Annex 9 Guidelines On Packaging For Pharmaceutical Products

From human waste to nuclear waste, the question of how we must manage what we no longer want, in terms of either recycling or disposal, is one of the most pressing issues in environmental law. Alexander Gillespie addresses the gaps in previous literatu

Documentation of compliance with the legislation is a corner stone in the control of food contact materials (FCM). In-house control is an important pre-requisite to limit contamination from FCM and shall be based on the declaration of compliance and supporting documentation at the responsible business operators in the supply chain. The goal of this project was to develop a Nordic checklist on documentation of compliance for FCM. The Nordic checklist contains several templates. The different templates provide check points on the minimum requirements for a declaration of compliance for all types of materials. The templates are meant to be used by industry and trade as guidance for drafting a declaration of compliance. Furthermore, the check lists are also meant to be tools for the public food and FCM inspection.

This three-volume set of Pharmaceutical Dosage Forms: Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacture of parenteral dosage forms, effectively balancing theoretical considerations with the practical aspects of their development. As such, it is recommended for scientists and engineers in the pharmaceutical industry and academia, and will also serve as an excellent reference and training tool for regulatory scientists and quality assurance professionals. First published in 1984 (as two volumes) and then last revised in 1993 (when it grew to three volumes), this latest revision will address the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. The third edition of this book maintains the features that made the last edition so popular but comprises several brand new chapters, revisions to all other chapters, as well as high quality illustrations. Volume three presents: •An in-depth discussion of regulatory requirements, quality assurance, risk assessment and mitigation, and extractables/leachables. •Specific chapters on parenteral administrations devices, injection site pain assessment, and parenteral product specifications and stability testing. •Forward-thinking discussions on the future of parenteral product manufacturing, and siRNA delivery systems. •New chapters covering recent developments in the areas of visual inspection, quality by design (QbD), process analytical technology (PAT) and rapid microbiological methods (RMM), and validation of drug product manufacturing process.

This book is the 4th in a series of Acute Care books written with the aim to address the NEEDS of health care providers when handling the acutely ill patients. Globally it has become apparent that the study of pharmacology and subsequent clinical training has not always adequately equipped young doctors with the ability to administer drugs to their patients safely and confidently, particularly in the critically ill patient. Compounding this issue is the lack of resource material related to these pharmacological concepts contained in one book that can help health care providers to understand and manage drug therapy in the acute situation. In spite of progressively newer and more developed protocols, guidelines, algorithms and many other books addressing the technical aspects of what needs to be done, most health care providers still find it difficult to grasp the basic pharmacological knowledge and rationally deliver the CARE that is required in the acute phase of patient management. The editors/authors have therefore aimed for a book that highlights topics and pharmacological issues pertinent to management of patients in their hour of need. This is a multi-author book but the style has been guided by 3 editors. The editors have used a different perspective – that of normalizing abnormal physiological processes with pharmacological agents – to address the GAPS in a bedside to bench approach. The details are pared down but important principles/concepts are emphasized.

Global Legislation for Food Packaging Materials

Chemistry and Technology of Agrochemical Formulations

Forty-seventh Report

International Regulation, Comparative and Contextual Perspectives

Guidelines for the Implementation of MARPOL

Guidance Manual for the Control of Transboundary Movements of Recoverable Wastes

Diversity and Design explores how design - whether of products, buildings, landscapes, cities, media, or systems - affects diverse members of society. Fifteen case studies in television, marketing, product design, architecture, film, video games, and more, illustrate the profound, though often hidden, consequences design decisions and processes have on the total human experience. The book not only investigates how gender, race, class, age, disability, and other factors influence the ways designers think, but also emphasizes the importance of understanding increasingly diverse cultures and, thus, averting design that leads to discrimination, isolation, and segregation. With over 140 full-color illustrations, chapter summaries, discussion questions and exercises, Diversity and Design is a valuable tool to help you understand the importance of designing for all.

A collection of recommended procedures for analysis and specifications for the determination of pharmaceutical substances, excipients and dosage forms intended to serve as source material for reference by any WHO member state.

Providing a truly global overview of legislation in all major countries, this practical volume contains the information vital for manufactures of food contact materials and food producers, facilitating a comparison of the requirements and making mutual requirements easier to identify. It covers not only plastics but also other food contact materials, such as paper, board, coatings, ceramics, cork, rubber, and textiles.

