



Site Quality Self-Assessment

based on

Rx-360 Supplier Assessment Questionnaire

Module 2, Site Specific Information and

Module 4, Warehouse & Distribution

Relevant for **Millipore SAS**

39, Route Industrielle de la Hardt

67120 Molsheim, France

An affiliate of Merck KGaA, Darmstadt, Germany

The site self-assessment covers our quality management system for the following activities:

- Manufacturing of devices media and equipment for fluid analysis and purification and manufacturing of single use components and water purification systems
- Warehousing and distribution



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 templates, Module 2 and Module 4. The contents of this questionnaire are built on the Rx-360 questionnaires SAQ2 version 3.0 and SAQ4 version 3.1 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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MilliporeSigma in the U.S. and Canada.

Please check here if additional documents are attached.

SECTION 1. General Site Information

1.1	Site or Facility-Specific Name: Millipore SAS
1.2	Address: Millipore SAS 39, Route Industrielle de la Hardt 67120 Molsheim France GPS Coordinates: 48.5418 Latitude ; 7.5297 Longitude
1.3	Phone: +33 3 90 46 90 00
1.4	Email: Please contact your local Sales representative
1.5	Fax: None
1.6	Website: www.sigmaaldrich.com

SECTION 2. General Site Operating Information

2.1	What year did the site start operating? 1972
2.2	<p>What is the primary activity of the site? (e.g. manufacturing, distribution, etc.)</p> <p>SLS BioMonitoring: Design, development, production engineering, planning, manufacturing and distribution of devices, equipment, media, for fluid analysis and purification.</p> <p>SLS LabWater: Production engineering manufacturing and distribution of water purification systems for laboratories.</p> <p>PS SSU: Manufacturing of single use components and delivery of engineered systems and technical solutions for fluid storage, filtration, and separation.</p> <p>SLS and PS: Scientific, commercial, technical and validation support to customers.</p> <p>Maintenance and repair for biomonitoring and process solution equipment's</p> <p>SLS: Science & Lab Solutions PS: Process Solutions SSU: Systems & Single Use</p> <p>Comment: the Validation Services Laboratory has its own SSA, titled "Validation Services, Site Quality Self-Assessment" .</p>

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.): 51487 m ²	
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): Hours of Operation included between 7:00AM and 6:30PM. Production Hours (product line / Operation depending): a) 2X8: 6:00AM-02:00PM / 02:00PM-10:00PM b) 5X8: 6:00AM-01:00PM / 01:00PM-08:00PM / 08:00PM-06:00AM c) Night crew: 10:00PM-06:00AM d) Week-end: 06:00AM-06:00PM No shutdown.	
2.6	Total number of employees on site: ~2340	
2.7	Total number of employees in Quality: 215	
2.8	Total number of employees in Manufacturing: ~760	
2.9	<p>What quality management system is utilized on site?</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 Please describe: ISO 17025 for BioMonitoring Quality Control Lab, ISO 14001, ISO 50001, ISO 45001	
	<p>Which Regulatory initiatives does the site follow/comply with?</p> <input checked="" type="checkbox"/> REACH <input checked="" type="checkbox"/> RoHs <input type="checkbox"/> Ca Prop. 65 <input checked="" type="checkbox"/> WEEE	
2.10	Does the company/site have an export license?	<input checked="" type="checkbox"/> Yes <input 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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A If yes, please specify. N/A	
2.12	By whom is the site inspected (regulatory or third party) and list inspections within the last three years: DQS	
2.13	How often, as an annual average, is the site audited by customers or third parties? ~30	

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. 13-15 May 2025 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? <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: .BioMonitoring: Testing, Sterilization/ Irradiation .Systems & Single Use (SSU): Systems: Testing NovaSeptum: Testing, Sterilization Mobius: Testing, Sterilization .LabWater Solutions & Instruments (LWS&I): Testing
2.19	Please check the supplier controls in place for this facility:
2.19a	Quality Agreements with Suppliers <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19b	Subcontractor Qualification/Audit Program <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19c	Periodic Review of Supplier Performance <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19d	Supplier Feedback Program <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19e	Approved Material Supplier List <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19f	Approved Service Supplier List <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

Additional comments:

2.2: Some products can be manufactured by external qualified 3rd party suppliers. Some equipments can be manufactured by Peenya Site where Molsheim Site is the legal owner. For these products, customer audit requests will be managed by the Peenya site, while any product quality complaints will be handled by the Molsheim site.

