Annex 4 Supplementary Guidelines On Good Manufacturing

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: - WHO guidelines on good herbal processing practices for herbal medicines; - Guidelines on good manufacturing practices for the manufacture of herbal medicines; - Considerations for requesting analysis of medicine samples; - WHO model certificate of analysis; - WHO guidance on testing of "suspect" falsified medicines; - Good pharmacopoeial practices - Chapter on monographs for compounded preparations; - Good pharmacopoeial practices - Chapter on monographs on herbal medicines; - Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products; - Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical

products regulatory decisions; - Stability testing of active pharmaceutical ingredients and finished pharmaceutical products; and - Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities.

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.

The World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations advises the Director-General of WHO in the area of medicines quality assurance. It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality safety and efficacy in all WHO Member States. Its advice is developed through a broad consensus-building process and covers all areas of quality assurance of medicines from their development to their distribution to patients. In the area of quality control the Expert Committee reviewed new and revised specifications and

general texts for inclusion in The International Pharmacopoeia and received the annual report of the European Directorate for the Quality of Medicines & HealthCare (EDQM) the custodian centre for International Chemical Reference Substances (ICRS). The Committee adopted a number of monographs general texts and ICRS. It noted the report on Phase 5 of the External Quality Assurance Assessment Scheme (EQAAS) and on new approaches to ensure sustainability of this scheme through user fees. The Committee further received a concept paper on the benefits of good pharmacopoeial practices (GPhP) and was informed of progress achieved with developing a comprehensive document on GPhP through discussions at consecutive international meetings of world pharmacopoeias. In the various quality assurance-related areas the Expert Committee was presented with a number of new and revised guidelines related to good manufacturing practices (GMP) distribution and trade of pharmaceuticals and regulatory practice. It adopted eight guidelines and 16 technical supplements as listed below including a new guidance text on good review practice prepared under the leadership of the Asian-Pacific Economic Cooperation Regulatory Harmonization Steering Committee. The Committee took note of ongoing work to promote collaboration and information exchange

through the good regulatory practice project and welcomed the development of a comprehensive set of guidelines for all national regulatory authorities through this project. The report includes the following annexes which are recommended as new WHO guidelines: . Annex 1. Procedure of the development of monographs for inclusion in The International Pharmacopoeia (revision); . Annex 2. Updating mechanism for the section on radiopharmaceuticals in The International Pharmacopoeia (revision); . Annex 3. Supplementary guidelines on good manufacturing practices: validation; Appendix 7: non-sterile process validation (revision); . Annex 4. General guidance for inspectors on hold-time studies (new); . Annex 6. Recommendations for quality requirements when plant-derived artemisinin is used as a starting material in the production of antimalarial active pharmaceutical ingredients (revision); . Annex 7. Guidelines on registration requirements to establish interchangeability (revision); . Annex 8. Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generic) products (revision); . Annex 9: Good review practices guidelines for regulatory authorities (new). In addition 16 technical supplements to the WHO model guidance for the storage and transport of time- and temperature-

sensitive pharmaceutical products were adopted for publication in a format which is appropriate to the large volume of this guidance (Annex 5). The newly adopted monographs were adopted for inclusion in The International Pharmacopoeia. Following the implementation of the revised general monograph on parenteral preparations the Committee adopted the proposed endotoxin limits for 11 parenteral dosage form monographs lacking such specification together with related updates to relevant monographs. The Committee adopted 12 ICRS newly characterized by the custodian centre EDQM. The Committee further adopted the workplan for new monographs to be included in The International Pharmacopoeia.

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.

Fifty-third Report

Fifty-second Report

Appraisal and Evaluation in Central Government : Treasury Guidance

Recommendations for a Public Health Approach

A Revised Framework

tuberculosis preventive treatment

Data integrity is fundamental in a pharmaceutical and medical devices quality system. This book provides practical information to enable compliance with data integrity, while highlighting and efficiently integrating worldwide regulation into the subject. The ideas

presented in this book are based on many years' experience in regulated industries in various computer systems development, maintenance, and quality functions. In addition to case studies, a practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved.

