



Site Quality Self-Assessment

based on

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

Relevant for

Merck S.L.U.
**Poligono Industrial 08100 Mollet
del Valles Barcelona, Spain**
An affiliate of Merck KGaA, Darmstadt, Germany

The site Self-assessment covers our quality management system for the following regulated applications:
- Manufacturing of Excipients and APIs



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

Merck KGaA, Darmstadt, Germany
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany
Phone +49 6151 72-0

Sigma-Aldrich Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
3050 Spruce Street
St. Louis, MO 63103, USA
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EMD Millipore Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive Burlington,
MA 01803, USA
Phone +1 (781) 533-6000



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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Rx-360 Supplier Assessment Questionnaire : Site-Specific Information

Please check here if additional documents are attached.

SECTION 1. General Site Information	
1.1	Site or Facility-Specific Name: MERCK SLU An affiliate of Merck KGaA, Darmstadt, Germany
1.2	Address: Poligono Industrial 08100 Mollet del Vallès Barcelona, Spain GPS Coordinates: N41° 32.737' E002° 13.732'
1.3	Phone: +34 935 655 500
1.4	Email: Please contact your local sales representative
1.5	Fax: Please contact your local sales representative
1.6	Website: www.sigmaaldrich.com

SECTION 2. General Site Operating Information	
2.1	What year did the site start operating? 1974
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) Manufacturing of chemicals
2.3	To which, if any, subdivision of the parent company does the site belong?

SECTION 2. General Site Operating Information

	The site belongs to the Electronics business sector of Merck KGaA, Darmstadt, Germany			
2.4	Size of site (in sq. ft. or m.): 83700 sq m			
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): Production 24 h/day, Warehouse: 16 h/day, QC: 16 h/day, Offices: 8 h/day Shutdowns: 3 weeks in August, 1 week in Christmas			
2.6	Total number of employees on site: 80			
2.7	Total number of employees in Quality: 11			
2.8	Total number of employees in Manufacturing: 58			
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 checked="" type="checkbox"/> European GMP, Eudralex Volume 4 Part II <input checked="" type="checkbox"/> ICH Q7 <input type="checkbox"/> HACCP <input type="checkbox"/> ISO 22000 <input type="checkbox"/> Other</p> <p>Please describe:</p> <p>Which Regulatory Initiatives does the site follow/comply with?</p> <p><input checked="" 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 checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

SECTION 2. General Site Operating Information

2.11	Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If yes, please specify. FDA and Spanish Health Authorities		
2.12	By whom is the site inspected (regulatory or third party) and list inspections within the last three years: Generalitat de Catalunya (acting on behalf of Spanish Health Authorities): November 2021 Rx360: April 2021		
2.13	How often, as an annual average, is the site audited by customers or third parties? 12		
2.14	Has an Rx-360 audit been performed at this site? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Please also state the date of the audit if applicable. April 7-8 2021 http://rx-360.org/audit-programs/		
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? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
2.16	Are you willing to have your customers conduct audits on your site? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If answering yes, please specify the activities: Microbiological testing of finished product		
2.19	Please check the supplier controls in place for this facility:		
2.19a	Quality Agreements with Suppliers	<input type="checkbox"/> Yes	<input checked="" 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

SECTION 2. General Site Operating Information				
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 type="checkbox"/> Yes	<input checked="" 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:				

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 type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1e	Live virus or micro-organism	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input checked="" 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):			

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 checked="" type="checkbox"/>	<input type="checkbox"/>
4.1b	Access Controls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1c	Dedicated Personnel	<input type="checkbox"/>	<input checked="" 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):			
Additional Comments: For some products facility is dedicated, for others it is multipurpose				

SECTION 5. Site Operating Policies				
5.1	Does the site utilize the following written policies, programs, or procedures?			
Site Specific:		Yes	No	Not Applicable
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"/>
Quality:				
5.1i	Quality Control/Quality Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1j	Quality Manual	<input type="checkbox"/>	<input checked="" 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"/>
SECTION 5. Site Operating Policies				
		Yes	No	Not Applicable
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"/>
Business Continuity/Contingency Plan:				
5.1mm	Disaster Recovery Plan	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.1pp	Business Continuity/Contingency Plan	<input checked="" type="checkbox"/>	<input checked="" 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 the QA/QM have the authority to assign a disposition to materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.6	Does the 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 or 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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"/>

SECTION 6. Quality Assurance and Production				
		Yes	No	Not Applicable
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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.15	Are ICH Q3C solvents used in the manufacturing process of supplied materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.15a	If Yes, what class of solvent is used? Class 2 or 3, depending on product			
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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input 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 type="checkbox"/> City/potable water <input type="checkbox"/> Distilled water <input checked="" type="checkbox"/> Dionized water <input type="checkbox"/> Water for injection (WFI) <input type="checkbox"/> Reverse Osmosis <input type="checkbox"/> Clean steam <input 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 checked="" 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"/>

SECTION 6. Quality Assurance and Production				
		Yes	No	Not Applicable
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 checked="" type="checkbox"/>	<input 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:			
Additional Comments:				

SECTION 7. Laboratory Procedures				
<input type="checkbox"/> N/A for this Site				
		Yes	No	Not Applicable
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 re-testing 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 product 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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION 7. Laboratory Procedures		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
	Conformation/Compliance (CoC) for each lot or batch?			
7.12	Does the CoA/CoC contain the manufacture name and location?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.13	Does 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.15	If answering 'not applicable' for any of the above, please elaborate: We are not repacking product			
7.16	Additional Comments:			

SECTION 8. Packaging, Storage, and Transport		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.4	Are barcode readers in use and challenged regularly?	<input type="checkbox"/>	<input checked="" 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 checked="" 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 type="checkbox"/>	<input checked="" 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"/>

SECTION 8. Packaging, Storage, and Transport		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
8.14	Does the site distribute products via a third party?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.15	Are good distribution policies implemented?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.16	Are transport mechanisms dedicated?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Additional Comments:</p> <p>8.14-8.17 No direct delivery to customers. Products are shipped to affiliates of Merck KGaA, Darmstadt Germany who makes the final distribution to customers worldwide. For this reason these questions are not applicable to our site.</p> <p>8.3. Packaging and labeling are done during filling in production</p> <p>8.4 We use barcodes, the use was validated but it is not challenged regularly.</p> <p>8.9 There are no special conditions of storage for products covered in the questionnaire, for this reason label don't include requirements for storage conditions</p> <p>8.7 Some products include shelf life in label, others not</p>				

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

Date:08 June 2022

Title:Quality Head