2.10: for TFF systems

2.14 / 2.15 / 2.16: Our site is regularly audited by third-party organizations, such as Rx-360, ensuring that these solutions streamline your audit processes and maintain high-quality compliance through detailed and reliable reports. For more information about Rx-360 and its resources, you can visit the Rx-360.org website.

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 checked="" type="checkbox"/>	<input 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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1e	Live virus or micro-organism	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1f	Allergens	<input checked="" type="checkbox"/>	<input 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): N/A Additional Comments: 3.1.a: Beta-Lactam antibiotics are used as ingredient for a limited number of microbiological media. We have implemented measure to avoid cross contamination. 3.1.e: Milk and egg yolk			

SECTION 4. Cross-Contamination Control

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

Additional Comments:

N/A

SECTION 5. Site Operating Policies

5.1	Does the site utilize the following written policies, programs or procedures?			
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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1k	Periodic Product Quality Review	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1l	Master Validation Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1m	Risk Assessment Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1n	Supplier Approval Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1o	Monitoring and Review of Approved Suppliers	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1p	Mechanism to Reduce Testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1q	Receiving Incoming Inspection	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1r	Change Control Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1s	Document Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1t	Document Retention Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1u	Change Notification Procedures for Clients	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1v	Control of Nonconforming Material	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5.1w	Deviation/Investigation Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1x	Out of Specification Policy and Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1y	Sampling Procedure/Sampling Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1z	Raw Material Retention Program	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.1aa	CAPA Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1bb	Label Control and Accountability	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1cc	Product Release Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1dd	Employee Training Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ee	Stability, Expiration, and Shelf-Life Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ff	Product Retention Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1gg	Recall Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1hh	Customer Complaint Handling	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ii	Equipment validation/qualification procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1jj	Internal audit/self-inspection program procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1kk	Site Security/Site Access Control Policies	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ll	New Hire Program/Induction Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Business Continuity/Contingency Plan:				
5.1mm	Disaster Recovery Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1nn	Pandemic Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1oo	Supply Chain Emergency Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1pp	Business Continuity/Contingency Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1qq	Can the company provide a plan upon request? OR provide a short description below: It may be reviewed during an on-site audit after execution of our standard non-disclosure agreement.			

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"/>

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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 checked="" type="checkbox"/>	<input type="checkbox"/>
6.7	Does the facility utilize computerized systems for managing GxP activities and data?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.8	Are relevant computerized systems 21 CFR part 11 and EU GMP annex 11 compliant?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.9	Does the site use statistical methods for consistency and uniformity?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.10	Does the site use controlled documents for following and recording manufacturing instructions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.11	Does the company qualify and/or validate manufacturing procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.12	Is any environmental monitoring conducted in production/finishing areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.13	Does the site supply BSE/TSE declarations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input 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? N/A			
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 checked="" 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 checked="" type="checkbox"/> City/potable water <input type="checkbox"/> Distilled water <input type="checkbox"/> Dionized water <input type="checkbox"/> Water for injection (WFI) <input checked="" type="checkbox"/> Reverse Osmosis <input checked="" type="checkbox"/> Clean steam <input checked="" type="checkbox"/> Ultra-filtrated water (purified water) <input checked="" type="checkbox"/> Other: Mechanical Filtration, UV, water softener, Co2 degassing			
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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.25	Is the equipment multi-use?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.26	Does the site qualify equipment installation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.27	Does the site qualify equipment operation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.28	Does the site qualify equipment performance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.29	Are production critical use instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.30	Is rework allowed?	<input checked="" type="checkbox"/>	<input 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: 6.7 - 6.8 - 6.20 - 6.21: The site does not comply with GxP regulations. Molsheim site has no GMP production, no drugs manufacturing			