International Investment Treaties and Arbitration Across Asia examines whether and how the Asian region has or may become a significant 'rule maker' in contemporary international investment law and dispute resolution, focusing on the 'ASEAN+6' economies.

Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

MYCDCGP - Guidelines on Ebola Virus Diseases Management in Malaysia

Pharmaceutical Microbiological Quality Assurance and Control

Regulations and Quality

Who Expert Committee on Specifications for Pharmaceutical Preparations

Pharmaceutical Packaging Technology

The Marine Environment Protection Committee (MEPC) of IMO, at its sixty-second session in July 2011, adopted the Revised MARPOL Annex V, concerning Regulations for the prevention of pollution by garbage from ships, which enters into force on 1 January 2013. The associated guidelines which assist States and industry in the implementation of MARPOL Annex V have been reviewed and updated and two Guidelines were adopted in March 2012 at MEPC's sixty-third session. The 2012 edition of this publication contains: the 2012 Guidelines for the implementation of MARPOL Annex V (resolution MEPC.219(63)); the 2012 Guidelines for the development of garbage management plans (resolution MEPC.220(63)); and the Revised MARPOL Annex V (resolution MEPC.201(62)).

This Guidance Manual includes detailed explanations on how to implement the OECD Decision on the Control of Transboundary Movements of Recoverable Wastes.

Although the Bioequivalence (BE) requirements in many global jurisdictions have much in common, differences in certain approaches and requirements such as definitions and terms, choice of comparator (reference) product, acceptance criteria, fasted and fed studies, single and multi-dose studies, biowaivers and products not intended for absorption into the systemic circulation (locally acting medicines and dosage forms), amongst others, provide food for thought that standardisation should be a high priority objective in order to result in a harmonized international process for the market approval of products using BE. An important objective of Bioequivalence Requirements in Various Global Jurisdictions is to attempt to gather the various BE requirements used in different global jurisdictions to provide a single source of relevant information. This information from, Brazil, Canada, China, European Union, India, Japan, MENA, Russia South Africa, the USA and WHO will be of value to drug manufacturers, regulatory agencies, pharmaceutical scientists and related health organizations and governments around the world in the quest to harmonize regulatory requirements for the market approval of generic products.

This book covers the chemistry, physics, materials science, engineering, and therapeutic aspects of many different types of packaging materials, emphasizing throughout the applicability of various aspects of packaging science and technology. It also provides a simultaneous discussion of interrelated fields, and addresses the universal issues within these fields' application areas. Intended as a technical reference and as a study aid, it is relevant to anyone who studies or uses packaging or packaging materials. Packaging Technology and Engineering: Pharmaceutical, Medical and Food Applications begins with an overview of the history of the topic. It then offers chapters on the methods of obtaining raw materials, the chemistry of polymeric and non-polymeric packaging materials, physico-chemical quality parameters, and the manufacturing of packaging. Other topics look at: additives, use, suppliers, safety and environmental concerns, regulation, anti-fraud activities, new trends, and the future of packaging technology. The book also features numerous problems and worked solutions to aid student comprehension. Covers packaging and packaging materials, their properties and technologies Addresses the chemical engineering, physics, and chemistry of packaging materials, and the individual requirements for food, pharmaceutical, and medical device packaging Includes current issues such as environmental concerns and sustainability, recycling and after-use, anti-counterfeiting technology, and packaging regulations and guidelines Packaging Technology and Engineering: Pharmaceutical, Medical and Food Applications will appeal to all packaging technologists, scientists, and engineers in industry, and in regulatory agencies. It is also an excellent book for advanced students studying packaging courses, within pharmacy, pharmaceutical sciences, chemical sciences, biomedical sciences, medical sciences, engineering, product design and technology, and food science/technology.

Volume 3: Regulations, Validation and the Future

Pharmaceutical, Medical and Food Applications

Process Mapping

The International Pharmacopoeia

A Compendium of Guidelines and Related Materials. Good manufacturing practices and inspection

Air Navigation Law

Pharmaceutics: the science of medicine design explores the different forms that medicines can take, and demonstrates how being able to select the best form - be it a tablet, injectable liquid, or an inhaled gas - requires an understanding of how chemicals behave in different physical states.

