

Phebra develops, manufactures, and supplies high quality and innovative pharmaceuticals to meet the requirements of the hospital specialty pharmaceutical market. At Phebra we create critical medicines which save and improve lives. Working with us, you will have an opportunity to contribute and make a difference!

The following role is currently available. If you feel you meet the below criteria, we welcome applications from those presently employed at Phebra and applicants currently external to the business. Please feel free to share this information with people you know who may be interested in applying for this role.

Please apply by sending your resume and a covering letter to address how you meet the requirements of the role to [HR@phebra.com](mailto:HR@phebra.com)

<b>Role Title</b>	<b>Senior Regulatory Affairs Associate</b>		
<b>Department</b>	Regulatory Affairs		
<b>Hiring Manager</b>	Prisca Drysdale (Chief Global Regulatory Officer)		
<b>Job code</b>	INT23	<b>Closing Date</b>	30 July 2024
<b>About the role</b>	<p>The <b>Senior Regulatory Affairs Associate</b> is a permanent full-time opportunity, situated on site at the facility in Lane Cove, and reporting to our Regulatory Affairs Manager and Chief Global Regulatory Officer. The role works within a team of 5 other Associates and works alongside many other stakeholders within the business.</p> <p>To be successful within the role we require a proactive and strategic thinker who can contribute to the success of our 5-year strategic plan, working co-operatively with the wider team to achieve this.</p> <p>The <b>Senior Regulatory Affairs Associate</b> is responsible for various regulatory activities within Phebra including preparation of submissions for, and liaison with, local and global health authorities such as the TGA, MHRA, Health Canada. They will also be involved in determining strategic elements of submissions, such as timelines, routes of submission etc, and will take the responsibility for developing and drafting critical documents, where relevant.</p> <p>As one of the Senior Associates within the team, the role also has some responsibility for mentoring less experienced members of the team and assist with their development, providing opportunities for growth and providing advice wherever possible.</p> <p><b>The role is a full-time (37.5hr) permanent position, working onsite each day at our Lane Cove facility.</b></p>		
<b>About you</b>	<p><b>To be successful in this role you will require:</b></p> <ul style="list-style-type: none"> <li>- Minimum degree qualification in any scientific discipline</li> <li>- Strong experience (5+ years) with Regulatory Affairs roles working within the prescription pharmaceutical industry in Australia (Consideration also given to applicants who have comparable overseas markets, eg. US, Canada, Switzerland, UK)</li> <li>- Good understanding and knowledge of GMP and Chemistry Manufacturing and Controls (CMC)</li> <li>- Understanding of ICH and local guidelines</li> <li>- Experience working with TGA and Medsafe</li> <li>- Previous people management experience</li> <li>- Strong technical writing skills</li> <li>- Project management skills are preferred.</li> <li>- Mentoring experience for less experienced Regulatory Affairs Associates preferred.</li> <li>- <b>Full working rights in Australia is essential – if you have a temporary visa please address subclass and expiry during your application.</b></li> </ul>		

**Phebra are an equal opportunities employer, we are committed to diversity and inclusion within the workplace and believe that a diverse team with unique perspectives, ideas and experiences should be valued.**