



# Site Quality Self-Assessment

based on

## Rx-360 Supplier Assessment Questionnaire

### Module 4, Service Supplier Information

Relevant for

**Merck Ltd.**

**YBP West Tower 2F, 134 Godo-cho, Hodogaya-ku,  
Yokohama, Japan 240-0005**

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

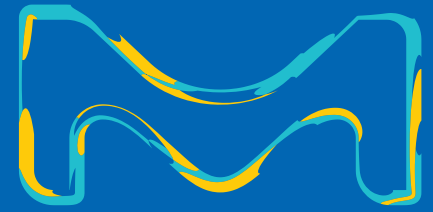
The site self-assessment covers our quality management system for the following activities:  
laboratory testing and validation services



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 4. The contents of this questionnaire are built on the Rx-360 questionnaire version 3.1 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.

Please check here if additional documents are attached.

### SECTION 1. Service Contact Information

1.1	Company and name of entity providing service: Merck Ltd., an affiliate of Merck KGaA, Darmstadt, Germany
1.2	Phone: Please contact your local Sales representative
1.3	Email: Please contact your local Sales representative
1.4	Website: <a href="https://www.sigmaaldrich.com/">https://www.sigmaaldrich.com/</a>
1.5	Please provide specific contact(s) for requesting service groups or for obtaining additional information, including telephone number or e-mail, as applicable. Please contact your local Sales representative

### SECTION 2. Service Specific

Please indicate the type of service(s) provided by selecting from the categories below. For categories marked by an asterisk (\*), please also complete the associated submodule.

Rx360 has developed these submodules for your convenience; please let us know if they serve your needs adequately ([info@rx-360.org](mailto:info@rx-360.org)).

<input checked="" type="checkbox"/> (1) Laboratory Services *	<input type="checkbox"/> (8) Sterilization Services *
<input type="checkbox"/> (2) Calibration Services *	<input type="checkbox"/> (9) Cleaning Services (Manufacturing, clean room, gowning/ laundry)
<input checked="" type="checkbox"/> (3) Validation and Qualification Services *	<input type="checkbox"/> (10) 3 <sup>rd</sup> Party Auditing Services
<input type="checkbox"/> (4) Engineering Services *	<input type="checkbox"/> (11) Pest Control
<input type="checkbox"/> (5) Consultant Services *	<input type="checkbox"/> (12) Disposal Services (Solvent, Product, Chemical)
<input type="checkbox"/> (6) Warehouse & Distribution *	<input type="checkbox"/> (13) Data Storage and Disposal (Electronic/Paper, Shredding, etc.)
<input type="checkbox"/> (7) Transportation Services *	<input type="checkbox"/> (14) Stability Services (outsourced stability storage and testing)

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(15) Other (describe service):

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### SECTION 3. General Site Operating Information

3.1	<p>Please provide the address and the site providing the services listed in section 2:</p> <p>Name of the site: Validation Services, Japan Street: YBP West Tower 2F, 134 Godo- cho, Hodogaya-ku City, State: Yokohama, Kanagawa Postal Code: 240-0005 Country: Japan</p> <p><input type="checkbox"/> This questionnaire applies to the following sites as well (with site name, address): N/A</p>
3.2	<p>Is the site registered with any government regulatory agency (FDA registration, etc.)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If yes, please specify:</p>
3.3	<p>Has the site been subjected to regulatory inspections? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>Please provide a list of inspections (regulatory agency and date of inspection) within the last three years:</p>
3.4	<p>Have there been any regulatory agency findings or refusals at the site in the last three years (i.e., warning letters, CEP suspension, import alerts, etc.)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If applicable, please provide details:</p> <p><input type="checkbox"/> Additional information attached.</p>
3.5	<p>Do you allow customer audits of your site? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Please list any requirements or restrictions:</p>
3.6	<p>On a yearly basis, what is the frequency of customer or regulatory body audits? <input type="checkbox"/> 0 <input checked="" type="checkbox"/> 1-3 <input type="checkbox"/> 4-9 <input type="checkbox"/> 10+</p>

**Comments (Please reference appropriate question number for any additional comments)**

N/A

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## SECTION 4. Service-Related Quality Management Systems