Additional Comments:

6.6 No for SSU Standard Hardware Products and LWS&I
 6.9 Yes for BioMonitoring, Novaseptum and Mobius, and LWS&I
 6.13 Product depending
 6.30 / 6.31 Under specific requirements

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 checked="" type="checkbox"/>	<input type="checkbox"/>
7.1b	Does the site have standard procedures for retesting samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2	Does the site have written and approved specifications and test methods?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.3	Are laboratory instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.4	Is there a standard procedure in place for analytical method development?	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7.8	Are standards traceable to their preparation and reagents used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.9	Are retention samples of finished products maintained?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7.10	Are shelf life/retest/expiration dates available and standardized?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.11	Does the company provide a certificate of analysis (CoA) and/or a Certificate of Conformation/Compliance (CoC) for each lot or batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.12	Does the CoA/CoC contain the manufacture name and location?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.13	Is the CoA/CoC signed/e-signed by a Quality representative?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.14	If a repacker performs analyses, will the CoA reflect both the original manufacturing site data as well as the repacking site data?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.15	If answering 'not applicable' for any of the above, please elaborate: No repacking			

Additional Comments:

7.1.a Yes for BioMonitoring and Novaseptum
 7.9 No for Mobius, SSU Systems, LabWater Solutions. Retains samples being set up on Aervent products - Yes for Novaseptum - Regarding BioMonitoring, retention samples for some of our references are kept according to internal procedures.
 7.11 Certificate of Quality (CoQ) provided for BioMonitoring, LWS&I, SSU - Certificate of Conformity (CoC) provided for LWS&I - Certificate of Analysis (CoA) provided or some BioMonitoring media products - Certificate of Irradiation provided for Mobius

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

Additional Comments:

- 8.2 The retention period and preservation conditions are described in a procedure.
- 8.3 Depending of the processes considered, labelling and primary packaging can be done during the production.
- 8.5 No for SSU and NA for SSU Systems
- 8.7 NA for SSU Systems
- 8.8 Serial number for SSU Systems
- 8.9 N/A for SSU Systems and LWS&I

8.10 All our containers are sealed by the carriers after loading
8.18 If product requirement

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

Title: Quality Specialist

Lead Date: 26 November 2025

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SECTION 1. Service Contact Information

1.1	Company and name of entity providing service: RHENUS LOGISTICS ALSACE
1.2	Phone: Please contact your local Sales representative
1.3	Email: Please contact your local Sales representative
1.4	Website: https://www.rhenus.group/fr/fr/
1.5	Please provide specific contact(s) for requesting service groups or for obtaining additional information, including telephone number or e-mail, as applicable. N/A

SECTION 2. Service Specific

Please indicate the type of service(s) provided by selecting from the categories below. For categories marked by an asterisk (*), please also complete the associated submodule.

Rx360 has developed these submodules for your convenience; please let us know if they serve your needs adequately (info@rx-360.org).

<input type="checkbox"/> (1) Laboratory Services *	<input type="checkbox"/> (8) Sterilization Services *
<input type="checkbox"/> (2) Calibration Services *	<input type="checkbox"/> (9) Cleaning Services (Manufacturing, clean room, gowning/ laundry)
<input type="checkbox"/> (3) Validation and Qualification Services *	<input type="checkbox"/> (10) 3 rd Party Auditing Services
<input type="checkbox"/> (4) Engineering Services *	<input type="checkbox"/> (11) Pest Control
<input type="checkbox"/> (5) Consultant Services *	<input type="checkbox"/> (12) Disposal Services (Solvent, Product, Chemical)
<input checked="" type="checkbox"/> (6) Warehouse & Distribution *	<input type="checkbox"/> (13) Data Storage and Disposal (Electronic/Paper, Shredding, etc.)
<input type="checkbox"/> (7) Transportation Services *	<input type="checkbox"/> (14) Stability Services (outsourced stability storage and testing)

