# Senior Quality Associate

## 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.

## The Role

The Senior Quality Associate is responsible for supporting the everyday operations of the Quality system for the business. The role ensures compliance to Good Manufacturing and Documentation Practices and any other relevant regulations and requirements.

Your responsibilities will include, but are not limited to:

- Preparing, reviewing, approving and issuing GMP documentation
- Involvement in the management and execution of change controls
- Involvement in activities for hosting internal and external audits
- Management of product returns, recalls and destructions as necessary
- Documenting and investigating any received quality complaints

- Review and completion of internal and external quality records
- Attendance at Supply/Logistics and Brand Team meetings
- Initiating quality deviations, supporting the investigation and root cause analysis and initiating any appropriate corrective and preventative actions (CAPA)
- Participation in overseeing contractor and supplier qualification, and preparation and approval of Quality agreements
- Oversight of commercial and supply agreements where required
- Review of batch documentation and provide relevant documentation to support release for supply activities
- Review of relevant materials to support a release for distribution of products to intended markets
- Coordination of validation projects, with preparation of validation documentation, and participation in validation activities, as required

## 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, the successful applicant will have:

- Tertiary qualification in Life Sciences, Pharmacy, Engineering or related
- Demonstrated experience in a regulated industry with a focus on Quality and current GxP and experience in the pharmaceutical industry
- Previous experience within in a batch release environment would be advantageous
- Experience in the operation of Quality Management Systems or equivalent

## 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!

## Apply now!

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

ST is an equal opportunity workplace.

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