



# Site Quality Self-Assessment

based on

## Rx-360 Supplier Assessment Questionnaire Module 2, Site Specific Information

Relevant for

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

**An affiliate of Merck KGaA, Darmstadt, Germany**

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

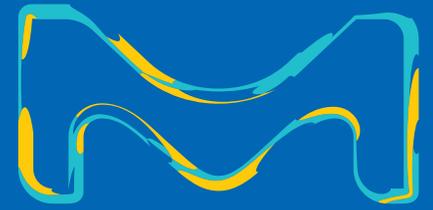
- Calibration, validation, installation, repair and maintenance service at customer site



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

Merck KGaA  
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 2. 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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64293 Darmstadt, Germany

The life science business of Merck KGaA,  
Darmstadt, Germany operates as  
MilliporeSigma in the U.S. and Canada.

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Please check here if additional documents are attached.

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### SECTION 1. General Site Information

1.1	Site or Facility-Specific Name: North America Lab Water Solutions Field Service
1.2	Address: 400 Summit Drive Burlington, MA 01803 USA  GPS Coordinates (Map Coordinates/Longitude & Latitude): 42.4733818 Latitude, -71.2159695 Longitude
1.3	Phone: Please contact MilliporeSigma Technical Service 1-888-MILLIQ8 (645-5478) or your local sales representative.
1.4	Email: LabWaterServiceRequest@milliporesigma.com
1.5	Fax: N/A
1.6	Website: 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.

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### 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.

- Laboratories  
 Calibration Services  
 Validation Services
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- 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:"

Lab Water Solutions system services can include Installation, Preventive Maintenance, Calibration and Repair.

### SECTION 3. Quality Management System (QMS)

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 to 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:			
3.4a	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:			
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: 1. Names of subcontractors used is confidential. 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  <input type="checkbox"/> See attached			
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: <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? 3 years but is dependent on outcome of annual categorization of all suppliers including subcontractors.			
3.5f	Is there a confidentiality agreement in place with the subcontractors?	<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

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

3.1 The MilliporeSigma Burlington, MA, USA location is the central headquarters for Lab Water Solutions Field Service North America Operations. However, field service engineers are located across North America, working at customer locations.

3.4.a Other: OSHA

3.5.b Other: Subcontractors are tracked and monitored internally including service performance.

3.5d If MilliporeSigma subcontracts all or any portion of the services, MilliporeSigma shall remain solely and fully responsible for compliance.

3.5g A service level agreement is not in place for all subcontractors (case by case decision).

**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
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**Additional 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

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

Title: North America Field Service Quality Specialist

Date: 07 May 2024

**Rx-360 Supplier Assessment Questionnaire**

Module 4: Service Supplier (Version 2.0)

Calibration Services Appendix

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<input checked="" 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 1 General Site Information
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:

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**SECTION 2. Calibration Service**

N/A

Examples of types of equipment your company calibrates:

Resistivity/temperature meters built-in into Milli-Q® Lab Water Solutions systems.

2.1	What type of calibrations do you perform? <input type="checkbox"/> In-House <input checked="" type="checkbox"/> Field <input type="checkbox"/> Both
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**Rx-360 Supplier Assessment Questionnaire**

Module 4: Service Supplier (Version 2.0)

Calibration Services Appendix

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 internally 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 checked="" 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 checked="" type="checkbox"/> Yes <input 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? Service instruments used for calibration are traceable to NIST standards.	
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? ISO 9001:2015	<input 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 type="checkbox"/> No <input checked="" 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 checked="" type="checkbox"/> Yes <input 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:	
2.12a	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 checked="" type="checkbox"/> Yes <input 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

**Rx-360 Supplier Assessment Questionnaire**

Module 4: Service Supplier (Version 2.0)

Calibration Services Appendix

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	Does the calibration laboratory have policies and procedures concerning records such as? (Please check all that apply): <input checked="" type="checkbox"/> Identification <input type="checkbox"/> Collection <input type="checkbox"/> Indexing <input type="checkbox"/> Access <input checked="" type="checkbox"/> Filing <input checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.13b	Corrective and preventative 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 type="checkbox"/> No <input checked="" 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 checked="" type="checkbox"/> Yes <input 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 calibration records, personnel records and copies of calibration certificates issued.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.13h	Independent review of records to ensure accuracy?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input 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 checked="" type="checkbox"/> Yes <input 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

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

2.5: The customer is informed, at a minimum, that the calibration has failed via the certificate.

2.13 Calibration services provided are on-site and not part of a calibration laboratory. Record copies are retained in our Customer Relationship Management (CRM) system as originals remain with the customer.

**Rx-360 Supplier Assessment Questionnaire**

Module 4: Service Supplier (Version 2.0)

Calibration Services Appendix

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

Title: North America Field Service Quality Specialist

Date: 07 May 2024

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Please check here if additional documents are attached.

### SECTION 1. General Site Information

1.1	Site or Facility-Specific Name: See Section 1 General Site Information.
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. Validation & Qualification Services

N/A

2.1	What types of validation services are offered? Please check all that apply. <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
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**Rx-360 Supplier Assessment Questionnaire**

Module 4: Service Supplier (Version 2.0)

Validation & Qualification Services Appendix

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	<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	Please list any regulatory or industry guidance documents used by company in developing validation protocol: USP Chapter <1058> on Analytical Instrument Qualification. Development of validation protocols are not the responsibility of Lab Water Solutions Field Service.			

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

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

Title: North America Field Service Quality Specialist

Date: 07 May 2024

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