(15) Other (describe service):

SECTION 3. General Site Operating Information

3.1	<p>Please provide the address and the site providing the services listed in section 2:</p> <p>Name of the site: RHENUS LOGISTICS ALSACE Street: 9 Rue de Chalon City, State: STRASBOURG Postal Code: 67100 Country: FRANCE</p> <p><input checked="" type="checkbox"/> This questionnaire applies to the following sites as well (with site name, address): 9a, 9b, 10 rue de chalon 67100 Strasbourg</p>
3.2	<p>Is the site registered with any government regulatory agency (FDA registration, etc.)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If yes, please specify:</p>
3.3	<p>Has the site been subjected to regulatory inspections? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>Please provide a list of inspections (regulatory agency and date of inspection) within the last three years:</p>
3.4	<p>Have there been any regulatory agency findings or refusals at the site in the last three years (i.e., warning letters, CEP suspension, import alerts, etc.)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If applicable, please provide details:</p> <p><input type="checkbox"/> Additional information attached.</p>
3.5	<p>Do you allow customer audits of your site? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Please list any requirements or restrictions: pre-notification of min. 4 weeks in advance according TQA signed between Millipore SAS and Rhenus</p>
3.6	<p>On a yearly basis, what is the frequency of customer or regulatory body audits? <input type="checkbox"/> 0 <input checked="" type="checkbox"/> 1-3 <input type="checkbox"/> 4-9 <input type="checkbox"/> 10+</p>

Comments (Please reference appropriate question number for any additional comments)

SECTION 4. Service-Related Quality Management Systems

4.1	What quality management system is utilized for the services provided? <input checked="" type="checkbox"/> ISO 9001 <input checked="" type="checkbox"/> ISO 13485 <input type="checkbox"/> ICH Q7 <input type="checkbox"/> Other, please describe:	
4.2	Are the following certifications in place for the service supplier? <input type="checkbox"/> ISO 17025 (testing and calibration laboratories) <input type="checkbox"/> ISO 11137 (irradiation/sterilizations) <input type="checkbox"/> ISO 17665-1 (moist heat sterilization) <input checked="" type="checkbox"/> ISO 14001 (environmental management systems) <input type="checkbox"/> ISO 45001 (occupational health and safety) <input checked="" type="checkbox"/> ISO 50001 (energy management systems) <input checked="" type="checkbox"/> Other, please describe: ISO 27001 Information Security Management	
4.3	Do you outsource any of the activities related to the provided services?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
4.3a	If yes, please list the outsourced activities: 1. 2. 3. <input type="checkbox"/> Additional information attached.	
4.3b	Please check which of the following would occur should activities be outsourced (check all that apply)? <input type="checkbox"/> Notify customers prior to any outsourcing of activities <input type="checkbox"/> Information would be noted on any supporting documentation <input type="checkbox"/> Other, please describe: <input type="checkbox"/> N/A (there would be no notification or way to tell any outsourced activities)	
4.3c	Does your company maintain a register/list of all subcontractors that are used for services?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

Comments (Please reference appropriate question number for any additional comments)

SECTION 5. Supplier Qualification Management

The following questions concern risk based upon Supplier Qualification Program:

