained new team members and provided technical support as necessary  Maintained the systems' validated state - managed requests in respect to system enhancements and master data requirements; worked with Site Subject Matter Experts and the support team to determine scope of work, defined project and validation tasks, developed overall project schedules with critical tasks and milestones, and assigned resources to ensure deadlines are met  Reviewed and approved all Computer System Life Cycle Documentation and Change Controls pertaining to the system; participated in internal and external audits as necessary  Created all system administration SOPs  Interfaced daily with multiple business units (i.e. Quality Control, QA Release, Manufacturing, IS, Technical Services, HR, Change Control, Document Control, SAP Team as well as the Corporate Labware LIMS Team) to resolve issues, determine best practices/ business processes or define scope of work for new requests  QC Systems Compliance Project Manager  Developed and implemented a COTS Validation Process and Administrative SOPs  Reviewed and approved all, including but not limited to: Validation Plans, Risk Assessment Reports, Regulatory and 21 CFR Part 11 Assessments, User and Functional Requirements, Design Specifications,

IQ/OQ/PQ validation protocols, Validation Summary Reports, and Decommissioning Plans related to QC Validation Projects  As part of the Site Validation/ Compliance Team, worked with multiple business units to ensure site validation processes/ procedures comply with corporate policies and as well as GMP and Part 11 regulations Consultant Matrix Resources - Clayton, NC June 2001 to June 2004 IS and QC Validation Project Manager  Responsibilities:  Managed multiple (custom-built systems and COTS) projects simultaneously, developed project plans, coordinated all resources and tasks; Successfully managed and implemented (10) QC systems on-time in one year  Worked closely with End-Users/ customers to create, review, and approve all System Life Cycle Documentation  Managed contract resources and mentored/ trained new team members on the current processes and procedures  Developed and implemented the use of a COTS Validation SOP for the Quality Control department Education Bachelor Degree in Communications in Communications/Journalism Shippensburg University - Shippensburg, PA Additional Information  Twelve plus (12+) years of management experience  Sixteen plus (16+) years of managing projects in a Pharmaceutical/ Biological/ Medical Device environment  Strong knowledge of change management, quality systems, and software/computer validation  Excellent communications, organizational and troubleshooting/ problem-solving skills  Valuable interpersonal skills: quickly build and maintain good rapport with client/customer  Team player, self-motivator, ability to work with little or no supervision  Comfortable in a fast-paced, constantly changing environment

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