Pharmaceutical Technology-IV

Good Manufacturing Practices

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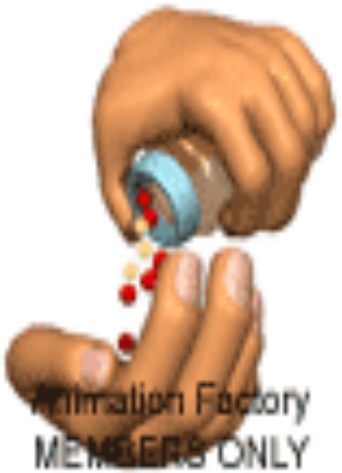
Drugs,

are the **mixtures of one or more active substances in pure form or together with some excipients and prepared by various methods in order to make them useful for the use of the patient .**



GMP

Give me

More

Paper ????

GMP Philosophy

It is not enough to determine only one method for the preparation of the drug.

The important things for the preparation of drugs are;

-- Implementation of the same method as effectice as for each preparation.

-- Getting the same quality every time

GMP is not related to preparation procedure but relataed to quality and repeatability of preparation

What is GMP

Good Manufacturing Practices is that part of Quality Assurance which ensures that Medicinal products are consistently produced and controlled to the quality standarts appropriate to their intended use and as required by the marketing authorisation or product spesification.

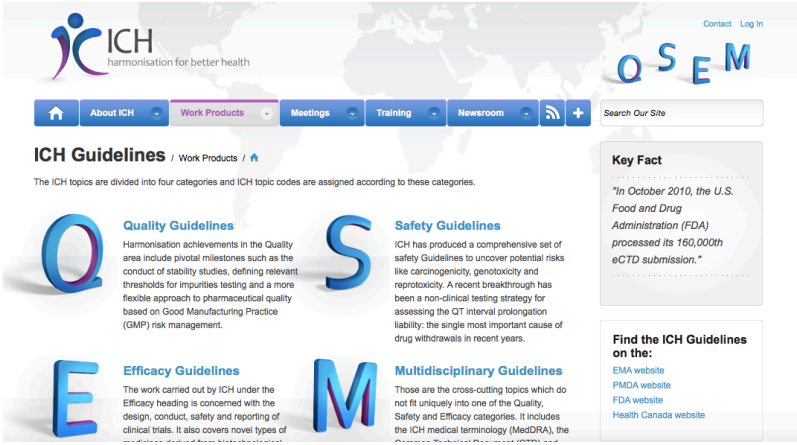
Why GMP ?

The GMP guide has been created for

- Safety

- Efficacy

- Quality of drugs



Why GMP ?

This system has been created to eliminate the risks of pharmaceutical production that can no longer be prevented during finished product testing.

GMP: Good Manufacturing Practice

GLP: Good Laboratory Practice

GCP: Good Clinical Practice

GSP: Good Storage Practice

Quality Guidelines / ICH Guidelines / Work Products /

Harmonisation achievements in the Quality area include pivotal milestones such as the conduct
approach to pharmaceutical quality based on Good Manufacturing Practice (GMP) risk manage

- Q1A - Q1F Stability
- Q2 Analytical Validation
- Q3A - Q3D Impurities
- Q4 - Q4B Pharmacopoeias
- Q5A - Q5E Quality of Biotechnological Products
- Q6A- Q6B Specifications
- Q7 Good Manufacturing Practice
- Q8 Pharmaceutical Development
- Q9 Quality Risk Management
- Q10 Pharmaceutical Quality System
- Q11 Development and Manufacture of Drug Substances

Safety Guidelines

- S1A - S1C Carcinogenicity Studies
- S2 Genotoxicity Studies
- S3A - S3B Toxicokinetics and Pharmacokinetics
- S4 Toxicity Testing
- S5 Reproductive Toxicology
- S6 Biotechnological Products
- S7A - S7B Pharmacology Studies
- S8 Immunotoxicology Studies
- S9 Nonclinical Evaluation for Anticancer Pharmaceuticals
- S10 Photosafety Evaluation
- S11 Nonclinical Paediatric Safety

