



# Site Quality Self-Assessment

based on

## Rx-360 Supplier Assessment Questionnaire Module 2, Site Specific Information

Relevant for

**Merck & Cie**  
**Weisshausmatte Industriegebiet**  
**Reuss, Zone N, CH-6460 Altdorf**  
An affiliate of Merck KGaA, Darmstadt, Germany

The site self-assessment covers our quality management system for the following regulated applications:  
- Manufacturing of biopharmaceutical process resins

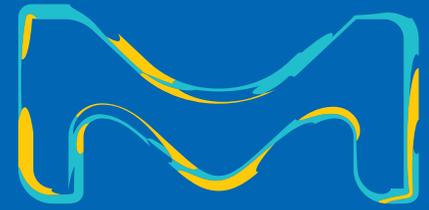
The site also processes GMP related products. For details, please refer to our GMP Quality Site Self-Assessment.



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.



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.

Please check here if additional documents are attached.

## SECTION 1. General Site Information

1.1	Site or Facility-Specific Name: Merck &Cie KmG, Altdorf An affiliate of Merck KGaA, Darmstadt, Germany
1.2	Address: Weishausmatte, Industriegebiet Reuss, Zone N, CH-6460 Altdorf GPS Coordinates: 46°52'01.3"N 8°38'00.0"E
1.3	Phone: +41 41 874 55 00
1.4	Email: Please contact your responsible Sales representative
1.5	Fax: +41 41 874 55 55
1.6	Website: sigmaaldrich.com

## SECTION 2. General Site Operating Information

2.1	What year did the site start operating? 1969
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) Manufacturing, packaging and release of Bioprocess Resins (BPR) Comment: Downsize filling of packaging sizes below 5 litre is done by Merck KGaA, Darmstadt, Germany Manufacturing, packaging and release of Active Pharmaceutical Ingredient (API) - for details see GMP Site Self-Assessment
2.3	To which, if any, subdivision of the parent company does the site belong? Life Science, which is a subdivison of Merck KGaA,Darmstadt, Germany
2.4	Size of site (in sq. ft. or m.): approx. 8500 m2
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): Office hours: 8.00 to 17.00 Monday to Friday Operating hours production: 5 days 3 shift modell from Sun 22.00 till Fr 21.00 Power Plant/Infra Structure: 24 h/ 7 days presence on site All other departments: Mon-Fri 7-12, 13-17

2.6	Total number of employees on site: 120
2.7	Total number of employees in Quality: 30
2.8	Total number of employees in Manufacturing: 45
2.9	<p>What quality management system is utilized on site?</p> <p><input checked="" type="checkbox"/> ISO 9001  <input type="checkbox"/> ISO 13485  <input type="checkbox"/> 21 CFR Part 210/211  <input type="checkbox"/> 21 CFR Part 820  <input type="checkbox"/> European GMP, Eudralex Volume 4 Part I  <input type="checkbox"/> European GMP, Eudralex Volume 4 Part II  <input type="checkbox"/> ICH Q7  <input type="checkbox"/> HACCP  <input type="checkbox"/> ISO 22000  <input checked="" type="checkbox"/> Other</p> <p>Please describe: internal QMS based on divisional quality marker requirement beyond ISO 9001</p> <p>Which Regulatory initiatives does the site follow/comply with?</p> <p><input checked="" type="checkbox"/> REACH  <input type="checkbox"/> RoHs  <input type="checkbox"/> Ca Prop. 65  <input type="checkbox"/> WEEE</p>
2.10	Does the company/site have an export license? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.11	<p>Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If yes, please specify.          Swissmedic registration No.: GMP-site 1002475 for the manufacturing of API</p>
2.12	<p>By whom is the site inspected (regulatory or third party) and list inspections within the last three years:</p> <p>Swissmedic/RFS March 2022 (API products)          HCS Halal Certification Service June 2022 (API products)          Blue Inspection Body GmbH (Rx-360) Sep 2022 (BPR products)          Russian Authority Jan 2023 (API products)          HCS Halal Certification Service June 2023 (API products)          Swissmedic/RFS March 2024 (API products)</p>
2.13	How often, as an annual average, is the site audited by customers or third parties? approx. 10
2.14	<p>Has an Rx-360 audit been performed at this site?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Please also state the date of the audit if applicable. 13-14 Sep 2022</p> <p><a href="#">Learn more about the Rx-360 Joint Audit Program® here.</a></p>
2.15	<p>Are you willing to have Rx-360 conduct an audit on behalf of your customers according to the Rx-360 audit programs on your site?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>

2.16	Are you willing to have your customers conduct audits on your site? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
2.17	Please list regulatory sanctions impacting the site within the last five years (i.e. warning letters, CEP suspension, import alerts, etc.): none
2.18	Does the site outsource any quality-related activity? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A  If answering yes, please specify the activities: - Maintenance & calibration of equipment - Microbial testing - Storage of stability samples - Special test procedures (e.g. particle size and ICP)
2.19	Please check the supplier controls in place for this facility:
2.19a	Quality Agreements with Suppliers <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19b	Subcontractor Qualification/Audit Program <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19c	Periodic Review of Supplier Performance <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19d	Supplier Feedback Program <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19e	Approved Material Supplier List <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19f	Approved Service Supplier List <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

**Additional comments:**

2.9.:Please note that the checks refer to non-GMP processing, manufacturing and release of Bioprocess Resins (BPR) only

The site also processes GMP products, please refer to GMP Site Self-Assessment.

