



**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 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 companies in Australia and New Zealand, including:

GlaxoSmithKline  
Mayne Pharma  
AstraZeneca  
Bernafon  
CSL  
Fonterra  
Hospira  
House With No Steps  
Invetech  
Intertek Caleb Brett  
Pharmatel  
Fresenius Kabi  
Probe Analytical  
Laboratories  
IG Science  
Chemeq

## Our industries

PharmOut consults to those industries subject to Australian, European and/or American 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 or GAP audits and assessments to FDA CFR 210/211
- 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 registration with the TGA
- Audit-readiness assessments for compliance with the Australian Pesticides & Veterinary Medicines Authority (APVMA) GMP Code.

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