Data Integrity in Pharmaceutical and Medical Devices Regulation Operations: Best Practices Guide to Electronic Records Compliance

Orlando Lopez
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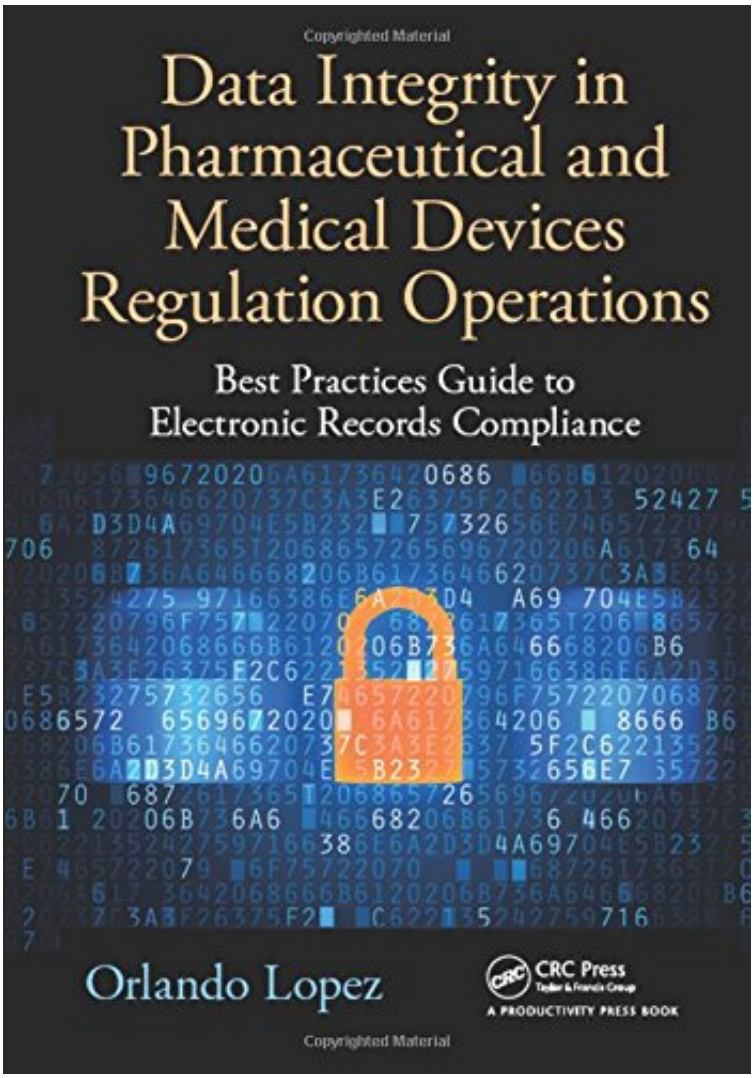

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Data integrity is fundamental in a pharmaceutical and medical devices quality system. This book provides practical information to enable compliance with data integrity, while highlighting and efficiently integrating worldwide regulation into the subject. The ideas presented in this book are based on many yearsrsquo; experience in regulated industries in various computer systems development, maintenance, and quality functions. In addition to case studies, a practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved.

About the AuthorOrlando Lopez Data Integrity SME Durham North Carolina USA Orlando has worldwide pharmaceutical experience with relevant work in computer systems regulatory requirements including US, EMA, Australian, Japanese, WHO, PIC/S, and ICH regulations and guidance's. Experience with direct participation in FDA agency remedial action plans, regulatory inspections, response activities, and consent decree remediation related verifications. He is a member of the data integrity (DI) Working Group (IVT), DI in Manufacturing System Track (PDA) and the Institute of Validation Technology Editorial Advisory Board. He is published in the Encyclopedia of Pharmaceutical Science and Technology, 4th Edition - Chapter 56 Computer Systems Validation (Taylor Francis Group, LLC).