



Validation Services Site Quality Self-Assessment

based on

Rx-360 Supplier Assessment Questionnaire

Module 2 (Site) and Module 4 (Service Supplier,
Laboratory Appendix)

Relevant for

EMD Millipore Corporation
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 regulated applications:

- laboratory testing, validation and compliance services



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 and 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 : Site-Specific Information

Please check here if additional documents are attached.

SECTION 1. General Site Information	
1.1	Site or Facility-Specific Name: Validation Services, North America
1.2	Address: EMD Millipore Corporation 400 Summit Drive Burlington, MA 01803 GPS Coordinates: 42.4733818 Latitude, -71.21596950000003 Longitude
1.3	Phone: +1 978-762-5100
1.4	Email: Please contact your local Sales representative
1.5	Fax: 781-533-3140
1.6	Website: http://www.emdmillipore.com

SECTION 2. General Site Operating Information	
2.1	What year did the site start operating? 1987
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) Laboratory Testing, Validation and Compliance Services
2.3	To which, if any, subdivision of the parent company does the site belong? Merck KGaA, Darmstadt, Germany

SECTION 2. General Site Operating Information

2.4	<p>Size of site (in sq. ft. or m.): Facility opened October 2017 Size of Facility 280,000 sq ft; Size of BSL2 laboratory area (square feet): 12,500</p>
2.5	<p>Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): Normal Schedule: Monday to Friday, 06:00 - 20:00</p>
2.6	<p>Total number of employees on site: Total Employees: 34 Laboratory: 20 Administrative/Other: 14</p>
2.7	<p>Total number of employees in Quality: 4</p>
2.8	<p>Total number of employees in Manufacturing: n/a</p>
2.9	<p>What quality management system is utilized on site?</p> <p> <input checked="" type="checkbox"/> ISO 9001 <input type="checkbox"/> ISO 13485 <input type="checkbox"/> 21 CFR Part 210/211 <input type="checkbox"/> 21 CFR Part 820 <input type="checkbox"/> European GMP, Eudralex Volume 4 Part I <input type="checkbox"/> European GMP, Eudralex Volume 4 Part II <input type="checkbox"/> ICH Q7 <input type="checkbox"/> HACCP <input type="checkbox"/> ISO 22000 <input type="checkbox"/> Other </p> <p>Please describe:</p> <p>Which Regulatory Initiatives does the site follow/comply with?</p> <p> <input type="checkbox"/> REACH <input type="checkbox"/> RoHs <input type="checkbox"/> Ca Prop. 65 <input type="checkbox"/> WEEE </p>

SECTION 2. General Site Operating Information	
2.10	Does the company/site have an export license? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.11	Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A If yes, please specify.
2.12	By whom is the site inspected (regulatory or third party) and list inspections within the last three years: DQS
2.13	How often, as an annual average, is the site audited by customers or third parties? Six audits per year
2.14	Has an Rx-360 audit been performed at this site? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Please also state the date of the audit if applicable. http://rx-360.org/audit-programs/
2.15	Are you willing to have Rx-360 conduct an audit on behalf of your customers according to the Rx-360 audit programs on your site? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
2.16	Are you willing to have your customers conduct audits on your site? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
2.17	Please list regulatory sanctions impacting the site within the last five years (i.e. warning letters, CEP suspension, import alerts, etc.): n/a
2.18	Does the site outsource any quality-related activity? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If answering yes, please specify the activities: ICP testing
2.19	Please check the supplier controls in place for this facility:
2.19a	Quality Agreements with Suppliers <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19b	Subcontractor Qualification/Audit Program <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

SECTION 2. General Site Operating Information				
2.19c	Periodic Review of Supplier Performance	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.19d	Supplier Feedback Program	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.19e	Approved Material Supplier List	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.19f	Approved Service Supplier List	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Additional comments:				

SECTION 3. Objectionable Materials on Site				
3.1	Does the site or production plant produce, process or store any of the following:	Yes	No	Not Applicable
3.1a	Beta-Lactam Antibiotics	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1b	Steroids and/or hormones	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1c	High potency compounds	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1d	Materials of animal origin/Biologics	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1e	Live virus or micro-organism	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1f	Allergens	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1g	Genetically Modified Organisms (GMO)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1h	Agrochemicals (Pesticides, Herbicides, Fungicides, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1i	Other (Please specify): Objectionable materials would only be those being sent to us by our customers to be used in testing. None of these are manufactured at this site. Pesticides are maintained and monitored through our Pest Control program for the facility.			

