

STANDARD OPERATING PROCEDURE (S.O.P)

تعليمات

SUBJECT :	Deviation Reporting		
Department :	Quality Assurance		
Document No. :	QQI-216-4/0		
Prepared By :	Reviewed By :	Approved By :	Issue Date : / /
QA. Section Head	QA. Vice Manager	Management Rep.	Modification Date: / /
			Due Date : / /
Dr. Mohamed Wallash	Dr. Eman Fekry	Dr. Wael Ebeid	Implementation Date: / /
Date: / /	Date: / /	Date: / /	Copy No. :
1.Purpose(الغرض): 2.Scope : مجال التطبيق	To provide instructions for the process of reporting, investigating & handling deviations from defined procedures and processes. 2.1 Documents covered under the scope of this standard operating procedure include the following, but are not limited to: • Standard Operating Procedures. • Manufacturing Procedures. • Packing Procedures. • Cleaning Procedures. • Environmental Monitoring. • Batch analysis (In-Process Control). • Utility Operations. • Calibration Procedures. 2.2 Out –Of Specifications (OOS); analytical results & stability results are not covered by this instruction and are detailed in (QQI-527).		
3.Responsibility: المسئولية	3.1 It is the responsibility of each production function/department to follow the procedure and system by which the root causes of deviation are identified, investigated and documented. 3.2 It is the responsibility of each production function/department to undertake and track appropriate and timely corrective and preventative actions. 3.3 It is the responsibility of Quality Assurance to approve deviation reports prior to product release decision.		

Sop Pharmaceutical Management Review Gmp Manual

Sarfaraz K. Niazi



Sop Pharmaceutical Management Review Gmp Manual:

Mastering Quality Assurance in Pharma: A Comprehensive Guide to cGMP, Risk Management 2025 AUTHOR:1-Vamsi Krishna Gottipati, AUTHOR:2-Prof (Dr) Rakesh Kumar Dwivedi, PREFACE In today's hyperconnected world the ability to integrate intelligent networking stringent quality management and resilient security measures has become a decisive competitive advantage As organizations strive to innovate at pace they face an intricate web of regulatory requirements technological complexities and evolving threat landscapes This book is crafted to guide professionals through these intersecting domains artificial intelligence in networking pharmaceutical quality systems under global cGMP standards and state of the art infrastructure security providing both conceptual frameworks and actionable insights The journey begins with Chapter 1 which introduces the principles of AI driven networking from dynamic traffic optimization to self healing network topologies This foundation sets the stage for Chapters 2-4 where we delve into the world of pharmaceutical quality We explored global cGMP requirements methods for designing and maintaining a robust Quality Management System and best practices for preserving documentation integrity and data trustworthiness These chapters underscore that quality is not a static target but a continuously evolving process driven by meticulous controls and unwavering compliance Chapters 5 and 6 focus on Quality Risk Management identifying assessing and mitigating risks across manufacturing operations Real world examples illustrate how risk based decision making reduces variability enhances product safety and fosters regulatory confidence Chapter 7 then broadens the conversation into a comprehensive guide to cGMP and risk management weaving together the theoretical underpinnings with hands on strategies for audit readiness change control and corrective actions Chapter 8 emphasizes quality control excellence covering analytical method validation in process controls and statistical quality tools that ensure every batch meets predetermined specifications As technology reshapes traditional workflows Chapter 9 examines digital transformation initiatives cloud migration data analytics and IoT integration that elevate quality management to new heights In Chapter 10 we address the cultural and organizational dimensions of quality leadership commitment continuous training and fostering a proactive quality first mindset that permeates every level of an enterprise With the convergence of microservices and containerized environments security is no longer an afterthought Chapter 11 presents a deep dive into holistic security patterns for microservices zero trust architectures service mesh encryption policy enforcement engines and automated drift detection You'll learn how to embed security throughout the development lifecycle ensuring that every service to service interaction adheres to the highest standards of trust and integrity Finally Chapter 12 casts a forward looking vision on infrastructure evolution serverless platforms that eliminate operational overhead edge computing that brings processing closer to data sources autonomous systems that self optimize and the emerging trends that will define the next decade Whether you are an IT architect a quality assurance leader in the pharmaceutical industry or a technology executive charting a digital transformation roadmap this book equips you with the knowledge and tools to

