

Annex 4

Supplementary guidelines on good manufacturing practices: validation

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Annex Supplementary Guidelines On Good Manufacturing

Shayne Cox Gad



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, 2022-12-22 The WHO Technical Report Series 1044 presents the fifty sixth report by the WHO Expert Committee on the Specifications for Pharmaceutical Preparations It provides comprehensive standards and guidelines for the quality assurance of medicines developed through extensive international consultation The report includes new guidance on various aspects such as good manufacturing practices for sterile products technology transfer for medicinal gases and the stability studies of medical products The WHO s publications aim to support national health strategies and address pressing public health concerns by disseminating authoritative information and guidance globally This report reflects the collective views of international experts contributing to the WHO s mission to attain the highest possible level of health for all people **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

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 *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

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> *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

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