

Compliance Course Modules



ICS ANALYTICS
Productivity with Compliance

Description

'Custom Courses' are constructed by selecting from the modules below. Courses are intended as an introduction to the techniques, as refresher training, or to address specific areas identified as requiring additional training.

Learner's Guides (course notes) are available for all participants. Practical exercises to reinforce theory can also be included if requested.

Modules on other topics can be developed to suit your needs.

Course Modules:

GMP PIC/S Regulatory Guidelines

GMP FDA Regulatory Guidelines

Quality Systems

- » Management Responsibility,
- » Personnel,
- » Change Control,
- » Production and Process Control,
- » Buildings and Facilities,
- » Equipment,
- » Packaging and Labelling,
- » Materials - quarantine system,
- » Electronic Records, and
- » Internal and external Audits/Inspections

Pharmaceutical Life Cycle

Course Leader:

Greg Jordan has over 30 years experience in the Pharmaceutical industry (Regulatory, QC, Stability and R&D). He has delivered courses in universities and companies in Australia and Asia

Bookings or Further Information:

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GLP OECD Guidelines

GLP FDA Guidelines

GLP ISO Guidelines

GLP Systems

- » Lab Organisation,
- » Laboratory Layout,
- » Sampling,
- » Lab Equipment and Instrumentation,
- » Laboratory Standards and Reagents,
- » Method Validation,
- » Quality of Data,
- » Records, Documents and Archives, and
- » Documentation and Errors.

Good Documentation Practice

Laboratory Investigation (OOS/OOT)

Work in Clean Rooms

Risk Assessment & Management