navigate complexity By uniting AI driven networking rigorous quality systems and resilient security frameworks you will be prepared to achieve regulatory compliance operational excellence and sustainable innovation in an ever changing landscape Let this comprehensive guide serve as both a reference and a catalyst for your organization s journey toward intelligent secure and quality driven operations Authors Vamsi Krishna Gottipati Prof Dr Rakesh Kumar Dwivedi *Enhancing compliance to good manufacturing practices and pharmaceutical quality system requirements in vaccine production* World Health Organization,2024-06-25 *Pharmaceutical Vendors Approval Manual* Erfan Syed Asif,2021-12-12 This book provides stepwise guidance on how to evaluate audit qualify and approve an active pharmaceutical ingredient API and packaging material manufacturer and supplier to enhance the GMP within the industry The book will also be beneficial for institutions conducting pharmaceutical technology courses in terms of GMP and GLP applications The Pharmaceutical Vendors Approval Manual provides readers and front line health care products manufacturers R D management and biotech laboratories all the information they need to know to develop a GMP oriented industry with trained and skilled personnel and manufacture products that meet GMP and regulatory requirements This book provides a simple concise and easy to use reference tool covering basic quality concepts and the elements of vendor s assessment qualification and approval required by the pharmaceutical educational institutions and professional certification bodies It is equally relevant to Quality Assurance officers Quality Control Analysts Quality Auditors and other personnel involved in GMP GLP services in the company The book will also be beneficial for the institutions conducting Pharmaceutical technology study courses in terms of GMP and GLP applications This book provides readers and front line health care products manufacturers R D management and biotech laboratories all the information they need to know to develop a GMP oriented industry with trained and skilled personnel and manufacture products that meet GMP and regulatory requirements covers basic quality concepts and the elements of vendor s assessment qualification and approval required by the pharmaceutical educational institutions and professional certification bodies provides stepwise guidance on how to evaluate audit qualify and approve an API and packaging material manufacturer and supplier to enhance the GMP within the industry provides ready to use regulatory documentation e g letter of commitment questionnaire SOP etc required for API and Packaging Materials contract Provided material can be easily tailored to incorporate changes to add in house vendor s qualification requirements Erfan Syed Asif Ph D is a Senior Consultant at PharmEng Technology [A Comprehensive Guide to Pharmaceutical Quality Assurance \(As per PCI Syllabus\)](#) Dr. Mohan Gandhi Bonthu, Dr. G. Raveendra Babu, Mr. L. Ramachandra Reddy, Dr. M. Kishore Babu, Dr. N. Sai Krishna,2025-09-05 This textbook offers a thorough exploration of Quality Assurance QA in the pharmaceutical industry tailored to meet the requirements of the Pharmacy Council of India PCI syllabus It comprehensively covers critical aspects of pharmaceutical quality systems including Good Manufacturing Practices GMP Total Quality Management TQM ICH Guidelines and ISO standards The book highlights key principles of drug quality control calibration validation and complaint

management emphasizing the application of scientific principles to guarantee product safety and efficacy With clear explanations and practical examples it is designed to equip both students and professionals with the essential knowledge and skills needed to maintain the highest standards of quality in pharmaceutical production and testing

GMP Audits in Pharmaceutical and Biotechnology Industries Mustafa Edik, 2024-06-28 The fact that good manufacturing practice GMP audits in the pharmaceutical and biotechnology industries have to be evaluated and with very limited resources has created a gap in this field The lack of trained and qualified GMP auditors is on the rise in all organizations that are required to implement FDA EMA MHRA WHO TGA and PIC S regulations This volume is an essential reference source for those organizations operating in the field of health and presents the basic knowledge needed to perform audits The author also provides useful tips and a selection of samples about GMP audits that are indispensable for professionals and health inspectors working in industry and health authorities Features An essential reference source for those organizations operating in the field of health and presents the basic knowledge needed to perform audits Anyone working in the manufacturing sector needs to be aware of GMP be able to identify operational flaws as well as legal violations and have a clear understanding of how to meet GMP standards Assists readers in understanding the importance of GMP and how they can apply each aspect in their working environment Covers a global regulatory landscape Suitable for relevant degree courses including industrial pharmaceuticals and pharmaceutical biotechnology

