

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 Template

Lanke Dedeepya



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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. *Pharmaceutical Vendors Approval Manual* Erfan Syed Asif, 2021-12-12 This book provides stepwise guidance on how to evaluate audit quality 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 quality 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. **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

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

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

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 **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 **Pharmaceutical Quality Systems** Oliver Schmidt,2000-04-30 When a pharmaceutical company decides to build a Quality System it has to face the fact that there aren't any guideline that define exactly how such a system has to be built With terms such as quality system quality assurance and quality management used interchangeably even defining the system's objectives is a problem This book provides a pr 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 Solid Oral Dose Process Validation Ajay Babu Pazhayattil,Naheed Sayeed-Desta,Emilija Fredro-Kumbaradzi,Jordan Collins,2018-11-16 Currently there are no process

validation PV textbooks addressing the lifecycle concepts Stage 1 2 3 Recent regulatory guidance s such as US FDA EMEA WHO PIC S have adopted the ICH lifecycle approach The concepts are now harmonized across regulatory guidance s and organizations have an opportunity to align PV activities for all regulated markets Therefore a need exists for consensus and direction on how to approach solid dose manufacturing process validation for regulatory compliance Solid Dose Process Validation The Basics Volume One and companion Solid Dose Process Validation Lifecycle Approach Application Volume Two also available as a set provide directions and solutions for these unmet needs for the pharmaceutical industry The topics and chapters give a systematic understanding for the application of lifecycle concepts in solid dose pharmaceutical manufacturing All approaches meet the regulatory requirements enlisted in the guidance s which is the precursor to applying the concepts This set is published as a comprehensive solution for solid dose process validation Since solid dose formulations encompass majority of the pharmaceutical preparations it is essential information for pharmaceutical professionals who use the process validation lifecycle approach

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

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

Validation Compliance Annual International Validation Forum, 1995-02-17 Offers an overview of validation and the current regulatory climate and provides a compendium of the regulations guidance documents issues compliance tools terminology and literature involved in computer systems validation Thoroughly examines regulations issued by the U S Food and Drug Administration the U S Environmental

Protection Agency and the European Union Furnishes case studies of real world situations **Leading Pharmaceutical Operational Excellence** Thomas Friedli,Prabir Basu,Daniel Bellm,Jürgen Werani,2013-11-26 Achieving operational excellence is a challenge for the pharmaceutical industry with many companies setting successful examples time and again This book presents such leading practices for managing operational excellence throughout the pharmaceutical industry Based on the St Gallen OPEX Model the authors describe the current status of OPEX and the future challenges that have to be dealt with The ample theoretical background is complemented hand in hand by case studies contributed by authors from leading pharmaceutical companies **Analytical Testing for the Pharmaceutical GMP Laboratory** Kim Huynh-Ba,2022-03-31 Provides practical guidance on pharmaceutical analysis written by leading experts with extensive industry experience Analytical Testing for the Pharmaceutical GMP Laboratory presents a thorough overview of the pharmaceutical regulations working processes and drug development best practices used to maintain the quality and integrity of medicines With a focus on smaller molecular weight drug substances and products the book provides the knowledge necessary for establishing the pharmaceutical laboratory to support Quality Systems while maintaining compliance with Good Manufacturing Practices GMP regulations Concise yet comprehensive chapters contain up to date coverage of drug regulations pharmaceutical analysis methodologies control strategies testing development and validation method transfer electronic data documentation and more Each chapter includes a table of contents definitions of acronyms a reference list and ample tables and figures Addressing the principal activities and regulatory challenges of analytical testing in the development and manufacturing of pharmaceutical drug products this authoritative resource Describes the structure roles core guidelines and GMP regulations of the FDA and ICH Covers the common analytical technologies used in pharmaceutical laboratories including examples of analytical techniques used for the release and stability testing of drugs Examines control strategies established from quality systems supported by real world case studies Explains the use of dissolution testing for products such as extended release capsules aerosols and inhalers Discusses good documentation and data reporting practices stability programs and the Laboratory Information Management System LIMS to maintain compliance Includes calculations application examples and illustrations to assist readers in day to day laboratory operations Contains practical information and templates to structure internal processes or common Standard Operating Procedures SOPs Analytical Testing for the Pharmaceutical GMP Laboratory is a must have reference for both early career and experienced pharmaceutical scientists analytical chemists pharmacists and quality control professionals It is also both a resource for GMP laboratory training programs and an excellent textbook for undergraduate and graduate courses of analytical chemistry in pharmaceutical sciences or regulatory compliance programs Enhancing compliance to good manufacturing practices and pharmaceutical quality system requirements in vaccine production World Health Organization,2024-06-25 *Elsevier's Veterinary Assisting Exam Review* Margi Sirois,Elsevier,2021-01-05 Prepare for

success on your Veterinary Assisting exam with a comprehensive review Elsevier's Veterinary Assisting Exam Review is the only review book for Veterinary Assistants An illustrated outline format makes it easier to review veterinary assisting topics such as laboratory examination room office and hospital procedures surgical preparation pharmacology imaging and client relations Written by experienced veterinary technician educator Margi Sirois this review also includes an Evolve website with nearly 1 000 exam questions and customizable practice tests UNIQUE The only review book on the market for Veterinary Assistants Convenient easy to follow outline format provides comprehensive coverage of key veterinary assisting concepts and topics High quality illustrations and clinical photos show equipment animal care and procedures Coverage of animal nursing includes small large and exotic animals as well as avian care Nearly 1 000 questions are provided on the Evolve website and allow you to select and answer questions in specific categories in Practice mode or to generate credentialing exam style tests in Exam mode Combination of questions answers and detailed rationales ensures that you fully comprehend the type of information being asked and why a specific answer choice is best

8th International Munich Chassis Symposium 2017 Prof. Dr. Peter E. Pfeffer, 2017-09-20 You can find in this book the development of highly and fully automatic driving and the increasing electrification of the powertrain now face chassis development with new challenges too Innovative chassis systems have to provide solutions for automated driving The efficient chassis of the future also has to keep an eye on CO₂ targets comfort and customer focus at all times A modern chassis has to provide for this in the form of innovations while taking the physical and mechanical interdependencies into account Confronting these new developments is a challenge for simulation and testing

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