

JOB DESCRIPTION

ROLE: Team Leader: Technology Transfer - F&D

SALARY AND BENEFITS: Negotiable

REPORTS TO: Sr. Manager – F&D

LOCATION: Baroda, India

PRIMARY RESPONSIBILITIES:

- Lead a team of technology transfer, monitor and track the scale-up and technology transfer activities - initiation, planning, execution, monitoring of Scale-up/Optimisation /Validation batches for new and existing projects.
- To evaluate gap analysis, risk assessment before start of technology transfer activities for site readiness.
- Give technical and functional input to team for scale-up and technology transfer of solid, semi-solid and liquid dosage forms.
- Sound technical knowledge on Scale-up of different dosage forms and familiar with all the equipments & processes.
- Trouble shooting and optimization of process parameters to minimize risk during tech transfer. Deep understanding of processes, functions, technologies, materials and equipment(s).
- Coordinate with cross-functional departments like purchase, QC/ADL, Production/F&D, QA and RA for smooth technology transfer and filing of the products.
- Documentation - preparation and review of documents like MFR, MPR, PVP, PVR, Sampling protocol, cleaning validation, Stability protocol, Hold time study protocol, Product specifications etc. as per regulatory requirements.
- Preparation of response to regulatory agency queries relevant to technology transfer.
- Knowledge of cGMP, GDP, ICH, EMA and SUPAC guidelines.

SECONDARY RESPONSIBILITIES:

- Scale-up lab management.
- Arrangement of materials and resources necessary for scale-up and technology transfer activities.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES:

- 6-9 years of experience in scale-up and technology transfer of products for regulated markets.
- Should have leadership skills.
- Sound knowledge on trouble shooting, process optimisation and documentation as per regulatory requirements.
- Knowledge of cGMP, GDP, ICH, SUPAC guidelines and well versed with challenges of regulatory requirements for new products approval and post approval changes.
- Good oral and written communication skills.