

Chapters of the relevant GMP guidelines in the USA, Europe, India and China

USA: 21 CFR Part 211

- A. General Provisions
- B. Organization and Personnel
- C. Buildings and Facilities
- D. Equipment
- E. Control of Components and Drug Product Containers and Closures
- F. Production and Process Controls
- G. Packaging and Labelling Control
- H. Holding and Distribution
- I. Laboratory Controls
- J. Records and Reports
- K. Returned and Salvaged Drug Products

ICH Q7

1. Introduction
2. Quality Management
3. Personnel
4. Buildings & Facilities
5. Process Equipment
6. Documentation and Records
7. Materials Management
8. Production and In-Process Controls
9. Packaging and Identification Labelling of APIs and Intermediates
10. Storage and Distribution
11. Laboratory Controls
12. Validation
13. Change Control
14. Rejection and Reuse of Material
15. Complaints and Recalls
16. Contract Manufacturers (Including Laboratories)
17. Agents, Brokers, Traders, Distributors, Repackers, and Relabellers
18. Specific Guidances for APIs Manufactured by Cell Cultures/Fermentation
19. APIs for Use in Clinical Trials

Europe: EU GMP Guideline Part I

1. Quality Management
2. Personnel
3. Premise and Equipment
4. Documentation
5. Production
6. Quality control
7. Contract Manufacture and Analysis
8. Complaints and Product Recall
9. Self Inspection

EU GMP Guideline Part II

1. Introduction
2. Quality Management
3. Personnel
4. Buildings & Facilities
5. Process Equipment
6. Documentation and Records
7. Materials Management
8. Production and In-Process Controls
9. Packaging and Identification Labelling of APIs and Intermediates
10. Storage and Distribution
11. Laboratory Controls
12. Validation
13. Change Control
14. Rejection and Reuse of Material
15. Complaints and Recalls
16. Contract Manufacturers (Including Laboratories)
17. Agents, Brokers, Traders, Distributors, Repackers, and Relabellers
18. Specific Guidances for APIs Manufactured by Cell Cultures/Fermentation
19. APIs for Use in Clinical Trials

India: Drugs & Cosmetics Act, Schedule M

1. General Requirements
2. Warehousing Area
3. Production Area
4. Ancillary Areas
5. Quality Control Area
6. Personnel
7. Health, Clothing and Sanitation of Workers
8. Manufacturing Operations and Controls
9. Sanitation in the Manufacturing Premises
10. Raw Materials
11. Equipment
12. Documentation and Records
13. Labels and other Printed Materials
14. Quality Assurance
15. Self Inspection and Quality Audit
16. Quality Control System
17. Specification
18. Master Formula Records
19. Packing Records
20. Batch Packaging Records
21. Batch Processing Records
22. Standard Operating Procedures (SOPs) and Records
23. Reference Samples
24. Reprocessing and Recoveries
25. Distribution Records
26. Validation and Process Validation
27. Product Recalls
28. Complaints and Adverse Reactions
29. Site Master File

Appendices

- 1-A Sterile Products
- 1-B Oral Solid Dosage Forms
- 1-C Oral Liquids
- 1-D Topical Products
- 1-E Metered-Dose-Inhalers
- 1-F Active Pharmaceutical Ingredients (Bulk Drugs)

China: SFDA GMP (1998 revised edition)

1. 总则
(General Provisions)
2. 机构与人员
(Organisation and Personnel)
3. 厂房与设施
(Buildings and Facilities)
4. 设备
(Equipment)
5. 物料
(Materials)
6. 卫生
(Hygiene and Sanitation)
7. 验证
(Validation)
8. 文件
(Documentation)
9. 生产管理
(Production Management)
10. 质量管理
(Quality Management)
11. 产品销售与收回
(Product Distribution and Recall)
12. 投诉与不良反应报告 (Complaints and Adverse Reactions Reports)
13. 自检
(Self-Inspection)
14. 附则
(Annex)

Appendices

1. 总则
(General Provisions)
2. 无菌药品
(Sterile Pharmaceuticals)
3. 非无菌药品
(Non-sterile Pharmaceuticals)
4. 原料药
(API)
5. 生物制品
(Biological Products)
6. 放射性药品
(Radiopharmaceuticals)
7. 中药制剂
(Traditional Chinese Medicine)

China: SFDA GMP (2010 revised edition)

1. 总则
(General Provisions)
2. 质量管理
(Quality Management)
3. 机构与人员
(Organisation and Personnel)
4. 厂房与设施
(Buildings and Facilities)
5. 设备
(Equipment)
6. 物料与产品
(Materials and Products)
7. 确认与验证
(Validation and Qualification)
8. 文件管理
(Document Management)
9. 生产管理
(Production Management)
10. 质量控制与质量保证
(Quality Control and Quality Assurance)
11. 委托生产与委托检验
(Contractual Production and Inspection)
12. 产品发运与召回
(Product Shipment and Recall)
13. 自检
(Self-Inspection)
14. 附则
(Annex)

Appendices

1. 无菌药品
(Sterile Pharmaceuticals)
2. 原料药
(API)
3. 生物制品
(Biological Products)
4. 血液制品
(Blood products)
5. 中药制剂
(Traditional Chinese Medicine)