5.1	Do you have a Supplier Qualification program?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
5.2	Does this program include qualification of subcontractors for outsourced activities related to the provided services?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
5.3	Which of the following tools are part of the supplier/subcontractor qualification? <input type="checkbox"/> Questionnaire / Self-Assessment <input checked="" type="checkbox"/> Audit (on-site, remote, Rx-360 or other 3 rd party audit program) <input type="checkbox"/> Periodic Review of Supplier Performance <input type="checkbox"/> Supplier Feedback program <input type="checkbox"/> If other (e.g., established relationship), please provide description/justification:			
5.4	How often are the suppliers/subcontractors audited? Once a year			
5.5	Is the following in place with suppliers/subcontractors? <input checked="" type="checkbox"/> Quality Agreement <input checked="" type="checkbox"/> Confidentiality Disclosure Agreement <input checked="" type="checkbox"/> Services Agreement			

Comments (Please reference appropriate question number for any additional comments)

SECTION 6. Personnel, Training and Education

6.1	Do you have written job descriptions for personnel providing the services listed in section 2?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
6.2	Are your personnel aware of the appropriate quality level that the services supplied are used for?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
6.3	Do you have a formal Employee Training Program?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
6.4	Do you maintain records of the training?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
6.5	Does the Training Program in place have the following elements? <input checked="" type="checkbox"/> Formal Introduction to Regulatory Guidance (GMP, GDP, ISO, etc.) <input checked="" type="checkbox"/> Periodic assessment of practical effectiveness? <input checked="" type="checkbox"/> Periodic refresher training programs for established employees?			

Comments (Please reference appropriate question number for any additional comments)

SECTION 7. Site Operating Policies

7.1	Please provide module 2 if available and skip this section 7. Otherwise, please complete below: <input type="checkbox"/> Module 2 attached.			
7.2	Does the site utilize the following written policies, programs, or procedures?			
Site Specific:		Yes	No	Not Applicable
7.2a	Environmental, Health and Safety	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2b	Facility Environmental Control Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2c	General Facility Cleaning Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2d	Hygiene and Sterilization Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.2e	Validated Equipment Cleaning Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2f	Preventative Maintenance Program/Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2g	Pest Control Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality:				
7.2h	Quality Control/Quality Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2i	Periodic Service Quality Review	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2j	Master Validation Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2k	Risk Assessment Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2l	Receiving Incoming Inspection	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2m	Change Control Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2n	Document Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2o	Document Retention Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2p	Change Notification Procedures for Clients	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2q	Deviation/Investigation Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2r	CAPA Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2s	Sampling Procedure/Sampling Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.2t	Certificate of Analysis/Quality Control and Accountability	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.2u	Recall Procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

7.2v	Customer Complaint Handling	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2w	Equipment validation/qualification procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2x	Internal audit/self-inspection program procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2y	Site Security/Site Access Control Policies	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Business Continuity/Contingency Plan:				
7.2z	Business Continuity/Contingency Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2aa	Disaster Recovery Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2bb	Pandemic Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2cc	Supply Chain Emergency Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2dd	Can the company provide a plan upon request? OR provide a short description below: Yes			

Comments (Please reference appropriate question number for any additional comments)

I certify that the information is correct and verifiable. Yes No

Title: Quality Delegate Distribution Molsheim

Date: 11 july 2025

<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: Rhenus Logistics Alsace SAS
1.2	Address: Warehouse SX1 : 9a rue de chalon 67000 Strasbourg Warehouse SX3 : 9b rue de chalon 67000 Strasbourg Warehouse SX5 : 10 rue de chalon 67000 Strasbourg GPS Coordinates (Map Coordinates/Longitude & Latitude): Warehouse SX1-SX3-SX5 : 48°34'04.7"N 7°47'24.1"E
1.3	Phone: Please contact your local Sales representative
1.4	Email: Please contact your local Sales representative
1.5	Fax: X
1.6	Website: http://www.rhenus.group
1.7	If there is an individual contact for the following areas, please provide name and preferred contact information (at a minimum, name and telephone number or email): N/A

SECTION 2. Warehousing, Distribution

N/A

2.1	Which of the following services are provided? (check all that apply) <input checked="" type="checkbox"/> Warehousing
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Rx-360 Supplier Assessment Questionnaire

