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Surbhi Saxena ⭐ Featured

Surbhi Saxena

IT Analyst seeking roles in Software Development,Requirement Gathering

,Configuration Management,COTS Validation,Relationship Management,Data Security,Change Management ,Service Delivery,MySQL,AWS,Agile/Waterfall Model

Current Designation: IT Analyst - Validation Consultant

Current Company: Tata Consultancy Services

Current Location: UK

Pref. Location: United Arab Emirates (UAE),United Kingdom (UK),United States (US)

Functional Area: IT Software - Application Programming / Maintenance

Role: Team Lead/Tech Lead

Industry: Strategy /Management Consulting Firms

Marital Status: Married

Key Skills: IT Analyst,Project Lead,Software Development,Requirement Gathering ,Configuration Management,COTS Validation,Relationship Management,Data Security,Change Management ,Service Delivery,MySQL,AWS,Agile/Waterfall Model

Total Experience: 6 Year(s) 0 Month(s)

Highest Degree: B.Tech/B.E. [Electronics/Telecommunication]

Verified : 📞 Phone Number | Email - id

Last Active: 20-Jan-21   Last Modified: 20-Jan-21

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Summary

Goal-oriented, versatile professional with 6 years of experience in computer system validation planning & compliance for Pharmaceutical, Biotech, Drug and Device Manufacturing Industry
    Proficient in following SDLC, Waterfall & Agile methodologies
    Familiar with various industry regulations such as 21 CFR Part 11, GxP, U.S. Code of Federal Regulations, European Directives and GAMP
    Successfully managed 8 applications in parallel
    Performance-driven professional; authored, reviewed and approved CSV deliverables Validation Project Plan, URS, TM, IQ, PQ, UAT (Plans, reports), release statements
    Played Key role in developing e-testing process instead of paper based approach due to Covid 19; conducted session for all business users for e-testing process.
    CSV Consultant; skilled in interacting with customers, 3rd Party Vendor Qualification on validation activities; delivering CSV related training, driving improvement & automation of processes

Work Experience

🔘 **Tata Consultancy Services** as IT Analyst - Validation Consultant
Oct 2019 to Till Date

Key Result Areas:
    Leading prospective and retrospective computer systems validation for U.S. and European regulations and company standards covering both laboratory and IT environments within the Pharma
    Working on U.S. FDA 21 CFR Part 11
    Heading validation release of various projects, managing change through entire validation lifecycle from initial change to production deployment in compliance with Global Regulatory requirements.
    Steering CSV task including validation package development, project plan, and effort estimation. Development & review of User Requirement Specifications URS, Functional Requirements Specification FRS and Requirement Traceability Matrix RTM Documents, Validation Protocols IQ/OQ/PQ documentation
    Driving session on Compliance & Validation role, for the Validation Team to guide regarding the entire process
    Establishing system design requirements, executing test scripts, summarizing validation activities and defining supporting procedures
    Liaising with business functions, developing & delivering robust training programmes for system users
    Maintaining an excellent working relationship with internal IT department and troubleshoot system issues
    Identifying & investigating potential system changes and support system-related Change Controls

🔘 **Larsen and Toubro Infotech** as Senior Software Engineer
Feb 2015 to Sep 2019

Growth Path: 2015 as Software Engineer || 2019 as Sr. Software Engineer
Highlights:

Authored, reviewed & approved CSV deliverables Validation Project Plan, URS, TM, IQ, PQ, UAT (Plans, reports), release statements

Gathered requirements, compiled project documentation, facilitated workshops to agree on scope and schedules, developing project plans for validation project

Managed end-to-end delivery cycle, requirement gathering, validating, analyzing, estimating, designing, developing, testing the solutions and creating high level and low level design documents

Interacted with customers to understand the requirement, analyze, design and implement the solution based on the given requirement

Collaborated with business & IT across all phases of software development life cycle

Delivered training & guided business users to use the new tool Cincom post migration from legacy system

Assisted in data migration from Legacy System Cameleon to new system Cincom

Proposed & formulated new value additions and process improvements to reduce the business process time and improve the quality for delivery of products on Assembly Line which was appreciated by Business Users

Bagged Excellent Customer Service Delivery Award for Cincom Support in 2017

Education

UG: **B.Tech/B.E. (Electronics/Telecommunication)** from **Chameli Devi Group of Institutions, RGPV** in **2014**

IT Skills

Skill Name	Version	Last Used	Experience
QDOC			
ValGenesis			
BMC Remedy			
MySQL			
CINCOM			
CAMELEON			
AWS			

Languages Known

Language	Proficiency	Read	Write	Speak
english				
hindi				

Affirmative Action

Category: **General**

Physically Challenged: **No**

Work Authorization

Job Type: **Permanent**

Employment Status: **Full time**