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Institute of Agricultural Research Statistics (India)

thoroughly revised to include the latest industry developments the second edition presents a comprehensive overview of computer validation and verification principles and how to put them into practice to provide the current best practice and guidance on identifying and implementing improvements for computer systems the text extensively reviews regulations of pharmaceuticals healthcare products blood processing medical devices clinical systems and biotechnology ensuring that organizations transition smoothly to the new system this guide explains how to implement the new gmp paradigm while maintaining continuity with current practices in addition all 24 case studies from the previous edition have been revised to reflect the new system

both pervasive and ubiquitous computerized systems are now an integral component of every corporate strategy in pharmaceutical and healthcare companies however when technology is combined with high risk public safety projects or the production and control of life saving medicines

or devices it is necessary to ensure that it is reliable quality

the book basic concepts of track and trace system for pharmaceutical industry is collection of my experience and guide of my team the book gives the clear understanding of serialization processes global standards regulatory requirements and supply chain visibility using various technologies like rfid al iot and blockchain etc complete understanding of regulatory requirements like dscsa eu fmd along with emerging markets concise explanations of terminologies the book basic for beginner and expert the peoples who s want to know all about the track and trace system

in an era of digital transformation within healthcare management this important book outlines an ecosystem perspective to illustrate how a range of actors can use digital technologies to offer better value within the provision of healthcare services from mobile applications to point of care diagnostic devices from ai enabled applications for data analysis to cloud models for service delivery and blockchain infrastructures it provides a roadmap for how healthcare organizations can leverage these digital technologies the book is also illustrated with case studies from different areas including software for medical diagnostics blockchain infrastructures for use in pharmaceutical supply chains and clinical trials and federated learning platforms for genomics covering key issues such as patients rights to data and written in the aftermath of the covid 19 pandemic the book will be essential reading for researchers postgraduate students and professionals interested in how technology can support and enable healthcare service provision

consequently product innovation should be considered in this context

this handbook details methods for sustainable compliance with gxps and 21 cfr part 11 validation

requirements regarding computerized systems in the pharmaceutical biotechnology and medical device industry the handbook follows fda guidelines and best industry practices in defining roles responsib

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