



# Site Quality Self-Assessment

based on

## Rx-360 Supplier Assessment Questionnaire Module 4, Service Supplier

Relevant for

**Lab Water Field Services locations in  
Western European countries**

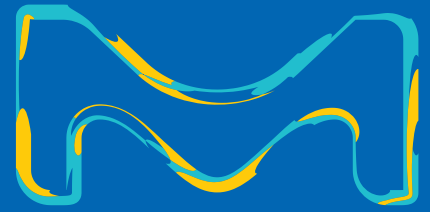
The site self-assessment covers our quality management system for the following applications:  
- installation, calibration, validation, repair and maintenance on Milli-Q® Lab Water Solutions Products



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 2.0 intact with no question added or deleted.

Rx-360's CEO/COO gave permission to Life Science to use the Rx-360 logo.



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## Rx-360 Supplier Assessment Questionnaire : Service Supplier

Please check here if additional documents are attached.

<b>SECTION 1. General Site Information</b>	
1.1	<p>Site or Facility-Specific Name: Lab Water Solutions Field Service organization working in Western European Countries</p>
1.2	<p>Address:</p> <p>Merck Chemicals and Life Science GesmbH Zimbagasse 5 1147 Wien Austria</p> <p>Merck Life Science BV Ildefonse Vandammestraat 5/7B 1560 Hoeilaart Belgium</p> <p>Merck Life Science A/S Vandtaarnsvej 62 A 2860 Soeborg Denmark</p> <p>Merck Life Science OY Keilaranta 6 02150 Espoo Finland</p> <p>Millipore SAS 1, rue Jacques Monod 78280 Guyancourt France</p>

Merck Chemicals GmbH  
Feldbergstr. 80  
64293 Darmstadt  
Germany

Merck Life Science Limited.  
Vale Road  
Y14 EK18 Arklow  
Ireland

Merck Life Science S.r.l.  
Via Monte Rosa, 93  
20149 Milano (MI)  
Italy

Merck Life Science N.V.  
Haarlerbergweg 21A,  
1101 CH Amsterdam  
Netherlands

Merck Life Science AS  
Drammensveien 123  
0277 Oslo  
Norway

Merck Life Science S.L.U Sucursal em Portugal  
Edificio Duo Miraflores, Alameda Fernao Lopes, 12 - 4(o)B  
1495-190 Alges  
Portugal

Merck Life Science S.L.U.  
Calle Maria de Molina, 40  
28006 Madrid  
Spain

Merck Life Science AB  
Froesundaviks Alle 1  
169 03 Solna  
Sweden

Merck & Cie  
Weisshausmatte  
6460 Altdorf  
Switzerland

	<p>Merck Life Science UK Limited  The Old Brickyard, New Road  SP8 4XT Gillingham  United Kingdom</p> <p>Location of Field service back office for United Kingdom:  Croxley Green Business Park Building 6  WD18 8YH Watford  United Kingdom</p> <p>GPS Coordinates (Map Coordinates/Longitude &amp; Latitude):</p>
1.3	<p>Phone:  please contact your Sales representative/technical services</p>
1.4	<p>Email:  please contact your local Sales representative</p>
1.5	<p>Fax:  please contact your local Sales representative</p>
1.6	<p>Website:  <a href="http://www.sigmaaldrich.com">www.sigmaaldrich.com</a></p>
1.7	<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 1.4</p> <p>Technical Services:  see 1.4</p> <p>Commercial/Business/Sales:  see 1.4</p> <p>Primary Site Contact:  see 1.4</p>

## SECTION 2. Service Specific

Does your service impact or involve any of the following categories? Please check all that apply and fill out the relevant submodule.

