

Human Error and bGMP®



Overview

96% of all errors involve 'human factors'.

True or False?

This 2 Day course is designed for supervisors/team leaders/managers that have responsibility for ensuring compliance and improving performance within the pharmaceutical work environment.

The course will focus on the role that managers have in ensuring that they effectively understand the requirements of cGMP and consequences of non-conformance. A key component of this course will be how to manage the behaviours of employees in accordance with GMP requirements and balancing the mix of maximising business performance and at the same time, maintaining a culture of compliance.

Human error accounts for a significant proportion of all the mistakes that occur in our industry and delegates will learn about what they can do to reduce error within their own work environment.

This course aims to introduce the delegates to new learning experiences, by adopting a 'Total Compliance Management' approach to meeting GMP requirements.

Key Subject Areas

- Definition of Human Error
- Job profiling and PPA DISC psychometric profiling
- Principles of Error Management
- Classifying Errors- Slips, Lapses, Mistakes and Violations
- What is bGMP®?
- cGMP Overview
- The role of the 'Manager' in Compliance Management
- The Regulatory Audit
- Measuring Quality?
- Sustainable solutions to Quality Problems
- Human Behaviours
- Performance managing employee behaviour- competence and competency
- Action Planning- setting objectives for workplace application

Course Format

The course is designed to provide a substantial mix of tutor presentation with student interactivity, allowing delegates the opportunity to Learn-Do-and then Apply their learning back in the workplace. Case Study examples are used throughout the programme, many providing examples of behavioural issues in other industry sectors which are analogous to those within the healthcare industry

As well as the new concepts introduced throughout the course, some may be familiar to delegates, but the key message throughout the programme is HOW they can then be applied back in the workplace to achieve sustainable business improvements.

Delegates will receive comprehensive notes and a copy of the presentation. Delegates will also be expected to produce an individual, and a team, objective action tree, based upon key learning points and their organisations specific needs.

Human Error and bGMP - 2 Day Training Course

Course Overview

Day One

Introductions

cGMP overview

Introduction to bGMP®

- Why adopt a behavioural approach to managing compliance?
- Overview of the concept of bGMP® - 'Drivers for Change'- PIMS model
- Group discussion and review of company quality issues
- Case Study exercise - when things go terribly wrong!!!

Human Error

- A definition of Human Error
- Models of Human error
- Root cause analysis- Error investigation techniques

Human Factors

- Case Study Exercise- Human Error
- General Categorisation of Human Error
- Causes of human errors in the Healthcare sector
- Correction and prevention of human errors
- Risk assessment techniques applied to errors

Day Two

The Role of “The ‘Compliant’ Manager”

- Introducing and auditing against standards
- Managing Change
- Managing Knowledge
- Managing Business Performance
- Responsibility for Quality, and measuring against KPI’s
- A new approach to management- ‘The Balanced Leader’

Group Exercise – Understanding and Identifying Human Behaviours

Performance Managing Human Behaviour

- Implementing a bGMP® programme
- Designing Competence models – COST profiling
- Job Profiling and PPA DISC psychometric profiling
- Competency frameworks
- Aligning compliance measures to performance management systems

Developing a bGMP® Compliance Action Plan

- Identifying organisational gaps
- Preparing an individual development plan
- Setting specific bGMP objectives