JD – Plant Head (Sterile Injectables)

Position

Plant Head – Sterile Operations & Compliance

Experience

18–25 years of progressive leadership experience in sterile pharmaceutical manufacturing with exposure to:

- Sterile liquids, lyophilized injectables, dry powder injectables
- Oncology, hormones, beta-lactam/antibiotics and high-potent products
- Manufacturing Operations, Quality Systems, Engineering, Validation and Tech Transfer
- Regulatory-approved facilities catering to US, EU and other regulated markets

Mandatory exposure to:

- USFDA, EMA, MHRA, PIC/S and WHO-GMP inspections
- Greenfield/Brownfield sterile projects
- Aseptic manufacturing and contamination control strategy implementation

Educational Qualification

B.Pharm / M.Pharm / M.Sc. / B.Tech (Chemical/Pharmaceutical Engineering preferred)

Key Responsibilities

Strategic & Operational Leadership

- Lead end-to-end plant operations including Production, Engineering, Warehouse, Utilities, Maintenance, EHS and Compliance functions.
- Drive operational excellence through productivity improvement, cost optimization, capacity enhancement and lean manufacturing initiatives.
- Ensure uninterrupted manufacturing operations with high equipment uptime, robust maintenance systems and effective resource utilization.
- Establish manufacturing strategies aligned with business growth and regulatory expectations for global markets.

Regulatory Compliance & Quality Systems

- Ensure sustained compliance with current cGMP requirements of USFDA, EMA, MHRA, PIC/S and WHO.

- Lead and manage regulatory inspections, customer audits and corporate audits with strong compliance outcomes.
- Drive implementation of Contamination Control Strategy (CCS), Quality Risk Management (QRM), Data Integrity and Quality Culture initiatives.
- Ensure effective investigation systems for deviations, OOS/OOT, CAPA, change control and risk assessments.

Sterile Manufacturing & Technical Oversight

- Provide technical leadership for aseptic processing, lyophilization, terminal sterilization and visual inspection operations.
- Support technology transfer, process validation, cleaning validation, media fills and continued process verification activities.
- Oversee qualification and lifecycle management of equipment, utilities and computerized systems.
- Ensure implementation of robust environmental monitoring and sterility assurance programs.

Projects & Engineering

- Lead expansion projects, facility upgrades and new line implementation as per USFDA and EU GMP expectations.
- Drive automation, digitalization and operational efficiency initiatives across plant operations.
- Review and approve URS, qualification protocols, layouts and engineering change proposals.

People Leadership

- Build and mentor high-performance cross-functional teams.
- Strengthen GMP and technical capability through structured training and succession planning.
- Foster a culture of compliance, accountability and continuous improvement.

Desired Competencies

- Strong knowledge of Annex 1, aseptic processing and sterile manufacturing regulations
- Proven experience handling regulatory inspections independently
- Expertise in quality systems, validation and manufacturing science
- Strong leadership, decision-making and stakeholder management skills
- Exposure to SAP/ERP and digital manufacturing systems preferred