- Laboratoires
- Calibration Services
- Validation Services
- Engineering Services
- Sterilization Services
- Consultant Services
- Warehouse, Distribution
- Transportation Services

If the offered service is not listed above, please fill and check related sections and describe your service within “Other:” Installation, calibration, validation, repair and maintenance on Milli-Q® Lab Water Solutions Products

<b>Section 3. Quality Management System (QMS)</b>		
3.1	Does the QMS apply to the services provided at this site?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3.2	If no to question 3.1, please identify the relevant QMS: N/A	
3.3	Please identify the last audit of the Quality Management System by the appropriate body: certified sites see ISO 9001 IQ Net certificate on <a href="http://www.sigmaaldrich.com">www.sigmaaldrich.com</a>	
3.4	Does the company or any of its employees belong to the following organizations? <input type="checkbox"/> ASQ <input type="checkbox"/> ISPER <input checked="" type="checkbox"/> Rx-360 <input type="checkbox"/> PDA <input type="checkbox"/> Other	
3.4.a	Do employees or consultants for the company hold certifications from the organizations listed above or other industry organizations? <input type="checkbox"/> ASQ <input type="checkbox"/> ISPE <input type="checkbox"/> PDA <input checked="" type="checkbox"/> Other ISO 9001 certification for the sites in: France, Belgium, Netherlands, Spain, Italy, Portugal, Denmark, Norway, Finland and United Kingdom. ISO 9001 QMS is applied in all sites listed ISO certification is planned later for other sites	
3.5	Do you subcontract any of your activities to outside companies?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
3.5a	If yes, please list: <span style="float: right;"><input type="checkbox"/> See attached</span> 1. We reserve the right to periodically subcontract services to companies which have been qualified. 2. N/A 3. N/A	
3.5b	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 checked="" type="checkbox"/> Other upon request	

	<input type="checkbox"/> N/A (there would be no notification or way to tell of any outsourced activities)	
3.5c	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
3.5d	Is there a quality agreement in place with subcontractors?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
3.5e	How often are the subcontractors audited? case by case decision	
3.5f	Is there a confidentiality agreement in place?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3.5g	Is there a services agreement in place with the subcontractors?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
<b>Comments</b> <b>(Please reference appropriate question number for any additional comments)</b>		
<p>3.5 d: our external Field Service Engineers are included in our QMS as we manage our selection, trainings, evaluation and we keep governance of all processes</p> <p>3.5g: a service level agreement is not in place for all subcontractors (case by case decision).</p> <p>General comments:</p> <ul style="list-style-type: none"> <li>- Quality personnel: a Quality manager oversees the Western Europe Field Service organization. A Continuous Improvement Coordinator is appointed by region or big sites to oversee the deviation and complaint investigations as well as the Corrective and Preventive Actions defined. A Calibration Coordinator is appointed by region or big sites to oversee the management of technicians tools as well as calibration when applicable.</li> <li>- Change control: WEU Field Service applies the change control procedure defined at the division level (Life Science). This procedure includes the process for assessing customer notification decision. Field Service calibration procedure includes customer notification section in case of OOS.</li> <li>- Release of services: All services performed are described in a service report. The service report is systematically sent by email to the customer service contact documented in the Work Order. The service report can be signed by customer service contact and field service engineer at the end of the intervention. Services are considered as complete after service report delivery. Customer has 5 business days to formally contradict it by informing our technical support.</li> </ul>		



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

- Management of Field Service Engineers tools: WEU 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 – in case of deviation FSE follow our deviation process which ensure no impact on service quality.

The calibration certificate of our instruments can be provided upon request. Dedicated resources, calibration coordinators, are overseeing the management of calibration and are trained to verify calibration certificates.

### Section 4. Personnel, Training and Education

4.1	Do you have written job descriptions for all personnel?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
4.2	Do you maintain records of the training?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
4.3	Are your personnel aware that the products/services supplied are used for the manufacturing of active pharmaceutical ingredients?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
4.4	Does the Training Program in place have the following elements:			
4.4a	Formal Introduction to Regulatory Guidance (GMP, GDP, ISO, etc.)?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
4.4b	Periodic assessment of practical effectiveness?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
4.4c	Periodic refresher training programs for established employees?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

#### Comments

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

4.4a All service personnel have formal ISO 9001:2015 training requirements. Service personnel going to GMP laboratory need to be trained according to customer's GMP/GLP procedures

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

Date: September 23, 2022

Title: Head of Lab Water Solutions Field Service Western Europe

**Rx-360 Supplier Assessment Questionnaire**  
**Module 4 : Service Supplier**  
**Calibration Services Appendix**  
**Version 2.0**

Please check here if additional documents are attached.

