



# Site Quality Self-Assessment

based on

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

Relevant for

**North America Service Repair Center**  
**80 Ashby Road**  
**Bedford, MA 01730, USA**  
An affiliate of Merck KGaA, Darmstadt, Germany

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

- Calibration, repair and preventive maintenance service



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

Merck KGaA, Darmstadt, Germany  
Corporation with General Partners  
Frankfurter Str. 250  
64293 Darmstadt, Germany  
Phone +49 6151 72-0

Sigma-Aldrich Corporation  
A subsidiary of Merck KGaA, Darmstadt, Germany  
3050 Spruce Street  
St. Louis, MO 63103, USA  
Phone +1 (800) 521-8956 / +1 (314) 771-5765

EMD Millipore Corporation  
A subsidiary of Merck KGaA, Darmstadt, Germany  
400 Summit Drive Burlington,  
MA 01803, USA  
Phone +1 (781) 533-6000



## 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 Repair Center
1.2	Address: 80 Ashby Road Bedford, MA 01730 USA  GPS Coordinates (Map Coordinates/Longitude & Latitude): 42.4841446 N Latitude, 71.2699192 W Longitude
1.3	Phone: +1 800-645-5476, for all other inquires contact your local sales representative
1.4	Email: Please contact MilliporeSigma Technical Service or your local sales representative
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: Contact name can be disclosed by MilliporeSigma Technical Service Technical Services: See section 1.3 Commercial/Business/Sales: See section 1.4 Primary Site Contact: See section 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:" Preventive Maintenance & Repair Services

<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., September 8-10, 2021 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. 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 Processing summary of service with outsourced party provided in the Performance Report	

	<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 supplier 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>		
3.5.d If MilliporeSigma subcontracts all or any portion of the services, MilliporeSigma shall remain solely and fully responsible for compliance.		
3.5.g A service level agreement is not in place for all subcontractors (case by case decision).		

<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>				
4.4 All service personnel have formal ISO 9001:2015 training. Supplemental requirements to training for regulatory guidance are according to the customer's site, with the need evaluated on a case by case basis.				

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

Date: 08 November 2021

Title: North America Field Service Quality Specialist