

SOP FOR ANNUAL PRODUCT REVIEW

1. Purpose

- 1.1. The purpose of this document is to describe the procedure for annual review of products manufactured during a year.

2. Scope:

- 2.1. It is applicable to Quality Assurance Department.

3. Responsibility:

- 3.1. Quality Assurance Manager

4. Procedure:

- 4.1. Annual product review shall be conducted each year in the month of January.
- 4.2. Product review shall be based on following critical parameters of product batches:
 - ☐ Assay
 - ☐ PH
- 4.3. Review shall be done for all batches of each product manufactured during a year.
- 4.4. Annual Product Review (APR) report shall be generated after completion of product batch data and signed by concerned authorized personnel.
- 4.5. Recommendations on deviations shall be forwarded to production department for necessary action.

5. List of Recipients:

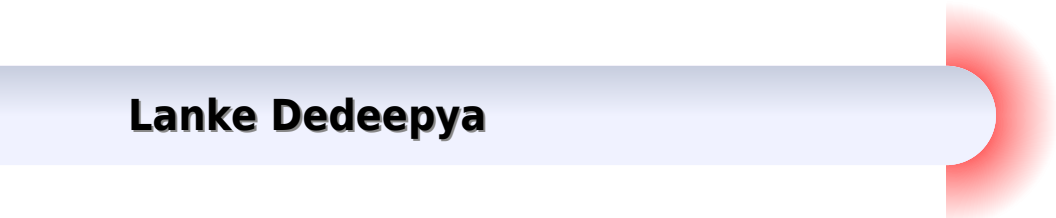
- 5.1. Quality Assurance Manager

6. Attached Forms/ Annexures:

- 6.1. Annual Product Review (APR) format

Annual Product Review Sop

Lanke Dedeepya



Annual Product Review Sop:

A BOOK OF ANNUAL PRODUCT QUALITY REVIEW FOR ACTIVE PHARMACEUTICAL INGREDIENTS AND ITS COMPARISON BETWEEN THE USA & EUROPE REGULATORY ASPECTS Lanke Dedeepya, 2022-05-11 Annual Product quality review verifies the consistency of the existing manufacturing processes and determines the quality and process defects of the products. It also determines possible improvements of the methods and process and the trend of yield analytical results and manufacturing parameters of the product are also highlighted. Annual product quality review APQR shall be completed within 90 days for example Annual product quality review APQR for products manufactured during the period of January 2020 to December 2020 shall be completed by March 2021

Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics Carmen Medina, 2003-12-09 This text lists the necessary steps for meeting compliance requirements during the drug development process. It presents comprehensive approaches for validating analytical methods for pharmaceutical applications

Quality Control Training Manual Syed Imtiaz Haider, Syed Erfan Asif, 2016-04-19 Written to help companies comply with GMP GLP and validation requirements imposed by the FDA and regulatory bodies worldwide. Quality Control Training Manual Comprehensive Training Guide for API Finished Pharmaceutical and Biotechnologies Laboratories presents cost effective training courses that cover how to apply advances in the life sciences to produce commercially viable biotech products and services in terms of quality safety and efficacy. This book and its accompanying downloadable resources comprise detailed text summaries test papers and answers to test papers providing an administrative solution for management. Provides the FDA Health Canada WHO and EMEA guidelines directly applicable to pharmaceutical laboratory related issues. Offers generic formats and styles that can be customized to any organization and help management build quality into routine operations to comply with regulatory requirements. Contains ready to use training courses that supply a good source of training material for experienced and inexperienced practitioners in the biotechnology biopharmaceutical industries. Includes downloadable resources with downloadable training courses that can be adopted and directly customized to a particular organization. Supplies ready to use test papers that allow end users to record all raw data up to the issuance of the attached certificate. The biotechnology bioscience industries are regulated worldwide to be in compliance with cGMP and GLP principles with particular focus on safety issues. Each company must create a definite training matrix of its employees. The training procedures in this book enable end users to understand the principles and elements of manufacturing techniques and provide documentation language ranging from the generic to the specific. The training courses on the downloadable resources supply valuable tools for developing training matrices to achieve FDA Health Canada EMEA MHRA UK WHO and GLP compliance

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

Quality Assurance Dr. R. Sundhararajan, Dr. M.V. Kumudhavalli, Dr. Minal T, 2022-03-03 Explore the budget friendly e Book version of Quality Assurance for B Pharm 6th Semester following the PCI Syllabus Published by Thakur Publication this digital edition delivers the same comprehensive content at just a fraction of the cost of the paperback Don't miss out on this opportunity to save 60% compared to the physical edition Grab your copy today and elevate your learning experience