<b>SECTION 1. General Site Information</b>	
1.1	Site or Facility-Specific Name: See Section 1 General Site Information: page 3 to page 5
1.2	Address:  GPS Coordinates (Map Coordinates/Longitude & Latitude):
1.3	Phone:
1.4	Email:
1.5	Fax:
1.6	Website:
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): Quality:  Technical Services:  Commercial/Business/Sales:  Primary Site Contact:

## Section 2. Calibration Service

N/A

<b>Section 2. Calibration Service</b>		<input type="checkbox"/> N/A	
<b>Examples of types of equipment your company calibrates:</b>			
<b>Resistivity/temperature meters built-in into Milli-Q® water purification systems</b>	<b>We provide TOC recalibrated boards for the TOC Monitor built-in into Milli-Q® water purification systems. it is considered out of the scope of this document</b>		
2.1	What type of calibrations do you perform? <input type="checkbox"/> In-House <input checked="" type="checkbox"/> Field <input type="checkbox"/> Both		
2.2	Prior to initiating calibration activities does the service supplier:		
2.2a	Determine the customer specified requirements including delivery and post-delivery activities?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	
2.2b	Determine the statutory and regulatory requirements for specified or intended use?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	
2.2c	Ensure that product requirements are defined and all differences related to customer requirements are resolved?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	
2.2d	Ensure that customer requirements are communicated to relevant personally conducting services, both initially and if there are any changes?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	
2.2e	Ensure that procedures are in place to ensure effective communication to customers regarding (select all that are relevant) <input checked="" type="checkbox"/> Product information <input checked="" type="checkbox"/> General inquiries		

	<input checked="" type="checkbox"/> Contracts <input checked="" type="checkbox"/> Orders <input type="checkbox"/> Customer complaints	
2.3	Is there an Out-of-Trend (OOT) Program in place?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.4	Is there a Risk Management program in place to address any Out-of-Trend (OOT) calibration artifacts found?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.5	Does the program include notification to the customer for Out-of-Trend (OOT) that may affect the customer process	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.6	Are calibration artifacts traceable to a recognized calibration source? (ex. NIST)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.6a	If so, which one? Traceable NIST resistors are used for the calibration of resistivity cells	
2.7	Does the site calibrate uncertainty data for the calculations provided?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.8	Are there quality checks, review and oversight for calibration services?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.9	What quality system standard do they follow?	<input checked="" type="checkbox"/> N/A
2.10	If the calibration service provider is part of an organization performing activities other than calibration, are the responsibilities of key personnel defined in order to identify potential conflicts of interest?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.11	Does the calibration service provider have policies and procedures that define actions to be taken if any of the testing calibration work or the results of the calibration do not confirm to internal procedures or the agreed requirements of a customer?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.12	Does the calibration service provider have policies and procedures that define the management and actions in response to <u>nonconforming work</u> such as:	
2.12 a	Halting of work?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

2.12b	Withholding of test reports and calibration certificates?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.12c	Determination of the significance of nonconforming results?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.12d	Immediate corrective action?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.12e	Determine acceptability?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.12f	Notification of customers?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.12g	Authorization of resuming work?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.13	<p>Does the calibration laboratory have policies and procedures concerning records such as? Please check all that apply.</p> <input checked="" type="checkbox"/> Identification <input type="checkbox"/> Collection <input type="checkbox"/> Indexing <input type="checkbox"/> Access <input type="checkbox"/> Filing <input type="checkbox"/> Storage <input checked="" type="checkbox"/> Maintenance and disposal of quality and technical records concerning calibration	
2.13a	Reports from internal audits and management reviews concerning calibration?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.13b	Corrective and preventive actions concerning calibration?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.13c	Calibration records stored and controlled in a secured area?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.13d	Protection and back-up records stored electronically?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.13e	Prevent unauthorized access to or amendment of records?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.13f	Direct recording of direct observations including “as found” and “as left”, actions taken, final calibration data, etc.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.13g	Retention of records of original observations, derived data and sufficient information in order to establish an audit trail? This includes	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

