Job Title	Regulatory Affairs Associate - IBL	Dept	Regulatory Affairs
Line Manager Job Title	Regulatory Affairs Manager	Location	Abbotsford

Key Responsibilities

The GlaxoSmithKline (GSK) Regulatory Affairs Department provides the primary link between GSK and the Regulatory Authorities in Australia and New Zealand (TGA/Medsafe). The Regulatory Department supports all activities relating to securing medicines approval in Australia and New Zealand and maintaining the currency of GSK product licenses.

The Regulatory Affairs Associate – IBL is a key team member and responsibilities include:

- Assistance with regulatory applications to the TGA and Medsafe.
- Project work pertaining to medicines, such as managing labelling updates and other internally or externally driven initiatives.
- Management of databases, processes and improvements within the department, web-based duties.
- Management of labelling text to accompany our medicines (e.g. consumer medicine information leaflets, product information).
- Maintain product compliance in line with corporate and regulatory standards.
- Administrative duties pertaining to regulatory applications, such as mail, invoicing and submissions.

Unique selling points of the IBL role

The Job: This is a real job with real responsibilities. Your tenure at GSK will provide you with invaluable experience, broad exposure to different areas of the Regulatory Affairs Department as well as our local and global business, and networking opportunities. You will also be provided the opportunity to contribute and lead important projects in a high-performance culture.

Development: You will be assigned a mentor and be provided with formal training and development opportunities. Importantly, you will be part of a fun-loving and supportive team that has a great diversity in experiences and backgrounds to support you.

Positive patient impact: In regulatory affairs, you will have the opportunity to serve patients and improve their outcomes through ensuring compliance with the rapidly evolving regulatory framework and supporting access to important medicines with timely and quality regulatory applications.

Required Skills / Background

- You must be in your penultimate/ultimate year of a Bachelor's Degree which includes but is not limited to Pharmaceutical Sciences, Public Health, Biological Sciences.
- Interest in pursuing a career in the pharmaceutical healthcare industry is favourable.
- Strong passion and knowledge in regulatory affairs (preferred).
- Awareness of the drug development process (preferred).
- Excellent written and verbal English communication skills.
- Proficient in routine IT software packages.
- Customer and patient focus.
- High attention to detail, rigor and process.
- Experience in project management is desirable in order to manage and prioritise multiple ongoing projects.
- Demonstrated ability and desire to learn.
- Teamwork, ability to build and maintain relationships.
- Support change and innovation.
- Strategic thinking and problem-solving skills.
- Display work ethic according to GSK values.

Values	Expectations
Patient focus **Transparency** **Respect** **Integrity**	**Courage**: Challenge status quo when appropriate to pursue business objectives and patient outcomes, interact proactively with colleagues, looks for ways to improve ways of working. **Accountability**: Hold yourself and others to commitments, independently manage regulatory applications and projects, prioritise work that supports GSK's strategy, ensure a high level of compliance. **Development**: Take ownership of own development. **Teamwork**: Align performance objectives and work together with team, and other teams, in support of the business. Contribute to a positive and inclusive work culture.