Quality Operations Procedures for Pharmaceutical, API, and Biotechnology Syed Imtiaz Haider, Erfan Syed Asif, 2012-06-06 To stay in compliance with regulations pharmaceutical medical and biotech companies must create quality SOPs that build in the regulatory requirements into actions and describe personal flow internal flow flow of information and processing steps Quality Operations Procedures for Pharmaceutical API and Biotechnology and the accompanying CD ROM take into account all major international regulations such as FDA EU GMP cGMP GLP PDA technical monographs PDA technical reports PMA concepts journals of PDA GCP and industry standard ISO 9000 to be in compliance with documentation guidelines No other resource deals exclusively with the key elements of quality control and quality assurance procedures for pharmaceutical operations and provides hands on templates to be tailored to achieve global regulatory compliance The book provides instant answers about what to include in critical quality assurance and quality control SOPs and how to enhance productivity The CD ROM contains nineteen quality control and thirty three quality assurance SOPs designed so that users can input them into their computers and use their Microsoft Word programs to edit and print these documents The book ensures minimization of the number of documents helping to reduce the nightmare like aura that surrounds an FDA audit The SOPs exclusively refer to the documents specially required for compliance however specific formats are not included to ensure that the electronic templates can be easily used by pharmaceutical bulk pharmaceutical medical device and biotechnology industries The combination of text and CD ROM presents a ready to use resource on the quality systems of aseptic pharmaceutical non aseptic production and to provide general information and guidelines They comprise a tool that can be used to develop a set of quality SOPs in order to support the road map

established for the on time successful start up of the facility operation in compliance with the GMP requirements *Good Manufacturing Practices for Pharmaceuticals* Joseph D. Nally, 2016-04-19 With global harmonization of regulatory requirements and quality standards and national and global business consolidations ongoing at a fast pace pharmaceutical manufacturers suppliers contractors and distributors are impacted by continual change Offering a wide assortment of policy and guidance document references and interpretations this Sixth Edition is significantly expanded to reflect the increase of information and changing practices in CGMP regulation and pharmaceutical manufacturing and control practices worldwide An essential companion for every pharmaceutical professional this guide is updated and expanded by a team of industry experts each member with extensive experience in industry or academic settings **Process Validation & cGMP (Part - 2)** Mr. Rohit Manglik, 2024-03-24 Advances knowledge of continuous process monitoring quality by design and advanced regulatory compliance in manufacturing Process Validation in Manufacturing of Biopharmaceuticals Gail Sofer, 2000-03-24 A study of biopharmaceutical process validation It aims to enable developers and producers to ensure safe products reduce the risk of adverse reactions in patients and avoid recalls by outlining sophisticated validation approaches to characterize processes process intermediates and final product fully The text emphasizes cost effectiveness wh

Establishing A CGMP Laboratory Audit System David M. Bliesner, 2006-04-20 The first systematic hands on auditing guide for today s pharmaceutical laboratories In today s litigious environment pharmaceutical laboratories are subject to ever stricter operational guidelines as mandated by the FDA and must be able to establish and demonstrate sustainable operational practices that ensure compliance with the current good manufacturing practice CGMP regulations David Bliesner s *Establishing a CGMP Laboratory Audit System A Practical Guide* is designed to provide laboratory supervisors and personnel with a step by step hands on audit system that they can rely on to ensure their facility remains compliant with all current and future requirements Focusing on a team approach the author uses detailed flowcharts checklists and descriptions of the auditing process to help readers develop a new audit system or upgrade their current system in order to Improve current compliance Demonstrate sustainable compliance Produce data for federal inspections Avoid regulatory action Enhanced with detailed checklists and a wealth of practical and flexible auditing tools on CD ROM this book provides an ideal resource for new and future laboratory personnel and an excellent means for keeping existing industry practitioners up to date on the nuances of operating a consistently compliant pharmaceutical laboratory **Modern Aspects of Pharmaceutical Quality Assurance** Minal Ghante, Manohar Potdar, Vidhya Bhusari, 2024-03-11 The pharmaceutical quality system ensures that the process performance is suitably achieved the product quality is regularly met improved opportunities are identified and evaluated and the knowledge is constantly expanded Auditing also plays a crucial role within the pharmaceutical industry It helps to assess and review quality to improve and build a better system for the benefit of companies This book aims to develop a tool that will substantially decrease the number of Inspectional Observations and

Warning letters thus eliminating Import Alerts and Consent Decree This book targets the Pharmaceutical Industry and students of Pharmaceutical Quality Assurance so they can get in hand ready consolidated information on Pharmaceutical Quality guidelines Quality metrics and implementation of simplified SOP guidelines plant layouts to implement Quality metrics for Pharmaceutical Manufacturing systems in tablets capsules liquid orals and semi solid dosage forms The chapters cover the various aspects of Pharmaceutical Quality Assurance The selection of topics is mainly based on the requirements of Pharmaceutical regulatory guidelines of India the UK the USA Australia and South Africa Each chapter includes the abstract detailed explanation implementation guidelines flowcharts layouts and Standard Operating Procedure of quality metrics for the Pharmaceutical Manufacturing System **GMP Compliance, Productivity, and Quality** Vinay Bhatt,1998-06-30

