# Comprehensive Compliance Checklist for a Pharmaceutical Company

## Quality Management System (QMS)

1. Documented Quality Policy and Objectives ☐ Yes ☐ No
2. Implementation of a robust Quality Manual aligned with regulatory requirements ☐ Yes ☐ No
3. Defined roles and responsibilities for quality oversight ☐ Yes ☐ No
4. Periodic Management Reviews of the QMS ☐ Yes ☐ No
5. Change Control procedures in place and effectively managed ☐ Yes ☐ No

## Good Manufacturing Practices (GMP)

6. Compliance with FDA 21 CFR Parts 210 & 211 / EU GMP guidelines ☐ Yes ☐ No
7. Controlled manufacturing environment with proper cleanliness standards ☐ Yes ☐ No
8. Equipment qualification (IQ/OQ/PQ) and maintenance records ☐ Yes ☐ No
9. Batch records and Master Manufacturing Records (MMRs) documented and reviewed ☐ Yes ☐ No
10. In-process and final product testing protocols ☐ Yes ☐ No

## Good Laboratory Practices (GLP)

11. Compliance with FDA 21 CFR Part 58 / OECD GLP Guidelines ☐ Yes ☐ No
12. Calibration and maintenance of laboratory equipment ☐ Yes ☐ No
13. Data integrity practices (ALCOA principles) ☐ Yes ☐ No
14. Proper storage and retention of laboratory records and samples ☐ Yes ☐ No
15. Qualification of laboratory methods and instruments ☐ Yes ☐ No

## Good Clinical Practices (GCP)

16. Compliance with ICH E6 (R2) and FDA regulations ☐ Yes ☐ No
17. Clinical trial protocols approved by Institutional Review Boards (IRBs) ☐ Yes ☐ No
18. Informed consent documentation process ☐ Yes ☐ No
19. Investigator site qualification and monitoring ☐ Yes ☐ No

20. Accurate and complete Clinical Trial Master File (TMF) management ☐ Yes ☐ No

## Good Distribution Practices (GDP)

21. Compliance with WHO and EU GDP guidelines ☐ Yes ☐ No
22. Controlled storage and transport conditions for products ☐ Yes ☐ No
23. Supplier and distributor qualification programs ☐ Yes ☐ No
24. Traceability and recall procedures ☐ Yes ☐ No
25. Secure supply chain management and risk assessments ☐ Yes ☐ No

## Vendor and Supplier Management

26. Qualification and approval of all vendors and suppliers ☐ Yes ☐ No
27. Periodic audits of Contract Manufacturing Organizations (CMOs) and Contract Research Organizations (CROs) ☐ Yes ☐ No
28. Quality Agreements in place with all third parties ☐ Yes ☐ No
29. Performance monitoring and risk-based evaluations ☐ Yes ☐ No

## Data Integrity and Electronic Systems Compliance

30. Compliance with FDA 21 CFR Part 11 and EU Annex 11 ☐ Yes ☐ No
31. Controlled access to electronic systems (user roles and permissions) ☐ Yes ☐ No
32. Audit trails enabled and regularly reviewed ☐ Yes ☐ No
33. Backup and disaster recovery systems implemented ☐ Yes ☐ No

## Training and Competency

34. Documented training programs for all employees ☐ Yes ☐ No
35. Job-specific training and competency assessments ☐ Yes ☐ No
36. Regular GMP, GDP, GCP, and GLP refresher training ☐ Yes ☐ No
37. Training records maintained and accessible ☐ Yes ☐ No

## Internal and External Audits

38. Annual internal audit program covering all GxP areas ☐ Yes ☐ No
39. Risk-based audit scheduling and execution ☐ Yes ☐ No
40. Corrective and Preventive Actions (CAPA) management post-audit ☐ Yes ☐ No
41. Vendor and supplier audit program established ☐ Yes ☐ No

## Risk Management and Continuous Improvement

42. Implementation of ICH Q9 Quality Risk Management principles ☐ Yes ☐ No
43. Risk assessments conducted for critical processes and systems ☐ Yes ☐ No
44. Ongoing improvement initiatives for quality and compliance processes ☐ Yes ☐ No
45. CAPA effectiveness checks ☐ Yes ☐ No

## Regulatory Compliance and Inspections

46. Preparedness for FDA, EMA, MHRA, and other regulatory body inspections ☐ Yes ☐ No
47. Response procedures for regulatory findings and Form 483 observations ☐ Yes ☐ No
48. Timely submission of regulatory reports (e.g., Annual Product Reviews, stability reports) ☐ Yes ☐ No
49. Maintenance of regulatory licenses and product registrations ☐ Yes ☐ No

## Environmental, Health, and Safety (EHS)

50. Compliance with OSHA, EPA, and local environmental regulations ☐ Yes ☐ No
51. Hazardous material handling procedures in place ☐ Yes ☐ No
52. Regular EHS training for employees ☐ Yes ☐ No
53. Emergency preparedness and response plans ☐ Yes ☐ No

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