**SECTION 3. Objectionable Materials On Site**

3.1	Does the site or production plant produce, process or store any of the following?	Yes	No	Not Applicable
3.1a	Beta-Lactam Antibiotics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1b	Steroids and/or hormones	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

3.1c	High potency compounds	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1d	Materials of animal origin/Biologics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1e	Live virus or micro-organism	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1f	Allergens	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1g	Genetically Modified Organisms (GMO)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1h	Agrochemicals (Pesticides, Herbicides, Fungicides, etc.)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1i	Other (Please specify):  API: The manufacturing of the Aminoglycoside Gentamicin Sulfate (manufactured in an isolated containment, as verified in various audits) was discontinued in 2023.			

**SECTION 4. Cross-Contamination Control**

4.1	Are any of the following cross-contamination controls in place?	Yes	No	Not Applicable
4.1a	Dedicated Facilities	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1b	Access Controls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1c	Dedicated Personnel	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4.1d	Dedicated Gowning	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1e	Procedural Controls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1f	Other (Please specify): n/a			

**Additional Comments:**

Access control is in place for the warehouse.

### SECTION 5. Site Operating Policies

SECTION 5. Site Operating Policies				
5.1	Does the site utilize the following written policies, programs or procedures?			
Site Specific:		Yes	No	Not Applicable
5.1a	Environmental, Health and Safety	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1b	Facility Environmental Control Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1c	General Facility Cleaning Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1d	Hygiene and Sterilization Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1e	Validated Equipment Cleaning Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1f	Preventative Maintenance Program/Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1g	Pest Control Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1h	Master Production Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality:				
5.1i	Quality Control/Quality Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1j	Quality Manual	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1k	Periodic Product Quality Review	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1l	Master Validation Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1m	Risk Assessment Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1n	Supplier Approval Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1o	Monitoring and Review of Approved Suppliers	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1p	Mechanism to Reduce Testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1q	Receiving Incoming Inspection	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1r	Change Control Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1s	Document Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1t	Document Retention Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1u	Change Notification Procedures for Clients	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1v	Control of Nonconforming Material	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1w	Deviation/Investigation Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1x	Out of Specification Policy and Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1y	Sampling Procedure/Sampling Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1z	Raw Material Retention Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1aa	CAPA Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1bb	Label Control and Accountability	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1cc	Product Release Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1dd	Employee Training Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5.1ee	Stability, Expiration, and Shelf-Life Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ff	Product Retention Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1gg	Recall Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1hh	Customer Complaint Handling	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ii	Equipment validation/qualification procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1jj	Internal audit/self-inspection program procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1kk	Site Security/Site Access Control Policies	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ll	New Hire Program/Induction Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Business Continuity/Contingency Plan:**

5.1mm	Disaster Recovery Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1nn	Pandemic Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1oo	Supply Chain Emergency Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1pp	Business Continuity/Contingency Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1qq	Can the company provide a plan upon request? OR provide a short description below:			

**Additional Comments:**

5.1qq: Disaster Recovery Plan by IT is in place. Business Continuity/Contingency Plan can be presented on an onsite audit or upon request.

**SECTION 6. Quality Assurance and Production**

		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
6.1	Does the site have an independent and defined Quality Assurance/Quality Management Division?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2	Does QA/QM have authority over the following:			
6.2a	Policies and procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2b	Review of documentation for release?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2c	Release or rejection of incoming materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.3	Does QA/QM investigate and resolve quality complaints?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.4	Does QA/QM investigate and resolve internal deviations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.5	Does QA/QM have the authority to assign a disposition to materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.6	Does QA/QM review manufacturing and testing records prior to release?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.7	Does the facility utilize computerized systems for managing GxP activities and data?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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6.8	Are relevant computerized systems 21 CFR part 11 and EU GMP annex 11 compliant?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.9	Does the site use statistical methods for consistency and uniformity?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.10	Does the site use controlled documents for following and recording manufacturing instructions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.11	Does the company qualify and/or validate manufacturing procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.12	Is any environmental monitoring conducted in production/finishing areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.13	Does the site supply BSE/TSE declarations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.14	Does the site supply a declaration of Elemental Impurities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.15	Are ICH Q3C solvents used in the manufacturing process of supplied materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.15a	If Yes, what class of solvent is used?			
6.16	Are stability studies carried out according to ICH guidance?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.17	Are solvents and mother liquor reused/recycled?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.18	Does the site have a process water treatment system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.18a	Please check all that apply to the system: <input checked="" type="checkbox"/> City/potable water <input type="checkbox"/> Distilled water <input checked="" type="checkbox"/> Dionized water <input type="checkbox"/> Water for injection (WFI) <input type="checkbox"/> Reverse Osmosis <input type="checkbox"/> Clean steam <input type="checkbox"/> Ultra-filtrated water (purified water) <input checked="" type="checkbox"/> Other: highly purified dionized water for analytical measurements			
6.19	Does the plant have a batch/lot system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19a	Is the system traceable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19b	Is it unique?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19c	Is batch/lot manufacturing continuous?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.19d	Is manufacturing batch by batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.20	Does the site perform on-plant audits prior to approving critical GxP suppliers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.21	Does the site audit critical GxP suppliers after initial approval?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.22	Does the site inspect incoming materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.23	Does the site test incoming materials to defined specifications?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.24	Does the site establish purchase specifications for raw materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.25	Is the equipment multi-use?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.26	Does the site qualify equipment installation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.27	Does the site qualify equipment operation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6.28	Does the site qualify equipment performance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.29	Are production critical use instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.30	Is rework allowed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.31	Is reprocessing allowed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.32	Are manufacturing and packaging activities traceable to the equipment, areas, and materials used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.33	Are production materials handled and stored in a manner to prevent degradation, contamination and cross-contamination?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.34	If answering 'not applicable' for any of the above, please elaborate:			

