



**Pharm**  **Out**

PharmOut is an international consultancy to the pharmaceutical, and medical device industries and to regulatory authorities.

We consult and train on regulatory GMP compliance, validation, product registration 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. Providing GxP training
5. Consulting on the Australian Therapeutic Goods Administration's drug and device registration process.

PharmOut tackles projects on a fixed price or hourly rate basis.

Our team includes:

- 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 industries**

PharmOut consults to those industries subject to European (EMA), U.S. (FDA) and Australian (TGA), drug and medical device 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, EMA 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, EMA, MHRA or TGA.



## Our Projects

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

Examples of projects we have completed include:

In the Phillipines, we trained the auditing team of the country's regulatory body in preparation for their application to join PIC/S.

In Australia, we validated a flu vaccine manufacturing process for a global biopharmaceutical company

In Singapore, we validated a clinical services computer system for a multinational specialist logistics company, supplying the pharmaceutical industry.

## Our people

PharmOut's team includes international GMP experts and consultants who previously held leadership roles within regulatory bodies.



PharmOut's Managing Director, Trevor Schoerie, has 21 years of manufacturing and 8 years of consulting experience in the chemical, pharmaceutical, pesticides & veterinary drugs industries. Trevor believes strongly in sensible, practical compliance that delivers business results, not just audit success.

His area of expertise is combining GMP compliance with continuous improvement methods such as Lean Manufacturing.



Bob Tribe is an experienced, approachable, industry veteran who has been a key player in the development of the GMP standards and their application within Australia and internationally. Bob was previously the Chief GMP Auditor for TGA, Australia (1980 – 2003) and Chairman of the Pharmaceutical Inspection Cooperation Scheme [PIC/S] (2000 – 2001). Current regulatory advisor to the ISPE, special advisor to a number of regulatory authorities seeking PIC/S accreditation.



Gordon Farquharson is widely recognised as a world leader and expert in sterile products manufacture, clean room design and maintenance and utilities for the same. Gordon is the Chair of British, CEN and ISO committees responsible for development and deployment of the ISO 14644 family of cleanroom standards. He is also an advisor to the EMeA concerning the revision to Annex 1 of the EU GMP in February 2008 and a member of the WHO expert committee (WHO Pharmaceutical Water GMP; Sterile GMP Annex 1).



Andrzej Wozniak was previously the Manager of the Medicines Audit Team with the Australian Therapeutic Goods Administration (TGA). He has extensive experience in biologicals, dossier review, product testing and auditing of all types of pharmaceutical manufacturers.

Andrzej also spent three years as chairperson of the TGA's Technical Working Group for Sterile Medicines and was a member of the PIC/S Expert Circle for APIs and a committee member during the period 2004-2010.

Contact details can be found on:  
[www.pharmout.net](http://www.pharmout.net)

