



GMP Audit Trainer: Good Manufacturing Practices Made Easy (Paperback)

By Brendan Cooper

Createspace Independent Publishing Platform, United States, 2017. Paperback. Condition: New. Language: English. Brand new Book. Both internal and external GMP audits/inspections are a key requirement of Quality Management systems across medical device, biotechnology and pharmaceutical industries. Achieving a successful audit outcome is essential to maintaining an effective QMS and fundamental to retaining manufacturing licenses. In order to align systems and processes to ensure compliance and favorable audit outcomes personnel must understand the auditor focus and methodologies. This book summarises key areas that inspections cover along typical areas of risk and concern. The following chapters are included: Introduction to Good Manufacturing Preparation for Audits Inspection of Quality Systems During the Inspection, Biotechnology Inspection Guide, Medical Device Inspection Guide, Drugs Inspection Guide, Computerised Systems Inspection Guide, Validation of Hardware and Software, Electronic Records and Signatures Electronic Records Verification Methods.



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