

Training

PharmOut offers tailored onsite training courses to the pharmaceutical, life science and medical device industries.

Training teams together allows them to consider real-life issues during the session. It also helps change management as everyone has the same understanding of what is required.



cGMP Basics

Overview

Pharmaceutical manufacturers have to comply with the various cGMP (current Good Manufacturing Practices) regulations, according to the destination countries of their products.

Participants in this training course will learn the practical basics of compliance with these regulations. They will also learn how to avoid common mistakes, according to their operational needs.

Who should attend?

- Manufacturing staff
- Contractors
- Suppliers

Expected outcomes

After completing this training course, participants should be able to:

- Understand why the regulations are in place, who enforces them and the implications of non-compliance.
- Understand what actions they need to take to comply.
- Understand what they should and should not do in areas that are subject to cGMP regulations.

Topics covered

The following topics will be covered in the cGMP Basics course:

- Why it's important to ask and who to ask if you are unsure.
- Avoiding product contamination - microbiological, particulate and chemical.
- The records you need to create and the rules surrounding record keeping.
- Why and how to protect product manufacturing areas when work must be done in them.
- What to do if you accidentally change something or need to change something.
- How your own health impacts pharmaceutical products in production.
- Dress codes in different areas of a plant.
- Special requirements for sterile areas.

Length

One full day on your site.

Pre-requisites

None.

Assessment

Participants will be assessed during the training.

Cost

\$3000 for up to 15 participants

PharmOut

PharmOut Pty Ltd Australia

www.pharmout.com.au

+61 3 86 400 933