# Site Quality Self-Assessment

based on

## Rx-360 Supplier Assessment Questionnaire

Module 2, Site Specific Information

Relevant for

**Merck & Cie KmG Schaffhausen**
**Im Laternenacker 5 CH-8200 Schaffhausen**
**Switzerland**
**An affiliate of Merck KGaA,Darmstadt, Germany**

The site self-assessment covers our quality management system for the following activities:
Manufacturing of APIs, Nutrition supplement ingredient and Excipients

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
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 3.0 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: Merck & Cie KmG, Schaffhausen,<br>An affiliate of Merck KGaA, Darmstadt, Germany |
| 1.2 | Address: m Laternenacker 5<br>CH-8200 Schaffhausen<br>Switzerland<br><br>GPS Coordinates: 47°42'07.8"N 8°38'51.9"E |
| 1.3 | Phone: +41 (0)52 6307 272 |
| 1.4 | Email: Please contact your local Sales representative |
| 1.5 | Fax: 41 (0)52 6307 255 |
| 1.6 | Website: www.sigmaaldrich.ch |

## SECTION 2. General Site Operating Information

| | |
|---|---|
| 2.1 | What year did the site start operating?<br>1952 |
| 2.2 | What is the primary activity of the site? (e.g. manufacturing, distribution, etc.)<br>Manufacturing of active pharmaceutical chemicals (including narcotics), dietary supplements, intermediates, drug delivery compounds,<br>Contract Manufacturing.<br>Please note: This questionnaire is answered with focus on routine production and does not mirror development products in early clinical phases. |
| 2.3 | To which, if any, subdivision of the parent company does the site belong?<br>Life Science business sector of Merck KGaA, Darmstadt, Germany |
| 2.4 | Size of site (in sq. ft. or m.): 11'265 m2 |
| 2.5 | Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable):<br>Office hours: 7.00 - 17.00 Monday to Friday<br>Operation hours production: 2 shift system (16/7), 6.00 - 22.00 Monday to Sunday |
| 2.6 | Total number of employees on site: approx. 255 |

| | |
|---|---|
| 2.7 | Total number of employees in Quality: approx. 80 |
| 2.8 | Total number of employees in Manufacturing: approx. 45 |
| 2.9 | What quality management system is utilized on site?<br>☐ ISO 9001<br>☐ ISO 13485<br>☐ 21 CFR Part 210/211<br>☐ 21 CFR Part 820<br>☐ European GMP, Eudralex Volume 4 Part I<br>☒ European GMP, Eudralex Volume 4 Part II<br>☒ ICH Q7<br>☐ HACCP<br>☐ ISO 22000<br>☐ Other<br>Please describe:<br><br>Which Regulatory initiatives does the site follow/comply with?<br>☒ REACH<br>☐ RoHs<br>☐ Ca Prop. 65<br>☐ WEEE |
| 2.10 | Does the company/site have an export license? ☒ Yes ☐ No ☐ N/A |
| 2.11 | Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)?<br>☒ Yes ☐ No ☐ N/A<br><br>If yes, please specify.<br>Swissmedic: 511206-102731044 for the manufacturing of API and Narcotics<br>FDA: FEI 3002806918<br>Japan: AG21500068<br><br>D-U-N-S: 48-552-8488 |
| 2.12 | By whom is the site inspected (regulatory or third party) and list inspections within the last three years:<br>Swissmedic: March 2025<br>Rabbinate Zurich (Kosher Certificate): February 2025<br>Halal Certification Services: July 2024<br>Rabbinate Zurich (Kosher Certificate): February 2024<br>Halal Certification Services: July 2023<br>Rabbinate Zurich (Kosher Certificate): May 2023<br>Swissmedic: March 2023<br>Halal Certification Services: July 2022<br>Rabbinate Zurich (Kosher Certificate): June 2022 |
| 2.13 | How often, as an annual average, is the site audited by customers or third parties?<br>approx. 13 |
| 2.14 | Has an Rx-360 audit been performed at this site?<br>☐ Yes ☒ No<br><br>Please also state the date of the audit if applicable. see comments for a comparable third party audit. |

