



# Site Quality Self-Assessment

based on

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

Relevant for

**BioMonitoring Field Service Western Europe**  
**Millipore SAS**  
**39 ZI de la Hardt**  
**67120 Molsheim, France**

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

- Calibration, validation, consultant service at customer site and Molsheim Maintenance Center



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.



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.

## Rx-360 Supplier Assessment Questionnaire : Service Supplier

Please check here if additional documents are attached.

<b>SECTION 1. General Site Information</b>	
1.1	Site or Facility-Specific Name: Field Services organization for Biomonitoring working in Western European countries
1.2	Address: Millipore SAS 39 ZI de la Hardt 67120 Molsheim, France  GPS Coordinates (Map Coordinates/Longitude & Latitude): 48.541840, 7.531790
1.3	Phone: please contact your Sales representative / Commercial service
1.4	Email: please contact your local Sales representative / Commercial service
1.5	Fax: please contact your local Sales representative / Commercial service
1.6	Website: <a href="http://www.sigmaaldrich.com">www.sigmaaldrich.com</a>
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: see 1.4 Technical Services: see 1.4 Commercial/Business/Sales: see 1.4 Primary Site Contact:

see 1.4
---------

## 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 (IQ/OQ), PQ Consulting, Repair and Preventive Maintenance

<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 sigmaaldrich.com	
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 9001:2015 certification	
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 on site services to companies which are qualified. 2. 3.	
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 coordinator oversees the Western Europe Field Service organization. A Continuous Improvement Coordinator is appointed to oversee the deviation and complaint investigations as well as the Corrective and Preventive Actions defined. A Calibration Coordinator is appointed to oversee the management of technicians tools as well as calibration when applicable.</li> <li>- Release of services: All services performed are described in a service report. For on site services, 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. For services at the Molsheim Maintenance Center the service report is provided in the box with the instrument.</li> <li>- Documentation management: Original records are retained and archived as per internal GDP policy.</li> <li>- Management of calibration 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 and Molsheim Maintenance Center technicians always use calibrated tools – in case of deviation Field Service Engineer and Molsheim Maintenance Center technician follow our deviation process which ensure no</li> </ul>		

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.

<b>Section 4. Personnel, Training and Education</b>		
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input 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
<b>Comments</b>		
<b>(Please reference appropriate question number for any additional comments)</b>		
In addition to internal quality training our service personel can attend to GMP/GLP customer training		

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

Date: May 17th 2023

Title: Head of Field Service Western Europe