CLINIGEN	CLINIGEN GROUP Ltd
	Regulatory Affairs Manager

Job Profile: Responsible for regulatory submissions and maintenance of Global Marketing Authorisations for allocated projects
Provide support and advice relating to the regulation of Managed Access programs to internal customers and external Clinigen clients
Provide support and guidance in the collection, interpretation and dissemination of Regulatory Affairs Intelligence

Reporting to: Regulatory Affairs Director

Key Responsibilities:

Operational

- Regulatory responsibility for allocated projects on global licensed products within Clinigen Healthcare Ltd including applications for marketing authorizations in new territories, maintenance of existing licenses, variations to existing licenses, transfer of licenses to Clinigen
- Responsible for the provision of regulatory support for allocated Managed Access programs
- Responsible to support the development of regulatory strategies and provision of regulatory advice internally
- Represent Clinigen professionally in external meetings in a variety of contexts (regulatory authorities, conferences, business meetings)

Departmental

- Provide coaching and mentoring in specific areas of expertise to junior members of the department
- In case of line management responsibilities: Manage direct line reports and/or external consultants. Provide the necessary training and support to ensure that they are able to fulfil their roles
- Ensure proper filing of regulatory submissions and correspondence either internally or via external contractors
- Create and maintain allocated SOPs for Regulatory Affairs

Regulatory Intelligence and Compliance

- Ensure that all regulatory activities comply with current Regulatory Agencies requirements and guidelines
- Assist in establishing and maintaining the Regulatory Intelligence repository for the supply of unlicensed medicines up to date.

- Ensure that Regulatory Intelligence updates are effectively communicated within the company to help ensure regulatory compliance and proper planning
- Proactively build/strengthen contact with external stakeholder (Regulatory Agency, external experts, etc.) to help achieve strategic goals and objectives

Personal Development

- Develop and maintain effective external business relationships
- Develop and maintain effective business relationships with key Clinigen Group staff
- Participate fully in the Company's Personal Performance and Development process
- Undertake training and development relevant to the job.
- Adopt safe working practices in line with current Company procedures and to undertake appropriate training in Health and Safety
- Keep up to date with and implement new legislation as and when required

Additional duties:

The list of duties is not intended to be exhaustive, but gives a general indication of the tasks involved. It is the nature of the company that tasks and responsibilities are, in many circumstances, unpredictable and varied. All employees are, therefore, expected to work in a flexible way when the occasion arises and acknowledge that tasks not specifically covered in their job description are not excluded.

Requirements:

- Bachelor's Degree (or preferably higher degree) in Life Sciences or scientific discipline
- Minimum 4 years' experience within pharmaceutical industry/CRO. Ideally a minimum of 2 years in a client facing role
- Good knowledge of European Regulatory Affairs with experience in one of the followings: clinical trials, MAA procedures, post marketing maintenance
- Demonstrate ability to deliver results to the appropriate quality and timelines
- Proven ability to successfully manage regulatory submissions
- Proven ability to provide advice and training in areas of regulatory affairs
- Excellent organizational and project management skills
- Outstanding written, verbal and interpersonal communications skills
- Excellent ability to handle multiple tasks in a fast-paced and constantly changing environment

Application:

If this role is of interest to you, please email your CV to liezel@clinigen.co.za. Closing date for applications will be 16 February 2024.