TESTING COMPUTER SYSTEMS FOR FDA/MHRA COMPLIANCE

David Stokes





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are produced consistently and controlled to the quality standards appropriate for their intended use and as required by product specifications or marketing authorization Annex 11 details the European Medicines Agency EMA GMP requirements for computer systems The purpose of Annex 11 is Data Integrity and Compliance José Rodríguez-Pérez, 2019-05-08 Data integrity is a global mandatory requirement for the regulated healthcare industry It is more than a mere expectation it s a basic element of good documentation practices one of the most fundamental pillars of a quality management system Robustness and accuracy of the data submitted by manufacturers to regulatory authorities when bringing a medical product to market are crucial The purpose of this book is to consolidate existing data integrity principles and expectations from several regulatory sources including the U S Food and Drug Administration World Health Organization and European Medicines Agency into a single and handy document that provides detailed illustrative implementation guidance It serves as a means of understanding regulatory agencies position on good data management and the minimum expectation for how medical product manufacturers can achieve compliance Writing In-House Medical Device Software in Compliance with EU, UK, and US Regulations Philip S. Cosgriff, Matthew J. Memmott, 2024-03-26 This book is a comprehensive guide to producing medical software for routine clinical use It is a practical guidebook for medical professionals developing software to ensure compliance with medical device regulations for software products intended to be sold commercially shared with healthcare colleagues in other hospitals or simply used in house It compares requirements and latest regulations in different global territories including the most recent EU regulations as well as UK and US regulations This book is a valuable resource for practising clinical scientists producing medical software in house in addition to other medical staff writing small apps for clinical use clinical scientist trainees and software engineers considering a move into healthcare The academic level is post graduate as readers will require a basic knowledge of software engineering principles and practice Key Features Up to date with the latest regulations in the UK the EU and the US Useful for those producing medical software for routine clinical use Contains best practice Enhancing compliance to good manufacturing practices and pharmaceutical quality system requirements in vaccine production World Health Organization, 2024-06-25 The British National Bibliography Arthur James Wells, 2005 Laboratory Control System Operations in a GMP Environment David M. Bliesner, 2020-04-27 Develop an understanding of FDA and global regulatory agency requirements for Laboratory Control System LCS operations In Laboratory Control System Operations in a GMP Environment readers are given the guidance they need to implement a CGMP compliant Laboratory Control System LCS that fits within Global Regulatory guidelines Using the Quality Systems Approach regulatory agencies like the FDA and the European Medicine Agency have developed a scheme of systems for auditing pharmaceutical manufacturing facilities which includes evaluating the LCS In this guide readers learn the fundamental rules for operating a CGMP compliant Laboratory Control System Designed to help leaders meet regulatory standards and operate more efficiently the text includes chapters that cover Laboratory Equipment Qualification and

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