**Additional Comments:**

6.15a: ethanol residual solvent (class 3); 2-propanol residual solvent (class 3); acetone residual solvent (class 3)  
 6.30 Rework is basically allowed after approval of product management.

<b>SECTION 7. Laboratory Procedures</b>		<input type="checkbox"/> <b>N/A for this Site</b>		
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
7.1	Does the site have standard procedures for sample handling/tracking?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1a	Does the site have standard procedures for retaining samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1b	Does the site have standard procedures for retesting samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2	Does the site have written and approved specifications and test methods?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.3	Are laboratory instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.4	Is there a standard procedure in place for analytical method development?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.5	Does the site qualify and/or validate analytical test procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.6	Does the site perform stability testing on materials and/or products?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7.7	Are retention samples of key raw materials maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.8	Are standards traceable to their preparation and reagents used?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.9	Are retention samples of finished products maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.10	Are shelf life/retest/expiration dates available and standardized?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.11	Does the company provide a certificate of analysis (CoA) and/or a Certificate of Conformation/Compliance (CoC) for each lot or batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.12	Does the CoA/CoC contain the manufacture name and location?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7.13	Is the CoA/CoC signed/e-signed by a Quality representative?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.14	If a repacker performs analyses, will the CoA reflect both the original manufacturing site data as well as the repacking site data?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.15	If answering 'not applicable' for any of the above, please elaborate: 7.14 We do not have repacking sub-contractors who perform release testing. Downsize filling of bioprocess resins in smaller packaging sizes below 5 liter is performed at Merck KGA Darmstadt, Germany. Identity of resins is verified after downsize filling. This will not be reflected on the CoA.			

**Additional Comments:**

n/a

<b>SECTION 8. Packaging, Storage and Transport</b>		<input type="checkbox"/> N/A for this Site		
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
8.1	Does the site have a validated or qualified labeling system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.2	Are batch production records retained and available?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.3	Are packaging and labeling areas separate from production?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.4	Are barcode readers in use and challenged regularly?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.5	Are vision systems in use?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

8.6	Is product ever packaged without a label being initially applied (i.e. bright stocking)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.7	Do labels include shelf life/expiration dates?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.8	Do labels include lot/batch number?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.9	Do labels include requirements for storage conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.10	Is tamper evident seal used for each container of supplied materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.11	Does the company use a First-In-First-Out or First-Expiration-First-Out system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.12	Does the company maintain appropriate storage conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.12a	Are those storage conditions monitored and documented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.13	Does the site make available a description of storage and/or warehouse conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.14	Does the site distribute products via a third party?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.15	Are good distribution policies implemented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.16	Are transport mechanisms dedicated?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.17	Does the company validate shipping method?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.18	Does the company validate packaging methods?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Additional Comments:**

These entries refer to the 5 litre package size only. For other package sizes: please refer to the non-GMP site Self-Assessment Darmstadt, Germany

8.13 During an on-site audit. 8.14 Distribution only via distribution center Darmstadt 8.18 As part of manufacturing process qualification/validation

**I (Supplier) confirm that the information provided in this questionnaire is correct and can be verified.**

Title: Head of Quality Unit

Title: Responsible Person Bioprocess Resins

Date: 17. April 2024

**Additional Site-Specific Information**  
**(not based on Rx 360 Supplier Assessment Questionnaire)**

**9. Lot numbering information**

**E.g.: A12345678**

**letters = plant code**

**digits = running identification number the last two digits = last two digits of item number**

A lot is defined as a product volume produced during a fixed period of time or in dependence of the equipment used, respectively. The homogeneity is ensured by fulfilling the requirements defined in the SOP "Guidance for lot homogeneity".