1. ELIGIBILITY & SKILL SET

KEY BEHAVIOURIAL COMPETENCIES
Follow Code of Ethics set by the company
Be Punctual
Ability to work under pressure and withstand stress
Demonstrate Professionalism
Willing to take tough (non-populist) measures when required, Separates Professional and Social relations)
Ability to plan sub tasks very well based on an activity allocated
Ability to establish measure and meet customer requirements / service level agreements.
Effective written and verbal communication skills in English Language.
Shall have to travel & visit at any site as per project requirement.
Must be able to work in varying hours/days.
shares knowledge and expertise so others can learn and benefit
Recognizes own strengths and weakness and uses this knowledge to aid affective teamwork
Acknowledges other's skills and accomplishments
Resolving differences
Communicates thoughts and feelings to promote discussion and prevent escalation of conflict.
Express disagreements and feedback constructively
Listen to others point of view
Works towards joint solutions both inside and outside the team
Takes independent and immediate actions to solve problems and help others
Keeps pace with high volumes of work when necessary
Adapts to work style and priorities of others
Tracks progress and task and redirects effects to ensure deadlines and quality standards are met
Anticipates bottlenecks and takes actions to prevent problems
Fosters an environment of support and cooperation amongst all staff
Appreciates other contribution
SOFTWARE COMPETENCES
Microsoft Word
Microsoft Excel
Microsoft Project
Microsoft PowerPoint
AUTHORITIES (other than Routine Task, Roles & responsibilities)
Prepare/ Check Internal Policies, Standard operating procedures, Standard Design Guidelines

2. ROLES & RESPONSIBILITIES

ROLE/RESPONSIBILITIES (related to routine task)
Comprehend and implement internal standards & Guidelines while delivering any job task
Prepare/Review GMP documents (VMP, RA, URS) as per the international regulatory requirement for following equipment and systems of Oral Dosage, Injectable and Biotech formulation facility.
• Process equipment.
• HVAC system.
• Clean utility systems.
Prepare Qualification protocols (DQ, IQ, FAT, OC, PQ) as per the international regulatory requirement for following equipment and systems of Oral Dosage, Injectable and Biotech formulation facility.
• Process equipment.
• HVAC system.
• Clean utility systems.
Prepare/Review Commissioning Protocols/checklist for Utilities
Standardization of validation documents.
Supervise/witness qualification process at site.
Compile Final Validation documentation package.
Perform and support QA functions of Department
Plan subtask for self and subordinates and remain accountable for overall manhour expenses.
Conduct FAT, inspection of set-up / prepare Gap analysis report for core area of competence.
Conduct GxP Audits
Routine Correspondence with clients and all project stake holders effectively & impressively
Internal Correspondence (written) within department
Independently Clarify Client queries/comments technically in line with the regulatory / Standard international/ local guidelines
Project Monitoring & Control
Prepare and submit monthly Reports
Activity & resource Planning
Billing as per projections
Set PBIS/KRA for team
Identify training need for the team members and develop them for scope services
Keep the team motivated and remain responsible for team performance
TECHINCAL SKILLS / COMPETENCES
Knowledge and understanding of International Regulatory Guidelines and Regulatory requirements for CQV (USFDA, EU, ISPE, ICH etc.)
Experience of preparing qualification protocols for API, Oral Dosage, Injectable and Biotech formulation
Basic understanding of the following equipment and systems of API, Oral Dosage, Injectable and Biotech formulation facility from qualification point of view.
• Process equipment.
• HVAC system.
• Clean utility systems.
Experience of leading a team
Read and understand isometric, P&ID and as built drawings.