



# Site Quality Self-Assessment

based on

## Rx-360 Supplier Assessment Questionnaire

### Module 2 (Site specific information)

Relevant for

**Merck S.A. in Colombia and  
associated 3rd Party Logistics  
service provider (3PL)**

An affiliate of Merck KGaA, Darmstadt, Germany

The site self-assessment covers our quality management system for the following applications:  
- warehouse and distribution



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  
Phone +1 (800) 521-8956 / +1 (314) 771-5765

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.

<b>SECTION 1. General Site Information</b>	
1.1	<p>Site or Facility-Specific Name:</p> <ul style="list-style-type: none"> <li>- MERCK S.A.(An affiliate of Merck KGaA, Darmstadt, Germany)</li> <li>- Distri Cargo Operations: (3<sup>rd</sup> Party Logistics service provider (3PL) servicing product storage)</li> </ul>
1.2	<p>Address:</p> <ul style="list-style-type: none"> <li>- Offices: 9th Avenue # 101-67. Level 5, Office 501A; Bogotá, Colombia</li> <li>- Warehouse: Celta Trade Park, Km 7.5 Medellin Highway, Warehouse 131-8; Cundinamarca, Colombia</li> </ul> <p>GPS Coordinates:</p> <ul style="list-style-type: none"> <li>- Offices: 4.686338596604312, -74.04667866288992</li> <li>- Warehouse: 4.7640210813733646, -74.18558891870741</li> </ul>
1.3	<p>Phone:</p> <p>6014254770</p>
1.4	<p>Email:</p> <p><a href="https://www.sigmaaldrich.com/US/en/collections/offices#colombia">https://www.sigmaaldrich.com/US/en/collections/offices#colombia</a></p>
1.5	<p>Fax:</p> <p>N.A.</p>
1.6	<p>Website:</p> <p><a href="http://www.sigmaaldrich.com">www.sigmaaldrich.com</a></p>

<b>SECTION 2. General Site Operating Information</b>	
2.1	What year did the site start operating? 2021
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) Warehouse, distribution, and supply of Life Science products
2.3	To which, if any, subdivision of the parent company does the site belong? Merck KGaA, Darmstadt, Germany
2.4	Size of site (in sq. ft. or m.): General storage area (m2) 1600 m2 Flammable storage area(m2) 680 m2 Office area(m2) 500 m2
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): 06:00 - 20:00
2.6	Total number of employees on site: 28
2.7	Total number of employees in Quality: 1
2.8	Total number of employees in Manufacturing: 0
2.9	<p>What quality management system is utilized on site?</p> <p> <input 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: Comply with ISO 9001 requirements, but not certified</p> <p>Which Regulatory Initiatives does the site follow/comply with?</p>

<b>SECTION 2. General Site Operating Information</b>	
	<input type="checkbox"/> REACH <input type="checkbox"/> RoHs <input type="checkbox"/> Ca Prop. 65 <input type="checkbox"/> WEEE
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	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. INVIMA, Colombian health authority
2.12	By whom is the site inspected (regulatory or third party) and list inspections within the last three years: INVIMA, Narcotics, Police
2.13	How often, as an annual average, is the site audited by customers or third parties? 1-2 Government inspection per year 12 Customer audit per year
2.14	Has an Rx-360 audit been performed at this site? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Please also state the date of the audit if applicable.  <a href="http://rx-360.org/audit-programs/">http://rx-360.org/audit-programs/</a>
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: Third Party Warehouse
2.19	Please check the supplier controls in place for this facility:

<b>SECTION 2. General Site Operating Information</b>				
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 type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
2.19e	Approved Material Supplier List	<input type="checkbox"/> Yes	<input checked="" 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: Details supplier, technical and quality agreement Distri Group - 20521244				

<b>SECTION 3. Objectionable Materials on Site</b>				
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 checked="" type="checkbox"/>	<input 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 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): others are not applicable, no open product handling, only storage of finished goods			

<b>SECTION 4. Cross Contamination Control</b>				
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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4.1d	Dedicated Gowning	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4.1e	Procedural Controls	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4.1f	Other (please specify): N/A			
Additional Comments: N/A				

<b>SECTION 5. Site Operating Policies</b>				
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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1c	General Facility Cleaning Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1d	Hygiene and Sterilization Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1e	Validated Equipment Cleaning Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1y	Sampling Procedure/Sampling Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1z	Raw Material Retention Program	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1ff	Product Retention Program	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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"/>
<b>SECTION 5. Site Operating Policies</b>				
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
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 type="checkbox"/>	<input checked="" 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: No.			

