



# Site Quality Self-Assessment

based on

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

Relevant for

**Process Solution Field Service LATAM**  
**Rua Torre Eifel 100**  
**Parque Rincão, Cotia**  
**SP, 06705-481 , Brazil**

The site self-assessment covers our quality management system for the following applications:  
- Calibration, installation, repair and maintenance service at customer site



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

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

Sigma-Aldrich Corporation  
A subsidiary of Merck KGaA, Darmstadt, Germany  
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Phone +1 (800) 521-8956 / +1 (314) 771-5765

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



## Information

This document is based on the Rx-360 Consortium's Supplier Assessment Questionnaire template, Module 4. The contents of this questionnaire are built on the Rx-360 questionnaire version 2.0 intact with no question added or deleted.

Rx-360's CEO/COO gave permission to Life Science to use the Rx-360 logo.



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## Rx-360 Supplier Assessment Questionnaire : Service Supplier

Please check here if additional documents are attached.

<b>SECTION 1. General Site Information</b>	
1.1	<p>Site or Facility-Specific Name: Field Service organisation for Process Solutions Service in Brazil Merck S.A. - Brazil (An affiliate of Merck KGaA, Darmstadt, Germany)</p>
1.2	<p>Address: Rua Torre Eifel 100 Parque Rincão, Cotia SP, 06705-481 Brazil</p> <p>GPS Coordinates (Map Coordinates/Longitude &amp; Latitude): -23.595299680274383, 46.8829628626449</p>
1.3	<p>Phone: please contact your Sales representative / Commercial service</p>
1.4	<p>Email: please contact your local Sales representative / Commercial service</p>
1.5	<p>Fax: please contact your local Sales representative / Commercial service</p>
1.6	<p>Website: <a href="http://www.sigmaaldrich.com">www.sigmaaldrich.com</a></p>
1.7	<p>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):</p> <p>Quality: see 1.4</p> <p>Technical Services: see 1.4</p> <p>Commercial/Business/Sales: see 1.4</p>

	Primary Site Contact: see 1.4
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## SECTION 2. Service Specific

Does your service impact or involve any of the following categories? Please check all that apply and fill out the relevant submodule.

- 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:” Installation Services, Qualification Services (SAT IQ/OQ), support on PQ, Repair Services, Preventative Maintenance Services (PM).

<b>Section 3. Quality Management System (QMS)</b>		
3.1	Does the QMS apply to the services provided at this site?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3.2	If no to question 3.1, please identify the relevant QMS: N/A	
3.3	Please identify the last audit of the Quality Management System by the appropriate body:certified sites see ISO 9001 IQ Net certificate on SIAL.com	
3.4	Does the company or any of its employees belong to the following organizations? <input 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 type="checkbox"/> ASQ <input type="checkbox"/> ISPE <input type="checkbox"/> PDA <input checked="" type="checkbox"/> Other ISO 9001:2015 cite certification (PS field service is out of scope)	
3.5	Do you subcontract any of your activities to outside companies?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
3.5a	If yes, please list: <span style="float: right;"><input type="checkbox"/> See attached</span> 1. We reserve the right to periodically subcontract services to companies which have been qualified. 2. 3.	
3.5b	Please check which of the following would occur should activities be outsourced: (check all that apply)  <input type="checkbox"/> Notify customers prior to any outsourcing of activities <input type="checkbox"/> Information would be noted on any supporting documentation <input checked="" type="checkbox"/> Other upon request <input type="checkbox"/> N/A (there would be no notification or way to tell of any outsourced activities)	

3.5c	Does your company maintain a register/list of all subcontractors that are used for services?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3.5d	Is there a quality agreement in place with subcontractors?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
3.5e	How often are the subcontractors audited? case by case decision in function of the risk impact analyse	
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
<b>Comments</b> <b>(Please reference appropriate question number for any additional comments)</b>		
3.5d & 3.5g We have contracts in place with our sub-contractors that cover and define our expectations & requirements		

