

Pinnacle 21 is an established startup that builds software to streamline the drug approval process, bringing life-saving medicines to patients faster.

Quality Assurance Manager

At Pinnacle 21, we are always looking for exceptional team members. Our company and team are still in its earlier stages, meaning you will be crucial to shaping the future of company's Quality and Compliance systems. As we plan to make a lasting impact on the pharmaceutical industry we're looking for a motivated member to take part in continuing to foster one of the top companies in Philadelphia!

Work that matters Our teams work with the pharmaceutical industry to streamline the drug approval process, bringing life-saving medicines to patients that need them. We need to ensure everyone is informed, educated, and in sync to allow for a seamless and collaborative work experience.

Work autonomously Enjoy an autonomous environment, where we'll support your continuous improvement and foster your capabilities to manage ownership of multiple areas and projects in order to continually grow your skillset.

Global footprint We support a community of users from countries across the world that widely regard our software as the industry standard for clinical submission preparation.

What you'll be doing

Our QA team is responsible for quality assurance, quality control, and compliance operations at Pinnacle 21. The QA manager will establish quality plans and policies and report to senior management on a regular basis on compliance activities and findings. They will design, implement, and maintain QA and compliance programs including the quality infrastructure (SOP system, training program, and internal/external audit coverage). The QA manager will establish, maintain, and ensure effectiveness of quality programs and documentation to assure compliance in a GxP regulatory environment.

- Develop, author, and approve Pinnacle 21 Quality Process Documentation
- Provide GxP Quality Assurance oversight of vendors and maintain quality agreements

- Responsible for reviewing and approving all validation deliverables. As well as approving the test scripts.
- Responsible for reported non-conformances, deviations, and manage product complaint investigations and GXP archives.
- Ensure training programs meet GXP requirements.
- Direct development and implementation of quality systems to ensure product reliability, quality, efficacy, compliance to applicable Pinnacle 21 SOPs, GXP regulations and applicable client specific standards.
- Oversee compliance (GMP and GCP) 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 Pinnacle 21 departments in interpreting and implementing governmental and agency guidelines to assure compliance.
- Follow applicable regulations, including FDA, ICH, GXP, and Pinnacle 21 policies and procedures.
- Ensure that direct reports and consultants have completed the training necessary for their assigned responsibilities.
- Represent QA at project team meetings
- Provides Quality Assurance input to Company strategic goals in form of schedules, quality plans, and budgets.

What we're looking for

Must

- Demonstrable knowledge of international GMP regulations and guidelines, industry practices, and experience implementing Quality systems in a regulated environment
- Experience in managing and implementing a full software development life cycle
- Working knowledge of GLP and GCP international regulations
- Ability to critically review various types of internal documentation
- Outstanding written and verbal communication
- Excellent project management and leadership skills
- Anticipate and resolve issues independently with the understanding of when to seek assistance
- Strong attention to detail, organization and time management skills
- Ability to work as a team player with multi-disciplinary project teams

- Proficiency in Office 365 and other commonly used business solutions
- Minimally a BS degree in STEM, Masters preferred

Plus

- Prior experience within a growing software company
- Prior experience within Clinical Trials or Life Science industry

A bit about us

Pinnacle 21 is a startup making a big impact on regulatory review processes. Our flagship software provides the biopharmaceutical industry with the key to a fast, efficient drug review process. It's this technology that drives FDA's 21st Century Review Initiative, ensuring that submission data is compliant, useful and ready for review — which enables a more efficient review process. Our Great Place to Work certified workplace is constantly looking for new, motivated team members to come help us revolutionize clinical trials.