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use: Procedure for development of the WHO medicines quality assurance guidelines; Guidelines on Good Manufacturing Practices (GMP) for heating, ventilation and air-conditioning systems (HVAC) illustrative part; Guidance on GMP for Validation, including the general main text, analytical procedure validation, validation of computerized systems and qualification; in the area of interchangeability of multisource medicines: the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver; Guidelines on Import Procedures for pharmaceutical products; and the Good Practice Guidance document on implementing the collaborative procedures. All of the above are included in this report and recommended for implementation.

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.

This part of GB/T 2521 specifies the terms and definitions, classification, symbol and designation, general requirements, technical requirements, inspection and testing, judgement and reinspection rules, packaging, marking and quality certification as well as order contents of grain non-oriented steel strips (sheets) in nominal thicknesses of 0.35mm, 0.50mm and 0.65mm. This part is applicable to grain non-oriented steel strip (sheet) [hereinafter referred to as steel strip (sheet)] delivered in the fully-processed cold-rolled state in magnetic structure.

Dispute Settlement Reports 2018: Volume 8, Pages 3923 and 4796

GB/T 2521.1-2016 Safety of Machinery – Guidelines for the Understanding and Use of Safety of Machinery Standards (English Version)

Pharmaceutics

Recommendations on the Transport of Dangerous Goods: Model ...

Report of Cioms Working Group IX

Quality Assurance of Pharmaceuticals Manufactured in the Hospital

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) addresses classification and labelling of chemicals by types of hazards. It provides the basis for worldwide harmonization of rules and regulations on chemicals and aims at enhancing the protection of human health and the environment during their handling, transport and use by ensuring that the information about their physical, health and environmental hazards is available. The sixth revised edition includes, inter alia, a new hazard class for desensitized explosives and a new hazard category for pyrophoric gases; miscellaneous amendments intended to further clarify the criteria for some hazard classes (explosives, specific target organ toxicity following single exposure, aspiration hazard, and hazardous to the aquatic environment) and to complement the information to be included in section 9 of the Safety Data Sheet; revised and further rationalized precautionary statements; and an example of labelling of a small packaging in Annex 7.

The Dispute Settlement Reports are the WTO authorized and paginated reports in English. They are an essential addition to the library of all practicing and academic trade lawyers and needed by students worldwide taking courses in international economic or trade law. DSR 2018: Volume 8 reports on Australia - Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging (WT/DS435, WT/DS441, WT/DS458, WT/DS467).

Quality assurance of pharmaceutical products is a continuing concern of WHO. Despite efforts made around the world to ensure a supply of quality and effective medicines, substandard, spurious and counterfeit products still compromise health care delivery in many countries. To respond to the global need for adequate quality assurance of pharmaceuticals, WHO's Expert Committee on Specifications for Pharmaceutical Preparations has over the years made numerous recommendations to establish standards and guidelines and to promote the effective functioning of national regulatory and control systems and the implementation of internationally agreed standards by trained personnel. Many of the relevant documents endorsed by the Committee are reproduced in this volume providing guidance covering all aspects of good manufacturing practices (GMP). Important texts on inspection are also included. Most of the material has been published separately in the Expert Committee's reports. This compendium brings it together to make it more accessible and of greater practical value to those working in faculties of pharmacy, in medicines regulation and control and in the pharmaceutical industry. This is the second updated edition of the compendium and includes texts published in 2005 and 2006 in the WHO Technical Report Series.

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) covers all hazardous chemicals and has been developed through co-operation between the International Labour Office (ILO), the Organisation for Economic Co-operation and Development (OECD) and the United Nations on the basis of a mandate given in Agenda 21 by the 1992 United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro. While national or regional Governments are the primary audiences for this document, it also contains sufficient context and guidance for those in industry who will ultimately be implementing the requirements which have been adopted. This edition includes revisions relating to classification and labelling, and new provisions for aspiration hazards and new guidance on the use of precautionary statements and pictograms and on the preparation of safety data sheets.

Proceedings of the International Symposium on Drug Quality Assurance in the Hospital

Pharmaceutical Manufacturing Handbook

fifty-fifth report

Waste Policy

WHO Guidelines on Drawing Blood

Packaging Technology and EngineeringPharmaceutical, Medical and Food ApplicationsJohn Wiley & Sons

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use, in addition to 20 monographs and general texts for inclusion in The International Pharmacopoeia and 11 new International Chemical Reference Substances. The International Pharmacopoeia - updating mechanism for the section on radiopharmaceuticals; WHO good manufacturing practices for pharmaceutical products: main principles; Model quality assurance system for procurement agencies; Assessment tool based on the model quality assurance system for procurement agencies: aide-memoire for inspection; Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities; and Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part.

