

Annex 4

Supplementary guidelines on good manufacturing practices: validation

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Annex Supplementary Guidelines On Good Manufacturing

World Health Organization



Annex Supplementary Guidelines On Good Manufacturing:

WHO Expert Committee on Specifications for Pharmaceutical Preparations WHO Expert Committee on Specifications for Pharmaceutical Preparations. Meeting, World Health Organization, 2016 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 **WHO Expert Committee on Specifications for Pharmaceutical Preparations** World Health Organization, 2024-04-26 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 The Expert Committee develops standards through worldwide consultation and an international consensus building process The following new guidance texts were adopted and recommended for use WHO good manufacturing practices for excipients used in pharmaceutical products revision IAEA WHO good manufacturing practices for in house cold kits for radiopharmaceutical preparations new WHO good practices for pharmaceutical quality control laboratories revision WHO UNFPA female condom generic specification new WHO Biowaiver List proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate release updated solid oral dosage forms WHO guideline on Biopharmaceutics Classification System based biowaivers revision and Multisource generic pharmaceutical products guidelines on registration requirements to establish interchangeability republished All of the above are included in this

report and recommended for implementation

WHO Guidelines on Good Agricultural and Collection Practices [GACP] for Medicinal Plants World Health Organization, 2003-12-16 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 *WHO Expert Committee on Specifications for Pharmaceutical Preparations* WHO Expert Committee on Specifications for Pharmaceutical Preparations, World Health Organization, 2007 This report sets out the recommendations of an international group of experts relating to developments in the quality assurance of medicines and specifications for drug substances and dosage forms It contains guidelines of direct relevance to the UN Prequalification Programme for Priority Essential Medicines and for quality control laboratories including procedures governing the assessment of pharmaceutical products for procurement by UN agencies and for assessing the acceptability of quality control laboratories It also includes discussion regarding several monographs for inclusion in the International Pharmacopoeia relating to antiretrovirals including fixed dose combinations TB medicines and antimalarial and paediatric medicines

Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook Jordi Botet, 2015-09-28 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 *Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Volume 2. Good manufacturing practices and inspection* World Health Organization,2024-01-31 The GMP Compendium for Medical Products is a valuable resource for manufacturers regulators and other stakeholders involved in producing and distributing medical products It covers various topics from quality management systems to personnel hygiene equipment validation and complaint handling The guidance provided is based on the latest scientific and technical knowledge and considers the evolving regulatory landscape and the challenges faced by the industry **Principles of Parenteral Solution Validation** Igor Gorsky,Harold S. Baseman,2019-11-27

Principles of Parenteral Solution Validation A Practical Lifecycle Approach covers all aspects involved in the development and process validation of a parenteral product By using a lifecycle approach this book discusses the latest technology compliance developments and regulatory considerations and trends from process design to divesting As part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin this book incorporates numerous case studies and real world examples that address timely problems and offer solutions to the daily challenges facing practitioners in this area

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 *Technical Report Series* ,2006 Quality Assurance of Pharmaceuticals World Health Organization,2007 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

Ensuring the Integrity of Electronic Health Records Orlando López,2020-12-21 Data integrity is a critical aspect to the design implementation and usage of any system which stores processes or retrieves data The overall intent of any data integrity technique is the same ensure data is recorded exactly as intended and upon later retrieval ensure the data is the same as it was when originally recorded Any alternation to the data is then traced to the person who made the modification The integrity of data in a patient s electronic health record is critical to ensuring the safety of the patient This book is relevant to production systems and quality control systems associated with the manufacture of pharmaceuticals and medical device products and updates the practical information to enable better understanding of the controls applicable to e records The book highlights the e records suitability implementation and associated risk assessed controls and e records handling The book also provides updated regulatory standards from global regulatory organizations such as MHRA Medicines and Healthcare Products Regulatory Agency UK FDA Food and Drug Administration US National Medical Products Association China TGA Therapeutic Goods Administration Australia SIMGP Russia State Institute of Medicines and Good Practices and the World Health Organization to name a few

Frailty and Herbal Medicines- From Molecular Mechanisms to Clinical Efficacy Akio Inui,Jiang Bo Li,Koji Ataka,Ryuji Takahashi,Noiro Iizuka,2020-05-28

WHO Expert Committee on Biological Standardization World Health Organization. Expert Committee on Biological Standardization,World Health Organization,2016 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> WHO Expert Committee on Specifications for Pharmaceutical Preparations World Health Organization, 2006 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

Quality assurance of pharmaceuticals: a compendium of guidelines and related materials, tenth edition. Volume 1. Good practices and related regulatory guidance World Health Organization, 2024-10-24 This publication represents a significant achievement in our ongoing effort to ensure that everyone can reach the highest possible level of health Over the last three

decades we have seen the transformation of the pharmaceutical industry and the increasing intricacy of the product life cycle. The challenges we face today are very different from those we faced when the first edition of this Compendium was published in 1997. However, our mission remains the same: to promote health, keep the world safe, and serve the vulnerable. The new edition reflects the collective knowledge and expertise of countless professionals who have worked diligently to develop, revise, and implement WHO guidelines for pharmaceuticals. This includes experts from WHO Member States, our Expert Advisory Panels, and Expert Committees on Specifications for Pharmaceutical Preparations, and other organizations. It has undergone extensive consultation with stakeholders worldwide. This Compendium covers development through manufacturing and quality control to post-marketing surveillance. It provides a comprehensive framework for quality assurance that is both strong and flexible, capable of meeting the requirements of a rapidly changing global health landscape. The 10th edition is a collection of knowledge and tools for empowerment, enabling all stakeholders in the pharmaceutical industry to make informed decisions that prioritize patient safety and well-being.

EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP Orlando Lopez, 2015-04-06. Good Manufacturing Practice (GMP) ensures medicinal products are produced consistently and controlled to the quality standards appropriate for their intended use and as required by product specifications or marketing authorization. Annex 11 details the European Medicines Agency (EMA) GMP requirements for computer systems. The purpose of Annex 11 is **Good Design Practices for GMP Pharmaceutical Facilities** Terry Jacobs, Andrew A. Signore, 2016-08-19. 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. Good Pharmaceutical Freeze-Drying Practice Peter Cameron, 1997-06-30. 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 **WHO Drug Information**, 2005.

Data Integrity in Pharmaceutical and Medical Devices Regulation Operations Orlando Lopez, 2016-11-03. 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.

Annex Supplementary Guidelines On Good Manufacturing Book Review: Unveiling the Magic of Language

In a digital era where connections and knowledge reign supreme, the enchanting power of language has are more apparent than ever. Its capability to stir emotions, provoke thought, and instigate transformation is actually remarkable. This extraordinary book, aptly titled "**Annex Supplementary Guidelines On Good Manufacturing**," written by a highly acclaimed author, immerses readers in a captivating exploration of the significance of language and its profound affect our existence. Throughout this critique, we shall delve in to the book is central themes, evaluate its unique writing style, and assess its overall influence on its readership.

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Annex Supplementary Guidelines On Good Manufacturing Introduction

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