

JOB DESCRIPTION

ROLE: Research Scientist: Technology Transfer - F&D

SALARY AND BENEFITS: Negotiable

REPORTS TO: Sr. Manager – F&D

LOCATION: Baroda, India

PRIMARY RESPONSIBILITIES:

- Scale-up/ Optimisation /Validation batches execution and monitoring of solid, semi-solid and liquid dosage forms.
- Evaluation of gap analysis, risk assessment before start of technology transfer activities for site readiness.
- Batch size calculations, Selection of equipments for Scale-up/ Optimisation /Validation batches.
- Documentation - preparation of documents like MFR, MPR, PVP, PVR, Sampling protocol, cleaning validation, Stability protocol, Hold time study protocol, Product specifications etc. as per regulatory requirements.
- Trouble shooting and optimization of process parameters to minimize risk during tech transfer.
- Understanding of processes, functions, technologies, materials and equipment(s).
- Coordinate with cross-functional teams like purchase, QC/ADL, Production/F&D, QA and RA for smooth technology transfer and filing of the products.
- 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.
- Maintenance of inventory for Scale-up/ Optimisation /Validation batches.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES:

- 2-4 years of experience in scale-up and technology transfer of products for regulated markets.
- Preparation of scale-up documents like MFR, MPR, PVP, PVR, Sampling protocol, cleaning validation, Stability protocol, Hold time study protocol, Product specifications etc. as per regulatory requirements.
- Sound knowledge on trouble shooting, understanding of processes, functions, technologies, materials and equipments. Proven hands on experience.
- Good oral and written communication skills.