Providing a detailed and practical analysis of the entire scope of the law relating to vertical agreements, including the new general block exemption regulations and the Vertical Guidelines, this book is an indispensible tool for all practitioners active in the drafting or reviewing of vertical agreements.

The Pocket Book is for use by doctors nurses and other health workers who are responsible for the care of young children at the first level referral hospitals. This second edition is based on evidence from several WHO updated and published clinical guidelines. It is for use in both inpatient and outpatient care in small hospitals with basic laboratory facilities and essential medicines. In some settings these guidelines can be used in any facilities where sick children are admitted for inpatient care. The Pocket Book is one of a series of documents and

tools that support the Integrated Managem. This updated edition provides research scientists, microbiologists, process engineers, and plant managers with an authoritative resource on basic microbiology, manufacturing hygiene, and product preservation. It offers a contemporary global perspective on the dynamics affecting the industry, including concerns about preservatives, natural ingredients, small manufacturing, resistant microbes, and susceptible populations. Professional researchers in the cosmetic as well as the pharmaceutical industry will find this an indispensable textbook for in-house training that improves the delivery of information essential to the development and manufacturing of safe high-quality products

Fifty-sixth Report

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

fifty-fourth report

Pocket Book of Hospital Care for Children

fifty-fifth report

Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection

This report presents the recommendations of an

international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. The report is complemented by a number of annexes. These include: a list of available international chemical reference substances and international infrared spectra; supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms; updated supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines; supplementary guidelines on good manufacturing practices for validation; good distribution practices for pharmaceutical products; a model quality assurance system for procurement agencies (recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products); multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability; a proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms; and additional guidance for organizations performing in vivo bioequivalence studies. ...This is an excellent book with a misleading title... a good reference work for anyone seeking to understand the concept of validation and looking for general guidance on validation for both Active Pharmaceutical Ingredients (API) and finished pharmaceutical products. Annex 5 on Good

distribution practices (GDP) for pharmaceutical products is an excellent Annex that splits the task of GDP into 20, small, easy to digest sections that guide the reader through the process of understanding the complexity of controlling distribution of pharmaceutical products. It contains a comprehensive glossary of terms used in GDP... a useful reference book for anyone involved in Quality Assurance, Manufacturing of marketed products, Clinical Manufacturing and Development. - Industrial Pharmacy

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.

The International Pharmacopoeia contains a collection of recommended methods for analysis and quality specifications for pharmaceutical substances, excipients and products. This new edition consolidates the texts of the five separate volumes of the third edition and includes new monographs for antiretroviral substances (didanosine, indinavir sulfate, nelfinavir mesilate, nevirapine, ritonavir, saquinovir, and saquinovir mesilate) adopted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2004. It includes some additions and amendments to the general notices of the Pharmacopoeia, as well as some changes to its layout and format. Volume one contains monographs for pharmaceutical substances A to O and the General Notices; and volume two contains monographs for pharmaceutical substances P to Z, together with those for dosage forms and radiopharmaceutical preparations, the methods of analysis and reagents.

This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations to assure the quality safety and efficacy of vaccines blood products and other biological medicines and the establishment of international biological reference standards for these products and related diagnostic devices. The report of particular relevance to manufacturers and national regulatory authorities starts with a discussion of general issues brought to the Committee's attention. The second part of the report contains written specifications that establish international regulatory

expectations for the following products; DNA vaccines pertussis (whole cell) vaccine plasma (human) for fractionation rabies vaccine and rotavirus vaccine. The report also provides a risk assessment and defines conditions for the safe production of pandemic strain influenza vaccines. The third part of the report provides information on the status and development of international reference materials for various antibodies antigens blood products and related substances and in vitro diagnostic devices.

