Anubha Mukherjee

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PROFESSIONAL SYNOPSIS

Anubha is a Senior Manager in New Delhi, India. With over twenty years of experience in Consulting, she has extensive experience in design, development, implementation and management of information technology solutions for a wide range of industries and technologies. Her present area of focus is IT Compliance & Computer Systems Validation for the Life Sciences industry. Anubha has demonstrated competence and success in the following areas:

CORE COMPETENCIES

Computer Systems Validation and IT Compliance	○ Computer Systems Validation of Enterprise Systems, TrackWise Systems, Laboratory applications, SCADA Systems, MES and ERP Implementations ○ GxP Assessments and 21 CFR Part 11 Compliance ○ 21 CFR Part 11 GAP Assessments of GxP Systems ○ Computer Systems Validation of Chromatography Management Systems ○ Computer Systems Validation of Document Management Systems ○ Infrastructure Qualification for GxP applications
Practice Building and Project Management	○ Big-five consulting experience through Senior Manager level. Practice building, leading effective teams and working with global stakeholders ○ People management including internal teams, client staff and executives ○ Project planning, execution and control ○ Practice Building and leading effective teams ○ Management of geographically-dispersed teams, including global delivery model ○ Pre-Sales Support including effort estimation and Proposal preparation ○ PMO experience of full-lifecycle Oracle ERP implementation
Quality Management Systems	○ Creation of SOPs for IT Quality Management Systems ○ Creation of Master Validation Plan for CSV ○ Review and modification of IT Quality Management Systems ○ Assessment team member during successful CMM Level 5 assessment ○ Active member of SEPG in a CMM Level 5 organization

Work Experience	
Independent Consultant CSV: Indian CSV Consultancy, European Laboratory Management Consultancy: March 2018 Onwards	
Job Profile	○ Compliance support for a European Laboratory Management Consultancy remotely from India: Created SOPs for the Quality Management System for an ERP System
	○ Supporting an Indian Compliance and Quality Management Organization: ▪ Marketing support to identify global and Indian Clients ▪ Pre-Sales discussions with clients, ▪ Effort Estimation of projects ▪ Proposal preparation
Independent Consultant with an Indian Pharmaceutical Major: June 2017 to Feb 2018	
	○ Leading the Validation of a Global EDMS project which is being rolled out globally. She is responsible for the validation strategy and all the key validation deliverables. ○ Leading the Validation (Assessment for intended use) of a Validation Life Cycle Management tool which will be utilized for all the validation projects globally. All validation and testing activities will be managed using the tool. Guiding the team to ensure that the tool is fit for its intended use ○ Reviewing SOPs for the revised IT Quality Management System
Independent Consultant with a Global Pharmaceutical Company: September 2015 to June 2017	
	○ Responsible for the validation of the BMS System being implemented to control the temperature, relative humidity and differential pressure at the plant. The project includes qualification of the IT infrastructure for the BMS. Anubha was responsible for the project since initiation, and has been involved in the supplier qualification and vendor selection. She was responsible for managing the CSV implementation, review of all deliverables and interacting with the stakeholders and key users ○ Conducted a Gap Assessment for the BMS system which was implemented previously. The gap assessment was conducted with respect to 21 CFR Part 11 requirements and based on GAMP5 guidelines. ○ Responsible for the Chromatography System being implemented in the Quality Control division. Anubha was responsible for all the activities related to CSV, including vendor management, deciding the validation strategy, infrastructure qualification, review of all validation deliverables and interaction with all stake holders and key users. ○ The Quality Management System in India was being redeployed, and Anubha has been involved in the review of CSV SOPs. She was also part of the team developing the Sub Validation Master Plan for CSV.

