

1. Record Nr.	UNINA9910988285203321
Autore	Pazhayattil Ajay Babu
Titolo	Pharmaceutical Manufacturing Deviation and Failure Investigations : Principles, Practices, and Case Studies // by Ajay Babu Pazhayattil, Sanjay Sharma
Pubbl/distr/stampa	Cham : , : Springer Nature Switzerland : , : Imprint : Springer, , 2025
ISBN	3-031-86504-9
Edizione	[1st ed. 2025.]
Descrizione fisica	1 online resource (XIII, 152 p. 49 illus., 38 illus. in color.)
Collana	AAPS Introductions in the Pharmaceutical Sciences, , 2522-8358 ; ; 3
Disciplina	615
Soggetti	Pharmacology Pharmacy Pharmacovigilance Drug Safety and Pharmacovigilance
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
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.

2. Record Nr.	UNINA9910619462203321
Autore	Conde Silvia V
Titolo	Impact of Diet Composition on Insulin Resistance
Pubbl/distr/stampa	MDPI - Multidisciplinary Digital Publishing Institute, 2022
ISBN	3-0365-5406-8
Descrizione fisica	1 online resource (236 p.)
Soggetti	Biology, life sciences Food & society Research & information: general
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Sommario/riassunto	Insulin resistance is a key player in the pathology of cardiometabolic diseases - obesity, hypertension, dyslipidaemia, type 2 diabetes and NAFLD. These diseases are commonly associated with a peripheral insulin resistance, but an important role of insulin is played at brain circuitries that control food behaviour and autonomic activity. Brain insulin resistance is also associated with cognition impairment and Alzheimer Disease and other neurodegenerative diseases. Disruptions in diet composition, e.g. hypercaloric diets, and patterns, as well as nutritional status contribute to the genesis of insulin resistance. In contrast, hypocaloric diets, different feed regimens and some nutrients have beneficial impacts on insulin resistance and disease development. This special issue "Impact of diet composition on insulin resistance" is developed to compile studies that highlight the beneficial or

deleterious impact of different nutritional plans on insulin sensitivity and metabolism and that unravel mechanistic links between diet composition and nutritional status and the development of insulin resistance, both periphery and centrally.

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