TEXT BOOK OF MODERN PHARMACEUTICS Mrs. Ritu Bharti, Dr. S.P. Senthil, Dr. Pritam Rajkumar Siraskar, Dr. Rajkumari Thagele, Dr. Sanjeev Kumar Chauhan, 2025-11-03 Textbook of Modern Pharmaceutics is a comprehensive and meticulously crafted academic resource designed to meet the advanced curriculum standards prescribed by the Pharmacy Council of India for M Pharm students The book begins with detailed coverage of preformulation concepts emphasizing drug excipient interactions stability kinetics and dispersion systems such as emulsions suspensions and SMEDDS It also elaborates on large and small volume parenterals focusing on physiological and formulation considerations manufacturing and evaluation techniques A major strength of the book lies in its chapter on optimization techniques which introduces essential statistical tools like response surface methodology factorial and contour designs crucial for formulation development The section on validation provides exhaustive insight into various types of validation calibration URS DQ IQ OQ and PQ along with ICH and WHO regulatory guidelines In addition the book thoroughly explores current Good Manufacturing Practices cGMP detailing objectives policies facility layout and equipment maintenance ensuring compliance with global quality standards The industrial management chapter gives a clear view of production organization materials handling inventory control budgeting and sales forecasting integrating business management principles into pharmaceuticals Another highlight is the inclusion of Total Quality Management TQM emphasizing quality integration across all pharmaceutical operations The section on compression and compaction delves into tablet physics frictional effects and compaction profiling essential for solid dosage formulation It also

discusses consolidation diffusion and dissolution parameters linking them with pharmacokinetics and biopharmaceutical principles The book offers valuable tools such as Heckel plots Higuchi and Peppas models and similarity factors f_1 f_2 supported by statistical tests like t test ANOVA and chi square enabling precise data interpretation Written in a lucid easy to understand style with neatly labeled figures the text encourages self learning and conceptual clarity Overall this textbook integrates theoretical foundations experimental approaches and regulatory perspectives making it an indispensable guide for students educators researchers and professionals engaged in modern pharmaceutical formulation and development

Handbook of Pharmaceutical Manufacturing Formulations, Third Edition Sarfaraz K. Niazi, 2019-11-25 The Handbook of Pharmaceutical Manufacturing Formulations Third Edition Volume Two Uncompressed Solid Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing With thoroughly revised and expanded content this second volume of a six volume set compiles data from FDA and EMA new drug applications patents and patent applications and other sources of generic and proprietary formulations including author's own experience to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting A must have collection for pharmaceutical manufacturers educational institutions and regulatory authorities this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent Features Largest source of authoritative and practical formulations cGMP compliance guidance and self audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing bioequivalence testing and full compliance with drug product safety elements Written by a well recognized authority on drug and dosage form development including biological drugs and alternative medicines

Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing Hamid Mollah, Harold Baseman, Mike Long, 2013-02-01 Sets forth tested and proven risk management practices in drug manufacturing Risk management is essential for safe and efficient pharmaceutical and biopharmaceutical manufacturing control and distribution With this book as their guide readers involved in all facets of drug manufacturing have a single expertly written and organized resource to guide them through all facets of risk management and analysis It sets forth a solid foundation in risk management concepts and then explains how these concepts are applied to drug manufacturing Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing features contributions from leading international experts in risk management and drug manufacturing These contributions reflect the latest research practices and industry standards as well as the authors firsthand experience Readers can turn to the book for Basic foundation of risk management principles practices and applications Tested and proven tools and methods for managing risk in pharmaceutical and biopharmaceutical product manufacturing processes Recent FDA guidelines EU regulations and international standards governing the application of risk management to drug manufacturing

Case studies and detailed examples demonstrating the use and results of applying risk management principles to drug product manufacturing Bibliography and extensive references leading to the literature and helpful resources in the field With its unique focus on the application of risk management to biopharmaceutical and pharmaceutical manufacturing this book is an essential resource for pharmaceutical and process engineers as well as safety and compliance professionals involved in drug manufacturing

