



Site Quality Self-Assessment

based on

Rx-360 Supplier Assessment Questionnaire

Module 2, Site Specific Information

Relevant for

Process Solution Field Service LATAM

Via de Acesso Sul KM 30 Rodovia Anhanguera N°: KM 29,5 , Módulo B4 Galpão 01 ,Cajamar – SP – Brazil

An affiliate of Merck KGaA, Darmstadt, Germany

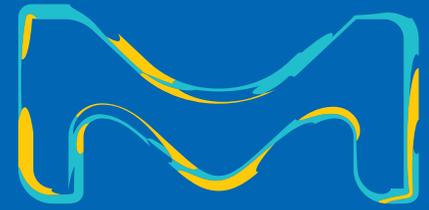
The site self-assessment covers our quality management system for the following applications:
- Calibration, installation, repair and maintenance service at customer site



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

Merck KGaA
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. 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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Please check here if additional documents are attached.

SECTION 1. General Site Information

1.1	Site or Facility-Specific Name: Field Service organization for Process Solutions Service in Brazil Merck S.A. - Brazil (An affiliate of Merck KGaA, Darmstadt, Germany)
1.2	Address: Via de Acesso Sul KM 30 Rodovia Anhanguera Nº: KM 29,5 Módulo B4 Galpão 01 Cajamar – SP – Brazil CEP: 07790-330 GPS Coordinates (Map Coordinates/Longitude & Latitude): 23°24'28.5"S 46°49'47.1"W
1.3	Phone: please contact your Sales representative / Commercial service
1.4	Email: please contact your Sales representative / Commercial service
1.5	Fax: please contact your Sales representative / Commercial service
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: see 1.4 Technical Services: see 1.4 Commercial/Business/Sales: see 1.4 Primary Site Contact: see 1.4

SECTION 2. Service Specific

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

- Laboratories
 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, Preventive Maintenance Services (PM).

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: 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 sigmaaldrich.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:			
3.4a	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:			
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: 1. We reserve the right to periodically subcontract services to companies which have been qualified. 2. 3. <input type="checkbox"/> See attached			
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: <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 with the subcontractors?	<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

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

3.4a: ISO 9001:2015 cite certification (PS field service is out of scope).

3.5b: Upon request

3.5d & 3.5g We have contracts in place with our sub-contractors that cover and define our expectations & requirements

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 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

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

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 trough the competency matrix document.

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

Title: Head of PS-FS Quality

Date: June 4th, 2024

**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	



3. Measuring Controls

a) Standards and Measuring & Testing Equipment (MTE)

	Yes	No
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

	Yes	No
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

	Yes	No
1. Scope for PS Field Services	On PS equipment	
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"/>

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	Yes	No
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	