4.1	What quality management system is utilized for the services provided? <input checked="" type="checkbox"/> ISO 9001 <input type="checkbox"/> ISO 13485 <input type="checkbox"/> ICH Q7 <input type="checkbox"/> Other, please describe:	
4.2	Are the following certifications in place for the service supplier? <input type="checkbox"/> ISO 17025 (testing and calibration laboratories) <input type="checkbox"/> ISO 11137 (irradiation/sterilizations) <input type="checkbox"/> ISO 17665-1 (moist heat sterilization) <input checked="" type="checkbox"/> ISO 14001 (environmental management systems) <input type="checkbox"/> ISO 45001 (occupational health and safety) <input type="checkbox"/> ISO 50001 (energy management systems) <input type="checkbox"/> Other, please describe:	
4.3	Do you outsource any of the activities related to the provided services?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
4.3a	If yes, please list the outsourced activities: 1.        Extractables and leachables test 2. 3.  <input type="checkbox"/> Additional information attached.	
4.3b	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, please describe: <input type="checkbox"/> N/A (there would be no notification or way to tell any outsourced activities)	
4.3c	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

**Comments (Please reference appropriate question number for any additional comments)**

N/A

## SECTION 5. Supplier Qualification Management

The following questions concern risk based upon Supplier Qualification Program:

5.1	Do you have a Supplier Qualification program?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
5.2	Does this program include qualification of subcontractors for outsourced activities related to the provided services?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
5.3	Which of the following tools are part of the supplier/subcontractor qualification? <input checked="" type="checkbox"/> Questionnaire / Self-Assessment <input type="checkbox"/> Audit (on-site, remote, Rx-360 or other 3 <sup>rd</sup> party audit program) <input checked="" type="checkbox"/> Periodic Review of Supplier Performance <input type="checkbox"/> Supplier Feedback program <input type="checkbox"/> If other (e.g., established relationship), please provide description/justification:			
5.4	How often are the suppliers/subcontractors audited? Critical Suppliers must be audited once every 3 years.			
5.5	Is the following in place with suppliers/subcontractors? <input type="checkbox"/> Quality Agreement <input type="checkbox"/> Confidentiality Disclosure Agreement <input checked="" type="checkbox"/> Services Agreement			

**Comments (Please reference appropriate question number for any additional comments)**

N/A

## SECTION 6. Personnel, Training and Education

6.1	Do you have written job descriptions for personnel providing the services listed in section 2?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
6.2	Are your personnel aware of the appropriate quality level that the services supplied are used for?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
6.3	Do you have a formal Employee Training Program?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
6.4	Do you maintain records of the training?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
6.5	Does the Training Program in place have the following elements? <input checked="" type="checkbox"/> Formal Introduction to Regulatory Guidance (GMP, GDP, ISO, etc.) <input checked="" type="checkbox"/> Periodic assessment of practical effectiveness?			

Periodic refresher training programs for established employees?

**Comments (Please reference appropriate question number for any additional comments)**

N/A

### SECTION 7. Site Operating Policies

7.1	Please provide module 2 if available and skip this section 7. Otherwise, please complete below: <input type="checkbox"/> Module 2 attached.
7.2	Does the site utilize the following written policies, programs, or procedures?
<b>Site Specific:</b>	
	<b>Yes</b> <b>No</b> <b>Not Applicable</b>
7.2a	Environmental, Health and Safety <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2b	Facility Environmental Control Policy <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2c	General Facility Cleaning Procedures <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2d	Hygiene and Sterilization Procedures <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2e	Validated Equipment Cleaning Procedures <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2f	Preventative Maintenance Program/Procedures <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2g	Pest Control Program <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<b>Quality:</b>	
7.2h	Quality Control/Quality Management Policy <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2i	Periodic Service Quality Review <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2j	Master Validation Plan <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2k	Risk Assessment Program <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2l	Receiving Incoming Inspection <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2m	Change Control Procedures <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2n	Document Management Policy <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2o	Document Retention Policy <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2p	Change Notification Procedures for Clients <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2q	Deviation/Investigation Procedure <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2r	CAPA Procedure <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7.2s	Sampling Procedure/Sampling Plan <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
7.2t	Certificate of Analysis/Quality Control and Accountability <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

7.2u	Recall Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2v	Customer Complaint Handling	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2w	Equipment validation/qualification procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2x	Internal audit/self-inspection program procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2y	Site Security/Site Access Control Policies	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Business Continuity/Contingency Plan:**

7.2z	Business Continuity/Contingency Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2aa	Disaster Recovery Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2bb	Pandemic Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2cc	Supply Chain Emergency Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7.2dd	Can the company provide a plan upon request? OR provide a short description below: Yes			
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**Comments (Please reference appropriate question number for any additional comments)**

N/A

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

Title: Quality Manager

Date: January-08-2026

Please check here if additional documents are attached.

