Site Quality Self-Assessment

based on

Rx-360 Supplier Assessment Questionnaire

Module 2, Site Specific Information

Relevant for

Lynx® Product Line:

Lynx®S2S, Lynx®ST products

The site self-assessment covers our quality management system for the following regulated applications:
- Manufacturing and packaging of Lynx products at our third party subcontractor site in Costa Rica

Lynx®CDR products are manufactured at another site. Please refer to our Site Self-Assessment Lynx CDR.

Rx 360 An International Pharmaceutical Supply Chain Consortium

Merck KGaA, Darmstadt, Germany is an active member of the Rx 360 Consortium.

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.

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☐ Please check here if additional documents are attached.	

SECTION 1. General Site Information

1.1	Site or Facility-Specific Name: The Lynx branded products are manufactured by third party subcontractor located in Costa Rica. Millipore Sigma Corporation's Supply Chain Management Group is responsible for Quality Assurance activities for these products.
1.2	Address: Adress of original manufacturer is disclosed in OMD letter in case a valid and signed confidentiality commitment is in place. Please contact your sales Representative GPS Coordinates: not disclosed
1.3	Phone: please refer to your Sales representative
1.4	Email: please refer to your Sales representative
1.5	Fax:
1.6	Website: www.emdmillipore.com

SECTION 2. General Site Operating Information

2.1	What year did the site start operating? 2012
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) Manufacturing, molding, assembly and packaging.
2.3	To which, if any, subdivision of the parent company does the site belong? not disclosed for third party manufacturer. Millipore Sigma is a business of Merck KGaA, Darmstadt, Germany
2.4	Size of site (in sq. ft. or m.): 320,785 sq.ft. Facilities
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): • Manufacturing - 3 shifts: • 6:00 am – 3:30pm • 3:30 pm – 10:00pm • 10:00 pm – 6:00 am Administrative 8:00 am to 5:00 pm
2.6	Total number of employees on site: 1566

2.7	Total number of employees in Quality: 164	
2.8	Total number of employees in Manufacturing: 1068	
2.9	What quality management system is utilized on site? ☐ ISO 9001 ☒ ISO 13485 ☐ 21 CFR Part 210/211 ☒ 21 CFR Part 820 ☐ European GMP, Eudralex Volume 4 Part I ☐ European GMP, Eudralex Volume 4 Part II ☐ ICH Q7 ☐ HACCP ☐ ISO 22000 ☒ Other Please describe: ISO Class 7 and ISO Class 8 controlled enviroments Which Regulatory initiatives does the site follow/comply with? ☒ REACH ☒ RoHs ☐ Ca Prop. 65 ☐ WEEE	
2.10	Does the company/site have an export license?	☒ Yes ☐ No ☐ N/A
2.11	Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)? ☒ Yes ☐ No ☐ N/A If yes, please specify. the third party manufacturer is FDA registered	
2.12	By whom is the site inspected (regulatory or third party) and list inspections within the last three years: FDA and third party certifier for ISO 13485	
2.13	How often, as an annual average, is the site audited by customers or third parties? a total average of 15 audits per year	
2.14	Has an Rx-360 audit been performed at this site? ☐ Yes ☒ No Please also state the date of the audit if applicable. Learn more about the Rx-360 Joint Audit Program® here.	
2.15	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? ☒ Yes ☐ No	
2.16	Are you willing to have your customers conduct audits on your site? ☒ Yes ☐ No	
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? ☐ Yes ☒ No ☐ N/A	

	If answering yes, please specify the activities: N/A			
2.19	Please check the supplier controls in place for this facility:			
2.19a	Quality Agreements with Suppliers	☒ Yes	☐ No	☐ N/A
2.19b	Subcontractor Qualification/Audit Program	☒ Yes	☐ No	☐ N/A
2.19c	Periodic Review of Supplier Performance	☒ Yes	☐ No	☐ N/A
2.19d	Supplier Feedback Program	☒ Yes	☐ No	☐ N/A
2.19e	Approved Material Supplier List	☒ Yes	☐ No	☐ N/A
2.19f	Approved Service Supplier List	☒ Yes	☐ No	☐ N/A