Chapter 3. Validation of Liquid Chromatographic Methods

Essential Oils in Food Processing: Chemistry, Safety and Applications

Quality Assurance of Pharmaceuticals

Who Expert Committee on Specifications for Pharmaceutical Preparations

Dare to Understand and Measure (DaTUM)

Liquid Chromatography

Examining the implications and practical implementation of multi-disciplinary International Conference on Harmonization (ICH) topics, this book gives an integrated view of how the guidelines inform drug development strategic planning and decision-making. • Addresses a consistent need for interpretation, training, and implementation examples of ICH guidelines via case studies • Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines • Uses case studies to help readers understand and apply ICH guidelines • Provides valuable insights into guidelines development, with chapters by authors involved in generating or with experience implementing the guidelines • Includes coverage of stability testing, analytical method validation, impurities, biotechnology

drugs and products, and good manufacturing practice (GMP) WHO Expert Committee on Specifications for Pharmaceutical PreparationsForty-ninthReportWorld Health Organization
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 consensusbuilding 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.
he present state-of-art book has been written as per the new syllabus of B. Pharmacy, introduced by Pharmacy Council of India (PCI). This book has an inclusive content that covers the wider aspects of pharmaceutical quality assurance required by under- graduates, post graduates, industry personnels, researcher, and students preparing for various competitive exams. The distinguishing feature of this book is that the book is written in lucid, simple and easy to understand language. The book is accompanied with Multiple Choice, Fill in the Blank, True-False, Short Answer and Long Answer type of questions

for the self- evluation of learning. The answers of the Multiple Choice, Fill in the Blank and True-False questions have also been given. Web links/further reading are included to help the readers for keeping themselves abreast with th latest developments in the h?eld of pharmaceutical quality assurance. Academicians and instructors in universities/colleges may use the book as primary or additional teaching material for under-graduate and post-graduate pharmacy courses.

Practical Guide for Non-Sterile Manufacturing

Data Integrity in Pharmaceutical and Medical Devices Regulation Operations

WHO consolidated guidelines on tuberculosis

ADDRESSING AGRICULTURE, FORESTRY AND FISHERIES IN NATIONAL ADAPTATION PLANS

WHO Guidelines on Good Agricultural and Collection Practices [GACP] for Medicinal Plants

Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing

In recent years, high prices of pharmaceutical products have posed challenges in high- and low-income countries alike. In many instances, high prices of pharmaceutical products have led to significant financial hardship for individuals and negatively impacted on healthcare systems' ability to provide population-wide access to essential medicines. Pharmaceutical pricing policies need to be carefully planned, carried out, and regularly checked and revised according to changing conditions. Strong, well-thought-out policies can guide well-informed and balanced decisions to achieve affordable

access to essential health products. This guideline replaces the 2015 WHO guideline on country pharmaceutical pricing policies, revised to reflect the growing body of literature since the last evidence review in 2010. This update also recognizes country experiences in managing the prices of pharmaceutical products.

The WHO consolidated guidelines on tuberculosis: tuberculosis preventive treatment provides a comprehensive set of recommendations for programmatic management of tuberculosis preventive treatment (PMTPT) geared towards the implementers of the WHO End TB Strategy and also for countries intent upon TB elimination (9). The guidelines are to be used primarily in national TB and HIV and maternal and child programmes or their equivalents in ministries of health and for other policy-makers working on TB, HIV, infectious diseases and maternal and child health. They are also appropriate for staff of ministries of justice, correctional services and other government agencies which deliver healthcare, including prison services, social services and immigration. The guidelines are also intended for clinicians in the public or the private sectors working on TB, HIV, infectious diseases, prevention, child health and

noncommunicable diseases such as chronic kidney disease and cancer. The persons directly affected by the guidelines are risk groups for whom TB preventive treatment is recommended. These guidelines provide guidance on the diagnosis of human immunodeficiency virus (HIV) infection, the use of antiretroviral (ARV) drugs for treating and preventing HIV infection and the care of people living with HIV. They are structured along the continuum of HIV testing, prevention, treatment and care. This edition updates the 2013 consolidated guidelines on the use of antiretroviral drugs following an extensive review of evidence and consultations in mid-2015, shared at the end of 2015, and now published in full in 2016. It is being published in a changing global context for HIV and for health more broadly.