### SECTION 1. General Site Information

1.1	Site or Facility-Specific Name: Validation Services, Japan
1.2	Address: YBP West Tower 2F, 134 Godo- cho, Hodogaya-ku, Yokohama, Japan  GPS Coordinates (Map Coordinates/Longitude & Latitude): Lat, Long: 35.46113,139.57826
1.3	Phone: Please contact your local Sales representative
1.4	Email: Please contact your local Sales representative
1.5	Fax: Please contact your local Sales representative
1.6	Website: <a href="https://www.sigmaaldrich.com/">https://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: Technical Services: Commercial/Business/Sales: Primary Site Contact:  Please contact your local Sales representative

### SECTION 2. Laboratories

N/A

2.1	Type of laboratory testing offered? <input type="checkbox"/> Chemical <input checked="" type="checkbox"/> Microbiological <input type="checkbox"/> Biological <input checked="" type="checkbox"/> Physical
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	<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	Type 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	Preventative 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 LIMs System?	<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 checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input 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 type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.16	Does the company qualify and/or validate analytical test procedures?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.17	Does the site perform stability testing on materials and/or products?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" 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 type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" 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 Certification 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 checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input 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: Testing performed is microbial retention and physical testing related to Millipore devices. the Validation Services Japan site does not manufacture anything that would require a CoA or CoQ			

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

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

Title: Quality Assurance Manager

Date: January 08, 2026

<input 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: Validation Services Japan
1.2	Address: YBP West Tower 2F, 134 Godo- cho, Hodogaya-ku Yokohama, Kanagawa, 240-0005, Japan  GPS Coordinates (Map Coordinates/Longitude & Latitude): Lat, Long: 35.46113,139.57826
1.3	Phone: Please contact your local Sales representative
1.4	Email: Please contact your local Sales representative
1.5	Website: <a href="https://www.sigmaaldrich.com/">https://www.sigmaaldrich.com/</a> .
1.6	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: Please contact your local Sales representative

### SECTION 2. Validation 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"/> Cleaning <input type="checkbox"/> Packaging <input type="checkbox"/> Shipping/Transportation <input type="checkbox"/> Computer Software / Hardware / Systems <input type="checkbox"/> Other:
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2.2	Do you have a protocol for reviewing validation reports?	<input checked="" type="checkbox"/> Yes	<input 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: FDA Guidance for Industry. Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice. Sept 2004. European Guidelines to Good Manufacturing Practice, Volume 4 Medicinal Products for Human and Veterinary Use, ANNEX 1 Manufacture of Sterile Medicinal Products, Aug. 2022. Japanese Guidance on the Manufacture of Sterile Pharmaceutical Products by Aseptic Processing, April 2011. PDA Journal of Pharmaceutical Science & Technology. Evaluation of Recovery Filters for Use in Bacterial Retention Testing of Sterilizing-Grade Filters. Vol. 50, No. 3 / May-June 1996, p 147-153. PDA Journal of Pharmaceutical Science & Technology, Technical Report No. 26. Sterilizing Filtration of Liquids. 2008 Supplement, Volume 62 Number S-5. Aseptic processing of health care products – Part 2: sterilizing filtration, ISO 13408-2: 2018.			

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

<b>SECTION 3. Qualification Services</b>		<input type="checkbox"/> N/A		
3.1	What types of qualification services are offered? Please check all that apply. <input type="checkbox"/> Site acceptance test (SAT) <input type="checkbox"/> Installation Qualification (IQ) <input type="checkbox"/> Operating Qualification (OQ) <input type="checkbox"/> Process Qualification (PQ) <input type="checkbox"/> Network Qualification (NQ) <input checked="" type="checkbox"/> Other: N/A			
3.2	Do you have a protocol for reviewing qualification reports?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
3.3	Are there quality checks, review and oversight for qualification services?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
3.4	Is there a process for handling deviations during the execution of qualification services?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
3.5	For standard qualification protocol are you doing full testing?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
	Comment:			

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3.6	For custom qualification protocol are you doing full testing?  Comment:	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
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**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: Quality Manager

Date: January 08, 2026