SOP Guidelines

Description: Launching for the first time ever, the most comprehensive and detailed guide to management of Quality Assurance in pharmaceutical production facilities. It includes Facility Design, Equipment Production Controls, Bulk Pharmaceutical Chemicals, Laboratory Controls, Personnel, Validation, Documentation and Audits. More...

One of the most important developments in the pharmaceutical industry in the last few years has been the coming into prominence of electronic documentation. Starting with electronic SOPs, developments have continued into Electronic Batch Records, ultimately weaving all this into a seamless Enterprise Resource Planning (ERP) IT network having an increasingly prominent role to play in manufacturing operations. Such electronic record keeping in the highly regulated pharmaceutical industry, is never easy. However, regulatory agencies in US and Europe have done commendable work to support and foster the growth of such systems within the pharmaceutical industry by developing and publishing official guidelines and standards to be observed. Consequently, the pharmaceutical industry has embraced the new electronic technology with enthusiasm. In this 2nd edition of the book therefore, a lot of information has been provided on this subject.

Owing to the changed scenario in the pharmaceutical manufacturing and control procedures, coupled with the risk based approach to pharmaceutical GMPs adopted by US FDA some years back, it was decided to update this book, to better reflect the current technical standards.

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