SECTION 4. Cross Contamination Control				
4.1	Are any of the following cross-contamination controls in place?	Yes	No	Not Applicable
4.1a	Dedicated Facilities	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1b	Access Controls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1c	Dedicated Personnel	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1d	Dedicated Gowning	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1e	Procedural Controls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1f	Other (please specify):			

Additional Comments:

SECTION 5. Site Operating Policies				
5.1	Does the site utilize the following written policies, programs, or procedures?			
Site Specific:		Yes	No	Not Applicable
5.1a	Environmental, Health, and Safety	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1b	Facility Environmental Control Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1c	General Facility Cleaning Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1d	Hygiene and Sterilization Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1e	Validated Equipment Cleaning Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1f	Preventative Maintenance Program/Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1g	Pest Control Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1h	Master Production Procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Quality:				
5.1i	Quality Control/Quality Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1j	Quality Manual	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1k	Periodic Product Quality Review	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1l	Master Validation Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1m	Risk Assessment Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1n	Supplier Approval Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1o	Monitoring and Review of Approved Suppliers	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1p	Mechanism to Reduce Testing	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1q	Receiving Incoming Inspection	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1r	Change Control Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1s	Document Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1t	Document Retention Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1u	Change Notification Procedures for Clients	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1v	Control of Nonconforming Material	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1w	Deviation/Investigation Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1x	Out of Specification Policy and Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1y	Sampling Procedure/Sampling Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1z	Raw Material Retention Program	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1aa	CAPA Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1bb	Label Control and Accountability	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1cc	Product Release Procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1dd	Employee Training Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ee	Stability, Expiration, and Shelf-Life Program	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1ff	Product Retention Program	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1gg	Recall Procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

5.1hh	Customer Complaint Handling	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ii	Equipment validation/qualification procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SECTION 5. Site Operating Policies				
		Yes	No	Not Applicable
5.1jj	Internal audit/self-inspection program procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1kk	Site Security/Site Access Control Policies	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ll	New Hire Program/Induction Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Business Continuity/Contingency Plan:				
5.1mm	Disaster Recovery Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1nn	Pandemic Preparedness Plan	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.1oo	Supply Chain Emergency Preparedness Plan	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.1pp	Business Continuity/Contingency Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1qq	Can the company provide a plan upon request? OR provide a short description below:			

SECTION 6. Quality Assurance and Production				
		Yes	No	Not Applicable
6.1	Does the site have an independent and defined Quality Assurance/Quality Management Division?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2	Does QA/QM have authority over the following:			
6.2a	Policies and procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2b	Review of documentation for release?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2c	Release or rejection of incoming materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.3	Does QA/QM investigate and resolve quality complaints?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.4	Does QA/QM investigate and resolve internal deviations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.5	Does the QA/QM have the authority to assign a disposition to materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.6	Does the QA/QM review manufacturing and testing records prior to release?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.7	Does the facility utilize computerized systems for managing GxP activities or data?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.8	Are relevant computerized systems 21 CFR part 11 and EU GMP annex 11 compliant?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.9	Does the site use statistical methods for consistency and uniformity?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.10	Does the site use controlled documents for following and recording manufacturing instructions?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

