GreyRigge Associates

Quality Management Systems

Overview

A structured introduction to the design, implementation and management of a pharmaceutical Quality Management System. Drawing on ICH Q7, Q9 and Q10 and current expectations from WHO, MHRA, FDA and PIC/S, the course covers the full QMS hierarchy from Quality Policy and Quality Manual through to SOPs, batch records and supporting quality systems. Regulatory inspection findings are used throughout to contextualise requirements and develop participants' ability to identify deficiencies and design effective remediation.

Course Structure

Module	Subject Area
Module 1	QMS Overview – Structure, Documentation Hierarchy and Essential Quality Systems
Module 2	Essential Quality Systems – Documentation, Change Management, Deviation Management, CAPA and Recalls
Module 3	Quality Fundamentals – Validation, Quality Risk Management, Data Governance and Product Management
Module 4	Quality Compliance Management – Outsourced Activities, Self-Inspection, Auditing and Periodic Quality Review

Audience

This course is suitable to pharmaceutical and biotechnology manufacturers at any stage of QMS development, from those building their quality infrastructure for the first time through to established manufacturers seeking to strengthen, audit or modernise existing systems. It is particularly relevant for generic drug manufacturers, speciality pharma companies, API producers and finished dose form manufacturers operating under GMP, as well as medical device organisations transitioning to or aligning with pharmaceutical-standard quality requirements. Contract manufacturing organisations, testing laboratories and regulatory affairs teams supporting GMP-regulated clients will also benefit.

Duration and Delivery

This course is delivered over one day and can be face-to-face or remotely. Course content and duration can be tailored to the specific needs of the requesting organisation, with individual modules offered as standalone sessions.

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