| | |
|---|---|
| | Learn more about the Rx-360 Joint Audit Program® here. |
| 2.15 | 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?<br>☒ Yes ☐ No |
| 2.16 | Are you willing to have your customers conduct audits on your site?<br>☒ Yes ☐ 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?<br>☒ Yes ☐ No ☐ N/A<br><br>If answering yes, please specify the activities:<br>- Manufacture of the first intermediate for some Folates<br>- Analysis with ICP (e.g. platinum content, elemental impurities |
| 2.19 | Please check the supplier controls in place for this facility: |

| | | | | |
|---|---|---|---|---|
| 2.19a | Quality Agreements with Suppliers | ☒ Yes | ☐ No | ☐ N/A |
| 2.19b | Subcontractor Qualification/Audit Program | ☒ Yes | ☐ No | ☐ N/A |
| 2.19c | Periodic Review of Supplier Performance | ☒ Yes | ☐ No | ☐ N/A |
| 2.19d | Supplier Feedback Program | ☒ Yes | ☐ No | ☐ N/A |
| 2.19e | Approved Material Supplier List | ☒ Yes | ☐ No | ☐ N/A |
| 2.19f | Approved Service Supplier List | ☒ Yes | ☐ No | ☐ N/A |

**Additional comments:**

Qualifyze GmbH (www.qualifyze.com), April 2022 and April 2025

## 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 | ☐ | ☒ | ☐ |
| 3.1b | Steroids and/or hormones | ☐ | ☒ | ☐ |
| 3.1c | High potency compounds | ☐ | ☒ | ☐ |

| | | | | |
|---|---|---|---|---|
| 3.1d | Materials of animal origin/Biologics | ☒ | ☐ | ☐ |
| 3.1e | Live virus or micro-organism | ☐ | ☒ | ☐ |
| 3.1f | Allergens | ☐ | ☒ | ☐ |
| 3.1g | Genetically Modified Organisms (GMO) | ☐ | ☒ | ☐ |
| 3.1h | Agrochemicals (Pesticides, Herbicides, Fungicides, etc.) | ☐ | ☒ | ☐ |
| 3.1i | Other (Please specify): comment to 3.1d: If products of animal origin are processed, a certificate based on no. 1483 of the European Pharmacopoeia (current edition including supplements) is required. | | | |

## 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 | ☒ | ☒ | ☐ |
| 4.1b | Access Controls | ☒ | ☐ | ☐ |
| 4.1c | Dedicated Personnel | ☐ | ☒ | ☐ |
| 4.1d | Dedicated Gowning | ☐ | ☒ | ☐ |
| 4.1e | Procedural Controls | ☒ | ☐ | ☐ |
| 4.1f | Other (Please specify): N/A | | | |