SECTION 6. Quality Assurance and Production				
		Yes	No	Not Applicable
6.11	Does the company qualify and/or validate manufacturing procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.12	Is any environmental monitoring conducted in production/finishing areas?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.13	Does the site supply BSE/TSE declarations?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.14	Does the site supply a declaration of Elemental Impurities?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.15	Are ICH Q3C(R4) solvents used in the manufacturing process of supplied materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.16	Are stability studies carried out according to ICH guidance?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.17	Are solvents and mother liquor reused/recycled?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.18	Does the site have a process water treatment system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.18a	Please check all that apply to the system: <input checked="" type="checkbox"/> City/potable water <input type="checkbox"/> Distilled water <input type="checkbox"/> Dionized water <input type="checkbox"/> Water for injection (WFI) <input checked="" type="checkbox"/> Reverse Osmosis <input type="checkbox"/> Clean steam <input checked="" type="checkbox"/> Ultra-filtrated water (purified water) <input type="checkbox"/> Other:			
6.19	Does the plant have a batch/lot system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.19a	Is the system traceable?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.19b	Is it unique?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.19c	Is batch/lot manufacturing continuous?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.19d	Is manufacturing batch by batch?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.20	Does the site perform on-plant audits prior to approving critical GxP suppliers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.21	Does the site audit critical GxP suppliers after initial approval?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.22	Does the site inspect incoming materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.23	Does the site test incoming materials to defined specifications?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.24	Does the site establish purchase specifications for raw materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.25	Is the equipment multi-use?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.26	Does the site qualify equipment installation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.27	Does the site qualify equipment operation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.28	Does the site qualify equipment performance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION 6. Quality Assurance and Production				
		Yes	No	Not Applicable
6.29	Are production critical use instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.30	Is rework allowed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.31	Is reprocessing allowed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.32	Are manufacturing and packaging activities traceable to the equipment, areas, and materials used?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.33	Are production materials handled and stored in a manner to prevent degradation, contamination and cross-contamination?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.34	If answering 'not applicable' for any of the above, please elaborate: Testing performed is microbial retention, physical testing, and extractables and leachables related to Millipore devices			
Additional Comments:				

SECTION 7. Laboratory Procedures				
<input type="checkbox"/> N/A for this Site				
		Yes	No	Not Applicable
7.1	Does the site have standard procedures for sample handling/tracking?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1a	Does the site have standard procedures for retaining samples?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.1b	Does the site have standard procedures for re-testing samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2	Does the site have written and approved specifications and test methods?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.3	Are laboratory instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.4	Is there a standard procedure in place for analytical method development?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.5	Does the site qualify and/or validate analytical test procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.6	Does the site perform stability testing on materials and/or products?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.7	Are retention samples of key raw materials maintained?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.8	Are standards traceable to their preparation and reagents used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.9	Are retention samples of finished product maintained?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.10	Are shelf life/retest/expiration dates available and standardized?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.11	Does the company provide a certificate of analysis (CoA) and/or a Certificate of	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

SECTION 7. Laboratory Procedures		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
	Conformation/Compliance (CoC) for each lot or batch?			
7.12	Does the CoA/CoC contain the manufacture name and location?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.13	Does the CoA/CoC signed/e-signed by a Quality representative?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.14	If a repacker performs analyses, will the CoA reflect both the original manufacturing site data as well as the repacking site data?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.15	If answering 'not applicable' for any of the above, please elaborate: Testing performed is microbial retention, physical testing, and extractables and leachables related to Millipore devices; the Validation Services site does not manufacture anything that would require a CoA or CoC			
7.16	Additional Comments:			

SECTION 8. Packaging, Storage, and Transport		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
8.1	Does the site have a validated or qualified labeling system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.2	Are batch production records retained and available?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.3	Are packaging and labeling areas separate from production?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.4	Are barcode readers in use and challenged regularly?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.5	Are vision systems in use?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.6	Is product ever packaged without a label being initially applied (i.e. bright stocking)?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.7	Do labels include shelf life/expiration dates?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.8	Do labels include lot/batch number?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.9	Do labels include requirements for storage conditions?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.10	Is tamper evident seal used for each container of supplied materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.11	Does the company use a First-In-First-Out or First-Expiration-First-Out system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.12	Does the company maintain appropriate storage conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.12a	Are those storage conditions monitored and documented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION 8. Packaging, Storage, and Transport		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
8.13	Does the site make available a description of storage and/or warehouse conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.14	Does the site distribute products via a third party?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.15	Are good distribution policies implemented?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.16	Are transport mechanisms dedicated?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.17	Does the company validate shipping method?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.18	Does the company validate packaging methods?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Additional Comments:				

Date:16th June 2023

Title:Quality Assurance Manager

**Rx-360 Supplier Assessment Questionnaire
Module 4 : Service Supplier**

**Rx-360 Supplier Assessment Questionnaire :
Service Supplier**

Please check here if additional documents are attached.

