

Good Manufacturing Practices (GMP's) Policy

The purpose of this policy is to ensure compliance with current Good Manufacturing Practice (GMP) regulations for foods.

It is the responsibility of all involved personnel at every level of the organization to act immediately if a risk of violating this policy is detected. Department Managers are accountable for compliance with this policy and the General Manager has final authority concerning any GMP issue.

As food handlers, we have a responsibility to our customers to maintain high standards of food safety. To ensure only safe, high quality products are produced, employees must follow all GMP's listed:

1. Personal Hygiene Requirements

Your personal hygiene is very important. All personnel working in the production area are expected to maintain a high degree of personal cleanliness. The following rules apply to you:

Cleanliness

1.1.1 Nails

- Keep finger nails clean and neatly trimmed. Dirty nails are a popular place for bacteria to hide and grow.
- Nail polish is not permitted in the production area. The polish may flake off and contaminate the product. Bacteria also hide in cracks in the nail polish.

1.1.2 Hair

- You must wear a protective hair net in the production area. There must be no exposed or loose hair protruding from under a hairnet. Hair carries many microorganisms. (1 hair follicle can contain up to 50,000 germs).
- Men with mustaches or beards must cover them fully with a beard net.

Jewelry

- All jewelry, including watches, must be removed when entering the plant. Plain wedding bands without stones or settings are allowed. This is not only to protect our products from contamination, but also to protect you from injury and/or the loss of a valuable possession. (Skin area underneath jewelry is a warm area and together with moisture and a little air, these are ideal conditions for bacteria to grow at a rapid rate).

1.1.3 Hands

Your hands can be the source of many microorganisms. The following rules apply to you: You must wash your hands with soap and water located at each hand washing station:

Good Manufacturing Practices Policy Manual

Joseph D. Nally



Good Manufacturing Practices Policy Manual:

Good Manufacturing Practices for Pharmaceuticals D. Nally Joseph, 2000-10-12 Highlighting key issues and differences among GMPs of Europe Canada and the WHO this reference examines US law and governmental policy affecting domestic and multinational pharmaceutical manufacturing The book recommend pragmatic ways to interpret and comply with FDA CGMP regulation and related criteria They focus on geographical redistribution of manufacturing facilities accommodation of a diversity of regulatory and statutory governance adaptation to disparate human resources and new growth areas of manufacture and distribution of homeopathic remedies and dietary supplements in addition to the greater quality control required of pharmacists and other authorized dispensers

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

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

The Certified Pharmaceutical GMP Professional Handbook Mark Allen Durivage, 2016-05-23 The purpose of this handbook is to assist individuals for the Certified Pharmaceutical Good Manufacturing Practices Professional CPGP examination and provide a reference for the practitioner The second edition reflects the Body of Knowledge which was updated in 2015 This edition has also incorporated additional information including updated references The updates reflect the current trends and expectations of the evolving pharmaceutical industry driven by consumer expectations and regulatory oversight This handbook covers compliance with good manufacturing practices GMPs as regulated and guided by national and international agencies for the pharmaceutical industry It covers finished human and veterinary drugs and biologics and combination

devices as well as their component raw materials including active pharmaceutical ingredients APIs and excipients and packaging and labeling operations

GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, (Volume 1 - With Checklists and Software Package) Leonard Steinborn, 2019-04-23 Volume 1 of this two part package provides a complete set of checklists for internal and contract device and drug manufacturers and developers contract software developers and suppliers of chemical printed material electronic component and general supplies It also includes a simulated QSIT audit and a new product market launch All of these

Handbook of Biogeneric Therapeutic Proteins Sarfaraz K. Niazi, 2002-08-15 More than 20 billion dollars worth of biopharmaceuticals are scheduled to go off patent by 2006 Given the strong political impetus and the development of technological tools that can answer the questions regulatory authorities may raise it is inevitable that the FDA and EMEA will allow biogeneric or biosimilar products Even with all the regulato

The ASQ Certified Pharmaceutical GMP Professional Handbook Mark Allen Durivage, 2024-09-30 The ASQ Certified Pharmaceutical GMP Professional Handbook assists candidates preparing for the Certified Pharmaceutical Good Manufacturing Practices Professional CPGP examination and serves as a handy reference guide for practitioners in the field This handbook covers compliance with good manufacturing practices GMPs as regulated and guided by national and international agencies for the pharmaceutical industry

