MD12-03 QUALITY AUDIT QUESTIONNAIRE

INSTRUCTIONS:

ONLY PERSONNEL AUTHORSED TO GIVE THE INFORMATION ABOUT THE COMPANY QMS SHOULD COMPLETE THIS QUESTIONNAIRE (RP, QP, QAM).

FILL IN ALL POSITIONS FOR THE QUESTIONNAIRE TO BE ASSESSED:

GENERAL		
1. Company Name		
2. Warehouse Address		
3. Office Address if different from the above		
4. Type of activities performed at your premises:		
• Manufacturing	Yes ☐ No ☐	
• Wholesale	Yes ☐ No ☐	
• Re-packaging	Yes ☐ No ☐	
• Distribution	Yes ☐ No ☐	
5. WDA (H) Number		
6. Date Granted		
7. Expiry		
8. Company registered on EudraGMDP website	Yes ☐ No ☐	
9. Year business started		
10. Inspection Authority		
11. Does your company manufacture any of the medicinal products supplied?	Yes ☐ No ☐	
12. Number of employees		
QUALITY SYSTEM		
13. Current Quality management System held:		
• ISO 9000	Yes ☐ No ☐	
• Other	Yes ☐ No ☐	
14. Date of Last Inspection		
15. Regulatory Body		
16. Type of Medicinal Products handled at your premises		
• Human medicines	Yes ☐ No ☐	
• Veterinary medicines	Yes ☐ No ☐	
• Medical Devices	Yes ☐ No ☐	
• Controlled Drugs	Yes ☐ No ☐	
17. Medicines that have special documentation requirements	Yes ☐ No ☐	
18. Do you have a procedure for all key tasks?	Yes ☐ No ☐	

PERSONNEL:	
19. Has the role and responsibilities of employees working in key positions been set out in their job descriptions?	Yes ☐ No ☐
20. Name of the Responsible Person (RP)	
21. Do you have a training programme?	Yes ☐ No ☐
22. Will all the new employees receive appropriate training before they start their job?	Yes ☐ No ☐
23. Do all the employees receive instructions on a regular basis?	Yes ☐ No ☐
24. Do you have a procedure for Hygiene?	Yes ☐ No ☐

PREMISES AND EQUIPMENT	
25. Do you have a written procedure for Cleaning?	Yes ☐ No ☐
26. Are the premises regularly cleaned as per the procedure?	Yes ☐ No ☐
27. Does the company have a cold storage facility available?	Yes ☐ No ☐
28. Does the company have a controlled drug storage facility?	Yes ☐ No ☐
29. Is the temperature in the warehouse including the cold storage facility regularly monitored and controlled?	Yes ☐ No ☐
30. Is the humidity in the warehouse including the cold storage facility regularly monitored and controlled?	Yes ☐ No ☐
31. Is there any security system in place to prevent unauthorised entries to the restricted area?	Yes ☐ No ☐
32. Do you have any back-up facility in the event of a power failure?	Yes ☐ No ☐

SOURCING OF MEDICINAL PRODUCTS	
33. From whom do you regularly purchase your medicines?	
• Direct from Manufacturer	Yes ☐ No ☐
• Licensed Wholesalers	Yes ☐ No ☐
• Authorised Distributors	Yes ☐ No ☐
• Brokers	Yes ☐ No ☐
34. Do you ensure that all medicines purchase are obtained from legitimate suppliers?	Yes ☐ No ☐
35. Do you have a procedure for suppliers' management?	Yes ☐ No ☐
36. Is an approved suppliers list maintained?	Yes ☐ No ☐
37. Is an approved customers list maintained?	Yes ☐ No ☐
38. Is there a system in place to ensure that the correct goods are supplied and their identification is not lost?	Yes ☐ No ☐

RECEIPT, HANDLING AND STORAGE	
39. Is there a system in place for checking all incoming goods?	Yes ☐ No ☐
40. Are all incoming goods checked for:	
• Suspected Falsified Medicines	Yes ☐ No ☐
• Tampering:	Yes ☐ No ☐
• Damage:	Yes ☐ No ☐
• Transport Temperature:	Yes ☐ No ☐
41. Do you have a batch numbering system in place?	Yes ☐ No ☐
42. Do you have a system in place to ensure that no expired medicinal products are shipped out?	Yes ☐ No ☐
43. Is there sufficient protection against pests?	Yes ☐ No ☐

44. Do you have a segregated area (Quarantine) for suspected falsified medicines and returned goods?	Yes ☐ No ☐

DOCUMENTATION AND INVENTORY MANAGEMENT	
45. Is your stock control system paper based or computerised?	
• Paper based	Yes ☐ No ☐
• Computerised	Yes ☐ No ☐
• Hybrid	Yes ☐ No ☐
46. Do you have a computerised system for Quality documents?	Yes ☐ No ☐
47. Have your computer systems been validated?	Yes ☐ No ☐
48. Do the computer systems have individual passwords and restricted access for all personnel?	Yes ☐ No ☐
49. Does your company have written procedures for all key tasks?	Yes ☐ No ☐

SELF-INSPECTIONS	
50. Do you have an internal audit programme?	Yes ☐ No ☐
51. Are internal audits performed as per your programme?	Yes ☐ No ☐
52. Is there a written procedure for disaster recovery?	Yes ☐ No ☐

COMPLAINTS AND RE- CALLS	
53. Do you have a re-call procedure?	Yes ☐ No ☐
54. Is there a procedure for dealing with deviation during storage of medicinal products including cold chain?	Yes ☐ No ☐
55. Do you have a procedure in place to inform the competent authority in the event of suspected falsified medicines?	Yes ☐ No ☐

SUB-CONTRACTORS	
56. Do you have any sub-contractors?	Yes ☐ No ☐
57. Do you have a written agreement to comply with GDP requirements?	Yes ☐ No ☐
58. Have all your sub- contractors been audited?	Yes ☐ No ☐

DOCUMENTS ATTACHED	
59. Copy of WDA(H)	Yes ☐ No ☐
60. Authorised English translation of WDA(H)	Yes ☐ No ☐
61. Copy of ISO 9000 or equivalent document	Yes ☐ No ☐
62. Copy of last inspection report	Yes ☐ No ☐

SIGNED BY THE AUTHORISED PERSON ON BEHALF OF THE COMPANY	
Print Name:	
Position Held:	
Contact Number:	
E mail address:	
Signature:	
Date:	

SIGNED BY THE AUTHORISED PERSON ON BEHALF OF FINNO MEDICAL	
RP Name print	
All questions checked and reviewed?	Yes ☐ No ☐
Add to Approved Supplier List?	Yes ☐ No ☐
Date and Signature	