



# Site Quality Self-Assessment

based on

## Rx-360 Supplier Assessment Questionnaire Module 2, Site Specific Information

Relevant for

**SAFC Biosciences, Inc.**

**11296 Renner Blvd, Lenexa, KS 66219 USA**

**13804 W 107th St, Lenexa, KS 66215 USA**

**5 Dutch Court, Sinking Spring, PA 19608 USA**

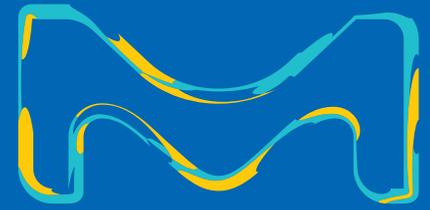
The site Self-assessment covers our quality management system for the following regulated applications:  
-Manufacturing of dry powdered cell culture media



As a trusted partner of our customers, we deliver quality  
- always.

Merck KGaA  
Corporation with General Partners  
Frankfurter Str. 250  
64293 Darmstadt, Germany

The life science business of Merck KGaA,  
Darmstadt, Germany operates as  
MilliporeSigma in the U.S. and Canada.



## Information

This document is based on the Rx-360 Consortium's Supplier Assessment Questionnaire template, Module 2. The contents of this questionnaire are built on the Rx-360 questionnaire version 2.0 intact with no question added or deleted.

Rx-360's CEO/COO gave permission to Life Science to use the Rx-360 logo.



Merck KGaA  
Corporation with General Partners  
Frankfurter Str. 250  
64293 Darmstadt, Germany

The life science business of Merck KGaA,  
Darmstadt, Germany operates as  
MilliporeSigma in the U.S. and Canada.

Please check here if additional documents are attached.

### SECTION 1. General Site Information

1.1	Site or Facility-Specific Name: MilliporeSigma
1.2	Address: 13804 W. 107th Street, Lenexa, KS 66215 USA 11296 Renner Boulevard, Lenexa, KS 66219 USA 5 Dutch Court, Sinking Spring, PA 19608 USA  GPS Coordinates: Latitude: 38.935775 Longitude: -94.745868 Latitude: 38.9240508 Longitude: -94.7796210 Latitude: 40.321583600 Longitude -76.051204200
1.3	Phone: Please contact your local Sales representative
1.4	Email: Please contact your local Sales representative
1.5	Fax: Please contact your local Sales representative
1.6	Website: <a href="http://www.sigmaaldrich.com">www.sigmaaldrich.com</a>

### SECTION 2. General Site Operating Information

2.1	What year did the site start operating? 1981: JRH Biosciences was established. Sigma-Aldrich acquired JRH in 2005. Merck KGaA Darmstadt, Germany acquired Sigma-Aldrich in 2015.
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) Primary activities include Procurement, Receiving, Manufacturing, Packaging Quality Control Testing and Distribution
2.3	To which, if any, subdivision of the parent company does the site belong? Merck KGaA Darmstadt, Germany parent - MilliporeSigma subsidiary of parent group
2.4	Size of site (in sq. ft. or m.): ~98,600 sq. ft. Rene Facility; ~35,000 sq. ft. Renner Facility; ~40,000 sq. ft. Sinking Springs Facility
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): 24 hours per day, 7 days per week

2.6	Total number of employees on site: 285
2.7	Total number of employees in Quality: 45
2.8	Total number of employees in Manufacturing: 156
2.9	<p>What quality management system is utilized on site?</p> <p><input checked="" type="checkbox"/> ISO 9001  <input type="checkbox"/> ISO 13485  <input type="checkbox"/> 21 CFR Part 210/211  <input type="checkbox"/> 21 CFR Part 820  <input type="checkbox"/> European GMP, Eudralex Volume 4 Part I  <input type="checkbox"/> European GMP, Eudralex Volume 4 Part II  <input type="checkbox"/> ICH Q7  <input type="checkbox"/> HACCP  <input type="checkbox"/> ISO 22000  <input checked="" type="checkbox"/> Other</p> <p>Please describe: EXCiPACT Pharmaceutical Auxiliary Materials</p> <p>Which Regulatory initiatives does the site follow/comply with?</p> <p><input type="checkbox"/> REACH  <input type="checkbox"/> RoHs  <input type="checkbox"/> Ca Prop. 65  <input type="checkbox"/> WEEE</p>
2.10	Does the company/site have an export license? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.11	<p>Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If yes, please specify.          USDA</p>
2.12	By whom is the site inspected (regulatory or third party) and list inspections within the last three years: USDA - February 2024, EXCiPACT - May 2024
2.13	How often, as an annual average, is the site audited by customers or third parties? 20-25
2.14	<p>Has an Rx-360 audit been performed at this site?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Please also state the date of the audit if applicable. April 2-3, 2024</p> <p><a href="#">Learn more about the Rx-360 Joint Audit Program® here.</a></p>
2.15	<p>Are you willing to have Rx-360 conduct an audit on behalf of your customers according to the Rx-360 audit programs on your site?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>
2.16	<p>Are you willing to have your customers conduct audits on your site?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>
2.17	Please list regulatory sanctions impacting the site within the last five years (i.e. warning letters, CEP suspension, import alerts, etc.): None

