



Pharmaceutical
Solutions
Regulatory Specialists

Regulatory Affairs Services and Consultancy

Pharmaceutical Solutions Ltd has a team of skilled Regulatory Affairs professionals who can help determine the most direct pathway to market. Our team can provide guidance on all aspects of Regulatory Affairs, Quality Assurance, Strategic and Technical Advice and Product Life Cycle Management in Australia and New Zealand.

Profile

- Extensive Local and International Industry Experience
- Broad Range of Services spanning the Product Life Cycle, Quality Assurance and Commercialisation
- Expertise in Bio-Pharmaceuticals (Innovator and Generic), OTC and Medical Devices
- Smoothing your navigation of the Australian and / or New Zealand Regulatory Environment for Earlier and Sustainable Market Access



Commercially Focussed
Current
Responsive



CLINICAL TRIAL

Our services include:

- ✓ Medsafe and TGA Regulatory Submissions
- ✓ Local Clinical Trial Sponsor
- ✓ Ongoing Health Authority Reporting

QUALITY

Our Services include:

- ✓ QA Consulting
- ✓ Recall and Crisis Management
- ✓ Product Quality Complaint Management and Resolution
- ✓ SOP Development and Training
- ✓ Quality System Development and Audits
- ✓ Product Compliance
- ✓ Medsafe Licensing and Application Support (Wholesale, Packing and Hawkers Licences)
- ✓ Responsible Person and Batch Release in New Zealand

REGULATORY AFFAIRS

Our services include:

- ✓ Product Sponsorship in Australia and New Zealand
- ✓ Regulatory Strategic Advice
- ✓ New Product Submissions: Prescription, OTC, Complimentary Medicines, Bio-Pharmaceuticals, Generics and Medical Devices
- ✓ Dossier Evaluation and Gap Analysis
- ✓ Variation and Changed Medicine Notifications
- ✓ Comprehensive Regulatory File Audits to ensure Regulatory Compliance
- ✓ Promotional Material Reviews
- ✓ Rescheduling and Reclassification Applications
- ✓ Technical Product Support and Advice
- ✓ Prescribing Information, Data Sheets and Consumer Medicine Information
- ✓ Labelling and Artwork Development and Review
- ✓ PHARMAC Applications
- ✓ Named Patient Supplies and Management
- ✓ Product Life Cycle Management

REGULATORY AFFAIRS SERVICE OFFERING

Benefits	Advantages
Contract Resource	Expertise and an extra pair of hands where and when you want it. Reduce your Fixed Costs and Drive Value.
Commercially Focused	Strategically Driven, providing Foresight and Planning to meet your Commercial Needs.
Current	Committed to on-going development and education. Recognised KOL's, driving leadership through Industry Association memberships and engagement with Government Agencies.
Responsive	Highly experienced leaders providing proactive advice on legislative and market changes.

Delivering Customer Value

Contact Details

For all enquiries please contact:

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