



# A WHO guide to good manufacturing practice (GMP) requirements

## Part 2: Validation

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GLOBAL PROGRAMME FOR VACCINES AND IMMUNIZATION  
VACCINE SUPPLY AND QUALITY  
GLOBAL TRAINING NETWORK



World Health Organization  
Geneva  
1997

# Who Guide To Gmp Requirements

**Gert Auterhoff**



## **Who Guide To Gmp Requirements:**

**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 Formulating Pharma-, Nutra-, and Cosmeceutical Products from Herbal Substances Anupama Singh, Hitesh Kulhari, Vikas Anand Saharan, 2025-08-12 A practical and up to date discussion of the formulation and design of dosage forms and delivery systems containing herbal ingredients In Formulating Pharma Nutra and Cosmeceutical Products from Herbal Substances Dosage Forms and Delivery Systems a team of distinguished researchers delivers a step by step approach to preparing and manufacturing dosage forms and delivery systems Intuitively organized with comprehensive coverage of the fundamentals functional materials manufacturing and marketing of pharmaceutical nutraceutical and cosmeceutical products the book also examines regulatory issues of quality safety and efficacy The authors discuss essential formulation development and delivery information for novel and controlled delivery systems of herbal ingredients Readers will also find A thorough introduction to the basic principles of developing modern pharma nutra and cosmeceutical products from herbal substances Comprehensive explorations of conventional formulations including issues of stability Practical discussions of advanced formulations including chronotherapeutic delivery systems liposome based delivery of phytoconstituents and nanoparticle mediated

delivery of herbal actives Complete treatments of regulatory challenges including nonclinical characterization and documentation for marketing authorizations of herbal formulations Perfect for professionals working in the herbal drug natural product and dietary supplement industries Formulating Pharma Nutra and Cosmeceutical Products from Herbal Substances will also benefit academic researchers and graduate students studying herbal research cosmetics and pharmaceutical sciences Guide to GMP of Japan Japan. Kōseishō. Yakumukyoku. Kanshi Shidōka,1983 WHO Expert Committee on Biological Standardization WHO Expert Committee on Biological Standardization. Meeting,World Health Organization,2014 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 biologicals 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 of revised WHO Recommendations and Guidelines for a number of vaccines blood products and related substances Specific discussion areas included the development of WHO guidance on the quality safety and efficacy of poliomyelitis vaccines oral live attenuated recombinant malaria vaccines diphtheria vaccines adsorbed tetanus vaccines adsorbed combined vaccines based on diphtheria and tetanus vaccines and Japanese encephalitis vaccines live attenuated Subsequent sections of the report then provide information on the current status and proposed development of international reference materials in the areas of vaccines and related substances blood products and related substances in vitro diagnostic device reagents biotherapeutics other than blood products and antibiotics A series of annexes are then presented which include an updated list of WHO Recommendations Guidelines and other documents on biological substances used in medicine Annex 1 followed by a series of WHO Recommendations and Guidelines adopted on the advice of the Committee Annexes 2 7 All additions made during the meeting to the list of International Standards and Reference Reagents for biological substances maintained by WHO are then summarized in Annex 8 EC Guide to Good Manufacturing Practice for Medicinal Products and Active Pharmaceutical Ingredients Gert Auterhoff,2002 Among other issues the edition deals with quality management personnel premises and equipment documentation production quality control contract manufacture and analysis complaints and product recall selfinspection Book jacket **Good Manufacturing Practices for Pharmaceuticals** Joseph D. Nally,2016-04-19 With global harmonization of regulatory requirements and quality standards and national and global business consolidations ongoing at a fast pace pharmaceutical manufacturers suppliers contractors and distributors are impacted by continual change Offering a wide assortment of policy and guidance document references and interpretations this Sixth Edition is significantly expanded to reflect the increase of information and changing practices in CGMP regulation and pharmaceutical manufacturing and control practices worldwide An essential companion for every pharmaceutical professional this guide is

updated and expanded by a team of industry experts each member with extensive experience in industry or academic settings Handbook of Pharmaceutical Manufacturing Formulations Sarfaraz K. Niazi,2016-04-19 Over the Counter products comprise a special category of healthcare products While these formulations have much in common with their prescription counterparts they are presented in this series separately because of their development approach taken labeling considerations required and support available from suppliers of ingredients in designing **Guide to Microbiological Control in Pharmaceuticals** S. P. Denyer,Rosamund M. Baird,1990 A handbook to the micro organism as a contaminant and as a potential growth medium focusing on the problems of microbiological control in pharmaceutical product design and manufacture Topics include the relative susceptibilities of product types and ingredients and factory hygiene **Targeted Radiopharmaceuticals and Imaging** Ved Srivastava,Rakhee Vatsa,2025-06-04 Targeted radiopharmaceutical therapy RPT is emerging as an innovative approach for treating a wide range of cancers Almost all radionuclides used in RPT emit photons that can be imaged enabling non invasive visualization of the therapeutic agent s biodistribution The remarkable potential of radiopharmaceutical therapy is now being recognized with recent FDA approval of several RPT drugs and a significant number of drug candidates in clinical development This book offers a comprehensive perspective on the different technologies and addresses the critical challenges in developing and commercializing radiopharmaceuticals It covers various topics from clinical applications to specific radiopharmaceutical biodistribution dosimetry and novel targets in oncology The chapters provide a cohesive picture of the advances in SPECT CT and PET CT imaging clinical trends in targeted therapies utilizing radioisotopes for cancer imaging and clinical applications of radiotracers within oncology areas It also delves into the manufacturing technologies and regulatory and supply logistics required to support the development of the next wave of targeted alpha therapies This resource is ideal for postgraduates and researchers in drug discovery and development in radionuclide therapy and imaging in cancer as well as medical professionals engaged in nuclear medicine and radiology

Quality in the Manufacture of Medicines and Other Healthcare Products John Sharp,J. R. Sharp,2000 This overview of quality assurance in pharmaceutical production describes the principles and practice and discusses specific quality issues providing a guide to both national and international regulatory requirements *A WHO Guide to Good Manufacturing Practice (GMP) Requirements* Gillian Chaloner-Larsson,World Health Organization,1997 Technical Reports Series ,2009 *Global Cosmetic Industry's Who's who Guide to Personal Care* ,2001 The Changing Role of Engineering in Orthopaedics ,1989 Proceedings of an international conference held April 1989 in London Thirty six papers consider the connections between orthopaedic surgery and mechanical engineering an inextricable linkage since the skeleton itself is an engineering framework Topics include joint replacement materials the me *Food, Drug, Cosmetic Law Quarterly* ,1991 **Food, Drug, Cosmetic Law Journal** ,1991 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

*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

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