

Sino-Innovax Pte Ltd

Job Description

Designation	Regulatory Affairs and Quality Assurance Executive		
Department	Regulatory Affairs and Quality Assurance	Reporting Officer	Jiaying
Duties and Responsibilities	<p><u>Regulatory Affairs (Therapeutic Products and Medical Devices)</u></p> <ol style="list-style-type: none"> 1. Stay abreast of local regulatory requirements related to the project. 2. Prepare and submit regulatory documents and applications for product registrations related to the project. 3. Act as a liaison between the company and regulatory agencies for matters specific to the project. 4. Assist in developing project-specific strategies to ensure ongoing compliance with regulatory standards. 5. Maintain accurate and up-to-date regulatory documentation for the project, ensuring accessibility for audits. 6. Work closely with cross-functional teams involved in the project, including overseas manufacturers, business development, design and marketing department to ensure regulatory considerations are integrated into project strategies. <p><u>Quality Assurance (Therapeutic Products and Medical Devices)</u></p> <ol style="list-style-type: none"> 1. Participate in internal and external audits to ensure adherence to quality management systems (QMS). 2. Assist in developing and implementing QA procedures and policies to meet regulatory requirements. 3. Collaborate with cross-functional teams to support regulatory and QA objectives. <p><u>Business Development</u></p> <ol style="list-style-type: none"> 1. Develop and maintain relationships with external vendors. 2. Assist with internal stakeholders, such as sales, customer support, and operation teams, and ensure alignment on product. 3. Provide customer service by addressing client concerns. 		
Qualifications and Technical Skills	<ol style="list-style-type: none"> 1. Degree in Life Sciences, Bio-Medical Engineering, or a related Science field. 2. Previous experience or internship in regulatory affairs or quality assurance within the therapeutic products/ medical device industry is preferred. 		
Work Experience	<ol style="list-style-type: none"> 1. Fresh graduates are encouraged to apply. 		
Soft Skills	<ol style="list-style-type: none"> 1. Able to work independently and in a cross functional team. 2. Ability to apply knowledge to general regulatory topics for projects assigned. 3. Computer literacy with knowledge of MS Office applications. 4. Good interpersonal, organizational, negotiation and problem-solving skills. 5. Excellent verbal and written communication skills. 6. Proactive, responsible, results driven, highly self-motivated, adaptable and a self-learner. 		