**Additional Comments:**

to 4.1a: dedicated and multipurpose equipment is in place

## 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 | ☒ | ☐ | ☐ |
| 5.1b | Facility Environmental Control Policy | ☒ | ☐ | ☐ |
| 5.1c | General Facility Cleaning Procedures | ☒ | ☐ | ☐ |
| 5.1d | Hygiene and Sterilization Procedures | ☒ | ☐ | ☐ |
| 5.1e | Validated Equipment Cleaning Procedures | ☒ | ☐ | ☐ |
| 5.1f | Preventative Maintenance Program/Procedures | ☒ | ☐ | ☐ |
| 5.1g | Pest Control Program | ☒ | ☐ | ☐ |
| 5.1h | Master Production Procedure | ☒ | ☐ | ☐ |
| **Quality:** | | | | |
| 5.1i | Quality Control/Quality Management Policy | ☒ | ☐ | ☐ |
| 5.1j | Quality Manual | ☒ | ☐ | ☐ |
| 5.1k | Periodic Product Quality Review | ☒ | ☐ | ☐ |
| 5.1l | Master Validation Plan | ☒ | ☐ | ☐ |
| 5.1m | Risk Assessment Program | ☒ | ☐ | ☐ |
| 5.1n | Supplier Approval Procedure | ☒ | ☐ | ☐ |
| 5.1o | Monitoring and Review of Approved Suppliers | ☒ | ☐ | ☐ |
| 5.1p | Mechanism to Reduce Testing | ☒ | ☐ | ☐ |
| 5.1q | Receiving Incoming Inspection | ☒ | ☐ | ☐ |
| 5.1r | Change Control Procedures | ☒ | ☐ | ☐ |
| 5.1s | Document Management Policy | ☒ | ☐ | ☐ |
| 5.1t | Document Retention Policy | ☒ | ☐ | ☐ |
| 5.1u | Change Notification Procedures for Clients | ☒ | ☐ | ☐ |
| 5.1v | Control of Nonconforming Material | ☒ | ☐ | ☐ |
| 5.1w | Deviation/Investigation Procedure | ☒ | ☐ | ☐ |
| 5.1x | Out of Specification Policy and Procedure | ☒ | ☐ | ☐ |
| 5.1y | Sampling Procedure/Sampling Plan | ☒ | ☐ | ☐ |
| 5.1z | Raw Material Retention Program | ☒ | ☐ | ☐ |
| 5.1aa | CAPA Procedure | ☒ | ☐ | ☐ |
| 5.1bb | Label Control and Accountability | ☒ | ☐ | ☐ |
| 5.1cc | Product Release Procedure | ☒ | ☐ | ☐ |
| 5.1dd | Employee Training Program | ☒ | ☐ | ☐ |
| 5.1ee | Stability, Expiration, and Shelf-Life Program | ☒ | ☐ | ☐ |
| 5.1ff | Product Retention Program | ☒ | ☐ | ☐ |
| 5.1gg | Recall Procedure | ☒ | ☐ | ☐ |
| 5.1hh | Customer Complaint Handling | ☒ | ☐ | ☐ |

| | | | | |
|---|---|---|---|---|
| 5.1ii | Equipment validation/qualification procedure | ☒ | ☐ | ☐ |
| 5.1jj | Internal audit/self-inspection program procedure | ☒ | ☐ | ☐ |
| 5.1kk | Site Security/Site Access Control Policies | ☒ | ☐ | ☐ |
| 5.1ll | New Hire Program/Induction Program | ☒ | ☐ | ☐ |
| **Business Continuity/Contingency Plan:** | | | | |
| 5.1mm | Disaster Recovery Plan | ☒ | ☐ | ☐ |
| 5.1nn | Pandemic Preparedness Plan | ☒ | ☐ | ☐ |
| 5.1oo | Supply Chain Emergency Preparedness Plan | ☒ | ☐ | ☐ |
| 5.1pp | Business Continuity/Contingency Plan | ☒ | ☐ | ☐ |
| 5.1qq | Can the company provide a plan upon request? OR provide a short description below: Will be provided only on special request. | | | |

## SECTION 6. Quality Assurance and Production

| | | Yes | No | Not Applicable |
|---|---|---|---|---|
| 6.1 | Does the site have an independent and defined Quality Assurance/Quality Management Division? | ☒ | ☐ | ☐ |
| 6.2 | Does QA/QM have authority over the following: | | | |
| 6.2a | Policies and procedures? | ☒ | ☐ | ☐ |
| 6.2b | Review of documentation for release? | ☒ | ☐ | ☐ |
| 6.2c | Release or rejection of incoming materials? | ☒ | ☐ | ☐ |
| 6.3 | Does QA/QM investigate and resolve quality complaints? | ☒ | ☐ | ☐ |
| 6.4 | Does QA/QM investigate and resolve internal deviations? | ☒ | ☐ | ☐ |
| 6.5 | Does QA/QM have the authority to assign a disposition to materials? | ☒ | ☐ | ☐ |
| 6.6 | Does QA/QM review manufacturing and testing records prior to release? | ☒ | ☐ | ☐ |
| 6.7 | Does the facility utilize computerized systems for managing GxP activities and data? | ☒ | ☐ | ☐ |
| 6.8 | Are relevant computerized systems 21 CFR part 11 and EU GMP annex 11 compliant? | ☒ | ☐ | ☐ |
| 6.9 | Does the site use statistical methods for consistency and uniformity? | ☒ | ☐ | ☐ |

