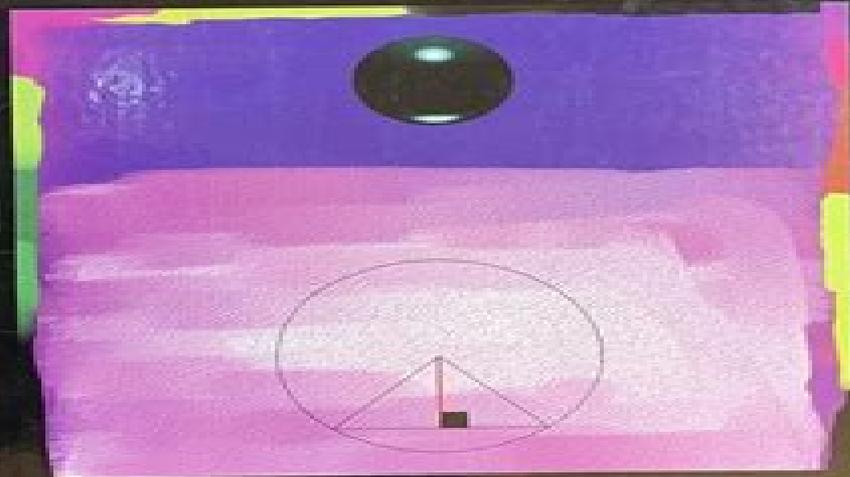


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 FIFTH EDITION

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Data integrity is a critical aspect to the design, implementation, and usage of any system which stores, processes, or retrieves data. The overall intent of any data integrity technique is the same: ensure data is recorded exactly as intended and upon later retrieval, ensure the data is the same as it was when originally recorded. Any alteration to the data is then traced to the person who made the modification. The integrity of data in a patient's electronic health record is critical to ensuring the safety of the patient. This book is relevant to production systems and quality control systems associated with the manufacture of pharmaceuticals and medical device products and updates the practical information to enable better understanding of the controls applicable to e-records. The book highlights the e-records suitability, implementation, and associated risk assessment, controls, and e-records handling. The book also provides updated regulatory standards from global regulatory organizations such as MHRA.

Medicines and Healthcare Products Regulatory Agency UK FDA Food and Drug Administration US National Medical Products Association China TGA Therapeutic Goods Administration Australia SIMGP Russia State Institute of Medicines and Good Practices and the World Health Organization to name a few

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*Boston University Journal of Science & Technology Law Boston University. School of Law,2003*

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**Improving Software Development Productivity** Randall W. Jensen,2014-08-26 Superior software productivity requires a relentless focus on people motivation and communication In Improving Software Development Productivity world renowned software engineering expert Dr Randall W Jensen introduces a proven quantitative approach to achieving this focus Jensen helps you measure your organization s capacity and productivity and then use that information to improve multiple facets of developer and team performance and to build more accurate estimates and schedules Focusing on management as the principal cost and schedule driver in software projects he demonstrates a powerful tool based on his Jensen II Seer model the model that underlies many leading software estimation tools Through real case studies you ll learn how to predict the productivity impact of any major management decision and quantitatively support a transition to extreme or agile software development environments For decades Jensen has been the

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