SECTION 1. General Site Information	
1.1	Site or Facility-Specific Name: Validation Services, North America
1.2	Address: EMD Millipore Corporation 400 Summit Drive Burlington, MA 01803 GPS Coordinates (Map Coordinates/Longitude & Latitude): 42.4733818 Latitude, -71.21596950000003 Longitude
1.3	Phone: (978) 762-5100
1.4	Email: n/a
1.5	Fax: 781-533-3140
1.6	Website: www.emdmillipore.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: Please contact your local Sales representative Technical Services: Please contact your local Sales representative Commercial/Business/Sales: Please contact your local Sales representative Primary Site Contact: n/a

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:”

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: ISO 9001:2015	
3.3	Please identify the last audit of the Quality Management System by the appropriate body: August 2020	
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 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 checked="" type="checkbox"/> ASQ <input type="checkbox"/> ISPE <input type="checkbox"/> PDA <input 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: <input type="checkbox"/> See attached 1. ICP testing 2. 3.	
3.5b	Please check which of the following would occur should activities be outsourced: (check all that apply) <input checked="" type="checkbox"/> Notify customers prior to any outsourcing of activities <input type="checkbox"/> Information would be noted on any supporting documentation <input 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3.5e	How often are the subcontractors audited? according to internal procedures	
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Comments (Please reference appropriate question number for any additional comments)		
Quality agreements and service agreements are in place with critical subcontractors as defined in internal procedures.		

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)		

Rx-360 Supplier Assessment Questionnaire
Module 4 : Service Supplier
Laboratory Appendix

Please check here if additional documents are attached.

SECTION 1. General Site Information	
1.1	Site or Facility-Specific Name: Validation Services, North America
1.2	Address: EMD Millipore Corporation 400 Summit Drive Burlington, MA 01803 GPS Coordinates (Map Coordinates/Longitude & Latitude): 42.4733818 Latitude, -71.21596950000003 Longitude
1.3	Phone: (978) 762-5100
1.4	Email: n/a
1.5	Fax: 781-533-3140
1.6	Website: www.emdmillipore.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: Please contact your local Sales representative Technical Services: Please contact your local Sales representative Commercial/Business/Sales: Please contact your local Sales representative Primary Site Contact: n/a

Section 2. Laboratories

N/A

2.1	Type of laboratory testing offered? <input checked="" type="checkbox"/> Chemical <input checked="" type="checkbox"/> Microbiological <input type="checkbox"/> Biological <input checked="" type="checkbox"/> Physical <input type="checkbox"/> Instrumental (e.g. ICP; AAS, LC-MS, HPLC, GC) <input type="checkbox"/> Virology <input type="checkbox"/> Other <input type="checkbox"/> See attached
2.2	Types of Services Offered? <input type="checkbox"/> Compendial (e.g. USP, EP, JP, ACS etc.) <input type="checkbox"/> Environmental <input type="checkbox"/> Stability testing <input checked="" type="checkbox"/> Other Laboratory testing, validation and compliance services <input type="checkbox"/> See attached
2.3	Are the following programs in place:
2.3a	Internal Audits <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.3b	Calibration <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.3c	OOS (Out-of-Specification) Procedure <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.3d	Preventive Maintenance <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.3e	GLP (Good Laboratory Practices) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
2.3f	GDP (Good Documentation Practices) <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.3g	Periodic Quality/Management Review Meeting <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.4	Does your laboratory use a LIMsSystem? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.5	Do you have a qualification program for instruments used in critical analytical testing? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

2.6	Does the company have a procedure that defines the need to requalify laboratory instruments based upon certain activities/changes?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.7	Does the company have a process for verification of the ability to conduct compendial tests?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.8	Does the company have a procedure for validating compendial methods that are modified by the company in order to ensure that all tests are still valid?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.9	Does the company have a procedure for method validation/method transfer for non-compendial methods?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.10	Does the site have standard procedures for sample handling?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.11	Does the site have standard procedures for retaining samples?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.12	Does the site have standard procedures for re-testing samples?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.13	Does the site have written and approved specifications and test methods?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.14	Are laboratory instruments calibrated regularly?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.15	Is there a standard procedure in place for analytical method development?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.16	Does the company qualify and/or validate analytical test procedures?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.17	Does the site perform stability testing on materials and/or products?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A

