



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

## Part 2: Validation

*Written by:*

Gillian Chaloner-Larsson, Ph.D., G.C.L. Bioconsult, Ottawa

Roger Anderson, Ph.D., Director of Quality Operations, Massachusetts Public Health Biologic Labs

Anik Egan, BSc., G.C.L. Bioconsult, Ottawa

*In collaboration with:*

Manoel Antonio da Fonseca Costa Filho, M.Sc., Consultant in Quality Assurance, Biomanguinhos/FIO CRUZ, Brazil

Dr Jorge F. Gomez Herrera, Director of Quality Assurance, Gerencia General de Biologicos y Reactivos, Secretaria De Salud, Mexico



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



World Health Organization  
Geneva  
1997

# Who Guide To Gmp Requirements

**Anupama Singh,Hitesh Kulhari,Vikas  
Anand Saharan**



## **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

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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

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web 1 do you have space with a sink pigs are a lot more involved than frogs and the preservatives will need to be drained and pigs rinsed this is not a good dissection for classrooms that do not have sinks 2 have your students completed the frog dissection

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web question is the trachea in front of or behind the esophagus cut into the thoracic cavity beneath the rib cage make sure you can locate the following structures heart lungs bronchi

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web figure 1 female injection site nipples umbilical cord figure 2 female genital papilla urogenital opening anus figure 3 male scrotum figure 4 male urogenital opening penis anus preparation and initial cuts tie one front leg of the animal with a string that passes underneath the dissecting pan to the other leg

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web pre lab before observing internal or external structures of the fetal pig use your dissection manual textbook and dissection notebook to answer the pre lab questions on the fetal pig you may have to refer to more than one dissection manual to answer all the questions so trade and share with other dissection groups

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web 1 determine the sex of your pig by looking for the urogenital opening on females this opening is located near the anus on males the opening is located near the umbilical cord if your pig is female you should also note that urogenital papilla is present near the genital opening males do not have urogenital papilla

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web the size of the testes varies significantly depending on the age of the fetal pig female in the female pig locate two bean shaped ovaries located just posterior to the kidneys and connected to the curly oviducts these typically are quite small in the fetal pig trace the oviducts toward the posterior to find that they merge at the uterus

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web obtain a fetal pig and identify the structures listed in figure 1 use figures 1 4 below to identify its sex use your pig and also a pig of the opposite sex to identify the structures in the photographs below the word urogenital refers to an opening that serves both the urinary excretory and the reproductive systems figure 1

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web 1 most of the pig s external features are familiar to you ears nose eyes etc on the belly you will see the umbilical cord which connected the fetal pig to its mother s placenta on either side of the umbilical cord you may see mammary papillae little nipples that will turn into teats in female pigs 2

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web are you ready for the lab practical i have completed the virtual pig dissection i have checked the the boxes on the lab guide and have found each of the organs structures listed i can spell all of the words on the lab guide i know the functions of each i have looked at each of the galleries and can identify structures on the pictures

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