

Site Quality Self-Assessment

based on

Rx-360 Supplier Assessment Questionnaire

Module 4, Service Supplier

Relevant for

Process Solution Field Service Shanghai, China

The site self-assessment covers our quality management system for the following applications:

- Calibration, installation, repair and maintenance service at customer site



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 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.

Self-Assessment PS Field Service China version 1.0



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

 \square 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 China
1.2	Address: 18F, No.3, Building C, The New Bund World Trade Center (Phase II), Lane 227 Dongyu Road, Shanghai, China, 200126 GPS Coordinates (Map Coordinates/Longitude & Latitude):
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.		
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?	Xes 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 brisk impact analyse	by case deci	sion in fund	ction of the
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?	Xes 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?	Xes Yes	🗌 No	N/A			
4.4	Does the Training Program in place have	the followin	g elements:				
4.4a	Formal Introduction to Regulatory Guidance (GMP, GDP, ISO, etc.)?	Yes Yes	🗌 No	□ N/A			
4.4b	Periodic assessment of practical effectiveness?	X Yes	🗌 No	N/A			
4.4c	Periodic refresher training programs for established employees?	The 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	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.	\square	Yes		No
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Date: July 27th 2023 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?		\square
2. ISO 14001 Certified?		\boxtimes
3. GMP or GLP certified?		\square

c) Change Control

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

d) Buildings/Utilities

	Yes	No
 Is there a defined schedule for housekeeping in service areas? 	\boxtimes	

2. Quality Organization

a) General

	Yes	Νο
 Is there an Organizational Chart available to customers during on-site audit? 		
 Can the Quality Unit escalate quality issues outside operations to life science (LS) or Merck KGaA, Darmstadt Germany Quality Unit? 	\boxtimes	
Are there requirements for when retraining should be conducted?		
4. How long are records of test results kept?	11 y	ears



3. Measuring Controls

a) Standards and Measuring & Testing Equipment (MTE)

	Yes	No
 Is maintenance/calibration coordinated by an electronic system? 	\square	
Are there systems to prevent inadvertent use of rejected standards and MTE?	\square	
Are storage areas for calibration standards and MTE restricted to authorized personnel?		
 Is there a procedure in place to notify customers of non- conforming standards? 	\square	
5. Is a 4:1 (TUR) uncertainty ratio between the standard and instrument calibrated maintained for all calibrations?	\boxtimes	
 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?	\boxtimes	
 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?	\square	
Are calibration labels placed on all equipment that is calibrated?		
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	\square	
b. Repairs activities	\square	
c. SAT Site Acceptance Test	\square	
d. IQ / OQ, PQ Support	\square	

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



	Yes	Νο
2. Is there a job description available for service staff?	\boxtimes	
3. Are records of service staff qualifications and training held?	\boxtimes	
4. Do you have a procedure and / or training management system?	\boxtimes	
5. Does the company use subcontractors to perform the service?	\boxtimes	
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?	\boxtimes	
8. Do you audit / evaluate your subcontractors?	\boxtimes	
9. Is each item of reference equipment uniquely identified?	\boxtimes	
10. Is all reference equipment traceably calibrated?	\boxtimes	
11. Do you have a procedure for qualification of reference equipment?	\boxtimes	
12. Do you have a procedure for scheduling services?	\boxtimes	
13. Do you have indicators for measuring service delivery?	\square	
14. Do you have a procedure for handling non-conformity?	\boxtimes	
15. Are documented technical procedures, service protocol, or methods maintained?	\boxtimes	
16. Do the work reference specify the manner of recording results?	\boxtimes	
17. Is a work reference required for service issued to all service staff?	\square	
18. Are the required calibration / verification points defined in advance?	\square	
19. Are copies of reference equipment certificates provided?	\square	
20. Do you have a process for handling repairs?	\square	
21. Do you have regional capability for your engineers?	\square	
22. Do you deliver specific documentation when carrying out the services(s)?		
23. Do you have a document archiving procedure?	\boxtimes	
24. Do you have a list of recommended spare parts?	At demand	