Pharmacovigilance Associate

- Exciting opportunity with an employer of choice.
- Work with global partners and highly innovative products.
- Part-time role, Mon-Fri 4 hours per day, based in Singapore.

The Role

We are seeking to appoint a Pharmacovigilance Associate on a permanent parttime basis (Mon-Fri, 4 hours per day). Reporting to the Pharmacovigilance Manager, you will be primarily responsible for safety activities for medicinal products in compliance with local regulations and company policies. Your key responsibilities will include:

- Accurate and timely processing, record keeping, regulatory reporting and follow-up of all incoming adverse events (AEs) for company products, in accordance with partner and regulatory requirements and ST procedures
- QA/QC of PV activities, including correct data entry, record keeping and periodic reconciliation of AEs and systems
- Notifying regulatory agencies and business partners accordingly and responding to requests from regulatory agencies
- Assisting with the collection, analysis, local literature surveillance and reporting on local pharmacovigilance data for marketed products and products supplied under ST access programs
- Ensuring pharmacovigilance activities are fully compliant with company
 ST standard procedures and regulatory requirements
- Working collaboratively and liaising with internal and external stakeholders as appropriate, to ensure Pharmacovigilance obligations are met
- Performing internal and external reconciliation activities for ST products
- Supporting the Pharmacovigilance Manager with risk management activities
- Supporting audits, inspections and CAPA management as required

What we are looking for

You will have:

- Diploma or Bachelor's degree in Pharmacy, Pharmaceutical Sciences, or Science majoring in Pharmacology or other relevant Medical / Health Sciences / Science
- Basic knowledge of Pharmacovigilance, pharmacology and the pharmaceutical industry
- Prior experience in a product / drug safety role within the pharmaceutical industry is desirable
- A well organised and customer-oriented approach
- Strong written and verbal communication skills
- The ability to analyse and collate data
- Excellent attention to detail and sound time management skills with the ability to be flexible and meet conflicting deadlines
- Excellent knowledge of MS Office and Mac systems
- Ability to work cross-functionally providing support to other departments as required

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, private health insurance, additional superannuation, well-being 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

ST has 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. Please submit your resume and covering letter to Jessica Fine at ifine@stbiopharma.com

ST is an equal opportunity workplace.

This role is only open to candidates that have full eligibility to live and work in Singapore.

Senior Medical Affairs Associate

The Role

The Senior Medical Affairs Associate is responsible for operational support of the medical plan for allocated Specialised Therapeutics (ST) portfolios and products, including medical affairs management, responding to medical enquiries and managing product access programs.

Your responsibilities will include, but are not limited to:

- Responding to medical enquiries on the company's portfolio of products from external (healthcare professionals and consumers) and internal stakeholders, ensuring that ST customers receive a timely and consistently high standard of medical information
- Providing advice and interpretation of product support materials
- Assisting in maintaining systems and processes for ST's Medical Information function
- Liaising with international partners to maintain and update a medical information database of Medical Letters
- Managing ST's Healthcare Professional (HCP) Portal and Access Programs
- Processing Access Program HCP and patient registrations, liaising with internal stakeholders to ensure the timely supply of products through our access programs, and maintaining patient trackers
- Collating, analysing and reporting on Medical Information and Access
 Program metrics to management and partner companies as required
- Managing the supply of product for Investigator Sponsored Studies (ISSs) and the release and tracking of clinical trial stock
- Participating in brand team meetings and providing operational medical support to Medical and Liaison teams

What we are looking for

The successful applicant will be self-motivated with the ability to operate in a collaborative and complex environment. You will have excellent time management

and organisational skills and strong attention to detail.

Additionally, you will have:

- Tertiary qualifications in Pharmacy or Medical / Health Sciences, Biology, Biotechnology or Pharmacology
- Demonstrable experience in a relevant role in the pharmaceutical industry
- Knowledge of the Medicines Australia Code of Conduct, TGA Advertising
 Code and other relevant Industry Codes of Conduct
- Strong written and verbal communication skills and the ability to analyse and collate data
- Ability to work cross-functionally providing support to other departments as required including Customer Service, Pharmacovigilance, Quality and Regulatory Affairs

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This is an exciting opportunity for a talented individual who would like to move their career forward with a collaborative team and an innovative organisation.

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

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This role is only open to candidates that have full eligibility to live and work in Australia.

Scientific Affairs Manager

The Role

The Scientific Affairs Manager is responsible for providing reliable, accurate and

up-to-date scientific, technical and clinical support regarding marketed and pipeline therapies to internal cross-functional, and external stakeholders. In addition, you will generate and deliver scientific insights relevant to the therapeutic areas in which Specialised Therapeutics (ST) operates.

Your responsibilities will include, but are not limited to:

- Maintaining a deep understanding of relevant therapeutic area science and displaying leading industry knowledge across all internal and external interactions
- Providing scientific, technical and clinical support in responding to nonstandard medical enquiries on the company's portfolio of products
- Ensuring the appropriate dissemination of scientific and clinical information regarding marketed and pipeline therapies
- Creating and reviewing promotional, non-promotional and educational materials in line with company SOPs, internal policies, industry codes of conduct and other relevant legislation
- Providing therapeutic area knowledge and training to the Marketing,
 Liaison, and other cross-functional teams as required
- Maintaining knowledge on the external competitive environment
- Participating in brand team meetings
- Providing scientific support and assistance to the Business Development team during new product evaluations/due diligence
- Participating in the assembly and management of Advisory Board and Educational meetings
- Supporting the Medical Lead ANZ with discrete projects

What we are looking for

The successful applicant will demonstrate a proven ability to understand and operate in a technically complex therapeutic area. You will have excellent time management and organisational skills and strong attention to detail.

Additionally, you will have:

 An advanced degree (e.g. PharmD, PhD, Masters degree) in a relevant scientific discipline

- Demonstrable prior experience in a relevant role in the pharmaceutical industry
- Experience in oncology and/or endocrinology therapeutic areas is preferred
- The ability to interpret and communicate complex scientific information to various audiences
- Demonstrated ability to build and maintain relationships with internal and external stakeholders
- Knowledge of relevant industry codes of conduct (such as Medicines Australia Code of Conduct, Medicines New Zealand Code of Practice, Singapore Association of Pharmaceutical Industries Code of Conduct) as well as the TGA Advertising Code
- A high level of commercial acumen

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