Essential Elements for a GMP Analytical Chemistry Department Thomas Catalano,2013-06-20 Essential Elements for a GMP Analytical Chemistry Department is a systematic approach to understanding the essential elements required for a successful GMP Analytical Department to function as an efficient and effective organization It describes in detail a department structure which allows for the necessary processes to become available to all its personnel in a way where there is a free flow of information and interaction The environment and culture created by this approach encourages and rewards the sharing of ideas skills and abilities among department personnel The essential elements such as SOP s regulatory guidance s guidelines project teams technical and department processes personnel motivation outsourcing and hiring the best is among the many topics that are discussed in detail and how they can be implemented to build an efficient and effective Analytical Department This book will serve as a valuable asset to the many companies required to perform GMP analytical method development validation analyses etc including start up virtual and generic pharmaceutical companies

Pharmaceutical Quality Assurance Mr. Manohar A. Potdar,2006 Data Integrity and Data Governance R. D. McDowall,2018-11-09 This book provides practical and detailed advice on how to implement data governance and data integrity for regulated analytical laboratories working in the pharmaceutical and allied industries

Good Manufacturing Practices for Pharmaceuticals, Seventh Edition Graham P. Bunn,2019-02-04 This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task oriented procedure based cultures to truly integrated quality business systems that are self detecting and correcting Chapter flow has been changed to adopt a quality systems organization approach and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends Key Features Presents insight into the world of pharmaceutical quality systems Analyzes regulatory trends and expectations Includes approaches and practices used in the industry to comply with regulatory requirements Discusses recent worldwide supply chain issues Delivers valuable information to a worldwide audience regarding the current GMP practices in the industry

Application of Project Management Principles to the Management of Pharmaceutical R&D Projects Thomas Catalano,2020-11-05 Dr Catalano has for the last ten years been doing consulting for the Pharmaceutical Industry During his consulting he discovered that small businesses such as generic startups and virtual companies do not have the budget or the resources to apply the computer software utilized in project management and therefore do not apply project management principles in their business model This reduces their effectiveness and increases

their operating cost Application of Project Management Principles to the Management of Pharmaceutical R D Projects is presented as a paper based system for completing all the critical activities needed apply the project management system This will allow these small business to take advantage of the project management principles and gain all the advantages of the system This book will be beneficial for beginners to understand the concepts of project management and for small pharmaceutical companies to apply the principles of project management to their business model

Handbook of Validation in Pharmaceutical Processes, Fourth Edition James Agalloco, Phil DeSantis, Anthony Grilli, Anthony Pavell, 2021-10-28 Revised to reflect significant advances in pharmaceutical production and regulatory expectations Handbook of Validation in Pharmaceutical Processes Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions As the industry s leading source for validation of sterile pharmaceutical processes for more than 10 years this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio pharmaceutical production processes Handbook of Validation in Pharmaceutical Processes Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals Key Features Provides an in depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program and suggests the newest and most advanced solutions Explores distinctive and specific process steps and identifies critical process control points to reach acceptable results New chapters include disposable systems combination products nano technology rapid microbial methods contamination control in non sterile products liquid chemical sterilization and medical device manufacture

Pharmaceutical Analysis for Small Molecules Behnam Davani, 2017-08-01 A comprehensive introduction for scientists engaged in new drug development analysis and approvals Each year the pharmaceutical industry worldwide recruits thousands of recent science graduates especially chemistry analytical chemistry pharmacy and pharmaceutical majors into its ranks However because of their limited background in pharmaceutical analysis most of those new recruits find making the transition from academia to industry very difficult Designed to assist both recent graduates as well as experienced chemists or scientists with limited regulatory compendial or pharmaceutical analysis background make that transition Pharmaceutical Analysis for Small Molecules is a concise yet comprehensive introduction to the drug development process and analysis of chemically synthesized small molecule drugs It features contributions by distinguished experts in the field including editor and author Dr Behnam Davani an analytical chemist with decades of technical management and teaching experience in compendial regulatory and industry This book provides an introduction to pharmaceutical analysis for small molecules non biologics using commonly used techniques for drug characterization and performance tests The driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to regulatory bodies for drug approval in

