DUKE

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Supplier Questionnaire FRM1

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SUPPLIER QUESTIONNAIRE

The Quality Management System requires qualifying information and periodic monitoring of suppliers. Information provided by the supplier will be used to assess the level of compliance with relevant SOPs, regulations and cGMP.

Directions: *Please complete this questionnaire and provide attachments as indicated. Return via email to: ORAQ-MC3_Quality@duke.edu within 10 business days.*

Supplier Name:	Contact Name/Title:
Supplier Address:	Phone: Fax: Email: Web Address:
Product/Service Name/Number:	Description:

	Yes	No	N/A	Comments	"X" if document provided
Organization / Background					
1. Is your organization certified by regulatory or accrediting agencies to provide the services listed above? 1a. If yes, please submit copies of applicable licenses, certificates, etc. (FDA, ISO, CLIA)	☐	☐	☐		☐
2. Is the final product being supplied licensed or cleared by the FDA & approved for human use?	☐	☐	☐		
3. Does the organization have shelf life studies for the product(s) being supplied? 3a. If Yes, please provide report for review or contact name for additional follow up.	☐	☐	☐		☐
4. Has your organization undergone an FDA inspection?	☐	☐	☐		
4a. If yes, provide the date of the last inspection					
4b. Were any 483s issued? If yes, provide response	☐	☐	☐		☐
5. Does your organization have a Disaster/Business Continuity Plan?	☐	☐	☐		

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6. Will your organization allow a representative of our organization to audit your compliance with your responses to this questionnaire? 6a. Provide the name of the responsible person to contact for requesting an on-site quality audit.	☐	☐	☐		
Quality Management					
7. Does your organization have a Quality Management Plan? 7a. If yes, please submit a summary of the major components of your quality system. 7b. Who is responsible for quality management? 7c. Who is responsible for quality assurance?	☐	☐	☐		☐
8. Does your organization have a system for performing internal assessments, reviewing your quality system & does management review the results?	☐	☐	☐		
9. Does your organization have procedures for:					
9a. Change control; notifying customers of changes that may affect the products or services provided prior to implementation of such changes?	☐	☐	☐		
9b. Document management, record retention?	☐	☐	☐		
9c. Corrective/preventive action; supporting timely responses to customers?	☐	☐	☐		
10. Does management sufficiently support ongoing employee development/training & is this documented?	☐	☐	☐		
11. Are training records available for review in an on-site audit?	☐	☐	☐		
Building / Facilities					
12. Are procedures in place for ongoing maintenance & cleaning of the facility to ensure the work environment is satisfactorily maintained?	☐	☐	☐		
13. Does your organization have procedures for environmental monitoring?	☐	☐	☐		
Equipment					
14. Does your organization have a system for ensuring that required equipment preventive maintenance & calibration are performed, documented, & reviewed for all equipment used in critical processes?	☐	☐	☐		

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15. Are written procedures & documentation of equipment qualifications maintained? (IQ/OQ/PQ)	☐	☐	☐		
16. Are calibration & test standards traceable to NIST? 16a. If no, specify standard	☐	☐	☐		
17. When an instrument is found to be out of tolerance, is there a procedure to investigate the event & assess whether process or product was impacted?	☐	☐	☐		
Supply Management					
18. Does your organization have a system for the receipt & storage of supplies, reagents & equipment to assure proper function &/or expected performance?	☐	☐	☐		
19. Do you perform quality audits on suppliers?	☐	☐	☐		
20. Are COA maintained for raw materials?	☐	☐	☐		
21. Does your organization have a written quarantine procedure as well as dedicated areas for quarantined & released raw materials?	☐	☐	☐		
22. Is testing conducted on raw materials prior to use. If yes, is this performed in-house or contracted to another facility?	☐	☐	☐		
23. How long are retains kept for applicable raw materials?			☐		
24. Does your organization have a written procedure for suppliers/subcontractor approval associated with this product?	☐	☐	☐		
25. Are quality checks performed & documented on incoming products?	☐	☐	☐		
Shipping / Final Product Inspection					
26. Does your organization have written procedures for inspecting, testing, handling, packaging, labeling & documenting final product(s)?	☐	☐	☐		
27. Are there procedures in place to ensure materials, components & final product are stored in environmentally monitored areas?	☐	☐	☐		
28. Is there a documented procedure for shipment of supplies/reagents/equipment to assure proper functioning or expected performance upon arrival?	☐	☐	☐		
Customer Complaints / Recall					
29. Is customer satisfaction assessed periodically?	☐	☐	☐		

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30. Do you have a written procedure for documenting, evaluating, & responding to customer complaints in a timely manner?	☐	☐	☐		
31. Is the production history traceable?	☐	☐	☐		

This Supplier Questionnaire has been completed & reviewed by representatives of our organization & found to be an accurate representation of our current operations.

_____ _____

Signature (Responsible Individual) **Date** **Title**

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Internal Use Only	
Date Received:	Reviewed by:
Recommended risk grade: ☐Z ☐A ☐B ☐C ☐D ☐E	
Does recommended risk grade differ from Supplier Impact Assessment? ☐ Yes ☐ No If yes, please explain:	
Additional information required: ☐ N/A	
Supplier has the current ability to supply the required product/material ☐ Yes ☐ No	
Re-qualification and/or audit based on performance, history, organizational change(s), & documentation suggesting supplier/product quality issues. Recommended Method(s): ☐ Updated Supplier Questionnaire: ☐ Annual ☐ Biennial ☐ Audit: ☐ Desk ☐ On-site ☐ Biennial ☐ Quadrennial ☐ Review of Supplier Qualifications	
Quality Manager/Director Approval:	Date:

Signature Manifest

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All dates and times are in Eastern Time.

COMM-QA-002 FRM1 Supplier Questionnaire

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Quality

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Austin Rudisill (ADR35)		31 Jul 2023, 02:05:03 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)		08 Aug 2023, 06:25:50 PM	Approved