



# Site Quality Self-Assessment

based on

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

Relevant for

**Merck Ltd. Atsugi Pharmaceutical Factory**  
**4050 Nakatsu, Aikawa-machi, Aiko-gun**  
**243-0303, Kanagawa, Japan**  
An affiliate of Merck KGaA, Darmstadt, Germany

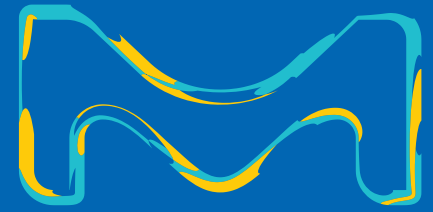
The site self-assessment covers our quality management system for the following activities:  
labeling and storage of Active Pharmaceutical Ingredients (API),  
in vitro diagnostic products (IVD), and Medical devices (MD)



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 3.0 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.

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<input type="checkbox"/> Please check here if additional documents are attached.	
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### SECTION 1. General Site Information

1.1	Site or Facility-Specific Name: Merck Ltd. Atsugi Pharmaceutical Factory An affiliate Merck KGaA, Darmstadt, Germany
1.2	Address: 4050 Nakatsu , Aikawa-machi, Aiko-gun 243-0303, Kanagawa, Japan GPS Coordinates: Latitude: 35.520840, Longitude: 139.341115
1.3	Phone: +81 46 286 8599
1.4	Email: Please contact your local Account Manager or Customer Service Representative
1.5	Fax: +81 46 285 1907
1.6	Website: N/A

### SECTION 2. General Site Operating Information

2.1	What year did the site start operating? 1989
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) The Atsugi Factory, located within the Atsugi Distribution Center, operates under Japanese regulatory approvals. It is responsible for the labeling and storage of Active Pharmaceutical Ingredients (API), in vitro diagnostic products (IVD), and Medical devices (MD).
2.3	To which, if any, subdivision of the parent company does the site belong? Life Science business of Merck KGaA, Darmstadt, Germany
2.4	Size of site (in sq. ft. or m.): 13,563.2 m <sup>2</sup>
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): Operation hours: 9:00 am - 5:30 pm Security: 24 hours
2.6	Total number of employees on site: 3
2.7	Total number of employees in Quality: 1
2.8	Total number of employees in Manufacturing: 2

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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: GMP Ministerial Ordinance and QMS Ministerial Ordinance Japan</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	<p>Does the company/site have an export license? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A</p>
2.11	<p>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</p> <p>If yes, please specify.  Licensed to manufacture pharmaceutical products, in vitro diagnostic products, and medical devices (packaging, labeling, and storage)</p>
2.12	<p>By whom is the site inspected (regulatory or third party) and list inspections within the last three years:  Kanagawa prefecture Oct. 2024</p>
2.13	<p>How often, as an annual average, is the site audited by customers or third parties?  1</p>
2.14	<p>Has an Rx-360 audit been performed at this site?  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Please also state the date of the audit if applicable.</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?  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
2.16	<p>Are you willing to have your customers conduct audits on your site?  <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>
2.17	<p>Please list regulatory sanctions impacting the site within the last five years (i.e. warning letters, CEP suspension, import alerts, etc.): N/A</p>
2.18	<p>Does the site outsource any quality-related activity?  <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If answering yes, please specify the activities: API and IVD testing</p>

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:**

This assessment sheet is intended for the following products regulated by Japan's Pharmaceutical and Medical Device Act.

160128,160125

1.04144.0003

SLAAJ33SS,SLAAV255F,SLFGI25LS,SLGLJ250S,SLGSJ33SS,SLGSV255F,SLGV0250S,SLGVJ25 LS,SLGVJ33RS,SLGVV255F,SLHAJ33SS,12613M

**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): Not available in the Atsugi Pharmaceutical Factory area.			

### 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4.1b	Access Controls	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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):			

**Additional Comments:**

N/A for labeling and storage only, as the product is not opened.

### SECTION 5. Site Operating Policies

5.1	Does the site utilize the following written policies, programs or procedures?	Yes	No	Not Applicable
<b>Site Specific:</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 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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1l	Master Validation Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input 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"/>
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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1nn	Pandemic Preparedness Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1oo	Supply Chain Emergency Preparedness Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1pp	Business Continuity/Contingency Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

5.1qq	Can the company provide a plan upon request? OR provide a short description below: BCP procedures have not been established at the site, but the company does have a comprehensive Business Continuity Plan in place.
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**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 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 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 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 checked="" 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:			
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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.19b	Is it unique?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.21	Does the site audit critical GxP suppliers after initial approval?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 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 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 for labeling and storage only, as no manufacturing activities are conducted.			
<b>Additional Comments:</b>				

<b>SECTION 7. Laboratory Procedures</b>		<input 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 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input 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 products maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.15	If answering 'not applicable' for any of the above, please elaborate: N/A is used as we only outsource JP testing to external testing labs.			

**Additional Comments:**

<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 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 checked="" type="checkbox"/>	<input 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 type="checkbox"/>	<input checked="" type="checkbox"/>

**Additional Comments:**

8.10 The use of tamper evident seals depends on the product.

8.16 The transport mechanisms are dedicated based on customer request.

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

Title API/IVD Manufacturing supervisor, Medical device Technical supervisor

Date: March,19.2025