Written by twenty eight experts filled with recommendations that can immediately be put into action this book provides the strategies and tactics required to link and harmonize manufacturing processes with GMP to achieve optimum operability and cost effective regulatory compliance Drawn from name brand and generic companies and regulatory and contract organizations across the globe the contributing authors bring readers a combined 450 years of hands on experience They offer thought provoking questions to help readers diagnose their company s challenges needs and available options all with the single purpose of achieving their ultimate goals quality high productivity and profitability Generic Drug Product Development Leon Shargel,Isadore Kanfer,2013-10-24

In this era of increased pharmaceutical industry competition success for generic drug companies is dependent on their ability to manufacture therapeutic equivalent drug products in an economical and timely manner while also being cognizant of patent infringement and other legal and regulatory concerns Generic Drug Product Development Solid Oral Dosage Forms Second Edition presents in depth discussions from more than 30 noted specialists describing the development of generic drug products from the raw materials to the development of a therapeutic equivalent drug product to regulatory approval Major topics discussed include Active pharmaceutical ingredients Experimental formulation development including a new section on Quality by Design QbD Scale up Commercial product formulation Quality control and bioequivalence Drug product performance ANDA regulatory process Post approval changes Post marketing surveillance Legislative and patent challenges This second edition also contains a new chapter on the relationship between the FDA and the United States Pharmacopeia and in Chapter 4 using specific examples the application of Quality by Design QbD during formulation development is examined The book is a thorough guide to the development of solid oral generic dosage formulations This textbook is ideal for the pharmaceutical industry graduate programs in pharmaceutical sciences and health professionals working in the area of generic drug development **Pharma Interview**

Questions and Answers Abhishek Chouhan, Pharma Interview Questions and Answers This book contain all the information that will help you crack any Pharmaceutical interview as well as Questions and Answers This book is suitable for Production Quality assurance Quality control Regulatory affairs Research and development product development and Pharmacovigilance

etc Computer Systems Validation Guy Wingate,2003-12-18 Both pervasive and ubiquitous computerized systems are now an integral component of every corporate strategy in pharmaceutical and healthcare companies However when technology is combined with high risk public safety projects or the production and control of life saving medicines or devices it is necessary to ensure that it is reliable quality *FDA's Generic Drug Enforcement and Approval Process* United States. Congress. House. Committee on Energy and Commerce. Subcommittee on Oversight and Investigations,1992 *Sterile Manufacturing* Sam A. Hout,2021-07-04 This book highlights key ideas and factors to coach and guide professionals involved in learning about Sterile Manufacturing and operational requirements It covers regulations and guidelines instituted by the FDA ISPE EMA MHRA and ICH emphasizing good manufacturing practice and inspection requirements in the manufacturing of medicinal products Additionally this book provides the fundamentals of aseptic techniques quality by design risk assessment and management in support of sterile operations applications It creates a link to the implementation of business practices in drug manufacturing and healthcare and forms a correlation between design strategies including a step by step process to ensure reliability safety and efficacy of healthcare products for human and animal use The book also provides a connection between drug production and regulated applications by offering a review of the basic elements of sterile processing and how to remain viable with solid strategic planning The book is a concise reference for professionals and learners in the field of sterile operations that governs primarily pharmaceutical and medical device space but can also extend to food and cosmetics that require clean aseptic manufacturing applications It also helps compounding pharmacists and GMP inspectors and auditors *Write It Down* Janet Gough,1999-10-01 A well understood tenet exists among the FDA and other regulatory bodies if you didn t write it down it didn t happen And if it didn t happen your company stands to lose time money and perhaps its competitive edge This book provides writers with the tools they need to put effective documentation in place It offers a broad range of documents representative of the types of writing in the healthcare industry from the laboratory and QA to manufacturing and regulatory affairs The book offers valuable insights into managing systems and producing documentation that meets the requirements of the binding regulations **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 va *Manufacturing of Quality Oral Drug Products* Sam A. Hout,2022-06-27 This book provides an understanding of what is required to engineer and manufacture drug products It bridges established concepts and provides for a new outlook by concentrating and creating new linkages in the implementation of manufacturing quality assurance and business practices related to drug manufacturing and healthcare products This book fills a gap by providing a connection between drug production and regulated applications It focuses on drug manufacturing quality techniques in oral

solid dosage and capsule filling including equipment and critical systems to control production and the finished products The book offers a correlation between design strategies and a step by step process to ensure the reliability safety and efficacy of healthcare products Fundamentals of techniques quality by design risk assessment and management are covered along with a scientific method approach to continuous improvement in the usage of computerized manufacturing and dependence on information technology and control operations through data and metrics Manufacturing and Quality Assurance of Oral Pharmaceutical Products Processing and Safe Handling of Active Pharmaceutical Ingredients API is of interest to professionals and engineers in the fields of manufacturing engineering quality assurance reliability business management process and continuous improvement life cycle management healthcare products manufacturing pharmaceutical processing and computerized manufacturing

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