Relying on practical examples from the authors' experience, this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non-sterile pharmaceuticals. Offers a comprehensive guidance for non-sterile pharmaceuticals microbiological QA/QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors' experience in globalized pharmaceutical companies and expert networks Offers a comprehensive guidance for non-sterile pharmaceuticals microbiological QA/QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors' experience in globalized pharmaceutical companies and expert networks

As was the case with Charles Ross's Packaging of Pharmaceuticals published by the UK Institute of Packaging in 1975 it is assumed that the reader of this book already has a broad understanding of the basics of packaging. If not the Packaging Users Handbook and the Handbook of Food Packaging are recommended. The packaging needs of pharmaceuticals are different in degree only from those of other perishable products such as processed foods. Because the required action of a medication can be nullified by any deterioration in its active principles the protection required from its packaging is at least an order of magnitude greater than that needed by foods for example. Functional efficiency is therefore of prime importance. Conversely the need for the packaging to 'sell' the medication is much less, hence the graphics required need only provide the right 'image' for the product when presented for use in hospital or surgery. Even when on sale at the pharmacy the 'appeal' required is that of providing hygiene and confidence more than anything else. Thus, the textual requirements are paramount including traceability (batch numbers, date-coding etc) in case of recall; while striking appearance to attract customer attention is in lower key. And with the increase in malicious tampering nowadays recall is more frequent.

Forty-eighth Report

Production and Processes

Packaging Technology and Engineering

Good Manufacturing Practices for Pharmaceuticals, Seventh Edition

Bioequivalence Requirements in Various Global Jurisdictions

Bacteriological Analytical Manual

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools. Standards are developed by the Expert Committee through worldwide consultation and an international consensus-building process. The following new guidance texts were adopted and recommended for use: Guidelines and guidance texts adopted by the Expert Committee on Specifications for Pharmaceutical Preparations; Points to consider when inc (HBELs) in cleaning validation; Good manufacturing practices: water for pharmaceutical use; Guideline on data integrity; WHO/United Nations Population Fund recommendations for condom storage and shipping temperatures; WHO/United Nations Population Fund guidance on testing of male latex condoms; WHO/United Nations Population Fund guidance on conducting post-market surveillance of condoms; WHO "Biowaiver List": proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms; WI of pharmaceutical products moving in international commerce; Good reliance practices in the regulation of medical products: high-level principles and considerations; and Good regulatory practices in the regulations of medical products. All of the above are included in this report and recommended for implementation.

Pharmaceutical packaging requires a greater knowledge of materials and a greater intensity of testing than most other packed products, not to mention a sound knowledge of pharmaceutical products and an understanding of regulatory requirements. Structured to meet the needs of the global market, this volume provides an assessment of a wide range of issues. It covers the entire supply chain from conversion of raw materials into packaging materials and then assembled into product packs. Integrating information from many drug delivery systems, the author discusses testi and the need to for additional safeguards.

This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Risk management of medicines is a wide and rapidly evolving concept and practice, following a medicine throughout its lifecycle, from first administration in humans through clinical studies and then marketing in the patient population at large. Previous reports from CIOMS I - VIII provided practical guidance in some essential components of risk management such as terminology and reporting of adverse drug reactions, management of safety information from clinical trials, and safety signal detection. Beyond the detection, identification, and characterization of risk, "risk minimiza prevention or mitigation of an undesirable outcome. Risk management always includes tools for "routine risk minimization" such as product information, the format depending on the jurisdiction, to inform the patient and the prescriber, all of which serve to prevent or mitigate adverse effects. Until this current CIOMS IX document, limited guidance has been available on how to determine which risks need "additional risk minimization," select the appropriate tools, apply and implement such tools globally and locally, and measure if they are effective and valuable. Included in the re evaluation of effectiveness of risk minimization, a discussion of future trends and developments, an annex specifically addressing vaccines, and examples from real life.

