

1. Record Nr.	UNINA9910580190703321
Titolo	ISMSI 2022 : 2022 6th International Conference on Intelligent Systems, Metaheuristics & Swarm Intelligence : Seoul Korea April 9-10, 2022 // general editor, Suash Deb
Pubbl/distr/stampa	New York : , : Association for Computing Machinery, , 2022
Descrizione fisica	1 online resource (117 pages)
Disciplina	006.3
Soggetti	Artificial intelligence Metaheuristics Swarm intelligence
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
2. Record Nr.	UNINA9911020240703321
Autore	Brown Michael A. <1945->
Titolo	A history of a cGMP medical event investigation / / Michael A. Brown
Pubbl/distr/stampa	Hoboken, N.J., : J. Wiley & Sons, c2013
ISBN	9781118494943 1118494946 9781283917537 128391753X 9781118494936 1118494938 9781118494882 1118494881
Descrizione fisica	1 online resource (251 p.)
Disciplina	615.5/8
Soggetti	Drugs - Side effects - Reporting - United States
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia

Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	<p>Title page; Copyright page; Dedication; Contents; Preface; ***; PART ONE: The Event; 1: Francesca; ***; PART TWO: Drug Discovery: Five Years Earlier; 2: Katlin BioScience: Transgenic Mouse Study; 3: Oxy-Fox Inhaler; 3.1 Kinnen Laboratories; 3.2 Kinnen Laboratories: Oxy-Fox Transfer; 3.3 Due-Diligence Team and Katlin Data Acceptance; PART THREE: Kinnen Oxy-Fox Inhaler Market Launch Program; 4: Agency IND and NDA Requirements, Six Sigma Charter, and Device Master Record; 4.1 Launch Team Meeting Number 1; ***; ***; ***; 4.2 Meeting with Medical Affairs: Toxicity Studies</p> <p>5: Meeting Minutes Guidelines5.1 Launch Team Meeting Number 2; ***; 6: Project Timing, Marketing Plan, and Offshore Molding; 6.1 Launch Team Meeting Number 3; 6.2 Project Financial Review; 6.3 Progress Meeting: Who Takes Credit for What?; 6.4 Morning meeting: Just-in-Time Manufacturing; 7: cGMP Process Validation Requirements; 7.1 Launch Team Meeting Number 4; ***; 8: Failure Mode Effects Analysis; 8.1 Launch Team Meeting Number 5; ***; 9: Design for Manufacturability, Design for Six Sigma, Concurrent Design; 9.1 Product Development Meeting Number 1; ***</p> <p>9.2 Update Meeting with Ed Chase and Gordon Taylor10: Design Fishbone Diagram; 10.1 Launch Team Meeting Number 6; 11: Product Specifications; 11.1 Product Development Meeting Number 2; 12: Design Control; 12.1 Design Team Meeting Number 7; 12.2 Product Development Staff Meeting; 12.3 Engineering One-on-One; 12.4 Program Update; 13: Design of Experiments (DOE); 13.1 Molding Team Meeting; 14: Start-Up Issues; 14.1 Oxy-Fox Inhaler Wrap-Up and Equipment Start-Up; ***; 14.2 The Final Management Review; ***; PART FOUR: Present Day: Funeral; 15: Grief; ***; 16: The Autopsy Results; *** 17: The Agency***; ***; PART FIVE: Agency Medical Event Letter; 18: Kinnen Notification; 18.1 Another Agency Letter; 18.2 Medical Event Review Meeting; ***; 19: Investigation Team Management; 19.1 Morning Meeting with Gail Strom, Marcia Hines, and Dan Garvey; 20: DMAIC Investigation Process; 21: Internal Quality Review; 21.1 Meeting with Gail Strom and Marcia Hines; 21.2 Executive Management Review; ***; ***; ***; 22: The Agency Audit Letter; ***; 23: Agency Arrival; ***; 24: The Audit</p> <p>24.1 Agency Meeting to Review Qualification Documents and the Quality Acceptance Records of First Lot to Stock***; 24.2 Agency Meeting to Review the Oxy-Fox Inhaler Lot Used in the NDA Clinical Studies; 24.3 Agency Meeting to Review the Design and Program Team Meeting Minutes; ***; 24.4 Agency Meeting to Review the Due-Diligence Report, Katlin Studies, and Oxy-Fox Design History File; ***; 25: End-of-Day Agency Wrap-Up Meeting; ***; 26: Kinnen Management Review; ***; ***; PART SIX: Reckoning; 27: Blame and Responsibility; 27.1 The Investigation Is a Public Record; 27.2 Kinnen Wrap-Up; *** 28: Closure</p>
Sommario/riassunto	Case study details the right way and the wrong way to successfully develop and market a new drug. Beginning with the untimely death of a young mother, A History of a cGMP Medical Event Investigation unfolds a fictitious case study that captures how unchecked human flaws during the development and launch of a new drug can lead to disastrous consequences. Moreover, it illustrates how and why Six Sigma principles and methods should be applied to fully comply with FDA regulations at every stage of drug development and commercialization. From initial transgenic mouse studies