2.18	Does the site outsource any quality-related activity? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A  If answering yes, please specify the activities: Qualified, approved contract test facilities utilized for select Quality Control testing not able to be performed on site.
2.19	Please check the supplier controls in place for this facility:
2.19a	Quality Agreements with Suppliers <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19b	Subcontractor Qualification/Audit Program <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19c	Periodic Review of Supplier Performance <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19d	Supplier Feedback Program <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19e	Approved Material Supplier List <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19f	Approved Service Supplier List <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

**Additional comments:**

2.19a Quality Agreements or Change Notification Commitments are in place with suppliers where possible. Suppliers with neither a Quality Agreement nor Change Notification Commitment require formal risk assessment/risk mitigation prior to use.

**SECTION 3. Objectionable Materials On Site**

3.1	Does the site or production plant produce, process or store any of the following?	Yes	No	Not Applicable
3.1a	Beta-Lactam Antibiotics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1b	Steroids and/or hormones	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1c	High potency compounds	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1d	Materials of animal origin/Biologics	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1e	Live virus or micro-organism	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1f	Allergens	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1g	Genetically Modified Organisms (GMO)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3.1h	Agrochemicals (Pesticides, Herbicides, Fungicides, etc.)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1i	Other (Please specify): 3.1b: Specific recombinant hormones such as Insulin-like Growth Factor and Hydrocortisone are verified as animal component free prior to use in certain cell culture media formulations. 3.1e: We have a separate suite for QC testing utilizing live virus. This suite is under restricted access, is equipped with a negative pressure air lock and requires additional gowning as outlined in our procedures. 3.1g: Raw materials sourced from US-grown soy or corn are used in specific media formulations. There is no separation of GMO soy or corn from non-GMO materials. While MilliporeSigma raw materials are potentially derived from these GMOs, they do not contain any self-replicating organisms.			

**SECTION 4. Cross-Contamination Control**

4.1	Are any of the following cross-contamination controls in place?	Yes	No	Not Applicable
4.1a	Dedicated Facilities	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1b	Access Controls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1c	Dedicated Personnel	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1d	Dedicated Gowning	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1e	Procedural Controls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1f	Other (Please specify): N/A			

**Additional Comments:**

N/A

**SECTION 5. Site Operating Policies**

5.1 Does the site utilize the following written policies, programs or procedures?				
<b>Site Specific:</b>		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
5.1a	Environmental, Health and Safety	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1b	Facility Environmental Control Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1c	General Facility Cleaning Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1d	Hygiene and Sterilization Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1e	Validated Equipment Cleaning Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1f	Preventative Maintenance Program/Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1g	Pest Control Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1h	Master Production Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Quality:</b>				
5.1i	Quality Control/Quality Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1j	Quality Manual	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1k	Periodic Product Quality Review	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1l	Master Validation Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1m	Risk Assessment Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1n	Supplier Approval Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1o	Monitoring and Review of Approved Suppliers	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1p	Mechanism to Reduce Testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1q	Receiving Incoming Inspection	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1r	Change Control Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1s	Document Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1t	Document Retention Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1u	Change Notification Procedures for Clients	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1v	Control of Nonconforming Material	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1w	Deviation/Investigation Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1x	Out of Specification Policy and Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1y	Sampling Procedure/Sampling Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1z	Raw Material Retention Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1aa	CAPA Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1bb	Label Control and Accountability	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1cc	Product Release Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1dd	Employee Training Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ee	Stability, Expiration, and Shelf-Life Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ff	Product Retention Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1gg	Recall Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5.1hh	Customer Complaint Handling	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ii	Equipment validation/qualification procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1jj	Internal audit/self-inspection program procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1kk	Site Security/Site Access Control Policies	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ll	New Hire Program/Induction Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Business Continuity/Contingency Plan:</b>				
5.1mm	Disaster Recovery Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1nn	Pandemic Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1oo	Supply Chain Emergency Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1pp	Business Continuity/Contingency Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1qq	Can the company provide a plan upon request? OR provide a short description below:			