The 'Addressing forestry and agroforestry in National Adaptation Plans: Supplementary guidelines' provide specific guidance for national adaptation planning in the forestry sector. They are intended to be used by national planners and decision–makers working on climate change issues in developing countries and authorities and experts who are contributing to climate change adaptation and NAP formulation and implementation.

WHO guideline on country pharmaceutical

pricing policies
The International Pharmacopoeia
Sixty-sixth Report
Pharmaceutical Microbiological Quality Assurance and Control
Cosmetic Microbiology
Applications

This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations for the production and control of vaccines and other biological substances, and the establishment of international biological reference materials. Following a brief introduction, the report summarizes a number of general issues brought to the attention of the Committee. The next part of the report, of particular relevance to manufacturers and national regulatory authorities, outlines the discussions held on the development and adoption of new and revised WHO Recommendations, Guidelines and guidance documents. Following these discussions, a WHO guidance document on Regulatory assessment of approved rDNA-derived biotherapeutics was adopted along with WHO Guidelines on the stability evaluation of vaccines for use under extended controlled temperature conditions and on WHO good manufacturing practices for biological products. In addition, revised WHO Recommendations to assure the quality, safety and efficacy of recombinant human papillomavirus virus-like particle vaccines were also

adopted by the Committee. Subsequent sections of the report provide information on the current status and proposed development of international reference materials in the areas of antibiotics; biotherapeutics other than blood products; blood products and related substances; in vitro diagnostic device reagents; and vaccines and related substances. A series of annexes are then presented which include an updated list of all WHO Recommendations, Guidelines and other documents on biological substances used in medicine (Annex 1). The above four WHO documents adopted on the advice of the Committee are then published as part of this report (Annexes 2-5). Finally, all additions and discontinuations made during the 2015 meeting to the list of International Standards, Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in Annex 6. The updated full catalog of WHO International Reference Preparations is available at:

http://www.who.int/bloodproducts/catalogue/en/.

This new edition incorporates revised guidance from H.M Treasury which is designed to promote efficient policy development and resource allocation across government through the use of a thorough, long-term and analytically robust approach to the appraisal and evaluation of public service projects before significant funds are committed. It is the first edition to have been aided by a consultation process in order to ensure the guidance is clearer and more closely tailored to suit the needs of users.

This toolkit aims to help countries in selecting and

analysing value chains for opportunities to improve climate change resilience and reduce gender inequalities. It intends to provide policy makers, planners, project developers, technical advisors and implementers at local, regional or national level with good practices of climate-resilient and gender-responsive value chain development. It aims to act as a repository of relevant tools and methodologies for identifying relevant stakeholders and engaging with them to collect data and analyse it to design interventions. Climate change threatens agricultural value chains, and having a gender-responsive value chain approach is useful in analysing the climate risks, as it looks at stages during and beyond production, while using a more systemic approach to risk management.

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.

Forty-eighth Report

A literature review of monitoring and evaluation (M&E) frameworks for Climate-Smart Agriculture

Supplementary guidelines

Volume 35
Guidelines for the Management of Common Childhood Illnesses
Fiftieth Report

A single source of authoritative information on all aspects of the practice of modern liquid chromatography suitable for advanced students and professionals working in a laboratory or managerial capacity Chapters written by authoritative and visionary experts in the field provide an overview and focused treatment of a single topic Each chapter emphasizes the integration of chromatographic methods and sample preparation, automation, and explains how liquid chromatography is used in different industrial sectors Focuses on expanding and illustrating the main features of the fundamental section, while demonstrating where and how the best practices of liquid chromatography are utilized Comprehensive coverage of modern liquid chromatography from theory, to methods, to selected applications Thorough selected references and tables with commonly used data to facilitate research, practical work, comparison of results, and decision making

The Addressing agriculture, forestry and fisheries in National Adaptation Plans – Supplementary guidelines (NAP–Ag Guidelines) provide specific guidance for national adaptation planning in the agricultural sectors. They are intended to be used by national planners and decision–makers working on climate change issues in developing countries and authorities and experts within the agriculture sectors who are contributing to climate change adaptation and NAP formulation and implementation.