EfficacyGuidelines-1

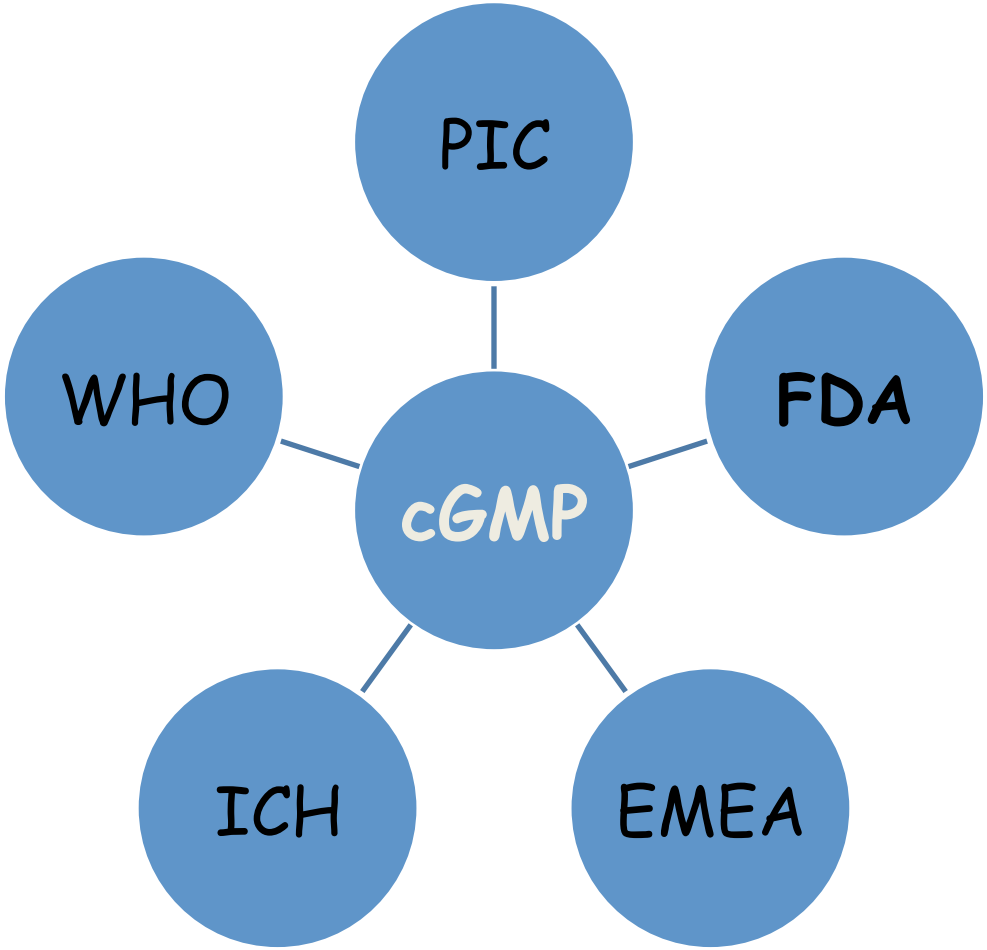
- E1 Clinical Safety for Drugs used in Long-Term Treatment
- E2A - E2F Pharmacovigilance
- E3 Clinical Study Reports
- E4 Dose-Response Studies
- E5 Ethnic Factors
- E6 Good Clinical Practice
- E7 Clinical Trials in Geriatric Population
- E8 General Considerations for Clinical Trials
- E9 Statistical Principles for Clinical Trials
- E10 Choice of Control Group in Clinical Trials

Efficacy Guidelines -2

- E11 - E11A Clinical Trials in Pediatric Population
- E12 Clinical Evaluation by Therapeutic Category
- E14 Clinical Evaluation of QT
- E15 Definitions in Pharmacogenetics / Pharmacogenomics
- E16 Qualification of Genomic Biomarkers
- E17 Multi-Regional Clinical Trials
- E18 Genomic Sampling
- E19 Safety Data Collection

- M1 MedDRA Terminology
- M2 Electronic Standards
- M3 Nonclinical Safety Studies
- M4 Common Technical Document
- M5 Data Elements and Standards for Drug Dictionaries
- M6 Gene Therapy
- M7 Mutagenic impurities
- M8 Electronic Common Technical Document (eCTD)
- M9 Biopharmaceutics Classification System-based Biowaivers
- M10 Bioanalytical Method Validation
- M11 Clinical electronic Structured Harmonised Protocol (CeSHarP)