Module 4: Service Supplier (Version 3.0)

Warehouse & Distribution Services Appendix

	<input checked="" type="checkbox"/> Distribution <input type="checkbox"/> Transportation			
2.2	Does the company maintain specialized storage conditions?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.2a	Does the site make available a description of storage and/or warehouse conditions?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.2b	Are those storage conditions monitored and documented?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.3	Does the company have policies or procedures that define the management and actions in response to storage condition excursions such as:			
2.3a	Investigation, root cause and CAPA for excursion?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.3b	Impact determination of excursion on stored items?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.3c	Notification to customers?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.4	Does the company distribute products via a third party?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.5	Are good distribution policies implemented?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.6	Are transport mechanisms dedicated?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.7	Does the company validate shipping methods?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.8	If answering 'not applicable' for any of the above, please elaborate:			

Additional Comments (please reference appropriate question number for any additional comments):

I certify that the information is correct and verifiable. Yes No

Title: Distribution Excellence Manager

Date: 11 July 2025

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

9. Warehouse and Distribution		Yes	No	N/A
9.1	What is the scope of the Molsheim Distribution?	A Global distribution hub serving all Life Science business units & all geographies. Average of 14,400 items in inventory & 800,000 order lines shipped per year		
9.2	How is it handled?	Logistics is operated by a Third-Party logistics supplier (3PL)		
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	Where is it located?	26,000 sqm dedicated to the company in Strasbourg, on a multi customers healthcare logistics campus		
9.7	What standards do you have in place?	The distribution team is part of the company ISO 9001 certification Third Party logistics supplier is ISO 9001, 13485 (Medical Devices), 14001, Good Distribution Practices (GDP) certified & specific authorizations & licenses: GMO, AEO, ABP. A TQA (Technical Quality Agreement) is signed between our company and Rhenus.		

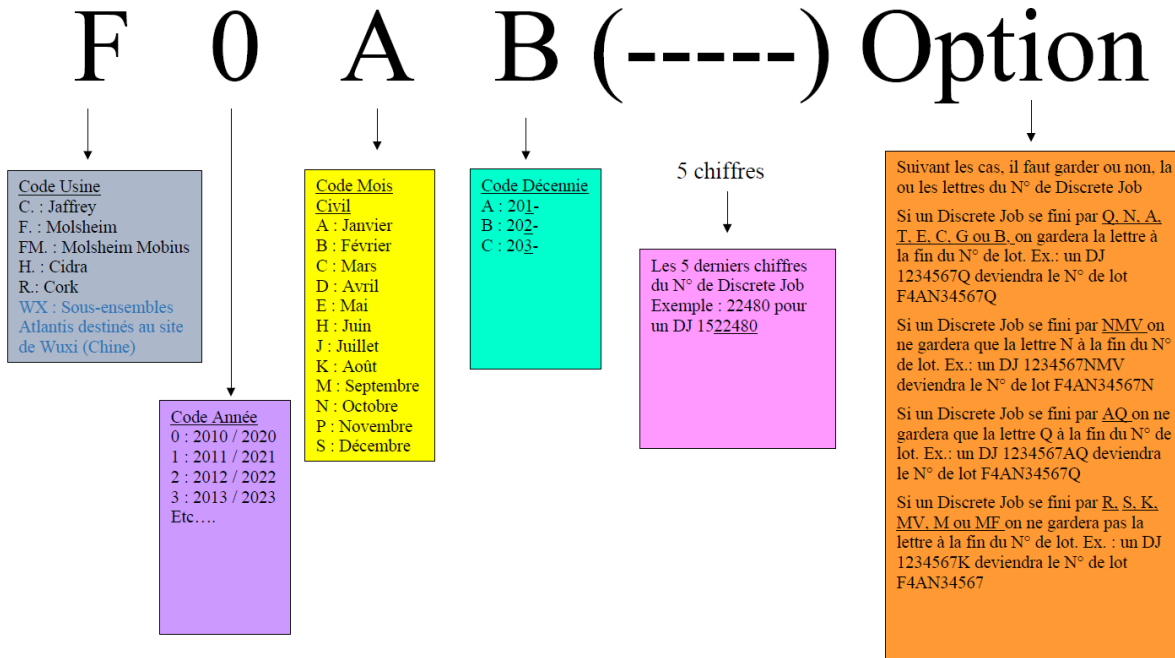
9.8	Do you have temperature-controlled areas?	We do have validated & temperature monitored storage areas, Ambient, 15-25°C, 2-8°C, -20°C, -80°C, -150°C & Liquid Nitrogen (-196°C)
9.9	Do you have alarms for temperature & hygrometry?	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
9.10	How do you manage your inventory?	Daily cycle count
9.11	Do you have validated packaging?	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <small>specific shipments</small>
9.12	How do you follow up your activity?	Daily operational follow up & monthly scorecards with management. One annual audit on site.

