



GROUP
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JOB DESCRIPTION

ROLE: Validation Engineer / Manager

SALARY AND BENEFITS: Negotiable

REPORTS TO: Head of Regulatory Special Projects

LOCATION: Vadodara

PRIMARY RESPONSIBILITIES:

This job exists to manage implementation of strategic computer systems such that they are validated in accordance with company and regulatory requirements and are maintained in accordance with those requirements.

SECONDARY RESPONSIBILITIES:

- Preparation and approval of validation documentation or management of the process (fulfilling the Quality Assurance role) in accordance with the relevant processes (e.g. Quality Management System).
- Planning and managing validation of high cost, complex, strategic systems using risk based approaches to ensure systems are fit for purpose, that significant risks are identified and mitigated, and that the approach and rigor of validation is in proportion to the risks the systems present to regulated business processes.
- Ensuring completion of Periodic Compliance Review activities and negotiating the required corrective actions.
- Validation planning for projects including project interaction with IT, software suppliers, and outsource companies.
- Project problem resolution/avoidance – this typically involves ongoing interaction with IT Managers/Directors, site Validation Managers and senior management of suppliers.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES:

- Managing the deployment, maintenance and inspection support of multiple (3-7) global projects including responsibility for the developing solutions that maintain compliance and keep validation on schedule and on budget.
- Managing Contingent Workers assigned to project activities including budgeting and managing the collection of data for the assigned KPIs and Service Level Agreements.
- Forecasting of project costs.
- Providing Compliance oversight and training to internal and external suppliers, e.g., IT teams outside GMS and globally sourced providers, as applicable.
- Minimise project costs with efficient planning and timely resolution of issues whilst ensuring compliance.