GMP RelatedEstablishment/Institudes



GMP RelatedEstablishment/Institudes

WHO: World Health Organization

FDA: Food and Drug Administration

EMA: European Medicine Agency

PIC: Pharmaceutical Inspection Convention

ICH: International Conference on Harmonization

GMP all over the world

- Conferences/Courses
- Webinars
- eLearning - NEW -
- Certification Programme
- In-house Training
- Literature
- GMP Discussion Forum
- Links
- ECA Working Groups
- Members Area
- About ECA
- Annual Meetings
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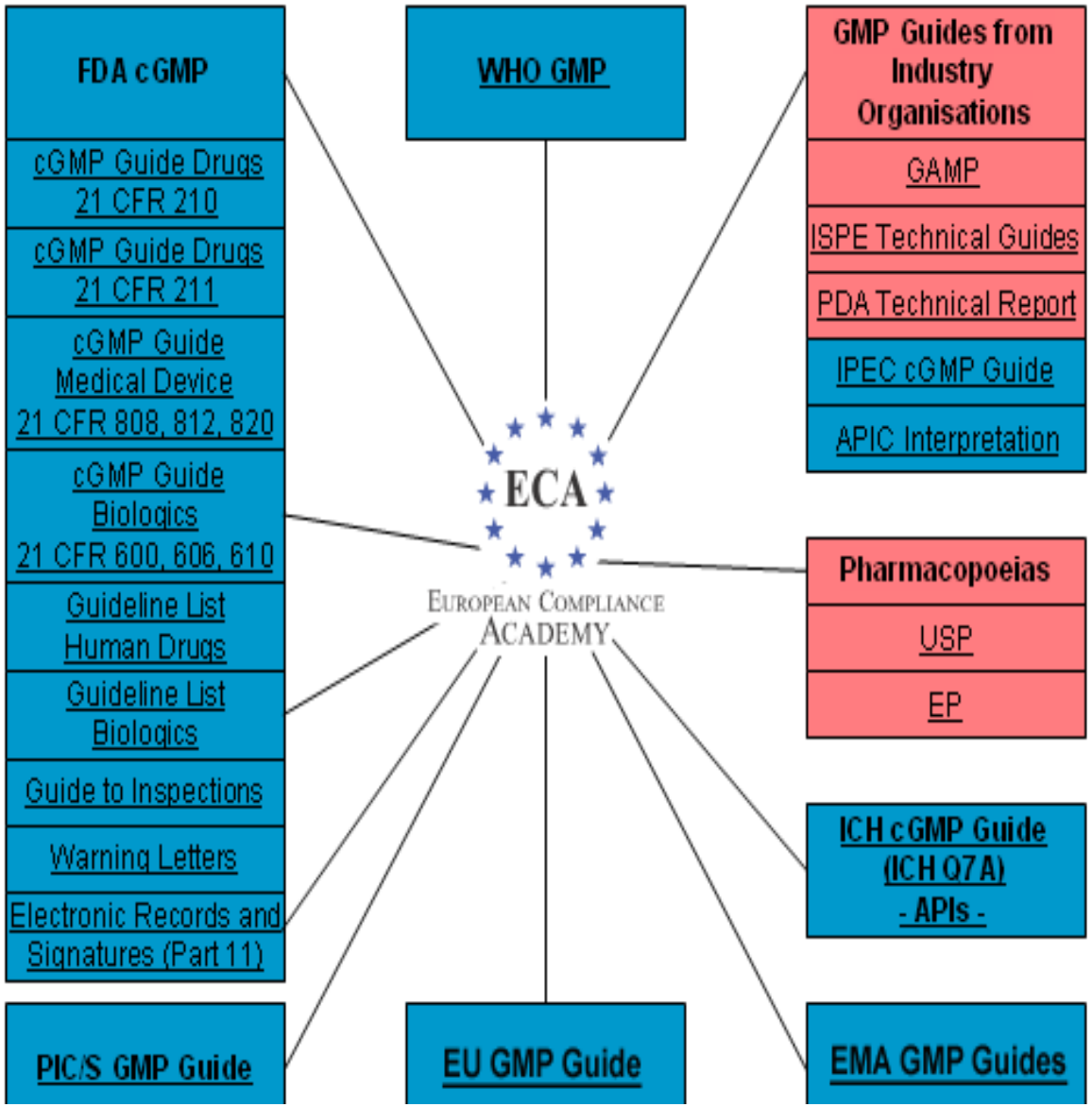

