



## **Comprehensive Compliance Checklist for a Radiopharmaceutical Company**

### **Quality Management System (QMS)**

1. Documented Quality Policy and Objectives ☐ Yes ☐ No
2. Implementation of a robust Quality Manual aligned with radiopharmaceutical regulatory requirements ☐ Yes ☐ No
3. Defined roles and responsibilities for radiation safety and 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) for Radiopharmaceuticals**

6. Compliance with FDA 21 CFR Parts 210 & 211 / EU GMP guidelines specific to radiopharmaceuticals ☐ Yes ☐ No
7. Controlled manufacturing environment with radiation protection measures ☐ Yes ☐ No
8. Qualification and maintenance of hot cells, isolators, and shielded equipment ☐ Yes ☐ No
9. Batch records and Master Manufacturing Records (MMRs) documented and reviewed ☐ Yes ☐ No
10. In-process and final product testing protocols for radioactive materials ☐ Yes ☐ No

### **Radiation Safety and Compliance**

11. Compliance with NRC and state-specific radiation safety regulations ☐ Yes ☐ No
12. Radiation protection program implementation (ALARA principles) ☐ Yes ☐ No
13. Proper handling, storage, and disposal of radioactive materials ☐ Yes ☐ No
14. Dosimetry monitoring and employee safety measures ☐ Yes ☐ No
15. Regular radiation safety audits and inspections ☐ Yes ☐ No



### **Good Laboratory Practices (GLP)**

- 16. Calibration and maintenance of radiochemical analysis equipment ☐ Yes ☐ No
- 17. Data integrity practices (ALCOA principles) for radioactive testing ☐ Yes ☐ No
- 18. Proper storage and retention of laboratory records and radioactive samples ☐ Yes ☐ No
- 19. Qualification of analytical methods for radiochemical purity and sterility ☐ Yes ☐ No

### **Good Distribution Practices (GDP) for Radiopharmaceuticals**

- 20. Compliance with WHO and EU GDP guidelines specific to radioactive products ☐ Yes ☐ No
- 21. Controlled transport of radiopharmaceuticals with time and temperature monitoring ☐ Yes ☐ No
- 22. Qualified suppliers and distributors for radiopharmaceutical logistics ☐ Yes ☐ No
- 23. Traceability and recall procedures for radioactive products ☐ Yes ☐ No

### **Vendor and Supplier Management**

- 24. Qualification and approval of vendors for radioactive components and services ☐ Yes ☐ No
- 25. Periodic audits of Contract Manufacturing Organizations (CMOs) and logistics partners ☐ Yes ☐ No
- 26. Quality Agreements in place with nuclear reactor suppliers and isotope producers ☐ Yes ☐ No

### **Training and Competency**

- 27. Radiation safety training programs for all employees handling radioactive materials ☐ Yes ☐ No
- 28. Job-specific GMP, GDP, and radiation safety competency assessments ☐ Yes ☐ No
- 29. Regular refresher training on handling radiopharmaceuticals ☐ Yes ☐ No

### **Internal and External Audits**

- 30. Annual internal audit program covering GMP, GDP, and radiation safety ☐ Yes ☐ No



31. Risk-based audit scheduling and execution for radiopharmaceutical operations

☐ Yes ☐ No

32. Corrective and Preventive Actions (CAPA) management post-audit ☐ Yes ☐

No

### **Risk Management and Continuous Improvement**

33. Implementation of ICH Q9 Quality Risk Management principles for radioactive materials ☐ Yes ☐ No

34. Risk assessments for radiation exposure and product contamination ☐ Yes ☐  
No

35. Ongoing improvement initiatives for radiation safety and quality compliance ☐  
Yes ☐ No

### **Regulatory Compliance and Inspections**

36. Preparedness for FDA, NRC, EMA, and other regulatory body inspections ☐  
Yes ☐ No

37. Response procedures for regulatory findings and Form 483 observations ☐ Yes  
☐ No

38. Timely submission of regulatory reports for radioactive products ☐ Yes ☐ No

39. Maintenance of regulatory licenses for radioactive materials ☐ Yes ☐ No

### **Environmental, Health, and Safety (EHS)**

40. Compliance with OSHA, EPA, NRC, and local environmental safety regulations  
☐ Yes ☐ No

41. Hazardous material handling and radiation waste disposal procedures ☐ Yes  
☐ No

42. Emergency preparedness for radiological incidents ☐ Yes ☐ No

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