Position Title:	**Vice President, Quality Assurance**
Department:	**Quality Assurance**

POSITION SUMMARY

The Vice President, Quality Assurance is responsible for ensuring that personnel, methods, corporate policies and SOPs comply with local, state, federal and country specific requirements as applicable, and GXP regulations/requirements. The Vice President will serve as the Head of Quality Assurance at TRACON Pharmaceuticals, Inc.

RESPONSIBILITIES AND DUTIES

- Provide GXP Quality Assurance, including QA oversight of vendors, SOPs, and document control systems.
- Responsible for the approval, release, and maintenance of manufactured drug batch records.
- Responsible for OOS and product complaint investigations and GXP archives.
- Ensure training programs throughout TRACON meet GXP and ICH requirements.
- Direct development and implementation of quality systems to ensure product reliability, quality, efficacy, compliance to applicable TRACON SOPs, GXP regulations and applicable country specific standards.
- Oversee compliance auditing program to fulfil regulatory requirements.
- Ensure CAPA findings from audits and regulatory inspections are effectively investigated and closed out.
- Provide expertise and guidance to departments in interpreting and implementing governmental and agency guidelines to assure compliance.
- Follow applicable regulations, including FDA, ICH, GXP, and TRACON policies and procedures.
- Ensure that quality contractors and consultants have completed the training necessary for their assigned responsibilities.
- Ensure that electronic records, electronic signatures and computer systems supporting GXP functions are compliant with 21 CFR 11.

REQUIREMENTS

- Bachelor's degree, Master's degree or PhD in science, pharmaceutical sciences or related field.
- Minimum of 15 years doing drug development in the pharmaceutical industry with at least 10 years of experience in Quality Assurance.
- Thorough knowledge of GMP, GCP and GLP regulations.
- Understanding of 21 CFR 11 regulations.
- Experience with establishing and/or maintaining GXP quality systems to support clinical development.
- Experience in identifying, writing, evaluating and closing CAPAs.

- Experience with conducting and managing internal and external audits.
- Preferred experience with complex biologics, Phase 1 through 3 stage product development. Technical knowledge of analytical method qualification, process validation and establishing product specifications.
- Experience with outsourced manufacturing and testing operations (prefer experience with both biologics and small molecules).
- Experience in working in compliance with US, EU and ICH GMP requirements, experience reviewing submission documentation, responses to regulatory inquiries and inspections.
- Excellent oral and written communication skills
- Strong interpersonal skills to effectively communicate with teams, peers, management and external contacts.
- Working knowledge of MS Office products including Word, Excel, Outlook, PowerPoint, and Project
- Comfortable in a fast-paced small company environment with minimal direction and able to adjust workload based upon changing priorities.