## SECTION 6. Quality Assurance and Production

		Yes	No	Not Applicable
6.1	Does the site have an independent and defined Quality Assurance/Quality Management Division?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2	Does QA/QM have authority over the following:			
6.2a	Policies and procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2b	Review of documentation for release?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2c	Release or rejection of incoming materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.3	Does QA/QM investigate and resolve quality complaints?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.4	Does QA/QM investigate and resolve internal deviations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.5	Does QA/QM have the authority to assign a disposition to materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.6	Does QA/QM review manufacturing and testing records prior to release?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.7	Does the facility utilize computerized systems for managing GxP activities and data?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.8	Are relevant computerized systems 21 CFR part 11 and EU GMP annex 11 compliant?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.9	Does the site use statistical methods for consistency and uniformity?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6.10	Does the site use controlled documents for following and recording manufacturing instructions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.11	Does the company qualify and/or validate manufacturing procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.12	Is any environmental monitoring conducted in production/finishing areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.13	Does the site supply BSE/TSE declarations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.14	Does the site supply a declaration of Elemental Impurities?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.15	Are ICH Q3C solvents used in the manufacturing process of supplied materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.15a	If Yes, what class of solvent is used?			
6.16	Are stability studies carried out according to ICH guidance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.17	Are solvents and mother liquor reused/recycled?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.18	Does the site have a process water treatment system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.18a	Please check all that apply to the system: <input checked="" type="checkbox"/> City/potable water <input type="checkbox"/> Distilled water <input checked="" type="checkbox"/> Dionized water <input type="checkbox"/> Water for injection (WFI) <input checked="" type="checkbox"/> Reverse Osmosis <input type="checkbox"/> Clean steam <input checked="" type="checkbox"/> Ultra-filtrated water (purified water) <input type="checkbox"/> Other:			
6.19	Does the plant have a batch/lot system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19a	Is the system traceable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19b	Is it unique?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19c	Is batch/lot manufacturing continuous?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.19d	Is manufacturing batch by batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.20	Does the site perform on-plant audits prior to approving critical GxP suppliers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.21	Does the site audit critical GxP suppliers after initial approval?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.22	Does the site inspect incoming materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.23	Does the site test incoming materials to defined specifications?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.24	Does the site establish purchase specifications for raw materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.25	Is the equipment multi-use?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.26	Does the site qualify equipment installation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.27	Does the site qualify equipment operation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.28	Does the site qualify equipment performance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.29	Are production critical use instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6.30	Is rework allowed?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.31	Is reprocessing allowed?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.32	Are manufacturing and packaging activities traceable to the equipment, areas, and materials used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.33	Are production materials handled and stored in a manner to prevent degradation, contamination and cross-contamination?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.34	If answering 'not applicable' for any of the above, please elaborate: N/A			

**Additional Comments:**

6.20: Audits are required for all critical suppliers. For instances where audits of new suppliers cannot be performed prior to approval, formal risk assessment/risk mitigation strategy is required for use.

<b>SECTION 7. Laboratory Procedures</b>		<input type="checkbox"/> N/A for this Site		
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
7.1	Does the site have standard procedures for sample handling/tracking?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1a	Does the site have standard procedures for retaining samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1b	Does the site have standard procedures for retesting samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2	Does the site have written and approved specifications and test methods?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.3	Are laboratory instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.4	Is there a standard procedure in place for analytical method development?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.5	Does the site qualify and/or validate analytical test procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.6	Does the site perform stability testing on materials and/or products?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7.7	Are retention samples of key raw materials maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.8	Are standards traceable to their preparation and reagents used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.9	Are retention samples of finished products maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.10	Are shelf life/retest/expiration dates available and standardized?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.11	Does the company provide a certificate of analysis (CoA) and/or a Certificate of Conformation/Compliance (CoC) for each lot or batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.12	Does the CoA/CoC contain the manufacture name and location?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.13	Is the CoA/CoC signed/e-signed by a Quality representative?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.14	If a repacker performs analyses, will the CoA reflect both the original manufacturing site data as well as the repacking site data?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.15	If answering 'not applicable' for any of the above, please elaborate: N/A			

**Additional Comments:**

N/A

<b>SECTION 8. Packaging, Storage and Transport</b>		<input type="checkbox"/> N/A for this Site		
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
8.1	Does the site have a validated or qualified labeling system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.2	Are batch production records retained and available?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.3	Are packaging and labeling areas separate from production?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.4	Are barcode readers in use and challenged regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.5	Are vision systems in use?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.6	Is product ever packaged without a label being initially applied (i.e. bright stocking)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.7	Do labels include shelf life/expiration dates?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8.8	Do labels include lot/batch number?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.9	Do labels include requirements for storage conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.10	Is tamper evident seal used for each container of supplied materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.11	Does the company use a First-In-First-Out or First-Expiration-First-Out system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.12	Does the company maintain appropriate storage conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.12a	Are those storage conditions monitored and documented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.13	Does the site make available a description of storage and/or warehouse conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.14	Does the site distribute products via a third party?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.15	Are good distribution policies implemented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.16	Are transport mechanisms dedicated?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.17	Does the company validate shipping method?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.18	Does the company validate packaging methods?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**Additional Comments:**

8.7 - All catalog products contain an expiration date. Expiration dates can be added to custom products but must be defined by the customer.

8.17 - Methods for direct shipment of products to customers are executed based on customer request.

8.18 - Primary packaging components are procured from approved vendors and inspected against approved specifications prior to use. For custom products, packaging configurations are established based on customer requirements.

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**I (Supplier) confirm that the information provided in this questionnaire is correct and can be verified.**

Title: Site Quality Manager

Date: 18th September 2024

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