	○ Introduced Infrastructure Qualification in all CSV projects, and created guidelines and overall strategy for infrastructure qualification ○ Responsible for the validation of a Stability Management system which will be rolled out in India to help with testing schedule management, sample management, reporting and statistical data analysis.
Independent Consultant with an Indian Pharmaceutical Major: October 2014 to September 2015	
	○ She has completed Gap Assessments for a TrackWise Application and a Documentum Application based on external and internal audit observations. A detailed Gap Assessment was conducted to identify gaps with respect to the CSV and IT Procedures in the organization and gaps in 21 CFR Part 11 Compliance. ○ She was responsible for the validation of several large IT applications including a ARCOS Privileged Identity Management System, a TrackWise System and a Documentum System amongst others. She was leading the validation of a D2 LSQM system which would replace the existing Documentum system. ○ She was involved in the remediation of the Governance Risk and Compliance (GRC) rule-set conflicts for GxP activities in the SAP implementation at the plant. An assessment of the SAP system for 21CFR part 11 compliance, security access control and validation was conducted by Ernst & Young (E&Y) in 2014. The observations, gaps and action items planned were implemented and reported in a Gap Assessment Summary Report
Independent Consultant: September 2013 to September 2014	
	○ Anubha was an IT advisor to a leading Architecture college and helped them in selection and implementation of an ERP and Education management system ○ Anubha was a key member of the senior management of a Life Sciences startup and made significant contributions in defining the service portfolio, establishing tie-ups with global partners and acquisition of global and local clients
Business & Decision GDC, Senior Manager: November 2009 to September 2013	
	○ Anubha was responsible for building the Life Sciences practice in India. This included pre-sales activities, proposal preparation, team building and overall management of Life Sciences projects in India. ○ She was responsible for delivery of Life Sciences Validation projects to ensure compliance with regulatory norms (E.g. US FDA) as part of B&D's RightDelivery® model. Currently managing validation projects with global scope for a Global Healthcare and Medical Devices Major, a key customer of the B&D Group.
GE Healthcare, Senior Project Manager & Validation Manager: August 2005 to March 2009	
	○ Responsible for management of Global IT projects for GE Healthcare entities and practice building activities. In addition as a CLR Leader, was responsible for the responsible for Validation and Verification of IT applications at GE Healthcare to

	ensure that they are compliant with FDA regulations for Medical Device manufacturers. Anubha managed several IT Validation projects to ensure that the GxP relevant projects are compliant with FDA norms and are ready for audits.
	Rapidigm Consulting: Practice Manager: June 2003 to March 2005
	○ Anubha was responsible for the offshore Oracle practice in India. Responsible for delivery management of offshore Oracle Application projects, implementation of quality systems, staffing and utilization of resources and pre-sales activities.

PERSONAL TRAITS

- Innovative manager with problem solving skills
- An excellent communicator with hone problem solving, analytical abilities and team management skills.
- Ready to accept changes and challenges
- Honest, and A person of strong integrity
- Good people manager
- Forward thinking, able to adapt to changing environments

Sample Global Computerized Systems Validation Experience

Sr. No.	Client	Type of System
1.	GE Healthcare	TrackWise system from Version 7.0.9.4 to Version 8.4 for a global healthcare major. This was a global implementation and supported ten business application modules such as Product Registration and Tracking, Complaints, CAPA, Investigation Reporting etc. Anubha was responsible for the Validation Strategy, the Validation Master Plan and the validation deliverables for all the modules implemented on the TrackWise platform.
2.	GE Healthcare	Electronic Lab Notebook (ELN) suite of products from Perkin Elmer. The ELN system was implemented at various R&D Divisions of a Healthcare major and is used by Chemists and Biologists conducting Drug Discovery and Pre-Clinical Studies It contains Discovery Chemistry and Biology IP data and compound database.
3.	GE Healthcare	Validation Suite for Oracle's Pedigree and Serialization Manager (OPSM): Business and Decision has created a comprehensive validation suite for its next generation solution in checking anti-counterfeits in the pharmaceutical sector. The Validation Package for OPSM can be utilized for implementation at client locations. Anubha was involved during the creation of validation suite templates for validation plans, functional requirement specifications, requirements traceability, risk assessment, dedicated business

		process flows, test plans, use cases and validation reports
4.	GE Healthcare	Chromatography Data Systems: Validation Manager for the global implementation of Chromeleon's Chromatography Management System for process control and production of X-Ray and MR contrast agents. Chromeleon from Thermo Fisher Scientific is a Chromatography Management System that controls analytical chromatographic instruments, collects data, processes data and reports. It was implemented at the R&D division of a Global Healthcare and Medical Devices Major across Europe and India. Chromeleon version 6.6 was upgraded to version 6.8, and the system was connected to 65 instruments, and complete validation was done.
5.	GE Healthcare	SAP Upgrade Project at the Medical Diagnostics Division of a Global Healthcare and Medical Devices Organization. The upgrade was from SAP R/3 Version 3.1i to SAP ERP 6.0 at various locations in North America and Canada. I was responsible for the completion of the Validation Plan and reviewing User Requirements.
6.	GE Healthcare	Led Compliance Legacy Remediation Workout for DI Services at Milwaukee: As a key member of the Validation team, Anubha was involved in the GxP Assessment and Criticality Assessment of numerous critical legacy applications used by the DI (Diagnostic Imaging) Services team. I led a compliance strategy workout for Legacy Applications from India where we decided on the future compliance roadmap for legacy applications along with the CIO and the business owners.
7.	GE Healthcare	FEMC (Field Engineers Mobile Computing): Validation of new release of web based FEMC application which included enhancements to improve information exchange with CARES (Computer Assisted Repairs and Engineering Servicing) and include Audit Trail of repair parts inventory.