Senior Director, Regulatory Solutions

This is a high-impact leadership role, ideal for a regulatory expert looking to shape and drive regulatory strategy in a dynamic and fast-paced environment

We are seeking an experienced and strategic regulatory affairs leader to drive global regulatory strategies and submissions, ensuring compliance with EMA, FDA, MHRA, and other regulatory agencies. The ideal candidate will bring a strong balance of high-level strategic vision and hands-on execution, with expertise in regulatory strategy, submissions, and agency interactions. This role requires exceptional leadership, project management, and collaboration skills to guide cross-functional teams in achieving regulatory milestones efficiently.

Key Responsibilities

- **Delivery and Regulatory expertise**
  - Develop and execute comprehensive regulatory and product development strategies across all phases, aligning with FDA, EMA, MHRA, and other agency requirements
  - Lead and mentor a team of regulatory affairs professionals, ensuring compliance with technical and quality standards for regulatory submissions
  - Provide strategic oversight and hands-on support in the preparation of regulatory submissions, including IND, NDA, MAA & ANDA
  - Help clients design effective regulatory strategies for getting products to market, including advice on clinical trial design, approval pathways, and potential regulatory challenges
  - Monitor regulatory changes and industry trends that could impact the client's products or regulatory filings
  - Act as a trusted advisor, ensuring the client's regulatory approach is aligned with industry standards and best practices.
  - Provide gap assessment strategies per eCTD requirements, while exhibiting knowledge of working across different RIM tools and module specific repositories
  - Act as a key point of contact for regulatory agency interactions, providing expert guidance on global regulatory requirements, expectations, and best practices
- **Project Oversight and management**
  - Collaborate with internal stakeholders, including regulatory teams, subject matter experts, and external sponsors, to ensure high-quality and timely deliverables in line with project budget and scope
  - Establish efficient workflows, timelines, and project management strategies to ensure timely and high-quality regulatory solutions
  - Identify potential regulatory risks and proactively develop mitigation strategies to address challenges in project execution and resource allocation
  - Plan timely invoicing and time tracking per project requirements

- **Line Management and career planning**
  - Oversee staff development, coaching, and strategic resource planning to optimize team capabilities and growth
  - Develop appropriate training protocols per business requirements
  - Execute and develop hiring plans per business objectives
- **Client Relationship management**
  - Participate in client engagements, including project scoping, proposal development, bid defence meetings, and account planning
  - Collaborate with business development and customer acquisition teams to identify and capitalize on new business opportunities
  - Build and maintain strong, long-term relationships with key stakeholders at client organizations
  - Act as the lead liaison between the client and the service provider, ensuring smooth communication and that the client's needs are addressed promptly

    - Ensure high levels of client satisfaction, which can lead to repeat business and referrals
- **Initiatives and innovation**
    - Contribute and further thought leadership agenda
    - Collaborate with internal and external teams to develop specific client solutions addressing unique drug development challenges within Regulatory, R&D or market access

Qualifications & Skills

- Master's degree in a scientific discipline required; advanced degree (M.Pharm./MSc, PhD) preferred
- 10+ years of regulatory affairs experience in the life sciences or consulting industry; prior experience in a CRO or consulting environment is highly desirable.
- 6+ years of leadership and people management experience within clinical and/or non-clinical regulatory functions
- Proven track record in regulatory submission preparation, including IND, NDA, MAA, and CTD, with expertise in eCTD and electronic submission processes.
- Strong understanding of global drug development regulations, lifecycle management, compliance, and business systems technology
- Experience with Regulatory intelligence tools like Cortellis, Tarius etc.
- Proficiency with project management tools and software such as MS Project, Office Timeline, SharePoint, and OneNote
- Excellent verbal and written communication skills with the ability to develop compelling regulatory narratives and deliver impactful presentations.
- Demonstrated ability to work cross-functionally, collaborate with internal and external stakeholders, and drive regulatory excellence