21 CFR 210

cGMP Guide Drugs
21 CFR 211

cGMP Guide
Medical Device
21 CFR 808, 812, 820

cGMP Guide
Biologics
21 CFR 600, 606, 610

Guideline List
Human Drugs

Guideline List
Biologics

Guide to Inspections

Warning Letters

Electronic Records and
Signatures

ISPE Technical Guides

PDA Technical Report

IPEC cGMP Guide

APIC Interpretation

Pharmacopoeias

USP

EP

**ICH cGMP Guide
(ICH Q7)**

EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines

Part I - Basic Requirements for Medicinal Products

- Chapter 1 Pharmaceutical Quality System (65 KB)into (into operation since 31 January 2013)
- Chapter 2 Personnel
  - Current (20 KB)
  - Deadline for coming into operation: 16 February 2014 (56 KB)*NEW*
- Chapter 3 Premise and Equipment (34 KB)
  - A revised version of Chapter 3 is in preparation. The public consultation on the proposed draft (53 KB)is currently closed.
- Chapter 4 Documentation (January 2011) (33 KB)
- Chapter 5 Production (50 KB)
  - A revised version of Chapter 5 is in preparation. The public consultation on the proposed draft (84 KB)is currently closed.
- Chapter 6 Quality Control (33 KB)
  - A revised version of Chapter 6 is in preparation. The public consultation on the proposed draft (62 KB)is currently closed.
- Chapter 7 on Outsourced activities (21 KB) (into operation since 31 January 2013)
  Chapter 7 Contract Manufacture and Analysis (22 KB)
- Chapter 8 Complaints and Product Recall (18 KB)
  - A revised version of Chapter 8 is in preparation. The public consultation on the proposed draft (79 KB)is currently closed
- Chapter 9 Self Inspection (11 KB)

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Part II - Basic Requirements for Active Substances used as Starting Materials

- Basic requirements for active substances used as starting materials (August 2014)

Part III - GMP related documents

- Site Master File
- Q9 Quality Risk Management
- Q10 Note for Guidance on Pharmaceutical Quality System
- MRA Batch Certificate
- Template for the "written confirmation" for active substances exported to the European Union for medicinal products for human use (Version 2, January 2013)
- Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities
- Guidelines of 19 March 2015 on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use (all language versions are available here). A risk assessment as set out in these guidelines should be carried out for excipients for authorised medicinal products for human use by 21 March 2016.
- Template for IMP batch release (applicable as from the date of entry into application of Regulation (EU) No 536/2014 on Clinical Trials)

Annexes

Table Eudralex	
Annex 1	Manufacture of Sterile Medicinal Products (122 KB)
Annex 2	Manufacture of Biological active substances and Medicinal Products for Human Use (171 KB) ((into operation since 31 January 2013)
Annex 3	Manufacture of Radiopharmaceuticals (68 KB)
Annex 4	Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal Products (14 KB)
Annex 5	Manufacture of Immunological Veterinary Medicinal Products (43 KB)
Annex 6	Manufacture of Medicinal Gases (48 KB)
Annex 7	Manufacture of Herbal Medicinal Products (23 KB)
Annex 8	Sampling of Starting and Packaging Materials (20 KB)

Annex 9	Manufacture of Liquids, Creams and Ointments (13 KB)
Annex 10	Manufacture of Pressurised Metered Dose Aerosol Preparations for Inhalation (17 KB)
Annex 11	Computerised Systems (revision January 2011) (22 KB)
Annex 12	Use of Ionising Radiation in the Manufacture of Medicinal Products (50 KB)
Annex 13	Manufacture of Investigational Medicinal Products (67 KB)
Annex 14	Manufacture of Products derived from Human Blood or Human Plasma (50 KB) - May 2011
Annex 15	Qualification and validation (136 KB)

Annex 16	Certification by a Qualified person and Batch Release (41 KB) A revised version of Annex 16 is in preparation. Stakeholders are invited to comment on this draft (150 KB) by 5 November 2013 at the latest. Comments should be sent by email to: ADM-GMDP@ema.europa.eu and SANCO-pharmaceuticals-D6@ec.europa.eu
Annex 17	Parametric Release (124 KB)
Annex 19	Reference and Retention Samples (24 KB)

Glossary

- Glossary (27 KB)

EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines

Part IV - GMP requirements for Advanced Therapy Medicinal Products

- Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products

Other documents related to GMP

- Compilation of Community Procedures on Inspections and Exchange of Information updated to include new EU formats and procedures
- A revised version of the "Guidelines on Good Distribution Practice of Medicinal Products for Human Use" was published in the Official Journal and is applicable as of 24 November 2013 (OJ C 343/1, 23.11.2013).
- Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (all language versions are available here). These guidelines will come into operation on 21 September 2015.

References

- Good Manufacturing Practices for Pharmaceuticals, Sidney H. Willing, Marcel Dekker, 2001.
- Pharmaceutical Pre-Approval Inspections, guide to regulatory Success, 2 nd. Ed, Martin, D. Hyness, 2008.
- Quality Guidelines
- ICH Gudilines for Efficacy, safety and quality
- http://www.picscheme.org
- https://ec.europa.eu/health/documents/eudralex/vol-4_de