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Department -- Chapter 9 Developing a Design Qualification Protocol as Standard Operating Procedure for a Pharmaceutical Plant Facility Meeting cGMP requirement for Liquid oral and Ointment Department -- Chapter 10 Developing a simplified model Standard Operating Procedure to implement quality metrics for Pharmaceutical Manufacturing System -- Chapter 11 Documentation and data integrity in Pharmaceutical Industry -- Chapter 12 Quality Risk Management. Chapter 13 Deviation, Change control and CAPA.

Sommario/riassunto

The pharmaceutical quality system ensures that the process performance is suitably achieved, the product quality is regularly met, improved opportunities are identified and evaluated, and the knowledge is constantly expanded. Auditing also plays a crucial role within the pharmaceutical industry. It helps to assess and review quality to improve and build a better system for the benefit of companies. This book aims to develop a tool that will substantially decrease the number of Inspectional Observations and Warning letters, thus eliminating Import Alerts and Consent Decree. This book targets the Pharmaceutical Industry and students of Pharmaceutical Quality Assurance so they can get in hand-ready consolidated information on Pharmaceutical Quality guidelines, Quality metrics, and implementation of simplified SOP guidelines, plant layouts to implement Quality metrics for Pharmaceutical Manufacturing systems in tablets, capsules, liquid orals, and semi-solid dosage forms. The chapters cover the various aspects of Pharmaceutical Quality Assurance. The selection of topics is mainly based on the requirements of Pharmaceutical regulatory guidelines of India, the UK, the USA, Australia, and South Africa. Each chapter includes the abstract, detailed explanation, implementation guidelines, flowcharts, layouts, and Standard Operating Procedure of quality metrics for the Pharmaceutical Manufacturing System.