



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

## Part 2: Validation

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World Health Organization  
Geneva  
1997

# Who Guide To Gmp Requirements

**Gillian Chaloner-Larsson, World Health  
Organization**



## **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

A WHO Guide to Good Manufacturing Practice (GMP) Requirements Gillian Chaloner-Larsson,World Health Organization,1997 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

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      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

**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      **Targeted**

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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      Global Cosmetic Industry's Who's who Guide to Personal Care ,2001      Food, Drug, Cosmetic Law Quarterly ,1991      **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     *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

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is used to refer to a period between

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