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GxP in a nutshell

Overview

This 1 day course is designed for individuals who are new to the pharmaceutical environment. It is vitally important that all individuals who come to work in the pharmaceutical industry receive regular GxP training and this course provides a good introduction to the environment. However, it doesn't just cover WHAT the regulations say but it explores WHY they are important and what role individuals have to play. The course also explores importance of quality of product in context of the end user – The PATIENT!

Key Subject Areas

- The regulations and regulatory bodies
- From discovery to market
- Business activities
- Quality Assurance, Quality Control and GxP
- Quality Systems
- Documentation
- Roles and responsibilities

Duration

1 Day

Course Format

The course is designed to provide a substantial mix of tutor presentation with student interactivity, to enhance the learning. Delegates will receive comprehensive notes and a copy of the presentation.

Course Overview

- Introductions
- History of the development of the regulations
- Brief overview of the regulations
- Who are the regulators and what is their role
- Business activities and how they contribute to maintaining product quality (departmental roles eg Manufacturing, engineering, quality groups, IT etc.)
- Role of individuals in maintaining compliance with the regulations
- Difference between Quality Assurance, Quality Control and GxP
- Introduction to key Quality Systems and the role they play in maintaining quality
- The role of documentation and why it is important – Procedures and records
- 10 key fundamental principles of GxP