Additional Site-Specific Information

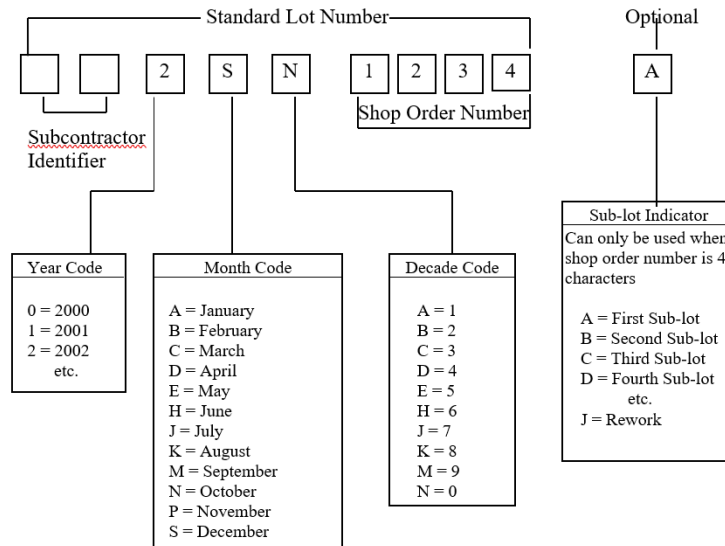
(not based on Rx 360 Supplier Assessment Questionnaire)

Lot numbering information

For standard products:



For LWS&I parts subcontracted:



For Novaseptum products:

The lot number has the format YYMMDD-PXN, where

- YY represents the two last digits of the current year,
- MM represents the month's ordinal number,
- DD represents the day when the production of this lot was initiated.
- P defines production site that manufactured
- X is a code that may be used for special lot's, the default value is X=0.
- N defines in which order production was started on the day in question N=1, when only one manufacturing run is initiated on the day in question.

For Contact plates and settle plates:

XXXXXX 6 numbers

Lot numbers are automatically assigned by the production system assuring full lot traceability. Numbering is assigned randomly, based on 6 digits derived from the job number system.

For Hycon contact slides and strips

XXXXXX 7 numbers

Lot numbers are automatically assigned by the production system assuring full lot traceability. Numbering is assigned randomly and corresponds to the job number system.

**Specific legal information for Molsheim plant-
important for French customers
(not based on Rx 360 Supplier Assessment Questionnaire)**

What is the SIRET code which is assigned to Molsheim Site by the “Institut national de la statistique et des études économiques (INSEE)”	434 691 192 00018
What is the SIREN code which is assigned to Molsheim Site by the “Institut national de la statistique et des études économiques (INSEE)”	434 691 192
What is the APE code (activité principale exercée), which is assigned by INSEE to any company and each of its establishments when it is registered in the SIRENE directory.	2829B