Additional comments:

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	☐	☒	☐
3.1b	Steroids and/or hormones	☐	☒	☐
3.1c	High potency compounds	☐	☒	☐
3.1d	Materials of animal origin/Biologics	☐	☒	☐
3.1e	Live virus or micro-organism	☐	☒	☐
3.1f	Allergens	☐	☒	☐
3.1g	Genetically Modified Organisms (GMO)	☐	☒	☐
3.1h	Agrochemicals (Pesticides, Herbicides, Fungicides, etc.)	☐	☒	☐
3.1i	Other (Please specify): N/A			

SECTION 4. Cross-Contamination Control

		Yes	No	Not Applicable
4.1	Are any of the following cross-contamination controls in place?			
4.1a	Dedicated Facilities	☒	☐	☐
4.1b	Access Controls	☒	☐	☐
4.1c	Dedicated Personnel	☒	☐	☐
4.1d	Dedicated Gowning	☒	☐	☐
4.1e	Procedural Controls	☒	☐	☐
4.1f	Other (Please specify): N/A			

Additional Comments:

SECTION 5. Site Operating Policies

	Does the site utilize the following written policies, programs or procedures?			
Site Specific:		**Yes**	**No**	**Not Applicable**
5.1a	Environmental, Health and Safety	☒	☐	☐
5.1b	Facility Environmental Control Policy	☒	☐	☐
5.1c	General Facility Cleaning Procedures	☒	☐	☐
5.1d	Hygiene and Sterilization Procedures	☒	☐	☐
5.1e	Validated Equipment Cleaning Procedures	☒	☐	☐
5.1f	Preventative Maintenance Program/Procedures	☒	☐	☐
5.1g	Pest Control Program	☒	☐	☐
5.1h	Master Production Procedure	☒	☐	☐
Quality:				
5.1i	Quality Control/Quality Management Policy	☒	☐	☐
5.1j	Quality Manual	☒	☐	☐

5.1k	Periodic Product Quality Review	☒	☐	☐
5.1l	Master Validation Plan	☒	☐	☐
5.1m	Risk Assessment Program	☒	☐	☐
5.1n	Supplier Approval Procedure	☒	☐	☐
5.1o	Monitoring and Review of Approved Suppliers	☒	☐	☐
5.1p	Mechanism to Reduce Testing	☒	☐	☐
5.1q	Receiving Incoming Inspection	☒	☐	☐
5.1r	Change Control Procedures	☒	☐	☐
5.1s	Document Management Policy	☒	☐	☐
5.1t	Document Retention Policy	☒	☐	☐
5.1u	Change Notification Procedures for Clients	☒	☐	☐
5.1v	Control of Nonconforming Material	☒	☐	☐
5.1w	Deviation/Investigation Procedure	☒	☐	☐
5.1x	Out of Specification Policy and Procedure	☒	☐	☐
5.1y	Sampling Procedure/Sampling Plan	☒	☐	☐
5.1z	Raw Material Retention Program	☒	☐	☐
5.1aa	CAPA Procedure	☒	☐	☐
5.1bb	Label Control and Accountability	☒	☐	☐
5.1cc	Product Release Procedure	☒	☐	☐
5.1dd	Employee Training Program	☒	☐	☐
5.1ee	Stability, Expiration, and Shelf-Life Program	☒	☐	☐
5.1ff	Product Retention Program	☒	☐	☐
5.1gg	Recall Procedure	☒	☐	☐
5.1hh	Customer Complaint Handling	☒	☐	☐
5.1ii	Equipment validation/qualification procedure	☒	☐	☐
5.1jj	Internal audit/self-inspection program procedure	☒	☐	☐
5.1kk	Site Security/Site Access Control Policies	☒	☐	☐
5.1ll	New Hire Program/Induction Program	☒	☐	☐
Business Continuity/Contingency Plan:				
5.1mm	Disaster Recovery Plan	☒	☐	☐
5.1nn	Pandemic Preparedness Plan	☒	☐	☐
5.1oo	Supply Chain Emergency Preparedness Plan	☐	☒	☐
5.1pp	Business Continuity/Contingency Plan	☒	☐	☐
5.1qq	Can the company provide a plan upon request? OR provide a short description below:			

