POSITION SUMMARY
Proactively assesses Quality Assurance and related compliance issues and risks in all operational areas for Reata (the “Company”). Provides strong leadership and expertise toward the establishment and maintenance of the quality and related compliance standards of the Company throughout the complete value chain of GXP activities. The incumbent will provide overall leadership and strategic development for the Quality Assurance function embracing applicable international standards. Building upon existing quality processes and established quality systems, the incumbent will proactively support collaboration and compliance across an extended alliance and external partner services provider network. S/he will develop, implement and communicate a clear strategic vision to maximize employee quality focus, while maintaining a strong independent role for compliance-related decisions and quality systems imperatives. The incumbent will review existing policies and procedures, identify gaps consistent with a graded approach based on the clinical stages of products under development, and support operational departments in developing and communicating new and enhanced policies and procedures. Finally, the incumbent will provide compliance support and advice to all aspects of the Company’s business activities and providing continuous improvement of processes regarding review of promotional and advertising materials, as required.

RESPONSIBILITIES
Additional representative responsibilities will include, but not necessarily be limited to, the following:
- Develop a robust quality system, foster best practices, and mentor and consult on Quality / Compliance techniques across the organization.
- Provide overall leadership for GXP compliance and establish comprehensive processes and systems that ensure compliance and that support collaboration while enabling developmental flexibility.
- Develop strong working relationships with key stakeholders, both within and outside the Company.
- Oversee all quality matters within the Company, including site activities such as GMP oversight of CROs and CMO, internal and external clinical trial GCP oversight and GLP study oversight, as applicable. Ensure personnel, process, documentation, and quality standards meet expectations for regulatory submissions, regulatory authority inspection readiness, and compliance with applicable guidelines.
- Revise and/or formulate quality and compliance policies in coordination with corporate management; ensure that all required systems and standard operating procedures are in place and current.
- Lead change in the organization to continuously adapt to a dynamic business environment; apply learning to enhance organizational performance.
- Perform monitoring and audits of Company operations and business environments to identify potential compliance risk areas; recommend and assist with the implementation of enhancements to existing policies and procedures and other corrective actions.
- Develop and maintain effective working relationships with stakeholder functions; foster an environment of collaboration, trust, quality, innovation, and continuous improvement within the compliance organization and between other functional departments.
- Identify and assess quality risks and ensure they are evaluated and managed appropriately in order to accomplish both business goals and regulatory and quality requirements.
- Develop and administrate budgets, expenditures and the allocation of resources for various compliance and external auditing / vendor qualification projects.
SENIOR DIRECTOR, QUALITY ASSURANCE

- Ensure meaningful quality agreements with key services providers are established and adhered to.
- Identify emerging trends / changes and redesign processes and practices accordingly.

CORPORATE COMMITMENTS
- Demonstrate commitment and support for company goals, objectives, and procedures.
- Represent the Company by developing collaborative relationships with site personnel, colleagues and vendors.
- Demonstrate professionalism and adherence to moral, ethical, and quality principles.
- Participate in corporate and departmental meetings.
- Comply with applicable regulations, GCP, and corporate policies and procedures.

QUALIFICATIONS
- Minimum BA / BS or equivalent scientific degree is required; an advanced degree is preferred.
- A minimum of 10 years of pharmaceutical industry experience in roles of increasing quality assurance responsibility.
- A “hands-on” self-starter with considerable managerial / leadership experience and a demonstrated ability to interact with various levels of management to accomplish goals and objectives.
- Appreciation for all aspects of the pharmaceutical business, from research through sales and marketing, with the ability to operate cross-functionally and/or globally to achieve Company goals.
- Comprehensive knowledge of GXP and other regulations for pharmaceuticals, along with an understanding of global quality standards and regulatory authority inspection trends in relation to product development, submission, and commercialization.
- Demonstrated ability to provide leadership for key strategic issues and significant quality policies, practices, and processes.
- Demonstrated ability to anticipate, proactively respond to trends and/or shifts in the external environment (e.g., regulatory, business partner relationships, industry standards).
- Excellent strategic skills with the ability to influence decisions at a senior level, both internally and externally.