

1 Overview

The Regulatory Affairs Department is the interface between a company and regulatory bodies (TGA/FDA/APVMA/NICNAS). This is an in-house role for writing and preparing documents for regulatory approval, and may be involved at all stages of drug/device/product development. The department ensures the maintenance of a company's existing Product Licences and liaises with authorities regarding any changes in labelling and packaging. Some departments will have major strategic input into the development process and will vet clinical development plans prior to implementation to ensure that adequate data is collected to satisfy the regulatory authorities.

2 Qualifications

- Undergraduate qualifications in pharmacy, pharmacology, biology, life sciences, chemistry (rarely) or a related discipline.
- Postgraduate qualifications in pharmaceutical science, or the Dip of Drug Development are highly desirable.

3 Salary Range

Permanent \$45,000 - \$110,000pa
Contract \$30.00 - \$65.00 ph

4 Previous Positions

- Regulatory Affairs Assistant
- Regulatory Compliance
- Pharmacist
- Academia/Postgraduate (rarely)

7 Typical Responsibilities

- Evaluate, prepare and submit drug registration applications and follow through the application during the evaluation phase to achieve a favourable outcome.
- Assist in the preparation of applications for registration of new products, variations to marketed products and clinical trial applications, where required
- Assist with responses to deficiency letters and other requests for data from regulatory agencies
- Maintain registration of currently approved products.
- Maintain and implement relevant importation/exportation licenses and the co-ordinate pure substance requests.
- Develop and maintain good working relationships with internal departments, health authorities and industry bodies, such as the APMA.
- Provide regulatory and product compliance expertise in the area of advertising and label claims for existing and new products.
- Provide brand/Marketing support for products marketed locally, e.g. consumer inquiries, Marketing and other department regulatory queries.
- Provide regulatory documentation required by other company functions or businesses.
- Ensure all business activities comply with relevant Acts, legal demands and ethical standards.
- Develop packaging for new & existing products and comply with government regulations.
- Review labelling, product information, consumer medicine information for compliance with relevant regulations and codes
 - Maintain contact with officials of the Australian TGA (and other regulatory bodies MOH-NZ, FDA-USA, and industry associations through attendance at meetings, conferences and seminars as appropriate

5 Industry Background

- Pharmaceutical
- Animal Health
- Biotech/Biomedical/Medical Devices
- CRO (Contract Research Organisation)
- Healthcare
- FMCG (h/hold products, cosmetics, personal care)
- Academia
- PhD (biological sciences, pharmacy, pharmacology)

6 Career Progression

- Other therapeutic areas
- Regulatory role in a related industry
- Senior Regulatory Affairs Associate
- Regulatory Projects Leader
- Regulatory Affairs Manager
- Project Manager
- Technical Manager

Regulatory Affairs Associate (Reg Affairs)



- To provide regulatory input to new product development and current product implementation for designated therapeutic areas
- Liaise with manufacturing sites and product teams when required