A process is described and defined in SOP

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?	☒	☐	☐
6.2	Does QA/QM have authority over the following:			
6.2a	Policies and procedures?	☒	☐	☐
6.2b	Review of documentation for release?	☒	☐	☐
6.2c	Release or rejection of incoming materials?	☒	☐	☐
6.3	Does QA/QM investigate and resolve quality complaints?	☒	☐	☐
6.4	Does QA/QM investigate and resolve internal deviations?	☒	☐	☐
6.5	Does QA/QM have the authority to assign a disposition to materials?	☒	☐	☐
6.6	Does QA/QM review manufacturing and testing records prior to release?	☒	☐	☐
6.7	Does the facility utilize computerized systems for managing GxP activities and data?	☒	☐	☐
6.8	Are relevant computerized systems 21 CFR part 11 and EU GMP annex 11 compliant?	☐	☒	☐
6.9	Does the site use statistical methods for consistency and uniformity?	☒	☐	☐
6.10	Does the site use controlled documents for following and recording manufacturing instructions?	☒	☐	☐
6.11	Does the company qualify and/or validate manufacturing procedures?	☒	☐	☐
6.12	Is any environmental monitoring conducted in production/finishing areas?	☒	☐	☐
6.13	Does the site supply BSE/TSE declarations?	☐	☐	☒
6.14	Does the site supply a declaration of Elemental Impurities?	☐	☐	☒
6.15	Are ICH Q3C solvents used in the manufacturing process of supplied materials?	☐	☐	☒
6.15a	If Yes, what class of solvent is used?			
6.16	Are stability studies carried our according to ICH guidance?	☐	☐	☒
6.17	Are solvents and mother liquor reused/recycled?	☐	☒	☐
6.18	Does the site have a process water treatment system?	☐	☒	☐
6.18a	Please check all that apply to the system: ☒ City/potable water ☐ Distilled water ☐ Dionized water			

	☐ Water for injection (WFI) ☐ Reverse Osmosis ☐ Clean steam ☐ Ultra-filtrated water (purified water) ☐ Other:			
6.19	Does the plant have a batch/lot system?	☒	☐	☐
6.19a	Is the system traceable?	☒	☐	☐
6.19b	Is it unique?	☒	☐	☐
6.19c	Is batch/lot manufacturing continuous?	☒	☐	☐
6.19d	Is manufacturing batch by batch?	☒	☐	☐
6.20	Does the site perform on-plant audits prior to approving critical GxP suppliers?	☒	☐	☐
6.21	Does the site audit critical GxP suppliers after initial approval?	☒	☐	☐
6.22	Does the site inspect incoming materials?	☒	☐	☐
6.23	Does the site test incoming materials to defined specifications?	☒	☐	☐
6.24	Does the site establish purchase specifications for raw materials?	☒	☐	☐
6.25	Is the equipment multi-use?	☒	☐	☐
6.26	Does the site qualify equipment installation?	☒	☐	☐
6.27	Does the site qualify equipment operation?	☒	☐	☐
6.28	Does the site qualify equipment performance?	☒	☐	☐
6.29	Are production critical use instruments calibrated regularly?	☒	☐	☐
6.30	Is rework allowed?	☒	☐	☐
6.31	Is reprocessing allowed?	☒	☐	☐
6.32	Are manufacturing and packaging activities traceable to the equipment, areas, and materials used?	☒	☐	☐
6.33	Are production materials handled and stored in a manner to prevent degradation, contamination and cross-contamination?	☒	☐	☐
6.34	If answering 'not applicable' for any of the above, please elaborate: The N/A for 6.13, 6.14, 6.15 and 6.16 is because the Lynx manufacturer is not responsible. The BSE/TSE statements and materials were all specified by MilliporeSigma and MilliporeSigma is responsible for all declarations of the materials used in manufacturing. MilliporeSigma is also responsible for performing stability studies on these products			

