

Veeva Vault eTMF Program Manager Veeva Vault eTMF Program Manager Veeva Vault eTMF Program Manager Ashland, MA Work Experience Veeva Vault eTMF Program Manager Parexel - Billerica, MA February 2019 to June 2019 Implemented Veeva configuration package. Directed requirements workshops for Global Clinical Staff. Tracked scope, schedule, budget, risks, issues, action item and escalations. Identified and documented requirements and specifications. Complied and followed CFR Part 11 validation guidelines. Responsible for overall Implementation Vault eTMF and IT Integration deliverable consisting of multiple integrations including CTMS, IMPACT, and Active Directory. Market Access/Pharmacy Hub Program Manager Insulet - Acton, MA October 2018 to February 2019 Program manage expansion of customer care support capacity to support new product release. Manage product release through integration of call center and third-party pharmacy hub provider. Oversee, support and interface with IT Project Manager and other business partners. Review, integrate and modify business processes of Insulet and third party. Review of call center technologies, strategies, call handling, training and communications. Manages dependencies, risks, plans, costs and resourcing for each project and dependencies across interlinked projects. Digital Workspace Solutions Capital Project Manager Amgen - Cambridge, MA June 2018 to October 2018 Managed multi-faceted IS implementation projects from initial to completion with a focus on organizational change management. Responsible for overall delivery of IS scope under the Next Generation Workspace construction projects, including managing all work streams: Network Infrastructure, automation and Control, End User Technology/Audio Visual. Primary liaison for coordination with external teams such as: construction, end users, SME's, Facilities, Technical IS Support with construction teams including external subcontract vendors. Infrastructure Project Manager Sanofi - Westborough, MA November 2017 to May 2018 Managed Infrastructure deliverables for buildout of 50 Binney Street, Cambridge. Led project team consisting of WAN, LAN, Wi-Fi, Telephony resources. Interfaced with Facilities construction and workstation buildout Coordinated services such as cable television, audio visual, printers. IT Integration Program Manager Ipsen Bioscience, Inc - Cambridge, MA May 2017 to August 2017 Led successful delivery of IT Tech Operations program to support a new

manufacturing facility. ? Directed team to complete a datacenter infrastructure qualification project per GMP. ? Worked with vendor, onsite and remote teams to install new system infrastructure: Empower3 FR3, FaciliWorks, Johnson Control BMS, Smart-View and Red Cloud security system. ? Implemented multiple vendor-hosted Cloud solutions such as ComplianceWire, Blue Mountain, and Box. Program consisted of other corporate-level project initiatives such as TrackWise and Easidoc. Established work plan and staffing for project activities as well as arranged for recruitment or assignment of project personnel. Followed 21 CFR Part 11 (Computer Systems), Part 210 and 211 (GMP), and Part 821 ISO 9001. Reviewed vendor contracts and project proposals to determine timeframe, funding limitations, procedures for accomplishment projects.

Senior IT Project Manager, Manufacturing and Supply Chain Biogen - Cambridge, MA June 2016 to December 2016 contract) Managed compliance project to install patch upgrade to Empower3 FR3 to six different domestic and international GxP instances. ? Team includes scientists, laboratory equipment support vendors, software vendor, Quality, IT Compliance, and IT Infrastructure support staff. ? Project scope includes six different deployments 21CFR Part 11 (QS), Part 211 (GMP). Led a remote core team to implement a CRO data automation project for routine, method and stability samples. Project introduced a new capability for CRO's to automatically deliver analytical data, results and metadata to Biogen Spectrus system. Scope included LIMS interface.

Revenue Cycle Transformation Senior IT Project Manager Fresenius Medical Care - Lexington, MA March 2016 to June 2016 contract) Managed project to implement integrated denial claim functionality to Soarian (eCF) system. Evaluated/reviewed/modified business remittance processing workflow for efficiency opportunities. Identified, tested and deployed product configuration and reporting deliverables. Lead multiple teams of 30+ members ( IT and Business) to meet project deliverables.

IS Project Manager Covidien/Medtronic - Mansfield, MA February 2015 to March 2016 contract) Managed project to create code to automate FDA submission of validated product data. Focused on initiatives to capture Unique Device Identifier (UDI) from multiple business channels to comply with FDA requirements. Master Data Management (MDM) data quality, data validation, fixes, enhancements, upgrades. Led multiple teams of 10+ members to meet project deliverables. UDI

efforts included working with service centers, field representatives and manufacturing centers to comply with FDA UDI labeling requirement. IT Project Manager CVS Retail - Woonsocket, RI (October 2014 to February 2015 contract) Managed a compliance project to develop, test and implement a new prescription label system for compounded medications in line with state regulation and USP standards for non-sterile compounds (USP 795). Led a 50+ team consisting of developers, architects, quality assurance analysts, business analysts, as well as off-shore and external vendor resources. Tracked resource allocation hours on a weekly basis using Clarity software. Corporate standard budget variance limited to 2%. Project included extensive coding with Oracle-based pharmacy system. Project Manager - Manufacturing, Quality and Corporate Operations Information Systems Sanofi - Westborough, MA (March 2012 to April 2014 contract) Deployed a global GxP Laboratory Information Management System (LIMS-Environmental Monitoring) within prescribed schedule and resources. Included configuration and change management per site specifications. Created new CATSWeb (GxP application) Validation and Production environments. Executed testing in Validation and Production environments. Project-managed the transition of a newly acquired device manufacturing company to Genzyme/Sanofi corporate accounting standards. Upgraded corporate site datacenter to qualified enterprise level complete with failover capabilities. Included storage area networks, load balancing, and virtual machines. Project Manager Takeda Pharmaceuticals - Cambridge, MA (October 2011 to March 2012 - Oncology Standards Management (contract) Streamlined specifications templates to align with Takeda's data terminology library and the Clinical Data Interchange Standards Consortium, Inc. (CDISC). Increased effective and overall success rate within areas utilizing data such as Study Data Tabulation Model (SDTM), and Trial Design Documents (TDDs). Education Certified Business Continuity Planner Institute for Continuity Management MBA Suffolk University - Boston, MA BA in Economics Wheaton College - Norton, MA

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