Comprehensive Compliance Checklist for a Medical Devices Company

Quality Management System (QMS)

1. Compliance with ISO 13485:2016 requirements ☐ Yes ☐ No
2. Documented Quality Policy and Objectives ☐ Yes ☐ No
3. Implementation of Design and Development Controls ☐ Yes ☐ No
4. Management Review of QMS performance ☐ Yes ☐ No
5. Effective Change Control management process ☐ Yes ☐ No

Good Manufacturing Practices (GMP)

6. Compliance with FDA 21 CFR Part 820 (Quality System Regulation) ☐ Yes ☐ No
7. Process validation for critical manufacturing steps ☐ Yes ☐ No
8. Equipment calibration and maintenance procedures ☐ Yes ☐ No
9. Documented Device History Records (DHR) and Device Master Records (DMR) ☐ Yes ☐ No
10. Control of non-conforming products ☐ Yes ☐ No

Risk Management

11. Implementation of ISO 14971:2019 Risk Management for Medical Devices ☐ Yes ☐ No
12. Conducting risk assessments throughout product lifecycle ☐ Yes ☐ No
13. Risk mitigation strategies documented and implemented ☐ Yes ☐ No
14. Post-market risk evaluation procedures ☐ Yes ☐ No

Design and Development Controls

15. Documented design inputs and outputs ☐ Yes ☐ No
16. Design Verification and Validation (V&V) procedures ☐ Yes ☐ No
17. Design Transfer process for manufacturing ☐ Yes ☐ No
18. Change management during design updates ☐ Yes ☐ No

Supplier and Vendor Management

19. Supplier qualification and approval process ☐ Yes ☐ No

20. Quality Agreements with critical suppliers ☐ Yes ☐ No
21. Ongoing supplier performance monitoring ☐ Yes ☐ No
22. Periodic audits of key suppliers ☐ Yes ☐ No

Production and Process Controls

23. Process validation and revalidation protocols ☐ Yes ☐ No
24. Documented work instructions and procedures ☐ Yes ☐ No
25. Production process monitoring and control ☐ Yes ☐ No
26. Traceability of product components and assemblies ☐ Yes ☐ No

Corrective and Preventive Actions (CAPA)

27. Documented CAPA procedures ☐ Yes ☐ No
28. Root cause analysis for non-conformances ☐ Yes ☐ No
29. Timely implementation of corrective actions ☐ Yes ☐ No
30. Effectiveness checks for CAPA closure ☐ Yes ☐ No

Complaint Handling and Reporting

31. Documented complaint handling procedures ☐ Yes ☐ No
32. Timely investigation and resolution of complaints ☐ Yes ☐ No
33. Medical Device Reporting (MDR) compliance ☐ Yes ☐ No
34. Trend analysis of complaints and adverse events ☐ Yes ☐ No

Post-Market Surveillance (PMS)

35. Implementation of a Post-Market Surveillance plan ☐ Yes ☐ No
36. Data collection and analysis from product performance ☐ Yes ☐ No
37. Corrective actions based on PMS findings ☐ Yes ☐ No
38. Periodic Safety Update Reports (PSURs) where applicable ☐ Yes ☐ No

Regulatory Compliance

39. Compliance with FDA, EU MDR, and other applicable regulations ☐ Yes ☐ No
40. Timely product registration and market authorization ☐ Yes ☐ No
41. Labeling and Unique Device Identification (UDI) compliance ☐ Yes ☐ No
42. Regulatory submissions for product changes ☐ Yes ☐ No

Training and Competency

43. Documented training programs for employees ☐ Yes ☐ No
44. Competency assessments for job-specific roles ☐ Yes ☐ No
45. Regular training on GMP, QSR, and ISO standards ☐ Yes ☐ No
46. Training records are maintained and accessible ☐ Yes ☐ No

Internal and External Audits

47. Annual internal audit program covering all QMS areas ☐ Yes ☐ No
48. Risk-based audit planning and execution ☐ Yes ☐ No
49. CAPA management for audit findings ☐ Yes ☐ No
50. Supplier audit program established ☐ Yes ☐ No

Environmental, Health, and Safety (EHS)

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

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