



Introduction to Good Manufacturing Practice

Course Description

Manufacturers of foods, pharmaceuticals, vaccines, and biologics adhere to the principles of Good Manufacturing Practice (GMP) so that products can be sold into regulated markets. This one-day course sponsored by the South African Association of Pharmacists in Industry introduces pharmacists, technical professionals, researchers and manufacturing personnel to the fundamental principles of GMP along with some historical background and insight into regulatory agencies. The course presents the ten overarching principles of Good Manufacturing Practice in lecture format and illustrates how GMP works in practice.

A formal study guide and competency exam is available on request from Far Sight Skills Development that can be used in-house to provide documented evidence of GMP competency – an important part of an employer's training records.

Course Outline (1 day format)

- 1.0 GMP History and Market Relevance
- 2.0 Inside Regulatory Agencies
- 3.0 Understanding “current” GMP Compliance
- 4.0 Legal framework
- 5.0 Principles of Good Manufacturing Practice with Examples
 - 5.01 Written Procedures with examples
 - 5.02 Following Written Procedures
 - 5.03 Documenting for Traceability
 - 5.04 Designing facilities and equipment
 - 5.05 Maintaining facilities and equipment
 - 5.06 Job Competence
 - 5.07 Cleanliness
 - 5.08 Validating Work
 - 5.09 Process Control
 - 5.10 Auditing for Compliance
- 6.0 Recap and Summary

About your Course Director

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Dale has over thirty years of experience in the chemical and bioprocess industries with heavy emphasis on the development of chemical, biochemical and bioprocess technology and the commercialization and manufacture of related products. He has been teaching and presenting public courses in chemical engineering technology, aseptic processing and regulatory compliance for the last fifteen years. Dale is currently Business Transformation Specialists for Far Sight Skills Development following on from eight years at National Bioproducts Institute (NBI) Durban, South African where he was responsible for producing parenteral blood plasma-derived therapeutic biologics. Prior to NBI Dale served as Bioprocessing Portfolio Manager for LIFElab (now the Technology Innovation Agency). Dale is appointed as an Extraordinary Professor at the University of Stellenbosch.