



Site Quality Self-Assessment

based on

Rx-360 Supplier Assessment Questionnaire

Module 4, Service Supplier Information

Relevant for

Lab Water Field Services locations in Western European countries

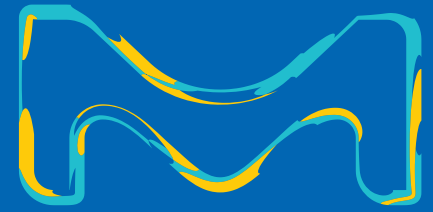
The site self-assessment covers our quality management system for the following activities:
installation, calibration, validation, repair and maintenance on Milli-Q® Lab Water Solutions Products



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 4. The contents of this questionnaire are built on the Rx-360 questionnaire 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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Please check here if additional documents are attached.

SECTION 1. Service Contact Information

1.1	Company and name of entity providing service: Lab Water Solutions Field Service organization working in Western European Countries
1.2	Phone: Please contact your Local Sales Representative/Technical Service
1.3	Email: Please contact your Local Sales Representative/Technical Service
1.4	Website: https://www.sigmaaldrich.com
1.5	Please provide specific contact(s) for requesting service groups or for obtaining additional information, including telephone number or e-mail, as applicable. Please contact your Local Sales Representative/Technical Service

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 checked="" 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 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)
<input checked="" type="checkbox"/> (15) Other (describe service): Lab Water Solutions Wated Purification System Services can include Installation and Preventive Maintenance	

SECTION 3. General Site Operating Information

3.1 Please provide the address and the site providing the services listed in section 2:

Name of the site: Millipore SAS
 Street: 1 Rue Jacques Monod
 City, State: Guyancourt
 Postal Code: 78280
 Country: France

This questionnaire applies to the following sites as well (with site name, address):
 Merck Chemicals and Life Science GesmbH
 Rechte Wienzeile 225 /Tür 501 A-1120 Wien
 Austria

Merck Life Science BV
 Idefonse Vandammestraat 5/7B
 1560 Hoeilaart
 Belgium

Merck Life Science A/S
 Vandtaarnsvej 62 A
 2860 Soeborg
 Denmark

Merck Life Science OY
 Keilaranta 6
 02150 Espoo
 Finland

Merck Chemicals GmbH
 Frankfurterstraße 133
 64293 Darmstadt
 Germany

Merck Life Science Limited.
 Vale Road
 Y14 EK18 Arklow
 Ireland

Merck Life Science S.r.l.

	<p>Via Monte Rosa, 93 20149 Milano (MI) Italy</p> <p>Merck Life Science N.V. Haarlerbergweg 21A, 1101 CH Amsterdam Netherlands</p> <p>Merck Life Science AS Drammensveien 123 0277 Oslo Norway</p> <p>Merck Life Science S.L.U Sucursal em Portugal Edificio Duo Miraflores, Alameda Fernao Lopes, n(o) 12, 5(o) 1495-190 Alges Portugal</p> <p>Merck Life Science S.L.U. Calle Maria de Molina, 40 28006 Madrid Spain</p> <p>Merck Life Science AB Froesundaviks Alle 1 169 03 Solna Sweden</p> <p>Merck & Cie Weisshausmatte 6460 Altdorf Switzerland</p> <p>Merck Life Science UK Limited The Old Brickyard, New Road SP8 4XT Gillingham United Kingdom</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?</p> <p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Please list any requirements or restrictions: .</p>
3.6	<p>On a yearly basis, what is the frequency of customer or regulatory body audits?</p> <p><input checked="" type="checkbox"/> 0</p> <p><input type="checkbox"/> 1-3</p> <p><input type="checkbox"/> 4-9</p> <p><input type="checkbox"/> 10+</p>

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

SECTION 4. Service-Related Quality Management Systems

4.1	<p>What quality management system is utilized for the services provided?</p> <p><input checked="" type="checkbox"/> ISO 9001</p> <p><input type="checkbox"/> ISO 13485</p> <p><input type="checkbox"/> ICH Q7</p> <p><input type="checkbox"/> Other, please describe:</p>			
4.2	<p>Are the following certifications in place for the service supplier?</p> <p><input type="checkbox"/> ISO 17025 (testing and calibration laboratories)</p> <p><input type="checkbox"/> ISO 11137 (irradiation/sterilizations)</p> <p><input type="checkbox"/> ISO 17665-1 (moist heat sterilization)</p> <p><input type="checkbox"/> ISO 14001 (environmental management systems)</p> <p><input type="checkbox"/> ISO 45001 (occupational health and safety)</p> <p><input type="checkbox"/> ISO 50001 (energy management systems)</p> <p><input type="checkbox"/> Other, please describe:</p>			
4.3	<p>Do you outsource any of the activities related to the provided services?</p>	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
4.3a	<p>If yes, please list the outsourced activities:</p> <p>1. Services on Lab Water Solution Water Purification Systems</p> <p>2. N/A</p> <p>3. N/A</p> <p><input type="checkbox"/> Additional information attached.</p>			
4.3b	<p>Please check which of the following would occur should activities be outsourced (check all that apply)?</p> <p><input type="checkbox"/> Notify customers prior to any outsourcing of activities</p>			

	<input type="checkbox"/> Information would be noted on any supporting documentation <input checked="" type="checkbox"/> Other, please describe: Subcontractors are tracked and monitored internally including service performance <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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

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

4.1: ISO 9001 certification for the sites listed in 3.1. except Switzerland
4.3: If subcontractors are used for all or any portion of the services, Merck shall remain solely and fully responsible for compliance

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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input 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 type="checkbox"/> Audit (on-site, remote, Rx-360 or other 3 rd party audit program) <input checked="" 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? Case by case decision	
5.5	Is the following in place with suppliers/subcontractors?	<input type="checkbox"/> Quality Agreement <input type="checkbox"/> Confidentiality Disclosure Agreement <input checked="" type="checkbox"/> Services Agreement

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

5.5: A Services Agreement is not in place for all suppliers (case by case decision).