<b>SECTION 6. Quality Assurance and Production</b>				
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.3	Does QA/QM investigate and resolve quality complaints?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.6	Does the QA/QM review manufacturing and testing records prior to release?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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"/>



<b>SECTION 6. Quality Assurance and Production</b>				
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.11	Does the company qualify and/or validate manufacturing procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.12	Is any environmental monitoring conducted in production/finishing areas?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.13	Does the site supply BSE/TSE declarations?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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(R4) solvents used in the manufacturing process of supplied materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.16	Are stability studies carried out according to ICH guidance?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.18a	Please check all that apply to the system: <input type="checkbox"/> City/potable water <input type="checkbox"/> Distilled water <input 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: N/A			
6.19	Does the plant have a batch/lot system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input checked="" type="checkbox"/>
6.19d	Is manufacturing batch by batch?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.23	Does the site test incoming materials to defined specifications?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.24	Does the site establish purchase specifications for raw materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

<b>SECTION 6. Quality Assurance and Production</b>				
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
6.25	Is the equipment multi-use?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.30	Is rework allowed?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.31	Is reprocessing allowed?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.32	Are manufacturing and packaging activities traceable to the equipment, areas, and materials used?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.33	Are production materials handled and stored in a manner to prevent degradation, contamination and cross-contamination?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.34	If answering 'not applicable' for any of the above, please elaborate: The site does not perform manufacturing			
Additional Comments: N/A				

<b>SECTION 7. Laboratory Procedures</b>				
<input checked="" type="checkbox"/> <b>N/A for this Site</b>				
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
7.1	Does the site have standard procedures for sample handling/tracking?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.1a	Does the site have standard procedures for retaining samples?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.1b	Does the site have standard procedures for re-testing samples?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.2	Does the site have written and approved specifications and test methods?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.3	Are laboratory instruments calibrated regularly?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.4	Is there a standard procedure in place for analytical method development?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.5	Does the site qualify and/or validate analytical test procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.6	Does the site perform stability testing on materials and/or products?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.7	Are retention samples of key raw materials maintained?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.8	Are standards traceable to their preparation and reagents used?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.9	Are retention samples of finished product maintained?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

<b>SECTION 7. Laboratory Procedures</b>		<input checked="" type="checkbox"/> <b>N/A for this Site</b>		
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
7.10	Are shelf life/retest/expiration dates available and standardized?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.12	Does the CoA/CoC contain the manufacture name and location?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.13	Does the CoA/CoC signed/e-signed by a Quality representative?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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: not applicable for warehouse and distribution activities			
7.16	Additional Comments: N/A			

<b>SECTION 8. Packaging, Storage, and Transport</b>		<input type="checkbox"/> <b>N/A for this Site</b>		
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
8.1	Does the site have a validated or qualified labeling system?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.2	Are batch production records retained and available?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.3	Are packaging and labeling areas separate from production?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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"/>

<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>
8.12a	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 checked="" type="checkbox"/>	<input type="checkbox"/>
8.18	Does the company validate packaging methods?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Additional Comments: Supplementary Labelling				

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

Date:09 Mar 2022

Title:Quality Specialist

**Additional Site-Specific Information (Colombia)**  
**(not based on Rx 360 Supplier Assessment Questionnaire)**

<b>9. Warehouse and Distribution</b>		<b>Yes</b>	<b>No</b>	<b>N/A</b>
9.1	What is the scope the warehouse in Columbia?	A Global distribution hub serving all Life Science business units & all geographies.		
9.2	How is it handled?	Logistics is operated by a Third-Party Logistics (3PL) supplier.		
9.3	Do you have signed Contracts & agreements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.4	Do you have a Service providers management in place?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.5	Do you audit your Service Providers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.6	What is size and location of warehouse?	1600 m <sup>2</sup> solely dedicated to Life Science finished goods; warehouse located in Cundinamarca, Colombia		
9.7	What standards do you have in place?	Third Party Logistics supplier is ISO 9001 certified : Offer of specialized goods storage and control services in Bogotá D.C and Cartagena D.T y C		
9.8	Do you have temperature-controlled areas?	We do have validated & temperature monitored storage areas: Ambient: 2 - 30°C. Refrigerated: 2 - 8°C. Freezer: -10 to -25°C. Ultra Cold: -65°C.		
9.8 a	Are warehouse rooms with different temperature conditions in place?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.8 b	Do you have alarms for temperature?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.8 c	Is the temperature monitored	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9.9	How do you manage your inventory?	Live count back and scheduled periodic cycle counts.
9.10	Describe dangerous goods storage.	Dangerous goods stored as per Hazard Class Segregation requirements. No explosive or radioactive hazard classes stored on site