Handbook of Pharmaceutical Granulation Technology Dilip M. Parikh, 2021-05-11 This fully revised edition of Handbook of Pharmaceutical Granulation Technology covers the rapid advances in the science of agglomeration process control process modelling scale up emerging particle engineering technologies along with current regulatory changes presented by some of the prominent scientist and subject matter experts around the globe Learn from more than 50 global subject matter experts who share their years of experience in areas ranging from drug delivery and pharmaceutical technology to advances in nanotechnology Every pharmaceutical scientist should own a copy of this fourth edition resource Key Features Theoretical discussions covering granulation and engineering perspectives Covers new advances in expert systems process modelling and bioavailability Chapters on emerging technologies in particle engineering Updated Current research and developments in granulation technologies

Quality Control and Regulatory Aspects for Biologicals Gauri Misra, 2024-04-22 This book serves as a comprehensive guide on quality control and regulatory aspects for biological products It covers a wide range of topics including regulatory requirements quality control strategies analytical methods and risk management It delves into the advantages and limitations of in vivo tests and discusses alternative methods that can be employed The book explores the use of animal based testing methods in quality control and examines viable alternatives Key Features Reviews various scientific and regulatory aspects involved in the quality control of biologicals Provides an overview of the roles of various national and international regulatory bodies and accreditation agencies Presents advanced analytical methods innovative technologies and the integration of molecular diagnostics in quality control processes Explores the use of animal based testing methods in

quality control as well as their alternatives Discusses guidelines and methodologies involved in the development of biological products Overall this book is an important reference source for various professionals in the pharmaceutical industry including researchers scientists quality control personnel and regulatory affairs professionals

Principles and Practice of Pharmaceutical Medicine Andrew J. Fletcher, Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier, 2003-01-31 Principles and Practice of Pharmaceutical Medicine begins with a detailed overview of its origins and goes on to examine current career opportunities education and training Encompassing the entire spectrum of pharmaceutical medicine it also discusses international drug development and registration including animal toxicology and human volunteers pharmacoeconomics and statistics medical services legal and ethical issues and business aspects It is the most up to date guide to drug development and marketing and the only book with an international outlook The authors are all experts in their field and include an assessment of the current status of their specialities This book provides an insight into how things may develop in the future It is designed to be a guide for those who are actually practicing pharmaceutical medicine

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

Validation Practices for Biotechnology Products J. K. Shillenn, 1996 Presents the current methods and practices by which companies that produce genetically altered drugs assure that all components and finished products have the identity strength quality and purity that is purported and represented Also considers possible improvements and whether industry standard

Federal Register, 2008

FDA Regulatory Affairs Douglas J. Pisano, David S. Mantus, 2008-08-11 Examines harmonization of the US Federal Food Drug and Cosmetic Act with international regulations as they apply to human drug and device development research manufacturing and marketing The Second Edition focuses on the new drug approval process cGMPs GCPs quality system compliance and corresponding documentation requirements Written in

Handbook of Toxicology, Second Edition Michael J. Derelanko, Manfred A. Hollinger, 2001-08-29 LOCATE FREQUENTLY USED INFORMATION EASILY AND QUICKLY Working in the laboratory or office you use a diverse assortment of basic information to design conduct and interpret toxicology studies and to perform risk assessments The Second Edition of the best selling Handbook of Toxicology gives you the information you need in a single reference source

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Pharmaceutical Production Facilities Design and Applications considers the concepts and constraints that have to be considered in the design of small medium and large scale production plants The layout along with the flow of materials and personnel through facilities are considered with reference to ensuring compliance with current good manufac **Handbook of Toxicology** Michael J. Derelanko,Carol S. Auletta,2014-03-07 The Handbook of Toxicology Third Edition provides an updated practical reference source for practicing toxicologists in the pharmaceutical and chemical industries contract laboratories regulatory agencies and academia Written by experts in their specific toxicology fields the chapters provide both fundamental and applied information Topics r 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 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 **Pharmaceutical Manufacturing Handbook** Shayne Cox Gad,2008-03-11 With its coverage of Food and Drug Administration regulations international regulations good

manufacturing practices and process analytical technology this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing In addition the book discusses quality assurance and validation drug stability and contamination control all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing

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