



# Site Quality Self-Assessment

based on

## Rx-360 Supplier Assessment Questionnaire

### Module 4, Service Supplier Information

Relevant for

**Merck Life Science Pvt. Ltd.**  
**50A, 2nd Phase, Ring Road, Peenya**  
**560058, Bangalore India**  
An affiliate of Merck KGaA, Darmstadt, Germany

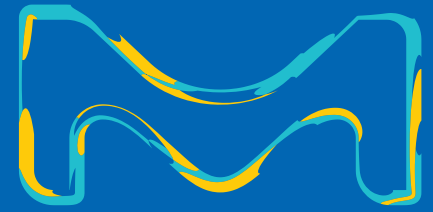
The site self-assessment covers our quality management system for the following activities:  
laboratory testing, validation and compliance services



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 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 Life Science Pvt. Ltd. (Formerly Millipore (India) Pvt. Ltd.) Validation Services, Bangalore, India.
1.2	Phone: +91-080-39596360 +91-080-39596350
1.3	Email: Please contact your local Sales representative
1.4	Website: www.sigmaaldrich.com
1.5	Please provide specific contact(s) for requesting service groups or for obtaining additional information, including telephone number or e-mail, as applicable.

### 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)
<input type="checkbox"/> (15) Other (describe service):	

### 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: Merck Life Science Pvt. Ltd. (Formerly Millipore (India) Pvt. Ltd.) An affiliate of Merck KGaA, Darmstadt, Germany</p> <p>Street: 50A, 2nd Phase, Ring Road, Peenya.</p> <p>City, State: Bangalore, Karnataka          Postal Code: 560058          Country: India</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:          N/A</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 type="checkbox"/> No <input checked="" type="checkbox"/> N/A</p> <p>If applicable, please provide details:  <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)**

## 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 checked="" 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.            Instrument calibration and qualification 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 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 checked="" 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)**

## 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 checked="" 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? 3 years			
5.5	Is the following in place with suppliers/subcontractors? <input checked="" 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)**

## 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?			

- Formal Introduction to Regulatory Guidance (GMP, GDP, ISO, etc.)
- 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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7.2t	Certificate of Analysis/Quality Control and Accountability	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.2u	Recall Procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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"/>
<b>Business Continuity/Contingency Plan:</b>				
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: Document# 20362168 LS Business Continuity Planning			

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

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

Title: Manager Quality, Validation Services

Date: 13 May 2025

**Rx-360 Supplier Assessment Questionnaire**

Module 4: Service Supplier (Version 3.0)

Laboratory Services Appendix (Version 3.0)

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**SECTION 1. General Site Information**

1.1	Site or Facility-Specific Name: Validation Services, Bangalore, India.
1.2	Address: Merck Life Science Pvt. Ltd. (Formerly Millipore (India) Pvt. Ltd.) 50A, 2nd Phase, Ring Road, Peenya. 560058- Bangalore, India An affiliate of Merck KGaA, Darmstadt, Germany  GPS Coordinates (Map Coordinates/Longitude & Latitude): Latitude: 13.028587; Longitude: 77.51925613
1.3	Phone: +91-080-39596360 +91-080-39596350
1.4	Email: Please contact your local Sales representative
1.5	Fax: +91-80-283-96345
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: 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: Please contact your local Sales representative

**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
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	<input checked="" 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 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 checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input 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 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: The Validation services site does not manufacture anything that would require a CoA or CoC			

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

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

Title: Manager Quality, Validation Services

Date: 13 May 2025

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### SECTION 1. General Site Information

1.1	Site or Facility-Specific Name: Validation Services, Bangalore, India.
1.2	Address: Merck Life Science Pvt. Ltd. (Formerly Millipore (India) Pvt. Ltd.) 50A, 2nd Phase, Ring Road, Peenya. 560058- Bangalore, India An affiliate of Merck KGaA, Darmstadt, Germany  GPS Coordinates (Map Coordinates/Longitude & Latitude): Latitude: 13.028587; Longitude: 77.51925613
1.3	Phone: +91-080-39596360 +91-080-39596350
1.4	Email: Please contact your local Sales representative
1.5	Fax: +91-80-283-96345
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: 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: Please contact your local Sales representative

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### SECTION 2. Validation & Qualification Services

N/A

2.1	What types of validation services are offered? Please check all that apply. <input checked="" type="checkbox"/> Process <input type="checkbox"/> Method
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	<input type="checkbox"/> Product <input type="checkbox"/> Equipment/Facilities <input type="checkbox"/> Packaging <input type="checkbox"/> Shipping/Transportation <input type="checkbox"/> Computer Software / Hardware / Systems <input type="checkbox"/> Other			
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: EMA European Guidelines to Good Manufacturing Practice, Volume 4 Medicinal Products for Human and Veterinary Use, ANNEX 1 Manufacture of Sterile Medicinal Products, Aug. 2022 FDA Guidance for Industry. Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice. Sept 2004 ISO Aseptic processing of health care products - Part 2: sterilizing filtration, ISO 13408-2: 2018 PDA Journal of Pharmaceutical Science & Technology. Evaluation of Recovery Filters For Use in Bacterial Retention Testing of Sterilizing-Grade Filters. Vol. 50, N° 3 / May-June 1996, p 147- PDA 153 PDA Journal of Pharmaceutical Science & Technology, Technical Report N° 26. Sterilizing Filtration of Liquids. 2008 Supplement, Volume 62 Number S-5 USP <1664> Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems USP <665> Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products USP <1665> Characterization and Qualification of Plastic Components and Systems used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products			

**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: Manager Quality, Validation Services

Date: 13 May 2025

## Additional Site-Specific Information Validation Services, Bangalore, India

### 1. General Information

#### a) Site Information

1. How is access to facility controlled?	Badge Access
2. SIC Code(s)	N/A
3. DUNS Number	N/A

#### b) 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"/>

#### c) 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 checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are the compressed air and vacuum systems monitored periodically?	<input type="checkbox"/>	<input checked="" 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. How long are records of test results kept?	Minimum 11 years	

### 3. Laboratory Controls

#### a) General

	Yes	No
1. 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"/>
2. Is access to the material and sample storage area(s) limited to authorized personnel?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. 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)**

	<b>Yes</b>	<b>No</b>
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"/>
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**

	<b>Yes</b>	<b>No</b>
1. To which standards organization is the instrumentation traceable?	NIST or NABL	
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: 13 May 2025

Title: Manager Quality, Validation Services