Additional Comments:

SECTION 7. Laboratory Procedures		☐ N/A for this Site		
		Yes	**No**	**Not Applicable**
7.1	Does the site have standard procedures for sample handling/tracking?	☒	☐	☐
7.1a	Does the site have standard procedures for retaining samples?	☒	☐	☐
7.1b	Does the site have standard procedures for retesting samples?	☒	☐	☐
7.2	Does the site have written and approved specifications and test methods?	☒	☐	☐
7.3	Are laboratory instruments calibrated regularly?	☒	☐	☐
7.4	Is there a standard procedure in place for analytical method development?	☒	☐	☐
7.5	Does the site qualify and/or validate analytical test procedures?	☒	☐	☐
7.6	Does the site perform stability testing on materials and/or products?	☒	☐	☐
7.7	Are retention samples of key raw materials maintained?	☐	☒	☐
7.8	Are standards traceable to their preparation and reagents used?	☒	☐	☐
7.9	Are retention samples of finished products maintained?	☐	☒	☐
7.10	Are shelf life/retest/expiration dates available and standardized?	☒	☐	☐
7.11	Does the company provide a certificate of analysis (CoA) and/or a Certificate of Conformation/Compliance (CoC) for each lot or batch?	☒	☐	☐
7.12	Does the CoA/CoC contain the manufacture name and location?	☒	☐	☐
7.13	Is the CoA/CoC signed/e-signed by a Quality representative?	☒	☐	☐
7.14	If a repacker performs analyses, will the CoA reflect both the original manufacturing site data as well as the repacking site data?	☐	☐	☒
7.15	If answering 'not applicable' for any of the above, please elaborate: N/A			

Additional Comments:

N/A

SECTION 8. Packaging, Storage and Transport		☐ N/A for this Site		
		Yes	**No**	**Not Applicable**
8.1	Does the site have a validated or qualified labeling system?	☒	☐	☐
8.2	Are batch production records retained and available?	☒	☐	☐
8.3	Are packaging and labeling areas separate from production?	☒	☐	☐
8.4	Are barcode readers in use and challenged regularly?	☒	☐	☐
8.5	Are vision systems in use?	☒	☐	☐
8.6	Is product ever packaged without a label being initially applied (i.e. bright stocking)?	☐	☒	☐
8.7	Do labels include shelf life/expiration dates?	☒	☐	☐
8.8	Do labels include lot/batch number?	☒	☐	☐
8.9	Do labels include requirements for storage conditions?	☐	☐	☒
8.10	Is tamper evident seal used for each container of supplied materials?	☒	☐	☐
8.11	Does the company use a First-In-First-Out or First-Expiration-First-Out system?	☒	☐	☐
8.12	Does the company maintain appropriate storage conditions?	☒	☐	☐
8.12a	Are those storage conditions monitored and documented?	☒	☐	☐
8.13	Does the site make available a description of storage and/or warehouse conditions?	☒	☐	☐
8.14	Does the site distribute products via a third party?	☐	☒	☐
8.15	Are good distribution policies implemented?	☒	☐	☐
8.16	Are transport mechanisms dedicated?	☒	☐	☐
8.17	Does the company validate shipping method?	☒	☐	☐
8.18	Does the company validate packaging methods?	☒	☐	☐

Additional Comments:

N/A

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

Title: Supplier Quality Engineering Manager

Date: 26th March 2024