Foreword

The Pharmaceutical industry is fast evolving with changing guidelines (US FDA, EMEA) aimed at driving higher standards on patient safety. Every year with new drafts/revisions, the Standard Operating Process (SOP) undergo revisions/changes. As a consequence, IT systems, software, hardware, devices need validation as per revised/new norms that drive compliance.

This book describes in easy language the terms, definitions, usage, criteria and the processes from a ‘Computer System Validation (CSV)’ perspective. This chapter aims to drive better understanding of computer system validation, its deliverables, associated risks, documentation required, including Safe Harbor and Good Practices. It has also dealt with electronic submissions, applications that are hosted on the cloud and their treatment.

Highly recommended for students, professionals who are setting a CSV environment, or to help prepare for a mock audit or submission, quality organizations and IT companies.

Arindam Dey is an exponent on this area and has carefully chosen to simplify and yet highlight the importance of CSV in Pharmaceutical and Med Device organizations.

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