EU Good Manufacturing Practice Guidelines

2023
Book 4C

# Good Manufacturing Practice in the European Union

## 2023 Reference Guide

- **The Rules Governing Medicinal Products in the EU Volume 4: Good Manufacturing Practice Guidelines**

**Part I - Basic Requirements for Medicinal Products**

- Chapter 1: Pharmaceutical Quality System
- Chapter 2: Personnel
- Chapter 3: Premises and Equipment
- Chapter 4: Documentation
- Chapter 5: Production
- Chapter 6: Quality Control
- Chapter 7: Outsourced Activities
- Chapter 8: Complaints and Product Recall
- Chapter 9: Self Inspection

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

**Part III - GMP Related Documents**

- Explanatory Notes on Site Master File
- ICH Q9 Quality Risk Management
- ICH Q10 Note for Guidance on Pharmaceutical Quality System
- MRA Batch Certificate
- Template for the 'Written Confirmation' for Active Substances Exported to the European Union
- Guideline On Setting Health Based Exposure Limits ror use in Risk Identification in the Manufacture of Different Medicinal Products in Shared Facilities
- Guidelines on the Formalised Risk Assessment for Ascertaining the Appropriate Good Manufacturing Practice for Excipients of Medicinal Products for Human Use

**Selected Annexes**

- Annex 1: Manufacture of Sterile Medicinal Products
- Annex 2: Manufacture of Biological Active Substances and Medicinal Products for Human Use
- Annex 11: Computerised Systems
- Annex 13: Manufacture of Investigational Medicinal Products
- Annex 14: Manufacture of Medicinal Products Derived from Human Blood or Plasma

- **Commission Directive 2003/94/EC on GMP**
- **Commission Delegated Regulation (EU) No. 1252/2014 with Regard to Principles and Guidelines of GMP**