Senior Regulatory Affairs Associate

The Role

We are seeking to appoint a Senior Regulatory Affairs Associate to join an experienced team responsible for registration activities related to new drug applications and product life cycle management, including preparing and maintaining regulatory files on various products within Specialised Therapeutics' portfolio. The Senior Regulatory Affairs Associate will be responsible for liaising with representatives of our licensing partners, contractors and regulatory authorities.

Your responsibilities will include:

- Preparation of regulatory dossiers for submission to the TGA in Australia, Medsafe in New Zealand and any other regional regulatory authorities as required
- Analyse regulatory issues and communicate effectively with key stakeholders
- Liaise with regulatory authorities in relation to the submission, evaluation and finalisation of regulatory dossiers, maintaining positive relationships and representing ST's interests during meetings
- Liaise with licensing partners to prepare regulatory dossiers and responses to questions raised by regulatory authorities during the evaluation
- Liaise with external consultants to prepare regulatory dossiers and responses to questions raised during the evaluation in SEA region
- Maintenance of regulatory files following product registration including submitting timely variations and renewal applications
- Maintenance of GMP clearance for registered products
- Liaise with Therapeutic and Medical Leads throughout the evaluation process and product launch activities
- Support the commercialisation of products through participation in local brand teams
- Collaborate closely with cross-functional teams, including Quality

Assurance, Medical Affairs and Marketing, to provide regulatory guidance and support throughout the product lifecycle
- Participate in/coordinate special project assignments

What we are looking for

- Bachelor's degree in a scientific discipline or related field
- Demonstrable experience in regulatory affairs within the pharmaceutical industry
- In-depth knowledge of Australian regulatory guidelines, regulations and processes applicable to pharmaceuticals
- Knowledge of New Zealand and/or Southeast Asia regulatory systems would be advantageous
- Excellent verbal and written communication skills
- Ability to operate in a complex environment with excellent organisational skills and the ability to successfully manage competing timelines
- Ability to critically appraise data and work in a high paced environment
- Independent in daily activities, with management oversight
- Meticulous attention to detail

What we offer you

This is an exciting opportunity to join a company with a growing product pipeline offering employees' a culture of support, encouragement, passion and recognition. We seek those who can bring a wealth of life experience and inspired ideas to our table. In return, we provide an inclusive and flexible workplace environment that nurtures enduring professional relationships. We provide wholesome remuneration packages with above average benefits including additional leave, additional superannuation, a wellbeing grant and your birthday off!

About Us

Specialised Therapeutics (ST) is the region's largest independent specialty

pharmaceutical company, providing new therapies and technologies to patients in Australia, New Zealand and across Southeast Asia. We partner with global pharmaceutical, biotech and diagnostic companies to bring novel healthcare opportunities to patients who are impacted by a range of diseases. Our mission is to provide specialty therapies where there is an unmet need. Our broad therapeutic portfolio currently includes novel agents in oncology, haematology, CNS, neurology, endocrinology, ophthalmology and supportive care, although it is not confined to these areas.

Culture

We have carefully cultivated a work environment in which our employees are constantly challenged to do their best and think differently. Our company is determinedly inquisitive, perceptive and courageous, and nurtures these qualities by employing people who share our passionate interest in making a difference in patients' lives. We pride ourselves on a friendly, collaborative, open, dynamic and inclusive team, with a permanent focus on the why.

Apply now!

If you are forward-thinking, dynamic in your outlook, and attracted to a challenge which is demanding and rewarding – this is your next step. If you believe you have the appropriate experience and energy for this position, please submit your resume and covering letter to Jessica Fine at jfine@stbiopharma.com

ST is an equal opportunity workplace. This role is only open to candidates that have full eligibility to live and work in Australia.

Pharmacovigilance Manager

- **Exciting opportunity with a 2023 & 2024 ‘Great Place to Work’**
- **Work with global partners and highly innovative products**
- **Full-time role, based in Kew**

The Role

We are currently seeking to appoint a Pharmacovigilance Manager to take responsibility for the management of the company’s pharmacovigilance system. You will act as the Pharmacovigilance contact person and Qualified Person responsible for Pharmacovigilance (QPPV) for local regulatory authorities, including 24-hour coverage.

Your role will include oversight and management of the following key areas:

- Adverse event case management
- Pharmacovigilance system implementation and operations
- Risk Management activities
- Pharmacovigilance agreements with partner companies and third parties
- Inspection readiness
- Clinical trial safety management
- Pharmacovigilance continuous improvement
- Providing strategic pharmacovigilance support and advice
- Leading and mentoring a Pharmacovigilance Associate to deliver high-performance results

What we are looking for

You will be relentless in your pursuit of excellence and proactive in identifying potential issues and working to resolve them within set timelines. Your previous experience in the areas of pharmacovigilance/drug safety within the pharmaceutical industry will ensure your success in this role.

You will be a strong collaborator and have exceptional interpersonal and communication skills, both verbal and written. In addition you will have:

- A tertiary qualification, ideally in pharmacy or nursing, although

pharmacology or medical biology will also be considered
- A post-graduate qualification in a related area would also be an advantage
- Knowledge and understanding of local and global pharmacovigilance guidelines
- The ability to work precisely according to procedures, rules and regulations
- A flexible approach, considering issues from a number of perspectives and summarising data to draw a conclusion
- Experience with medical devices will be an advantage, but not a requirement
- Previous experience in training/mentoring will be an advantage, but not a requirement
- A good understanding of normal and pathological physiological function
- Experience with product-oriented contact with doctors and patients

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