Detailed Position Description

Job title — Scientific Affairs Associate

Reporting to The Director

Hours Typically 0.5 - 1.0 FTE

Location Home-based role, travel 0 – 15% [e.g. local travel required for team meetings; interstate or overseas client-related travel]

Purpose of the position

Enimera RegsPlus Pty Ltd (ERPPL) is a consulting company providing superior Regulatory, Quality and Pharmacovigilance services to clients. Our clients range from start-ups to established organisations in the pharmaceutical, medical device and wellness sectors. We are built on the values of integrity, innovation, and agility. Deliberately small and agile, the ERPPL team consists of high-performing individuals who align with these values and operate in a respectful, proactive and collaborative fashion to progress healthcare through serving our clients. Client activities span across prescription medicines, consumer medicines and medical devices.

The Scientific Affairs Associate role is a senior operational role for a suitability experienced individual who can operate with minimal supervision to support ERPPL and client-related activities. The role may involve one or more of the disciplines described below, and the focus on each discipline may change depending on client and business needs.

Key responsibilities and duties

Including but not limited to

Regulatory Affairs (Regulatory)

With some assistance, and with developing knowledge, undertaking or providing assistance with activities such as…

Preparation and submission of Therapeutic Goods Administration (TGA) or Medsafe regulatory submissions for new medicines.
Preparation and submission of TGA or Medsafe regulatory submissions for post-market medicines – e.g. major and minor variations.
Preparation and submission of TGA GMP clearance applications.
Systematic literature reviews.
Regulatory activities for other regulators.
Development of regulatory strategies.
Keeping abreast of regulatory developments.
Other activities as driven by client or business needs.

Quality Assurance (QA)

Under supervision, and with growing knowledge, undertaking or providing assistance with activities such as…

Development and maintenance of Standard Operating Procedures (SOPs) and other associated documentation relating to the client's Australian and New Zealand Product Quality System.
Monitoring of compliance to PQS, and undertaking relevant activities (e.g recalls, product complaints).
Oversight and management of relevant external partners.
Keeping abreast of Quality developments.
Other activities as driven by client or business needs.

Pharmacovigilance (PV)	Under supervision, and with growing knowledge, undertaking or providing assistance with activities such as… Development and maintenance of Standard Operating Procedures (SOPs) and other associated documentation relating to the client's Australian and New Zealand PV system. Monitoring of compliance to the PV system, and undertaking relevant activities (e.g case reconciliation, training of client and ERPPL team members). Oversight and management of relevant external partners. Keeping abreast of PV developments. Other activities as driven by client or business needs.
Other activities	Client needs can vary, other activities may be required in order to meet client needs. Activities as relevant to operation as a high-performing member of the ERPPL team - e.g. participation in team meetings.

Academic qualifications

Essential	Honors or post-graduate degree in a relevant scientific or medical field.
Desirable	Demonstrated training or certification in one or more of the Regulatory/QA/PV disciplines.

Work experience and skills

Essential	Minimum 3 industry experience in Regulatory, QA and/or PV. Demonstrated solid working knowledge of one or more of these disciplines. Advanced Microsoft Office experience. Experience with Therapeutic Goods Administration (TGA) and Medsafe (NZ)-related activities.
Desirable	Demonstrated solid working knowledge of at least two of Regulatory, QA, and PV disciplines.

Personal qualities and behavioural traits

Integrity
Innovative
Agile and flexible, thrives in a high-paced environment
Commercial awareness
Open-minded, solution-oriented approach
Attention to accuracy and detail
Strict maintenance of confidentiality as it applies to ERPPL business operations and client-related activities.
Transparency and accuracy in recording of time, billable and non-billable
Being amendable to reasonable work across different timezones.

Key relationships

ERPPL	Interaction and collaboration with ERPPL team members and also members of the extended ERPPL team (e.g. subcontractors).
Client	Client contacts may include Executives and/or operational staff.
Regulator	TGA, Medsafe, others as appropriate.