Annex V

The Science of Medicine Design

Understanding Hidden Consequences

Cosmetics Legislation: Notes of guidance for testing of cosmetic ingredients for their safety evaluation

Fifty-Third Report

Packaging of Pharmaceuticals and Healthcare Products

The aviation community, in which the International Civil Aviation Organization (ICAO), the International Air Transport Association (IATA) and the Civil Air Navigation Services Organization (CANSO) play leading roles, is hard at work in bringing aviation into the 21st Century. In doing so, the United States and Europe have taken proactive steps forward in introducing modernization, particularly in moving towards more efficient air traffic management systems within NextGen and SESAR. Elsewhere, in the fields of personnel licensing, rules of the air, accident investigation and aeronautical charts and information, significant strides are being made in moving from mere regulation to implementation and assistance calculated to make all ICAO member States self sufficient in international civil aviation. However, these objectives can be achieved only if the aviation industry has a sustained understanding of the legal and regulatory principles applying to the various areas of air navigation. This book provides that discussion. Some of the subjects discussed in this book are: sovereignty in airspace; flight information and air defence identification zones; rules of the air; personnel licensing; meteorological services; operations of aircraft; air traffic services; accident and incident investigation; aerodromes; efficiency aspects of aviation and environmental protection; aeronautical charts and information; the carriage of dangerous goods; and NextGen and SESAR . Except for NextGen and SESAR, these subjects form the titles of the Annexes to the Chicago Convention that particularly involve the rights and liabilities of the key players involved in air navigation.

Phlebotomy uses large, hollow needles to remove blood specimens for lab testing or blood donation. Each step in the process carries risks - both for patients and health workers. Patients may be bruised. Health workers may receive needle-stick injuries. Both can become infected with bloodborne organisms such as hepatitis B, HIV, syphilis or malaria. Moreover, each step affects the quality of the specimen and the diagnosis. A contaminated specimen will produce a misdiagnosis. Clerical errors can prove fatal. The new WHO guidelines provide recommended steps for safe phlebotomy and reiterate accepted principles for drawing, collecting blood and transporting blood to laboratories/blood banks.

WHO's international guidelines, written and physical standards developed under the aegis of this Expert Committee for more than 60 years are designed to serve all Member States, international organizations, United Nations agencies, regional and interregional harmonization efforts, and underpin important initiatives, including the prequalification of medicines, the Roll Back Malaria Programme, Stop TB, essential medicines and medicines for children.

*The Forty-seventh WHO Expert Committee on Specifications for Pharmaceutical Preparations adopted 26 new monographs and general texts for inclusion in The International Pharmacopoeia,/I>. The specifications under development are internationally applicable test methodologies for anti-infective, antimalarial, antituberculosis, contraceptives and antiretroviral medicines, as well as medicines for children. In addition, the following four written standards were adopted in the area of quality assurance and are now available for implementation : * Release procedure for International Chemical Reference Substances (update); * WHO guideline on quality risk management (new) * WHO guideline on variations to a prequalified product (update) * Collaborative procedure between the WHO Prequalification of Medicines Programme and national medicines regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products (new).*

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.

Best Practices in Phlebotomy

Pharmacological Basis of Acute Care

Pharmaceutical Dosage Forms - Parenteral Medications

Technical Report Series

International Investment Treaties and Arbitration Across Asia

Practical Approaches to Risk Minimisation for Medicinal Products

Agrochemical products and adjuvants are of vital importance in agriculture, to protect food and fibre crops from weeds, insect pests and diseases, in order to feed and clothe the growing world population. In recent years there have been increasing pressures to produce agrochemical formulations which have a lower environmental impact and are safer in use. Enormous changes have taken place in the chemistry and technology of agrochemicals over the last twenty years or so and this book provides a timely review of the most important area of technology in the development of new products. This book covers issues around international product quality and safety standards and describes the current and likely future trends which will carry the industry forward into the next millennium. It brings together well known international experts with many years of practical experience from agrochemical companies, consultancies, academic institutions and regulatory bodies. Chemists and technologists involved in developing new or improved agrochemical formulations will find this book an essential reference in the course of their work. The book will also be of interest to those working in research and development departments of raw material suppliers, as a concise review of this important field.

Declaration of Compliance and Supporting Documentation

Practical Guide for Non-Sterile Manufacturing

Nordic Checklist Food Contact Materials

Diversity and Design

WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products, revision VI