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 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)

All service personnel have formal ISO 9001:2015 training requirements. Service personnel going to GxP laboratory need to be trained according to customer's GxP procedures

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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.2c	General Facility Cleaning Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.2f	Preventative Maintenance Program/Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

7.2g	Pest Control Program	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.2k	Risk Assessment Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2l	Receiving Incoming Inspection	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.2dd	Can the company provide a plan upon request? OR provide a short description below: Business Continuity/Contingency Plan : are overseen by the accountable site, EHS and business management.			

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

"N/A" as services are sold and provided at customer site.

Quality:

Quality personnel: A Quality Manager oversees the Western Europe Field Service organization. Designated personnel manage deviation and complaint investigations, as well as the defined Corrective and Preventive Actions. Additional personnel are responsible for managing technicians' tools and calibrations at area level

- Change control: Western Europe Field Service applies the change control procedure

defined at the division level (Life Science). This procedure includes the process for assessing customer notification decision.

- Release of services: Services performed are documented in a service report emailed to the customer contact listed in the Customer Relationship Management Tool. Services are considered complete upon report delivery, and customers have five business days to formally dispute it by contacting technical support

- Documentation management: Original records are retained and archived as per internal GDP policy.

- Management of Field Service Engineers tools: Field Service applies a specific procedure that determines the needs for calibration as well as periodicity of calibration of the tools. Process is set-up to ensure Field Service Engineers always have calibrated tools. The calibration certificate of our instruments can be provided upon request.

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

Title: Head of Lab Water Solutions Sales and Field Service Western Europe

Date: October 13th, 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: See Section 3 General Site Operating Information - Service Supplier
1.2	Address: See Section 3 General Site Operating Information - Service Supplier GPS Coordinates (Map Coordinates/Longitude & Latitude): See Section 3 General Site Operating Information - Service Supplier
1.3	Phone: See Section 1. Service Contact Information - Service Supplier
1.4	Email: See Section 1. Service Contact Information - Service Supplier
1.5	Website: See Section 1. Service Contact Information - Service Supplier
1.6	<p>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):</p> <p>Quality: See Section 1. Service Contact Information - Service Supplier Technical Services: See Section 1. Service Contact Information - Service Supplier Commercial/Business/Sales: See Section 1. Service Contact Information - Service Supplier Primary Site Contact: See Section 1. Service Contact Information - Service Supplier</p>

SECTION 2. Validation Services

N/A

2.1	What types of validation services are offered? Please check all that apply. <ul style="list-style-type: none"> <input type="checkbox"/> Process <input type="checkbox"/> Method <input type="checkbox"/> Product <input checked="" type="checkbox"/> Equipment/Facilities <input type="checkbox"/> Cleaning <input type="checkbox"/> Packaging <input type="checkbox"/> Shipping/Transportation <input type="checkbox"/> Computer Software / Hardware / Systems <input type="checkbox"/> Other:
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2.2	Do you have a protocol for reviewing validation reports?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
2.3	Are there quality checks, review, and oversight for validation services?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.4	Is there a process for handling deviations during the execution of a validation project?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.5	Please list any regulatory or industry guidance documents used by company in developing validation protocol: USP Chapter <1058> on Analytical Instrument Qualification			

Additional Comments (please reference appropriate question number for any additional comments):
 General comments on our Validation services:

Field Service Engineer performing the service are trained on Validation Services.

History of changes are in Validation workbooks. Customer are not proactively notify in case of changes in validation workbooks.

SECTION 3. Qualification Services		<input type="checkbox"/> N/A		
3.1	What types of qualification services are offered? Please check all that apply. <input type="checkbox"/> Site acceptance test (SAT) <input checked="" type="checkbox"/> Installation Qualification (IQ) <input checked="" type="checkbox"/> Operating Qualification (OQ) <input checked="" type="checkbox"/> Process Qualification (PQ) <input type="checkbox"/> Network Qualification (NQ) <input type="checkbox"/> Other:			
3.2	Do you have a protocol for reviewing qualification reports?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3.3	Are there quality checks, review and oversight for qualification services?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3.4	Is there a process for handling deviations during the execution of qualification services?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3.5	For standard qualification protocol are you doing full testing? Comment: test performed according to the service sold	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
3.6	For custom qualification protocol are you doing full testing? Comment: only standard qualification is sold	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A

Additional Comments (please reference appropriate question number for any additional comments):
 3.2: Qualification Protocols are reviewed and approved by the author, a technical reviewer and the product manager in our quality documentation”

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

Title: Head of Lab Water Solutions Sales and Field Service Western Europe

Date: October 13th, 2025