**JOB DESCRIPTION**

**1. PURPOSE OF THE JOB:**

**Job Context:** To lead and manage the strategic and operational performance of the Quality department, ensuring thesuccessful delivery of business objectives, whilst adhering to regulatory compliance and achieving business success.

**Challenges:**

To ensure the efficient and effective day to day running of the department.

**2. DETAILS OF THE JOB:**

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| **Designation & Job :** | India Quality Head | **Level :** | 13A |
| **Business Unit :** | 269 | **Function :** | CQA |
| **Country :** | India | **Work Location :** | Greater Noida |
| **Reporting Manager:** | Head Quality - Pharma | **Manager’s Manager:** | SVP & Head of Global Quality - Pharma |
| **Matrix Manager:** | NA | **Team Size :** | 25 |
|  |  | **Direct Reportees :** | 5 |
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**3. KEY ACCOUNTABILITIES:**

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| **Accountabilities Scope of work** | |
| **Establishment and Implementation of Quality Systems** | * Developing and implementing Quality department’s strategy, to ensure it meets business requirements. * Ensuring development of departmental SOPs in accordance with all Compliances. * Monitoring implementation of all systems to ensure all activities are performed in accordance with GMP, and other regulatory requirements - to ensure 100% customer satisfaction. * Design quality systems/SOPs to support external Mfg activities. * Strengthening GLP in R&D I, II & IV and establishment of Quality systems for cGMP area in R&D IV. |
| **Audit, Compliance & Approval** | * Leading customer and regulatory audits/inspections, as required.   + US-FDA, MHRA, ANVISA and other countries regulatory audit/compliance & approval of the regulated plant (Nanjangud, Roorkee & BE centre). * Acting as the main point of contact on all Quality matters with external agencies. * Maintaining and improving departmental operational performance, to meet the quality requirements of regulatory authorities, company SOPs and external and internal Customers.   + To ensure BMR/BPR compliance at Nanjangud and Roorkee for better regulation compliance.   + Ensure 21 CFR part 11 compliance at Nanjangud and Roorkee. * Ensuring appropriate investigation of discrepancies, errors, complaints, failures, in case any. |
| **Training & Development** | * Facilitate training to ensure development of all the employees on knowledge & understanding of documentation\CAPA\cGMP concepts\RA guidelines etc. * Strengthen & drive the culture of quality at manufacturing units & R&D by training & other interventions. * Managing, motivating, coaching and mentoring teams, to higher levels of management capability. |
| **Planning and Budgeting for quality** | Preparing and justifying the Quality department’s budget.   * Drive planning & budgeting process for Quality at Roorkee, Nanjangud & BE centre. |
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**4. KEY INTERFACES :**

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| **External Interfaces** | **Internal Interfaces** |
| Regulatory & other Govt. agencies (both national & international) | Manufacturing, R&D, Regulatory Departments |

**5. EDUCATION & EXPERIENCE :**

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| **Education Qualification(Highest )** | M.Sc / M.Pharm / Ph.D |
| **Desired Certifications :** | -- |
| **Experience Range :** | 20 to 25 Years |
| **No. of years post Highest Qualification :** | 20 Years |
| **Desirable experience :** | Industrial Experience |
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**6. SKILLS REQUIRED:**

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| **Skills** | **Description** |
| **Functional Skills** | Strategic thinking  Strong analytical and problem solving ability.  Excellent attention to detail  Excellent hold on Regulatory Standards |
| **Behavioral Skills** | Strong leadership/team management skills  Strong Communication & Interpersonal Skills  Ability to persuade |