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Annex 4

Supplementary guidelines on good manufacturing practices: validation

Annex 4 Supplementary Guidelines On Good Manufacturing

Purusotam Basnet

Annex 4 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 **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** 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 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 **Regulatory Affairs in Industrial Pharmacy in India** Madhu Verma,Iti Chauhan,2025-09-09 This book comprehensively explores the regulatory frameworks governing pharmaceutical manufacturing quality control and approvals in Indian pharmaceutical scenarios Tailored for industry professionals students and researchers it bridges the knowledge gaps in regulatory affairs in the pharmaceutical industry Covering key topics such as pilot plant scale up SUPAC Scale Up and Post Approval Changes technology transfer regulatory requirements and quality management systems it offers insights into navigating the complexities of Indian regulatory requirements A must read for those aiming to excel in pharmaceutical regulation the book serves as a roadmap for ensuring efficiency safety and compliance in pharmaceutical industries operating in India 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 *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 **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 and 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 *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 *Technical Report Series* ,2006 *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 **Promising Pharmaceuticals** Purusotam Basnet,2012-05-23 From the dawn of civilization humans have been dreaming of happy healthy

and long life Our life expectancy is twice longer than 100 years ago We know more about the diseases Therefore we have developed new drugs to fight against them The demand for drugs was so high that we developed Pharma industries Although Pharma industries took responsibility of producing the needed drugs and gave us a quality of life misuse of drugs brought further complication Therefore discovery production distribution and the phase of administration of patients quality assurance has to be controlled with a technological procedure and tight regulations to make the system as effective as possible for the benefit of human health Our book provides selected but vital information on the sources tools technologies and regulations regarding the current status of medicine development **Liquid Chromatography** Salvatore Fanali,Paul R. Haddad,Colin Poole,David K. Lloyd,2013-01-08 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 **WHO Drug Information** ,2005 *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 **WHO Expert Committee on Specifications for Pharmaceutical Preparations** ,2021-04-26 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 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 **Who Expert Committee on Biological Standardization** WHO Expert Committee on Biological Standardization. Meeting,World Health Organization,World Health Organization. Expert Committee on Biological Standardization,2013 The WHO Expert Committee on Biological Standardization ECBS met in Geneva from 17 to 21 October 2011 Introduction *Frailty and Herbal Medicines- From Molecular Mechanisms to Clinical Efficacy* Akio Inui,Jiang Bo Li,Koji Ataka,Ryuji Takahashi,Noiro Iizuka,2020-05-28

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