

Regxia Inc. – Job Posting

Position Title: Senior Regulatory Project Manager

Job Type: Fulltime, continuing Vaughan, ON & Virtual

**Reports To:** President, Vice President, General Manager

### **Organizational Overview**

Founded in 2007, Regxia is a unique scientific, regulatory and e-publishing consulting firm serving the pharmaceutical and biotechnology industries. At Regxia, the client is our primary focus. Taking a collaborative approach to every initiative, we deliver high quality customized solutions that foster long-term client relationships. The Regxia team prepares, adapts and submits dossiers and lifecycle eCTD submissions to the FDA and Health Canada. Working predominantly with SME and virtual companies, we handle the full regulatory lifecycle of our clients' novel and/or generic products as their surrogate regulatory and quality departments. Regxia maintains a core team of cross-functional regulatory, quality and e-Publishing experts capable of thinking critically, finding fresh and innovative ways to approach submission strategy. Regxia is poised for growth and we are seeking a highly motivated, experienced, knowledgeable and growth-minded Senior Regulatory Project Manager to join our management team.

#### **Position Overview**

Regxia Inc. requires a highly motivated, experienced, and growth-minded Senior Regulatory Project Manager to join our management team. Reporting directly to Regxia's Executive Team, this individual will be directly responsible for overseeing and providing leadership for the successful operations of Regxia's Regulatory, ePublishing, and Quality departments. This individual will be responsible for planning, execution, tracking, and delivery of all projects. Key to this position will be the evaluation, modernization, and formalization of Regxia's project management systems and alignment of departmental activities, policies and procedures to support achievement of organizational goals. General duties will include monitoring departments to ensure they are meeting project timelines, objectives and deliverables, working collaboratively with the Executive team, staff and clients/external partners, providing regular status updates to all project stakeholders, and performing other related duties as assigned. This position requires an individual with strong analytical and critical thinking, who is flexible and resourceful to deliver solutions and solve problems creatively.

## **Essential Functions and Responsibilities**

- Lead the evaluation, modernization, and formalization of the project management system.
- Facilitate functional project management activities.
- Support and assist cross-functional teams in preparing, and/or reviewing regulatory submissions.
- Manage assigned projects and staff, ensuring effective teamwork, high standards of work quality and organizational performance.



- Establish and maintain a productive working environment.
- Monitor and evaluate departmental and staff performance against goals and job / project descriptions.
- Work with business development and marketing to further develop Regxia's brand and client portfolio for regulatory and quality services, while assisting with improved quoting and invoicing for projects.
- Develop and implement new business strategies for creating or improving processes, procedures, and budgets to improve corporate performance.
- Other duties as assigned by management.

# **Employment Requirements**

- B.Sc. or equivalent post-secondary education in a science related field.
- 10+ years of combined Regulatory Affairs, Project Management related experience with relevant increasing responsibility.
- Experience managing project lifecycle from inception to completion for multiple complex, small and large-scale projects.
- 5+ years of progressive team management experience including management of multiple layers of staff.
- Ability to plan and prioritize activities across multiple projects to complete projects according to outlined scope, budget and timelines.
- Considerable experience building, leading, and providing work and performance direction to teams in a multi-disciplinary environment.
- Excellent command of the English language, both oral and written is mandatory.
- Proficient with MS Office Suite, Adobe Acrobat, and MS Project, Jira Core, or similar project management software.
- Experience with ePublishing software considered an asset.
- Project Management Professional (PMP) certification considered an asset.
- Post-graduate certificate in Regulatory Affairs is considered an asset.
- Understanding of business transformation in a private organization is an asset.

## **Compensation and Benefits**

This position offers a unique opportunity to join the management team during a period of growth. Regxia offers competitive salary and benefits programs including paid extended health and dental, educational assistance funding, and paid vacation, sick, and appointment leave.

### **How to Apply**

Candidates interested in applying for the position of Senior Regulatory Project Manager should submit their resume and cover letter (detailing specific relevant experiences) to Attn: Cameron McGregor, Human Resources at <a href="mailto:hr@regxia.com">hr@regxia.com</a>

Only candidates selected for an interview will be contacted.