



Pharm  **Out**

PharmOut is a boutique consultancy to the pharmaceutical, medical device and veterinary products industries.

We consult and train on regulatory GMP compliance, drug registration, validation and continuous improvement of manufacturing processes.

What we offer

PharmOut has five core offerings:

1. Providing consulting and resources for the validation of processes, equipment and computer systems.
2. Consulting on GxP compliance.
3. Consulting on how to combine GMP compliance with common continuous improvement techniques (6 sigma, Lean Manufacturing, 5S etc).
4. Training people in validation, GMP compliance and continuous improvement.
5. Consulting on the Australian Therapeutic Goods Administration's drug and device registration process.

PharmOut tackles validation, registration, compliance and continuous improvement projects on a fixed price or hourly rate basis.

Our team includes:

- Pharmaceutical Engineers
- GMP Consultants
- Validation Consultants
- Regulatory Affairs Consultants
- Professional Trainers
- Technical Writers and other life science specialists.

We can deliver highly experienced consultants or contractors at short notice.



Our Customers

PharmOut works with some of the most successful pharmaceutical and medical device companies in Australia and the Asia Pacific region:

GlaxoSmithKline

AstraZeneca

Bernafon

CSL

Fonterra

Intertek Caleb Brett

Mylan

Cochlear

Siemens

BioMerieux

QIMR

AC Immune

Abbott Australasia

PT. Sanbe Farma

Gilead

Our industries

PharmOut consults to those industries subject to Australian, European and/or U.S. food and drug regulations:

- Pharmaceutical manufacturers
- Medical device manufacturers
- Manufacturers of veterinary and pesticide products.

It's our job to not only know the relevant regulatory codes inside out, but to know how to comply with them cost effectively. Using a risk based approach we focus on the process areas that will have the most impact on product quality – rather than simply treating the whole process equally.

Some examples of our work:

- GLP/GMP Quality Management Systems, compliant with FDA, EMEA and TGA regulations (PIC/S).
- Audit readiness assessments and audit remediation to FDA CFR 210/211, CFR 820
- Implementing ISO 9001 for Pharmaceutical or ISO 13485 for Medical Device standards
- International Regulatory GMP assistance to obtain approval from the FDA, MHRA, Medsafe or TGA
- Part 11 and Annex 11 compliance to FDA, Medsafe and TGA requirements
- Preparation of dossiers for drug and device registration with the TGA.

**PharmOut Pty Ltd
Australia**

Unit 12,
40 Montclair Ave,
Glen Waverley,
VIC, 3150

t: +61 3 9561 8265

Level 40,
100 Miller Street
North Sydney, 2060,
NSW, Australia

t: +61 2 80 016 201

Level 2
147 Coronation Drive
Milton, QLD 4064

t: +61 7 31 055 990

www.pharmout.com.au

**PharmOut
New Zealand**

Level 3,
60 Cook Street
Auckland, 1141,
New Zealand

t: +64 9 889 3001

www.pharmout.co.nz

**PharmOut
South Africa**

Kelvin House
181 B Burger Street
PO Box 181
Pietermaritzburg 3201

t: +27 87 808 4940

www.pharmout.co.za

**PharmOut
Singapore**
3 Raffles Place,
#07-01 Bharat Building
Singapore, 048617

t: +65 6248 4693

www.pharmout.sg

