



# Site Quality Self-Assessment

based on

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

Relevant for

**Labwater Field Service North America**  
**400 Summit Drive, Burlington**  
**MA 01803, USA**

The site self-assessment covers our quality management system for the following applications:  
- Calibration, validation, installation, repair and maintenance service at customer site

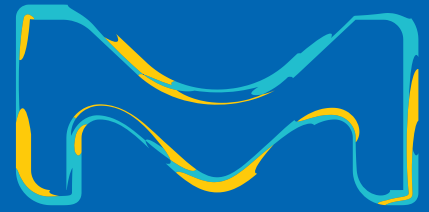


As a trusted partner of our customers, we deliver quality  
- always.

Merck KGaA, Darmstadt, Germany  
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EMD Millipore Corporation  
A subsidiary of Merck KGaA, Darmstadt, Germany  
400 Summit Drive Burlington,  
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## 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	Site or Facility-Specific Name: North America Lab Water Field Service
1.2	Address: 400 Summit Drive Burlington, MA 01803 USA  GPS Coordinates (Map Coordinates/Longitude & Latitude): 42.4733818 Latitude, -71.21596950000003 Longitude
1.3	Phone: Please contact MilliporeSigma Technical Service or your local sales representative 1-888-MILLIQ8 (645-5478)
1.4	Email: LabWaterServiceRequest@milliporesigma.com
1.5	Fax: N/A
1.6	Website: www.emdmillipore.com and www.sigmaaldrich.com
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: Zach Allen, zach.allen@milliporesigma.com Technical Services: See section 1.3 Commercial/Business/Sales: See section 1.4 Primary Site Contact:

Refer to quality contact listed above.

## 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, Preventive Maintenance, Calibration and Repair Services for Lab Water Systems

<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: DQS Inc., August 2020 for ISO 9001:2015	
3.4	Does the company or any of its employees belong to the following organizations? <input checked="" type="checkbox"/> ASQ <input type="checkbox"/> ISPER <input checked="" type="checkbox"/> Rx-360 <input checked="" 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 OSHA	
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 by our internal supplier management processes. 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 :Subcontractors are tracked, monitored internally <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? Dependent on annual categorization outcome of all suppliers including subcontractors.	
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>3.1 The MilliporeSigma location is the central headquarters for Lab Water Field Service North America Operations, however field service engineers work remotely across all North America onsite with customers.</p> <p>3.5d If MilliporeSigma subcontracts all or any portion of the services, MilliporeSigma shall remain solely and fully responsible for compliance.</p> <p>3.5g A service level agreement is not in place for all subcontractors (case by case decision).</p>		

#### 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 checked="" 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)**

4.3 Lab Water Systems provided and serviced by MilliporeSigma are used for a diverse range of applications including but not limited to research, food & beverage, clinical and pharmaceutical settings. Service Engineers are trained on awareness of critical lab water systems in support of customers. Customers/end users are responsible for communicating risk in regards to their individual applications to our service organization.

4.4a All service personnel have formal ISO 9001:2015 training requirements. Supplemental requirements to training according to GLP/ customer sites, evaluated case by case.

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

Date: 16 April 2021

Title: North America Field Service Quality Specialist