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Autore	Pazhayattil Ajay Babu
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Nota di contenuto	Chapter 1: Initial Actions and Information Gathering -- Chapter 2: Root Cause Analysis (RCA) Methods -- Chapter 3: Analytical Tools for Investigation and Generation of Supporting Evidence -- Chapter 4: Management of Deviation and Failure Investigation -- Chapter 5: Post-RCA Impact Assessment, CAPA, and Effectiveness Checks -- Chapter 6: Case Study: Dissolution OOT Observed for an Extended-Release Tablet Formulation -- Chapter 7: Case Study: OOS Uniformity of Dosage Units (Stratified Samples) for a Capsule Formulation -- Appendix I: Non-Conformance/Deviation Investigation -- Appendix II: OOS Failure Investigation -- Appendix III: Review of CDMO Investigation Report.
Sommario/riassunto	This book tackles the crucial topic of deviation and failure investigations in the pharmaceutical industry, recognizing their pivotal influence on regulatory outcomes. Extensive assessments, including analyses of US FDA warning letters and 483 reports, underscore the indispensable necessity of a robust investigation. The textbook thoroughly explores the standard tools and techniques for conducting scientifically grounded and data-driven investigations. Its overarching objective is to elucidate systematic investigation methodologies that yield effective corrective and preventive actions, ultimately reducing

regulatory risks. This book offers a comprehensive overview of standard tools and techniques, focusing on science-based and data-driven approaches. Tailored for professionals in pharmaceutical manufacturing, this book is your go-to resource for mastering investigations in the manufacturing of patient-critical pharmaceutical products.