The World Health Organization (WHO) Expert Committee

on Specifications for Pharmaceutical Preparations advises the Director-General of WHO in the area of medicines quality assurance. It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality, safety and efficacy in all WHO Member States. Its advice is developed through a broad consensus-building process and covers all areas of quality assurance of medicines, from their development to their distribution to patients. In the area of quality control, the Expert Committee reviewed new and revised specifications and general texts for inclusion in The International Pharmacopoeia, and received the annual report of the European Directorate for the Quality of Medicines & HealthCare (EDQM), the custodian centre for International Chemical Reference Substances (ICRS). The Committee adopted a number of monographs, general texts and ICRS. It noted the report on Phase 6 of the External Quality Assurance Assessment Scheme (EQAAS) and on new approaches to ensure sustainability of this scheme through user fees. The Committee further acknowledged the progress of good pharmacopoeial practices (GPhP), and adopted the document on GPhP which was prepared by the consecutive international meetings of world pharmacopoeias. In the various quality assurance-related areas the Expert Committee was presented with a number of new and revised guidelines related to good manufacturing practices (GMP), distribution and trade of pharmaceuticals and regulatory practice. It adopted 10 guidelines as listed below as well as 22 new specifications and general texts for inclusion in The International Pharmacopoeia. The Committee took note of ongoing work to promote collaboration and information exchange through the good regulatory practice project and welcomed the development of a

comprehensive set of guidelines for all national regulatory authorities through this project.
The third issue of Volume 35, includes Consultation Documents: - WHO Biowaiver Project – Preparation for Cycle V (2022): Prioritization Exercise of Active Pharmaceutical Ingredients on the WHO Model List of Essential Medicines for Solubility Determination and Biopharmaceutics Classification System-Based Classification- IAEA/WHO Guideline on Good Manufacturing Practices for Investigational Radiopharmaceutical Products - WHO Good Practices for Research and Development Facilities of Pharmaceutical Products - WHO Good Manufacturing Practices for Investigational Products - Medicinal Oxygen (oxygenium medicinalis) - Dolutegravir Dispersible Tablets (dolutegraviri compressi dispersibili) Issue 3 concludes with List No. 86 of Recommended International Nonproprietary Names (INN) for Pharmaceutical Substances.
Good Pharmaceutical Freeze-Drying Practice
WHO Drug Information
WHO Expert Committee on Specifications for Pharmaceutical Preparations
Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook
ICH Quality Guidelines
Forty-ninthReport

Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials

purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is 'current good manufacturing practice (CGMP)'', which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.

A guide to the use of essential oils in food, including information on their composition, extraction methods, and their antioxidant and antimicrobial applications Consumers' food preferences are moving away from synthetic additives and preservatives and there is an increase demand for convenient packaged foods with

long shelf lives. The use of essential oils fills the need for more natural preservativesto extend the shelf-life and maintaining the safety of foods. Essential Oils in Food Processing offers researchers in food science a guide to the chemistry, safety and applications of these easily accessible and eco-friendly substances. The text offers a review of essential oils components, history, source and their application in foods and explores common and new extraction methods of essential oils from herbs and spices. The authors show how to determine the chemical composition of essential oils as well as an explanation of the antimicrobial and antioxidant activity of these oils in foods. This resource also delves into the effect of essential oils on food flavor and explores the interaction of essential oils and food components. Essential Oils in Food Processing offers a: Handbook of the use of essential oils in food, including their composition, extraction methods and their antioxidant and antimicrobial applications Guide that shows how essential oils can be used to extend the shelf life of food products whilst meeting consumer demand for “natural” products Review of the use of essential oils as natural flavour ingredients Summary of relevant food regulations as pertaining to essential oils Academic researchers in food science, R&D scientists, and educators and advanced students in food science and nutrition can tap into the most recent findings and basic understanding of the chemistry, application, and safe us of essential oils in food processing.