order to market their products In addition related required supporting studies including good laboratory documentation practices including analytical instrument qualification are highlighted in this book Topics covered include Drug Approval Process and Regulatory Requirements private standards Pharmacopeias and Compendial Approval Process public standards Common methods in pharmaceutical analysis typically compendial Common Calculations for assays and impurities and other specific tests Analytical Method Validation Verification Transfer Specifications including how to handle out of specification OOS and out of trend OOT Impurities including organic inorganic residual solvents and elemental impurities Good Documentation Practices for regulatory environment Management of Analytical Laboratories Analytical Instrument Qualifications including IQ OQ PQ and VQ Due to global nature of pharmaceutical industry other topics on both regulatory ICH and Compendial harmonization are also highlighted Pharmaceutical Analysis for Small Molecules is a valuable working resource for scientists directly or indirectly involved with the drug development process including analytical chemists pharmaceutical scientists pharmacists and quality control quality assurance professionals It also is an excellent text reference for graduate students in analytical chemistry pharmacy pharmaceutical and regulatory sciences **Guide to Cell**

Therapy GxP Joaquim Vives, Gloria Carmona, 2015-07-24 Guide to Cell Therapy GxP is a practical guide to the implementation of quality assurance systems for the successful performance of all cell based clinical trials The book covers all information that needs to be included in investigational medicinal product dossier IMPD the launching point for any clinical investigation and beyond Guide to Cell Therapy GxP bridges a knowledge gap with the inclusion of examples of design of GLP compliant preclinical studies design of bioprocesses for autologous allogeneic therapies and instruction on how to implement GLP GMP standards in centers accredited with other quality assurance standards Guide to Cell Therapy GxP is an essential resource for scientists and researchers in hospitals transfusion centers tissue banks and other research institutes who may not be familiar with the good scientific practice regulations that were originally designed for product development in corporate environments This book is also a thorough resource for PhD students Post docs Principal Investigators Quality Assurance Units and Government Inspectors who want to learn more about how quality standards are implemented in public institutions developing cell based products Easy access to important information on current regulations state of the art techniques and recent advances otherwise scattered on various funding websites within conference proceedings or maintained in local knowledge Features protocols techniques for trouble shooting common problems and an explanation of the advantages and limitations of a technique in generating conclusive data Includes practical examples of successful implementation of quality standards *Validation of Pharmaceutical Processes* James P. Agalloco, Frederick J. Carleton, 2007-09-25 Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations this third edition of *Validation of Pharmaceutical Processes* examines and blueprints every step of the validation process needed to remain compliant and competitive The many chapters added to

the prior compilation examine via Good Design Practices for GMP Pharmaceutical Facilities Terry Jacobs, Andrew A. Signore, 2016-08-19 This revised publication serves as a handy and current reference for professionals engaged in planning designing building validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U S and internationally The new edition expands on facility planning with a focus on the ever growing need to modify existing legacy facilities and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings All chapters have been re examined with a fresh outlook on current good design practices

Biocontamination Control for Pharmaceuticals and Healthcare Tim Sandle, 2024-01-28 Biocontamination Control for Pharmaceuticals and Healthcare outlines a biocontamination strategy that tracks bio burden control and reduction at each transition in classified areas of a facility The first edition of the book covered many of the aspects of the strategy but the new official guidance signals that a roadmap is required to fully comply with its requirements Completely updated with the newest version of the EU GPM EN17141 the new edition expands the coverage of quality risk management and new complete examples to help professionals bridge the gap between regulation and implementation Biocontamination Control for Pharmaceuticals and Healthcare offers professionals in pharma quality control and related areas guidance on building a complete biocontamination strategy Includes the most current regulations Contains three new chapters including Application of Quality Risk Management and its Application in Biocontamination Control Designing an Environmental Monitoring Programme and Synthesis An Anatomy of a Contamination Control Strategy Offers practical guidance on building a complete biocontamination strategy Handbook of Pharmaceutical Manufacturing Formulations Sarfaraz K. Niazi, 2016-04-19 Over the Counter products comprise a special category of healthcare products While these formulations have much in common with their prescription counterparts they are presented in this series separately because of their development approach taken labeling considerations required and support available from suppliers of ingredients in designing

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