

Quality Manual Pharmaceutical Company

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during the past decades enormous progress and enhancement of pharmaceutical manufacturing equipment and its use have been made and while there are support documents books articles and online resources available on the principles of cleaning and associated processing techniques none of them provides a single database with convenient ready to use training tools until now cleaning validation manual a comprehensive guide for the pharmaceutical and biotechnology industries elucidates how to train the man power involved in development manufacturing auditing and validation of bio pharmaceuticals on a pilot scale leading to scale up production with over 20 easy to use template protocols for cleaning validation of extensively used equipments this book provides technical solutions to assist in fulfilling the training needs of finished pharmaceutical manufacturers drawing on the authors more than two decades of experience in the pharmaceutical and biotech industries the text offers hands on training based on current approaches and techniques the book does not merely provide guidelines or thought processes rather it gives ready to use formulas to develop master plan sops and validation protocols it includes cleaning procedures for the most commonly used equipment in various manufacturing areas and their sampling points using a pharmaceutical manufacturing site with both sterile and non sterile operations as the case facility it also provides the training guidelines on downloadable resources to enable users to amend or adopt them as necessary grounded in practicality the book s applicability and accessibility set it apart it can be used as a guide for implementing a cleaning validation program on site without the help of external consultants making it a resource that will not be found collecting dust on a shelf but rather referred to again and again

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comprehensive directory of databases as well as services involved in the production and distribution of information in electronic form there is a detailed subject index and function

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pharmaceutical quality control lab teaches you the history of regulations affecting quality control in pharmaceutical labs and their importance and the goes into the specifics of dealing with out of standard and out of trend in a pharmaceutical quality control lab

a robust compliance program is essential to protecting a company from running afoul of the myriad laws and regulations that have been enacted to combat fraud and waste the second edition of the pharmaceutical and medical device compliance manual includes guidance to help companies develop a compliance program tailored to today s complex enforcement and business environment study of this manual will enable compliance professionals and lawyers to understand the government s expectations of an effective compliance program and ethical business practices as well as how the government discovers potential enforcement actions its approach to pursuing such actions what behaviors can constitute mitigating factors for a company in the event of a legal violation coverage includes new chapters covering pharmaceutical industry interactions with patient organizations compliance 2 0 compliance analytics in the era of big datathe art and science of health care compliance in the pharmaceutical and medical device industries the manual will be a great tool for health and life sciences attorneys compliance officers and others in the pharmaceutical and medical devices industry

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