<b>Section 4. Personnel, Training and Education</b>		
4.1	Do you have written job descriptions for all personnel?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
4.2	Do you maintain records of the training?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
4.3	Are your personnel aware that the products/services supplied are used for the manufacturing of active pharmaceutical ingredients?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
4.4	Does the Training Program in place have the following elements:	
4.4a	Formal Introduction to Regulatory Guidance (GMP, GDP, ISO, etc.)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
4.4b	Periodic assessment of practical effectiveness?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
4.4c	Periodic refresher training programs for established employees?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
<b>Comments</b> <b>(Please reference appropriate question number for any additional comments)</b>		
4.4a Service personel going to GMP / GLP customers need to be trained according to customer's GMP/GLP procedures		

4.4c Refresher program is initial training content or mentoring after evaluation through the competency matrix document.

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

Date: March 31 2022

Title: Local PS-FS Quality Coordinator

**Additional - Specific Information  
PS-Field Service, all region excepted EMEA  
(not based on Rx 360 Supplier Assessment Questionnaire)**



## 1. General Information

### a) Site Information

1. How is access to facility controlled?	Badge access
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### b) Regulatory/Certification Information

Process Solution Field Service (PS FS) department only.	Yes	No
1. ISO 9001 Certified?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. ISO 14001 Certified?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. GMP or GLP certified?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

### c) 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"/>

### d) Buildings/Utilities

	Yes	No
1. Is there a defined schedule for housekeeping in service areas?	<input checked="" type="checkbox"/>	<input 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. Are there requirements for when retraining should be conducted?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. How long are records of test results kept?	11 years	



**Additional - Specific Information  
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### 3. Measuring Controls

#### a) Standards and Measuring & Testing Equipment (MTE)

	<b>Yes</b>	<b>No</b>
1. Is maintenance/calibration coordinated by an electronic system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Are there systems to prevent inadvertent use of rejected standards and MTE?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are storage areas for calibration standards and MTE restricted to authorized personnel?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Is there a procedure in place to notify customers of non-conforming standards?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Is a 4:1 (TUR) uncertainty ratio between the standard and instrument calibrated maintained for all calibrations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. If a 4:1 (TUR) uncertainty ratio cannot be maintained is the customer informed? Note: Yes. Information on Service executed Protocol signed by customer.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Are standards and MTE labeled with a unique number?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8. Are standards and MTE labeled with calibration that contain the date calibrated and calibration due date?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

#### b) Traceability, Uncertainty and Calibration Methods

	<b>Yes</b>	<b>No</b>
1. To which standards organization is the instrumentation traceable?	Example: Cofrac (France) or NIST (NA) or local specific country ISO17025 lab	
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"/>

### 4. General information's

	<b>Yes</b>	<b>No</b>
1. Scope for PS Field Services	<b>On PS equipment</b>	
a. Preventive maintenance	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Repairs activities	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. SAT Site Acceptance Test	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. IQ / OQ, PQ Support	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**Additional - Specific Information  
PS-Field Service, all region excepted EMEA  
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	<b>Yes</b>	<b>No</b>
2. Is there a job description available for service staff?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Are records of service staff qualifications and training held?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Do you have a procedure and / or training management system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Does the company use subcontractors to perform the service?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Does your company have a formal procedure for the approval, management of subcontractors?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Do subcontractors have written procedures for servicing of actual equipment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8. Do you audit / evaluate your subcontractors?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9. Is each item of reference equipment uniquely identified?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10. Is all reference equipment traceably calibrated?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
11. Do you have a procedure for qualification of reference equipment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
12. Do you have a procedure for scheduling services?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
13. Do you have indicators for measuring service delivery?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
14. Do you have a procedure for handling non-conformity?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
15. Are documented technical procedures, service protocol, or methods maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
16. Do the work reference specify the manner of recording results?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
17. Is a work reference required for service issued to all service staff?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
18. Are the required calibration / verification points defined in advance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
19. Are copies of reference equipment certificates provided?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
20. Do you have a process for handling repairs?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
21. Do you have regional capability for your engineers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
22. Do you deliver specific documentation when carrying out the services(s)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
23. Do you have a document archiving procedure?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
24. Do you have a list of recommended spare parts?	At demand	