Comprehensive Compliance Checklist for a Biotechnology Company

Quality Management System (QMS)

1. Documented Quality Policy and Objectives aligned with biotech industry standards ☐ Yes ☐ No
2. Defined roles and responsibilities for quality oversight across R&D and manufacturing ☐ Yes ☐ No
3. Periodic Management Reviews of the QMS with data-driven decisions ☐ Yes ☐ No
4. Change Control procedures in place and effectively managed for biotech processes ☐ Yes ☐ No

Good Manufacturing Practices (GMP)

5. Compliance with FDA 21 CFR Parts 210 & 211 / EU GMP guidelines ☐ Yes ☐ No
6. Process validation for complex biologics manufacturing (e.g., cell and gene therapies) ☐ Yes ☐ No
7. Facility and equipment qualification for aseptic processing and containment ☐ Yes ☐ No
8. Batch records and Master Manufacturing Records (MMRs) documented and reviewed ☐ Yes ☐ No
9. Robust environmental monitoring programs for biotech production areas ☐ Yes ☐ No

Good Laboratory Practices (GLP)

10. Compliance with FDA 21 CFR Part 58 / OECD GLP Guidelines ☐ Yes ☐ No
11. Validated bioanalytical methods for product characterization ☐ Yes ☐ No
12. Data integrity and traceability throughout preclinical studies ☐ Yes ☐ No
13. Proper storage and retention of biological samples and research data ☐ Yes ☐ No
14. Qualification and calibration of laboratory instruments ☐ Yes ☐ No

Good Clinical Practices (GCP)

15. Compliance with ICH E6 (R2) and FDA regulations for clinical trials ☐ Yes ☐ No

16. Robust Clinical Development Plans (CDP) for biologics and advanced therapies ☐ Yes ☐ No
17. Proper handling and storage of investigational medicinal products (IMPs) ☐ Yes ☐ No
18. Comprehensive Clinical Trial Master File (TMF) management ☐ Yes ☐ No
19. Patient safety monitoring and adverse event reporting ☐ Yes ☐ No

Good Distribution Practices (GDP)

20. Compliance with WHO and EU GDP guidelines for biologics distribution ☐ Yes ☐ No
21. Cold chain logistics management for temperature-sensitive products ☐ Yes ☐ No
22. Supplier and distributor qualification programs ☐ Yes ☐ No
23. Traceability and recall procedures for biological materials ☐ Yes ☐ No
24. Secure supply chain management for cell and gene therapies ☐ Yes ☐ No

Vendor and Supplier Management

25. Qualification of Contract Manufacturing Organizations (CMOs) and Contract Research Organizations (CROs) ☐ Yes ☐ No
26. Quality Agreements tailored to biotech-specific processes ☐ Yes ☐ No
27. Vendor risk assessments and performance monitoring ☐ Yes ☐ No
28. Periodic audits of material suppliers and critical service providers ☐ Yes ☐ No

Data Integrity and Electronic Systems Compliance

29. Compliance with FDA 21 CFR Part 11 and EU Annex 11 for electronic records ☐ Yes ☐ No
30. Data integrity practices (ALCOA+) across R&D, clinical, and manufacturing data ☐ Yes ☐ No
31. Validated electronic systems for batch release and quality management ☐ Yes ☐ No
32. Audit trails enabled and regularly reviewed for critical systems ☐ Yes ☐ No

Training and Competency

33. Specialized training programs for biotech manufacturing and research staff ☐ Yes ☐ No
34. Competency assessments for handling biological materials and aseptic techniques ☐ Yes ☐ No
35. Regular refresher training on GMP, GLP, GCP, and data integrity ☐ Yes ☐ No
36. Training records maintained and accessible for regulatory review ☐ Yes ☐ No

Internal and External Audits

37. Annual internal audit program covering all GxP and R&D activities ☐ Yes ☐ No
38. Risk-based audit scheduling and execution ☐ Yes ☐ No
39. Corrective and Preventive Actions (CAPA) management post-audit ☐ Yes ☐ No
40. Vendor and supplier audit program tailored to biotech operations ☐ Yes ☐ No

Risk Management and Continuous Improvement

41. Implementation of ICH Q9 Quality Risk Management principles ☐ Yes ☐ No
42. Risk assessments for cell therapy, gene therapy, and biologics manufacturing ☐ Yes ☐ No
43. Continuous improvement initiatives for product quality and patient safety ☐ Yes ☐ No
44. CAPA effectiveness checks and trending analysis ☐ Yes ☐ No

Regulatory Compliance and Inspections

45. Preparedness for FDA, EMA, MHRA, and other regulatory body inspections ☐ Yes ☐ No
46. Management of Investigational New Drug (IND) and Biologics License Application (BLA) submissions ☐ Yes ☐ No
47. Response procedures for regulatory findings and Form 483 observations ☐ Yes ☐ No
48. Maintenance of regulatory licenses and biotech product registrations ☐ Yes ☐ No

Environmental, Health, and Safety (EHS)

49. Compliance with OSHA, EPA, and local biosafety regulations ☐ Yes ☐ No
50. Biosafety level (BSL) classification and compliance for lab operations ☐ Yes ☐ No
51. Proper handling and disposal of biohazardous materials ☐ Yes ☐ No
52. Regular EHS and biosafety training for all staff ☐ Yes ☐ No

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Need help improving your compliance strategy? **Let's connect!**