Site Quality Self-Assessment

based on

Rx-360 Supplier Assessment Questionnaire

Module 4, Service Supplier

Relevant for

Process Solution Field Service Japan
DiverCity Tokyo Office Tower 15F
1-1-20 Aomi, Koto-ku
Tokyo, 135-0064, Japan

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

Rx 360 An International Pharmaceutical Supply Chain Consortium

Merck KGaA, Darmstadt, Germany is an active member of the Rx 360 Consortium.

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
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Sigma-Aldrich Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
3050 Spruce Street
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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.

SECTION 1. General Site Information	
1.1	Site or Facility-Specific Name: Field Service organisation for Process Solutions Service in Japan
1.2	Address: DiverCity Tokyo Office Tower 15F 1-1-20 Aomi, Koto-ku Tokyo, 135-0064, Japan GPS Coordinates (Map Coordinates/Longitude & Latitude): Latidude: 35.6185 Longitude:139.7817
1.3	Phone: please contact your Sales representative / Commercial service
1.4	Email: please contact your local Sales representative / Commercial service
1.5	Fax: please contact your local 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.

- ☐ 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).

Section 3. Quality Management System (QMS)		
3.1	Does the QMS apply to the services provided at this site?	☒ Yes ☐ No ☐ 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? ☐ ASQ ☐ ISPER ☒ Rx-360 ☐ PDA ☐ Other	
3.4.a	Do employees or consultants for the company hold certifications from the organizations listed above or other industry organizations? ☐ ASQ ☐ ISPE ☐ PDA ☒ Other ISO 9001:2015 cite certication (PS field service is out of scope)	
3.5	Do you subcontract any of your activities to outside companies?	☒ Yes ☐ No
3.5a	If yes, please list: ☐ See attached 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) ☐ Notify customers prior to any outsourcing of activities ☐ Information would be noted on any supporting documentation ☒ Other upon request ☐ 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?	☒ Yes ☐ No ☐ N/A
3.5d	Is there a quality agreement in place with subcontractors?	☐ Yes ☐ No ☒ 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?	☒ Yes ☐ No ☐ N/A
3.5g	Is there a services agreement in place with the subcontractors?	☒ Yes ☐ No ☐ N/A
Comments (Please reference appropriate question number for any additional comments)		
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?	☒ Yes	☐ No	☐ N/A
4.2	Do you maintain records of the training?	☒ Yes	☐ No	☐ N/A
4.3	Are your personnel aware that the products/services supplied are used for the manufacturing of active pharmaceutical ingredients?	☒ Yes	☐ No	☐ 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.)?	☒ Yes	☐ No	☐ N/A
4.4b	Periodic assessment of practical effectiveness?	☒ Yes	☐ No	☐ N/A
4.4c	Periodic refresher training programs for established employees?	☐ Yes	☐ No	☒ N/A
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 competancy 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

b) Regulatory/Certification Information

Process Solution Field Service (PS FS) department only.	Yes	No
1. ISO 9001 Certified?	☐	☒
2. ISO 14001 Certified?	☐	☒
3. GMP or GLP certified?	☐	☒

c) Change Control

	Yes	No
1. Do you have a computerized Change Control process?	☒	☐
2. Does the Change Control Procedure include equipment, facilities, materials, utilities, documentation, and testing?	☒	☐

d) Buildings/Utilities

	Yes	No
1. Is there a defined schedule for housekeeping in service areas?	☒	☐

2. Quality Organization

a) General

	Yes	No
1. Is there an Organizational Chart available to customers during on-site audit?	☒	☐
2. Can the Quality Unit escalate quality issues outside operations to life science (LS) or Merck KGaA, Darmstadt Germany Quality Unit?	☒	☐
3. Are there requirements for when retraining should be conducted?	☒	☐
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?	☒	☐
2. Are there systems to prevent inadvertent use of rejected standards and MTE?	☒	☐
3. Are storage areas for calibration standards and MTE restricted to authorized personnel?	☒	☐
4. Is there a procedure in place to notify customers of non-conforming standards?	☒	☐
5. Is a 4:1 (TUR) uncertainty ratio between the standard and instrument calibrated maintained for all calibrations?	☒	☐
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.	☒	☐
7. Are standards and MTE labeled with a unique number?	☒	☐
8. Are standards and MTE labeled with calibration that contain the date calibrated and calibration due date?	☒	☐

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?	☒	☐
3. Are calibration labels placed on all equipment that is calibrated?	☒	☐
4. Are customers notified in the event of an OOT that impacts their testing?	☒	☐

4. General information's

	Yes	No
1. Scope for PS Field Services	On PS equipment	
a. Preventive maintenance	☒	☐
b. Repairs activities	☒	☐
c. SAT Site Acceptance Test	☒	☐
d. IQ / OQ, PQ Support	☒	☐

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