| | | | | |
|---|---|---|---|---|
| 6.10 | Does the site use controlled documents for following and recording manufacturing instructions? | ☒ | ☐ | ☐ |
| 6.11 | Does the company qualify and/or validate manufacturing procedures? | ☒ | ☐ | ☐ |
| 6.12 | Is any environmental monitoring conducted in production/finishing areas? | ☒ | ☐ | ☐ |
| 6.13 | Does the site supply BSE/TSE declarations? | ☒ | ☐ | ☐ |
| 6.14 | Does the site supply a declaration of Elemental Impurities? | ☒ | ☐ | ☐ |
| 6.15 | Are ICH Q3C solvents used in the manufacturing process of supplied materials? | ☒ | ☐ | ☐ |
| 6.15a | If Yes, what class of solvent is used? Detailed information are provided on the Certificate of Analysis. | | | |
| 6.16 | Are stability studies carried our according to ICH guidance? | ☒ | ☐ | ☐ |
| 6.17 | Are solvents and mother liquor reused/recycled? | ☒ | ☐ | ☐ |
| 6.18 | Does the site have a process water treatment system? | ☒ | ☐ | ☐ |
| 6.18a | Please check all that apply to the system:<br>☒ City/potable water<br>☐ Distilled water<br>☐ Dionized water<br>☐ Water for injection (WFI)<br>☐ Reverse Osmosis<br>☐ Clean steam<br>☐ Ultra-filtrated water (purified water)<br>☒ Other: Endotoxin controlled purified water. The water is produced by filtration, softener and reversed osmosis followed by electric deionsation. The water is stored permanently ozonized. | | | |
| 6.19 | Does the plant have a batch/lot system? | ☒ | ☐ | ☐ |
| 6.19a | Is the system traceable? | ☒ | ☐ | ☐ |
| 6.19b | Is it unique? | ☒ | ☐ | ☐ |
| 6.19c | Is batch/lot manufacturing continuous? | ☐ | ☒ | ☐ |
| 6.19d | Is manufacturing batch by batch? | ☒ | ☐ | ☐ |
| 6.20 | Does the site perform on-plant audits prior to approving critical GxP suppliers? | ☒ | ☐ | ☐ |
| 6.21 | Does the site audit critical GxP suppliers after initial approval? | ☒ | ☐ | ☐ |
| 6.22 | Does the site inspect incoming materials? | ☒ | ☐ | ☐ |
| 6.23 | Does the site test incoming materials to defined specifications? | ☒ | ☐ | ☐ |
| 6.24 | Does the site establish purchase specifications for raw materials? | ☒ | ☐ | ☐ |
| 6.25 | Is the equipment multi-use? | ☒ | ☐ | ☐ |
| 6.26 | Does the site qualify equipment installation? | ☒ | ☐ | ☐ |
| 6.27 | Does the site qualify equipment operation? | ☒ | ☐ | ☐ |
| 6.28 | Does the site qualify equipment performance? | ☒ | ☐ | ☐ |

| | | | | |
|---|---|---|---|---|
| 6.29 | Are production critical use instruments calibrated regularly? | ☒ | ☐ | ☐ |
| 6.30 | Is rework allowed? | ☐ | ☒ | ☐ |
| 6.31 | Is reprocessing allowed? | ☒ | ☐ | ☐ |
| 6.32 | Are manufacturing and packaging activities traceable to the equipment, areas, and materials used? | ☒ | ☐ | ☐ |
| 6.33 | Are production materials handled and stored in a manner to prevent degradation, contamination and cross-contamination? | ☒ | ☐ | ☐ |
| 6.34 | If answering 'not applicable' for any of the above, please elaborate: N/A | | | |

**Additional Comments:**

to 6.17: Formic acid is reused after destillation. The reuse is only once for max 4 batches of the same product in the same campaign.