	calibration records, personnel records and copies of calibration certificates issued.	
2.13h	Independent review of records to ensure accuracy?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.14	Control of monitoring and measuring devices:	
2.14a	Are documented procedures in place to control, calibrate and maintain inspection, measuring and test equipment (including test software) that is used to demonstrate conformance to specified requirements?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.14b	Is measuring equipment calibrated or verified at specific intervals prior to use, using measurement standards traceable to international or national measurements standards?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.14c	Is measuring equipment identified to provide calibration status?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.14d	Is measuring equipment protected from damage and deterioration?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.14e	Is measuring equipment controlled to ensure adjustments are not made that could invalidate measurements results?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
2.14f	Are documented procedures in place requiring investigation and impact assessment when equipment is found to be out of calibration?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.14g	Are records of calibration for measuring and test equipment maintained?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.14h	Is the computer software used for monitoring and measurements of requirements verified prior to use and reconfirmed as necessary?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
<b>Comments</b>		
<b>(Please reference appropriate question number for any additional comments)</b>		
<p>General comments:</p> <p>- All answers provided concern the service of calibration of resistivity cells built into the water systems. For TOC monitors built into the water system, we provide off-the-shelf recalibrated board. As a result, TOC recalibrated boards are not taken into account in this document.</p> <p>Question 2.1: The Calibration service for resistivity/temperature meters is performed on the field.</p>		

Question 2.2: In the calibration procedure, there are instructions for Field Service Engineers on how to handle out-of-trend calibration when Field Service Engineers are at customer site.  
Question 2.5: The customer is informed that the calibration has failed via the certificate  
Question 2.8: The calibration includes a final verification of resistivity and temperature  
Question 2.13 and 2.13b: Information is kept in our Customer Relationship Management (CRM) system.

**Rx-360 Supplier Assessment Questionnaire**  
**Module 4 : Service Supplier**  
**Validation & Qualification Services Appendix**  
**Version 2.0**

Please check here if additional documents are attached.

<b>SECTION 1. General Site Information</b>	
1.1	Site or Facility-Specific Name: See Section 1 General Site Information: page 3 to page 5
1.2	Address:  GPS Coordinates (Map Coordinates/Longitude & Latitude):
1.3	Phone:
1.4	Email:
1.5	Fax:
1.6	Website:
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): Quality:  Technical Services:  Commercial/Business/Sales:  Primary Site Contact:

<b>Section 2. Validation &amp; Qualification Services</b>	<input type="checkbox"/> N/A
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2.1	<p>What types of validation services are offered? Please check all that apply.</p> <input type="checkbox"/> Process <input type="checkbox"/> Method <input type="checkbox"/> Product <input checked="" type="checkbox"/> Equipment/facilities <input type="checkbox"/> Packaging <input type="checkbox"/> Shipping/Transportation <input type="checkbox"/> Computer software / Hardware / Systems <input type="checkbox"/> Other	
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	<p>Please list any regulatory or industry guidance documents used by company in developing validation protocol:  USP Chapter &lt;1058&gt; on Analytical Instrument Qualification</p>	
<b>Comments</b> <b>(Please reference appropriate question number for any additional comments)</b>		
<p>Question 2.3: Our Qualification Protocols are reviewed and approved by the author, a technical reviewer and the product manager in our quality documentation systems  Question 2.4: Our Field Service Engineers follow a training dedicated to Validation. It includes instructions on how to handle deviations during the execution of a validation project</p> <p>General comments on our Validation services:  - We have implemented Good Documentation Management procedures and practices.  - We provide history of changes in our Validation workbooks. We do not proactively notify our customers in case of changes in our validation workbooks.  - We have a certifying training policy in place. We can provide training certification upon request.</p>		

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

Date: 23 September 2022

Title: Head of Milli-Q Lab Water Solutions Field Service Western Europe