

Annex 4

Supplementary guidelines on good manufacturing practices: validation

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Annex 4 Supplementary Guidelines On Good Manufacturing

World Health Organization



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

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 *WHO Expert Committee on Specifications for Pharmaceutical Preparations* World Health Organization,2019-05-29 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 **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 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 *Technical Report Series*, 2010 **WHO Drug Information**, 2005 Biopharmaceuticals Gary Walsh, 1998-06-18 Biopharmaceuticals Biochemistry and Biotechnology provides a comprehensive and up to date overview of the science and medical applications

of biopharmaceutical products Specific chapters detail therapeutic substances such as interferons interleukins and growth factors as well as hormones therapeutic enzymes blood products antibodies and vaccines While the emphasis is placed upon polypeptide based therapeutic agents the potential applications of nucleic acids with regard to gene therapy and antisense technology are considered in the final chapter In addition other chapters detail regulatory issues as applied to biopharmaceuticals and how such products are manufactured in practice The author has produced an up to date easy to read book and each chapter is supplemented with a substantial further reading section It is of particular relevance to students undertaking advanced undergraduate or postgraduate courses in biotechnology biochemistry pharmaceutical science or medicine Its scope also renders it an ideal reference for those already employed in the bio pharmaceutical sector who wish to gain a better overview of the industry in which they work

Freeze-Drying Georg-Wilhelm Oetjen, 1999-03-03 Many modern medicines such as blood derivatives vaccines and antibiotics are freeze dried This is considered the best method of transforming the perishable substances into a form that keeps well This book describes the rules of freeze drying

WHO Global Atlas of Traditional, Complementary, and Alternative Medicine C. K. Ong, 2005 Through global and regional maps and tables the map volume provides a visual representation of topics such as the popularity of herbal traditional medicine Ayurveda Siddha Unani traditional Chinese medicine homeopathy acupuncture chiropractic osteopathy bone setting spiritual therapies and others national legislation and traditional medicine policy public financing legal recognition of traditional medicine practitioners by their area of therapy education and professional regulation conventional health care practitioners who are entitled to provide various traditional complementary and alternative therapies and many other aspects

WHO Expert Committee on Biological Standardization World Health Organization. Expert Committee on Biological Standardization, 1950

The Encyclopedia of Cell Technology, 2 Volume Set, 2000-02-08 The Encyclopedia of Cell Technology provides complete coverage of all aspects of both animal and plant cultures Coverage includes ethical and regulatory issues the basic science of cells and cell culture techniques and equipment used in growing cultures and harvesting product product development and classification licensing and patenting as well as the history of cell technology

The International Pharmacopoeia World Health Organization, 1979 The International Pharmacopoeia contains a collection of recommended methods for analysis and quality specifications for pharmaceutical substances excipients and products Volume five of this publications describes methods and procedures for the quality control of pharmaceutical substances and tablets tests for dosage forms for suppositories and ophthalmic preparations and a new section on quality control of anti malarials Supplementary information on International Chemical Reference Substances and International Reference Spectra and on the establishment maintenance and distribution of chemical reference substances are also included

Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board, 1973

Yearbook of European Environmental Law, 2008

History of Modern Biotechnology, 2000 History of Modern

Biotechnology divided into two volumes 69 70 is devoted to the developments in different countries N W F Kossen The Morphology of Filamentous Fungi H Bockeer W A Knorre Antibiotica Research in Jena from Penicillin Nourseothricin to Interferon K Schugerl Development of Bioreaction Engineering R Katzen G T Tsao A View of the History of Biochemical Engineering J M Woodley Selected Advances in Enzyme Technology H R Bungay Computer Applications in Bioprocessing W Beyeler E DaPra K Schneider Automation of Industrial Bioprocesses **Encyclopedia of Separation Science** Michael Cooke, C. F. Poole, 2000 Congressional Record United States. Congress, 2004 *Control of Foodborne Trematode Infections* World Health Organization, WHO Study Group on the Control of Foodborne Trematode Infections, 1995 Draws attention to the serious and growing public health problem posed by foodborne trematode infections These infections which affect an estimated 40 million persons are linked to several serious diseases including cholangiocarcinoma in Opisthorchis infections cholangiocarcinoma and gall stone in Clonorchis infection and severe clinical liver disease in Fasciola infection Infection is acquired via the consumption of raw or inadequately processed freshwater fish shellfish and aquatic plants Awareness of the magnitude of suffering and disease caused by foodborne trematode infections has increased dramatically following recent changes in Eastern Europe where millions of people are now known to be infected with Opisthorchis and where cholangiocarcinoma is the leading cause of hepatic cancer The misdiagnosis of tuberculosis in persons suffering from paragonimiasis poses yet another public health problem of growing concern The book which has three parts aims to assemble all the practical and technical information needed to develop effective strategies for control The first part presents basic information about foodborne trematode infections their modes of transmission and the methods available for control Also included is the first detailed analysis of the geographical distribution of foodborne trematode infections The second part provides a state of the art review of what is known about the clinical features of these diseases patterns of morbidity and mortality the parasites and their intermediate snail hosts The final part summarizes country experiences in the epidemiology and control of foodborne trematode infections

Whispering the Secrets of Language: An Psychological Quest through **Annex 4 Supplementary Guidelines On Good Manufacturing**

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