2.18	Are retention samples of key raw materials maintained?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.19	Are standards traceable to their preparation and reagents used?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.20	Are retention samples of finished product maintained?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.21	Are shelf life/retest/expiration dates available and standardized?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.22	Does the company provide a certificate of analysis (CoA) and/or a Certificate of Conformation/Compliance (CoC) for each lot or batch?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.23	Is the CoA/CoC signed/e-signed by a quality representative?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.24	Does the company have a procedure for notifying customers of preliminary OOS results?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.25	Does the company have a procedure for notifying customers of a confirmed OOS result?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.26	If answering 'not applicable' for any of the above, please elaborate: We are a non-manufacturing site. We provide filter testing service for customers.			
Comments				
(Please reference appropriate question number for any additional comments)				

Additional Site-Specific Information
Validation Services, North America
(not based on Rx 360 Supplier Assessment Questionnaire)

1. General Information

a) Site Information

1. How is access to facility controlled?	Badge access
2. SIC Code(s)	382698
3. DUNS Number	00-105-0152

b) Change Control

	Yes	No
1. Do you have a computerized Change Control process?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Does the Change Control Procedure include equipment, facilities, materials, utilities, documentation, and testing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are you willing to enter into a change notification commitment with customers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

c) Buildings/Utilities

	Yes	No
1. Do backup power systems exist for critical equipment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Is there a defined schedule for housekeeping in service areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Is there a floor plan for the lab?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

d) Equipment/Utilities

	Yes	No
1. Are environmental conditions controlled in locations where the environment can affect service operation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Have compressed air and vacuum systems been validated?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. Are the compressed air and vacuum systems monitored periodically?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Is the HVAC system monitored periodically?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Does the laboratory have HEPA filtered air, and are the filters on a defined frequency for testing/recertification?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

2. Quality Organization

a) General

	Yes	No
1. Is there an Organizational Chart available to customers during on-site audit?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Can the Quality Unit escalate quality issues outside operations to life science (LS) or Merck KGaA, Darmstadt Germany Quality Unit?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Do you have a validation master plan?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. How long are records of test results kept?	11 years	

3. Laboratory Controls

a) General

	Yes	No
1. Are there controls to avoid use of expired reagents and reference standards?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Are there controls to prevent the mix-up of controls, standards, and samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are there controls to prevent inadvertent use of rejected materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Does the laboratory have validated refrigerators, cold rooms and freezers for the storage of customer product and laboratory materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Is access to the material and sample storage area(s) limited to authorized personnel?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Are laboratory personnel notified in the event of a temperature excursion during non-business hours?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

b) Standards and Measuring & Testing Equipment (MTE)

	Yes	No
1. Are calibration standards and MTE kept in a secure area?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Is maintenance/calibration coordinated by an electronic system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are there systems to prevent inadvertent use of rejected standards and MTE?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Are storage areas for calibration standards and MTE restricted to authorized personnel?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Is there a procedure in place to notify customers of non-conforming standards?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

	Yes	No
6. Are there requirements for environmental conditions for the use of standards and MTE?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Are there controls in place to maintain defined environmental conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8. Is a 4:1 (TUR) uncertainty ratio between the standard and instrument calibrated maintained for all calibrations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9. Are standards and MTE labeled with a unique number?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10. Are standards and MTE labeled with calibration that contain the date calibrated and calibration due date?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

c) Traceability, Uncertainty and Calibration Methods

	Yes	No
1. To which standards organization is the instrumentation traceable?	NIST or manufacturer specification	
2. Is there an Out of Tolerance procedure?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are calibration labels placed on all equipment that is calibrated?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Are customers notified in the event of an OOT that impacts their testing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

I (Supplier) confirm that the information provided in this questionnaire is correct and can be verified.

Date: 16 Jun23

Title: Quality Assurance Manager