POSITION TITLE	**HEAD OF QUALITY ASSURANCE**
REPORTS TO	**VP REGULATORY AFFAIRS & QUALITY ASSURANCE—DOTTED LINE TO CEO**
MANAGES	**CLINICAL AND MANUFACTURING QUALITY ASSURANCE & COMPLIANCE**
LOCATION	**MONTREAL, QUEBEC, CA OR CHARLOTTE, NC**

DUTIES AND RESPONSIBILITIES

- Together with Sr. Management, drives a culture of quality throughout the organization;
- Defines globally-coordinated clinical/CMC quality assurance and compliance objectives, quality assurance systems, quality agreements, training programs and policies;
- Organizes, manages and evaluates all clinical/CMC vendors and clinical sites;
- Ensures compliance with relevant Company, local law and regulatory authority requirements;
- Evaluates clinical/CMC audit findings and responds to these findings with process and procedure improvements that drive quality system efficiency and effectiveness;
- Performs risk assessment and supports risk-based decision-making regarding projects and resources;
- Provides clinical/CMC quality assurance expertise, coaching and mentorship to all operating groups through active participation in cross-functional teams;
- Provides clinical/CMC quality support and assistance to Regulatory Affairs;
- Maintains relationships with regulatory authorities and provides support to answering Regulatory (FDA, EMA, etc.) questions/comments during filing review;
- Provides support to internal and external Company initiatives as required, including participation in due diligence processes, R&D development programs, and third-party sourcing;
- Participates in the development and implementation of processes methods, procedures and regulations necessary for the efficient operation of the department; and
- Able to travel as needed, and participate in audits as required, within North America and abroad.

EDUCATION, BACKGROUND, KNOWLEDGE AND SKILLS

- Fifteen (15) plus years of pharmaceutical industry experience in quality assurance;
- Advanced degree preferred (M.S. or Ph.D.) in Life Sciences, or equivalent;
- Experience as a GxP leader for a drug development program (including Phase II studies);
- Extensive knowledge of global GMP, GCP and GLP;
- Proficiency with: pharmaceutical product development and clinical study processes, quality assurance and compliance techniques and U.S. and European regulations;
- Small company experience utilizing a highly outsourced model;
- NDA filing and approval experience highly preferred; and
- Experience with matters of Corporate Commercial Compliance is a plus.

KEY ATTRIBUTES

- An ethical, resourceful, confident professional with strong problem/conflict solving, verbal and written communication and interpersonal/team skills;
- A natural partner and educator with the capability to firmly enforce standards;
- Strong initiative and organizational skills with the ability to multi-task and prioritize assignments; and
- Demonstrated ability to identify and resolve issues, meet deadlines and manage crises.

Milestone Pharmaceuticals is an equal opportunity employer