Senior Reg Affairs Specialist

About the Job

The Senior Regulatory Affairs Specialist is responsible for supporting regulatory activities associated with the registration of Eirgen/OPKO human and veterinary products across global markets, including the US, EU, and Japan. The role also includes acting as a Regulatory Compliance liaison with project teams for both already registered products and new product development.

The specialist will coordinate the delivery of project plans and milestones in line with agreed timelines and support the tracking and reporting of key departmental performance metrics. The role involves mentoring and supporting members of the Regulatory Affairs team and wider project teams on designated projects, providing guidance to ensure high-quality regulatory submissions and effective project execution.

Your areas of responsibility will include:

Project Planning & Coordination

- Actively plan regulatory requirements to ensure major milestone targets for each product are visible to all team members and key stakeholders, supporting on-time market entry.
- Determine tasks and resources required to deliver each regulatory milestone and project deliverable.
- Take direct responsibility for regulatory activities associated with clinical trials, including regulatory approvals and Investigational Medicinal Product (IMP) management.

Regulatory Compliance

- Oversee licence maintenance activities, providing regulatory support to internal teams and external customers.
- Act as a regulatory compliance liaison with Quality Assurance (QA) and cross-functional project teams.

Licensing Activities

- Manage licensing and lifecycle maintenance of existing Marketing Authorisation Applications in key markets including Europe, the US, Japan, Canada, South America, Asia, and the Middle East.

Dossier Preparation

- Lead the preparation and submission of regulatory dossiers to target markets, working closely with internal teams such as R&D, Quality Control, Production, and external experts as required.

Strategic Regulatory Planning

- Support the strategic planning of regulatory activities to enable successful market entry and ongoing compliance for Eirgen's products in global markets.

Coaching and Mentorship

- Provide mentoring and support to members of the Regulatory Affairs team and broader project teams to promote early issue resolution, knowledge sharing, and skills development.

Project Cost Management

- Manage and monitor regulatory project-related costs to ensure alignment with projected budgets and approved financial plans.

Regulatory Intelligence & Policy Monitoring

- Monitor global regulatory changes, guidance updates, and industry trends relevant to target markets.
- Interpret the impact of regulatory developments on Eirgen's product portfolio and advise relevant internal stakeholders to ensure continued compliance and readiness.

Perform additional team tasks as agreed to support effective running of the Business.

About you

You are a positive and inclusive specialist with a minimum 5 years' experience in a Regulatory Affairs. Proven experience leading or mentoring regulatory activities and teams, including prior responsibility for coordination or oversight of projects. Familiarity with regulatory submissions for global markets, including EU, US, and Asia-Pacific regions. Strong understanding of applicable guidelines and standards (e.g., ICH, EMA, FDA, JP, Health Canada).

You will draw from your many skills such as your excellent communication skills, ability to influence and form positive collaborative relationships, continuous improvement mindset and problem-solving ability.

Degree in Science or related discipline.

Working at Eirgen – What to expect
At Eirgen, we have developed a diverse, people-centric, high-performance culture where people are enabled to achieve their potential.
If you are working at Eirgen, then we think you've got something special. Our employees are high-performing and work as part of a cohesive team, they are dedicated people who are driven to succeed and are rewarded with competitive salaries and an attractive range of benefits including opportunities for career progression and continuing education.

Apply for the above role by sending your CV to *opportunities@eirgen.com* ***including the job title in the subject.***
Closing Date is 28th July 2025