Medicinal plant materials are supplied through collection from wild populations and cultivation. Under the overall

context of quality assurance and control of herbal medicines WHO developed the Guidelines on good agricultural and collection practices (GACP) for medicinal plants providing general technical guidance on obtaining medicinal plant materials of good quality for the sustainable production of herbal products classified as medicines. These guidelines are also related to WHO's work on the protection of medicinal plants aiming promotion of sustainable use and cultivation of medicinal plants. The main objectives of these guidelines are to: (1) contribute to the quality assurance of medicinal plant materials used as the source for herbal medicines to improve the quality safety and efficacy of finished herbal products; (2) guide the formulation of national and/or regional GACP guidelines and GACP monographs for medicinal plants and related standard operating procedures; and (3) encourage and support the sustainable cultivation and collection of medicinal plants of good quality in ways that respect and support the conservation of medicinal plants and the environment in general. These guidelines concern the cultivation and collection of medicinal plants and include certain post-harvest operations. Good agricultural and collection practices for medicinal plants are the first step in quality assurance on which the safety and efficacy of herbal medicinal products directly depend. These practices also play an important role in protection natural resources of medicinal plants for sustainable use.

This text is devoted to pharmaceutical freeze-drying in all its forms and in all its technological variations. Whether you freeze-dry nonsterile tablets or you lyophilize

injectables, this book covers all the technological and regulatory requirements. Written by a panel of leading practitioners in the pharmaceutical industry -- production experts, regulatory inspectors, technical consultants, and equipment suppliers -- the information is relevant, usable, and timely. Practical, "how to" chapters serve as training aids, and each section stands on its own as a concise, easy-to-access resource for both managers and technicians.

International Convergence of Capital Measurement and Capital Standards

Pharmaceutical Quality Assurance

Best Practices Guide to Electronic Records Compliance

The Green Book

Technical Report Series

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).

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 including Health Based Exposure Limits (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; WHO Certification Scheme on the quality 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.

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

Method-validation experiments are intended to demonstrate that an analytical method will yield acceptable method performance.

Several works provide guidance outlining requirements for method validation, and numerous articles demonstrate how to perform LC method validation according to these guidelines. While traditional validation experiments provide useful information about method characteristics, they do not directly address an important feature of an analytical method: agreement of the measured value with the true value. In this chapter, traditional method validation guidance and the associated method characteristics are discussed. In addition, recent approaches that incorporate risk and a more rigorous assessment of method variability are also briefly described.

Addressing forestry and agroforestry in National Adaptation Plans

Fortieth Report

WHO Expert Committee on Biological Standardization

Forty-seventh Report

An Implementation Guide

Toolkit for value chain analysis and market development integrating climate resilience and gender responsiveness

The main objective of this report is to review the monitoring and evaluation (M&E) frameworks, tools and guidance documents that are available for

climate-smart agriculture (CSA), and in particular for objective ("pillar") two on adaptation and resilience. The report is a literature review and does not propose a new methodology. It is not an exhaustive list, but summarises the main M&E frameworks. This report represents the first step towards the development of operational guidelines for the design and implementation of national M&E frameworks for CSA, to be developed during the first quarter of 2019. The envisioned operational guidelines will address the core constraints and needs of Member States on both the design and implementation of an M&E system that can simultaneously address CSA and sector reporting requirements for the 2030 Agenda climate instruments. These guidelines will address the principal need expressed by Member States that M&E systems and indicators should be simple and not onerous. The intended users are practitioners designing CSA projects at country level and policy-makers coordinating national-sector monitoring and reporting efforts on climate change under the following

three global agreements: the United Nations 2030 Agenda for Sustainable Development, the Sendai Framework for Disaster Risk Reduction, and the United Nations Framework Convention on Climate Change (UNFCCC) Paris Agreement of 2015.

Integrating agriculture in National Adaptation Plans (NAP-Ag) Programme

Good Design Practices for GMP Pharmaceutical Facilities

A Practical Approach

Vertical Agreements in EU Competition Law