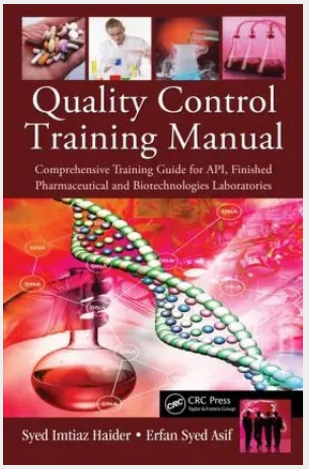
Haider / Asif

Quality Control Training Manual

Comprehensive Training Guide for API, Finished Pharmaceutical and Biotechnologies Laboratories

Written to help companies comply with GMP, GLP, and validation requirements imposed by the FDA and regulatory bodies worldwide, Quality Control Training Manual: Comprehensive Training Guide for API, Finished Pharmaceutical and Biotechnologies Laboratories presents cost-effective training courses that cover how to apply advances in the life sciences to produce commercially viable biotech products and services in terms of quality, safety, and efficacy. This book and its accompanying downloadable resources comprise detailed text, summaries, test papers, and answers to test papers, providing an administrative solution for management. - Provides the FDA, Health Canada, WHO, and EMEA guidelines directly applicable to pharmaceutical laboratory-related issues - Offers generic formats and styles that can be customized to any organization and help management build quality into routine operations to comply with regulatory requirements - Contains ready-to-use training courses that supply a good source of training material for experienced and inexperienced practitioners in the biotechnology/biopharmaceutical industries - Includes downloadable resources with downloadable training courses that can be adopted and directly customized to a particular organization - Supplies ready-to-use test papers that allow end users to record all raw data up to the issuance of the attached certificate The biotechnology/bioscience industries are regulated worldwide to be in compliance with cGMP and GLP principles, with particular focus on safety issues. Each company must create a definite training matrix of its employees. The training procedures in this book enable end users to understand the principles and elements of manufacturing techniques and provide documentation language ranging from the generic to the specific. The training courses on the downloadable resources supply valuable tools for developing training matrices to achieve FDA, Health Canada, EMEA, MHRA UK, WHO, and GLP compliance.



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