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

| | | | | |
|---|---|---|---|---|
| 7.7 | Are retention samples of key raw materials maintained? | ☒ | ☐ | ☐ |
| 7.8 | Are standards traceable to their preparation and reagents used? | ☒ | ☐ | ☐ |
| 7.9 | Are retention samples of finished products maintained? | ☒ | ☐ | ☐ |
| 7.10 | Are shelf life/retest/expiration dates available and standardized? | ☒ | ☐ | ☐ |
| 7.11 | Does the company provide a certificate of analysis (CoA) and/or a Certificate of Conformation/Compliance (CoC) for each lot or batch? | ☒ | ☐ | ☐ |
| 7.12 | Does the CoA/CoC contain the manufacture name and location? | ☒ | ☐ | ☐ |
| 7.13 | Is the CoA/CoC signed/e-signed by a Quality representative? | ☒ | ☐ | ☐ |
| 7.14 | If a repacker performs analyses, will the CoA reflect both the original manufacturing site data as well as the repacking site data? | ☐ | ☐ | ☒ |
| 7.15 | If answering 'not applicable' for any of the above, please elaborate: 7.14: Our company does not have repacking sub-contractors who perform release testing | | | |

**Additional Comments:**

N/A

| SECTION 8. Packaging, Storage and Transport | | ☐ N/A for this Site | | |
|---|---|---|---|---|
| | | **Yes** | **No** | **Not Applicable** |
| 8.1 | Does the site have a validated or qualified labeling system? | ☒ | ☐ | ☐ |
| 8.2 | Are batch production records retained and available? | ☒ | ☐ | ☐ |
| 8.3 | Are packaging and labeling areas separate from production? | ☒ | ☐ | ☐ |
| 8.4 | Are barcode readers in use and challenged regularly? | ☒ | ☐ | ☐ |
| 8.5 | Are vision systems in use? | ☐ | ☒ | ☐ |
| 8.6 | Is product ever packaged without a label being initially applied (i.e. bright stocking)? | ☐ | ☒ | ☐ |
| 8.7 | Do labels include shelf life/expiration dates? | ☒ | ☐ | ☐ |

| | | | | |
|---|---|---|---|---|
| 8.8 | Do labels include lot/batch number? | ☒ | ☐ | ☐ |
| 8.9 | Do labels include requirements for storage conditions? | ☒ | ☐ | ☐ |
| 8.10 | Is tamper evident seal used for each container of supplied materials? | ☒ | ☐ | ☐ |
| 8.11 | Does the company use a First-In-First-Out or First-Expiration-First-Out system? | ☒ | ☐ | ☐ |
| 8.12 | Does the company maintain appropriate storage conditions? | ☒ | ☐ | ☐ |
| 8.12a | Are those storage conditions monitored and documented? | ☒ | ☐ | ☐ |
| 8.13 | Does the site make available a description of storage and/or warehouse conditions? | ☒ | ☐ | ☐ |
| 8.14 | Does the site distribute products via a third party? | ☐ | ☒ | ☐ |
| 8.15 | Are good distribution policies implemented? | ☒ | ☐ | ☐ |
| 8.16 | Are transport mechanisms dedicated? | ☐ | ☒ | ☐ |
| 8.17 | Does the company validate shipping method? | ☒ | ☐ | ☐ |
| 8.18 | Does the company validate packaging methods? | ☐ | ☒ | ☐ |

**Additional Comments:**

N/A

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

Title: Head of Quality Unit

Date: 03 April 2025

# Additional Site-Specific Information

# (not based on Rx 360 Supplier Assessment Questionnaire)

**9. Lot numbering information**

**Description of lot numbering system:**

ABCDXXXXYY
ABCD: Code for product
XXXX: Four digits for lot number (ongoing) YY: Portion number etc.