Specialised Therapeutics®

SENIOR REGULATORY AFFAIRS ASSOCIATE

- **Working with global partners**
- **Highly innovative products**

About Us

Specialised Therapeutics (ST) is an independent international biopharmaceutical company providing new specialist medicines and technologies to patients in Australia, New Zealand and South East Asia. As a company, we do this by partnering with global pharmaceutical companies, championing their products from pre-registration to full commercialisation in key regions. At ST, our primary objective is to enable people with unmet medical needs access to breakthrough, innovative therapies.

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. ST prides itself on a friendly, collaborative, open, dynamic and inclusive team, with a permanent focus on the why.

The Role

We are currently seeking to appoint an experienced Senior Regulatory Affairs Associate on a full-time basis to join our team based out of our head office in Kew. Reporting directly to the Senior Manager, Regulatory Affairs, this new position will be responsible for preparing and maintaining regulatory files on various products within ST as well as any further related projects and works as required. The role will involve liaising and developing strong relationships with representatives of ST's licensing partners, contractors and regulatory authorities.

In addition, other key responsibilities of this role include:

- Preparation of regulatory dossiers for submission to Therapeutic Goods Administration (TGA) in Australia and Medsafe in New Zealand
- Liaison with TGA and/or Medsafe in relation to submission, evaluation and finalisation of regulatory dossiers
- Liaison with employer's clients to prepare regulatory dossiers and co-ordinate the reply to TGA and/or Medsafe questions raised during the evaluation
- Liaison with employer's consultants to prepare regulatory dossiers and co-ordinate the reply to questions raised during the evaluation in SEA region
- Maintenance of regulatory files following product registration
- Maintenance of GMP clearance for registered products
- Liaison with Brand Managers throughout the evaluation process and product launch activities
- Assisting the Quality Manager with QA support functions, such as protocol writing, SOP writing, Record Management, Customer Complaints, as required

What we are looking for

The successful candidate will be a highly motivated and driven professional with outstanding people and organisational skills.
You will also have:

- Bachelor's degree in Science
- Minimum 5 years of pharmaceutical regulatory experience

- Strong knowledge of TGA processes. Additional knowledge of New Zealand or South East Asia regulatory systems would be advantageous
- Ability to operate in a complex environment with excellent organisational and time management skills. Independent in daily activities, with management oversight

This is an exciting opportunity for a talented individual who would like to take ownership for this newly created role and join a collaborative team within an innovative organisation.

If you believe you have the appropriate experience, energy and business acumen for this position, please submit your resume and covering letter to kdecarolis@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.