

MANAGER, QUALITY SYSTEMS

The Manager of Quality Systems must have experience in current Good Manufacturing Practice (cGMP) quality systems related to API and the drug product. The candidate must also have demonstrated skill sets in quality systems requirements to ensure compliance to Good Laboratory Practice (GLP) in support of company sponsored non-clinical studies and Good Clinical Practice (GCP) in support of company sponsored clinical studies.

He/she is responsible for maintaining, enhancing and at times developing quality programs and systems such as day to day quality activities, employee training, vendor assessment, deviation and investigation follow-up and closure as well as trending and tracking of quality documents.

Key responsibilities for this role include:

- Oversees generation and review of documents used in GXP systems.
- Experience and an understanding in analytical laboratory data and systems
- Oversees the implementation and maintenance of QM systems and activities.
- Responsible for ensuring that the organizations manufacturing practices, quality systems, policy and procedures related to quality and compliance meet all Federal, State, EU and Onconova standards.
- Reviews and approves investigations of production or quality management problems and/or recommends corrective action.
- Review and release of production batch records to assure that no errors have occurred and if errors have occurred they have been fully investigated and corrected.
- Review new regulations in a timely manner and perform and/or assist system owners in performing gap analysis and revisions to current systems.
- Responsible for conducting root cause analysis investigations, batch record review and change control management.
- Establish, compile, review and trend quality metrics for Onconova and third party contractors for CAPA, deviations and investigations, change control, training, etc.
- Participate in regulatory inspections and maintain a working knowledge of worldwide regulatory requirements.
- Understanding of process validation and technology transfer requirements
- Communicate project objectives and risks to senior management in a clear and timely manner

EXPERIENCE AND QUALIFICATIONS:

A Bachelor's degree with a preference for a concentration in Pharmaceutical Sciences field.
5 years of relevant and current work experience with a working knowledge of the pharmaceutical industry and drug development process.

Strong knowledge of FDA, EU, and ICH Regulatory requirements and guidelines specific to the areas of product quality, cGMP, GLP and GCP regulations.

Strong knowledge of cGMP quality system requirements for parenteral and solid dosage forms.

Demonstrated development experience on Phase 3/Commercial drug product desirable
Experience with PAI would be a plus. Intermediate to advanced experience with MS Project as well as other MS Office software preferred