



Site Quality Self-Assessment

based on

Rx-360 Supplier Assessment Questionnaire

Module 4, Service Supplier Information

Relevant for

Azenta Life Sciences

3PL servicing Merck KGaA, Darmstadt, Germany

Im Leuschnerpark 1b, Griesheim, 6434, Germany

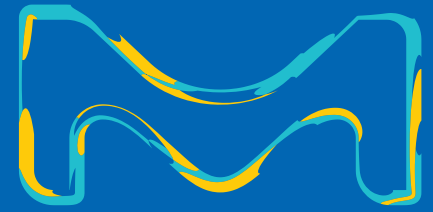
The site self-assessment covers our quality management system for the following activities: warehouse



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.



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Please check here if additional documents are attached.

SECTION 1. Service Contact Information

1.1	Company and name of entity providing service: Warehouse in Germany for Merck KGaA, Darmstadt, Germany Life Science products Site is 3rd Party Logistics service provider managed by Azenta Life Sciences Legal Entity Name: Azenta Germany GmbH. Entity/Location: Griesheim, Germany
1.2	Phone: Please contact your responsible Sales representative
1.3	Email: Please contact your responsible Sales representative
1.4	Website: https://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. N/A

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).

<input 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 type="checkbox"/> (3) Validation and Qualification Services *	<input type="checkbox"/> (10) 3 rd 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 checked="" 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: Azenta Germany GmbH Street: Im Leuschnerpark 1b City, State: Griesheim Postal Code: 64347 Country: Germany</p> <p><input type="checkbox"/> This questionnaire applies to the following sites as well (with site name, address):</p>
3.2	<p>Is the site registered with any government regulatory agency (FDA registration, etc.)? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If yes, please specify: US FDA (HCT/P), German AMG authorities, German Department of Health authorities (German Infection Protection Act, German Work Safety Regulation, German Biological Ordinance Regulation), German Genetic Engineering authorities, German Veterinary authorities, German GLP authorities. Scope always "Storage"</p>
3.3	<p>Has the site been subjected to regulatory inspections? <input checked="" type="checkbox"/> Yes <input 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: 2024: Luftfahrtbundesamt LBA, German AMG authorities 2023: RP Darmstadt – Federal GLP Inspectorate, Luftfahrtbundesamt LBA, RP Darmstadt – Federal Work Safety Department, RP Darmstadt – Federal Dangerous Goods & Work Safety Department</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 checked="" type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If applicable, please provide details: N/A</p> <p><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: Audits need to be announced. Timeline because of busy audit schedule at least 2 months up front. Shorter timelines only available if openings are available.</p>

3.6	On a yearly basis, what is the frequency of customer or regulatory body audits? <input type="checkbox"/> 0 <input type="checkbox"/> 1-3 <input type="checkbox"/> 4-9 <input checked="" type="checkbox"/> 10+
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Comments (Please reference appropriate question number for any additional comments)

Azenta Germany receives around 20-25 client audits per year. The global QMS system at all 9 biorepository storage locations receives around 100 audits (Onsite & Remote) + around 80 paper-based qualifications per year.

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 checked="" 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 type="checkbox"/> ISO 14001 (environmental management systems) <input 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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
4.3a	If yes, please list the outsourced activities: 1. N/A 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 checked="" 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 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)

4.1: Azenta QMS is ISO 9001:2015 and US CAP BAP program certified/accredited.

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 rd party audit program) <input checked="" type="checkbox"/> Periodic Review of Supplier Performance <input type="checkbox"/> Supplier Feedback program <input checked="" type="checkbox"/> If other (e.g., established relationship), please provide description/justification: SCAR program			
5.4	How often are the suppliers/subcontractors audited? Depending on the risk rating of the supplier every 2, 3 or 5 years.			
5.5	Is the following in place with suppliers/subcontractors? <input type="checkbox"/> Quality Agreement <input checked="" type="checkbox"/> Confidentiality Disclosure Agreement <input checked="" type="checkbox"/> Services Agreement			

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

5.5: Quality Agreement is in place for certain suppliers, but not all.

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? <input checked="" type="checkbox"/> Formal Introduction to Regulatory Guidance (GMP, GDP, ISO, etc.) <input checked="" type="checkbox"/> Periodic assessment of practical effectiveness? <input checked="" type="checkbox"/> Periodic refresher training programs for established employees?			

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

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?			
Site Specific:		Yes	No	Not Applicable
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"/>
Quality:				
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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input 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"/>
Business Continuity/Contingency Plan:				
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 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: The documents can be reviewed during an audit.			

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

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

Title: Senior Specialist - Global Regulatory Compliance

Date: 20. August 2025

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SECTION 1. General Site Information

1.1	Site or Facility-Specific Name: Warehouse in Germany for Merck KGaA, Darmstadt, Germany Life Science products Site is 3rd Party Logistics service provider managed by Azenta Life Sciences . Legal Entity name: Azenta Germany GmbH
1.2	Address: Im Leuschnerpark 1b, 64347 Griesheim, Germany GPS Coordinates (Map Coordinates/Longitude & Latitude): 49.86582389911172, 8.59073938066108 https://maps.app.goo.gl/Pu3Ybuh2Exxegg4q9
1.3	Phone: Please contact your responsible Sales representative
1.4	Email: Please contact your responsible Sales representative
1.5	Fax: N/A
1.6	Website: https://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: Technical Services: Commercial/Business/Sales: Please contact your responsible Sales representative Primary Site Contact:

SECTION 2. Warehousing, Distribution	<input type="checkbox"/> N/A
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2.1	Which of the following services are provided? (check all that apply) <input checked="" type="checkbox"/> Warehousing <input type="checkbox"/> Distribution <input type="checkbox"/> Transportation			
2.2	Does the company maintain specialized storage conditions?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.2a	Does the site make available a description of storage and/or warehouse conditions?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.2b	Are those storage conditions monitored and documented?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.3	Does the company have policies or procedures that define the management and actions in response to storage condition excursions such as: Yes. SOP in place defining certain alarm scenarios including temperature excursions and malfunctioning equipment scenarios. Each scenario for each storage temperature has an escalation plan defined.			
2.3a	Investigation, root cause and CAPA for excursion?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.3b	Impact determination of excursion on stored items?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.3c	Notification to customers?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.4	Does the company distribute products via a third party?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.5	Are good distribution policies implemented?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.6	Are transport mechanisms dedicated?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.7	Does the company validate shipping methods?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.8	If answering 'not applicable' for any of the above, please elaborate: 2.3b: Owner of the material/product is the client. Only the client has the required information available to determine the impact. 2.7: shipping methods are determined by the client. Azenta establishes the shipping methods following client instructions. Client Specific SOP in place.			

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

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

Title: Senior Specialist - Global Regulatory Compliance

Date: 20. August 2025