



Site Quality Self-Assessment

based on

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

Relevant for

**Merck Millipore Ltd. Tullagreen,
Carrigtwohill
T45 KD29 County Cork, Ireland**
An affiliate of Merck KGaA, Darmstadt, Germany

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

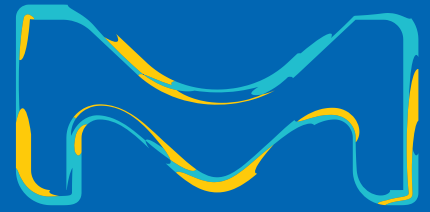
Manufacturing of medical devices, filtration products, chromatography adsorbents, immobilized enzymes and other ligands for modification and purification of biomolecules



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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Darmstadt, Germany operates as
MilliporeSigma in the U.S. and Canada.

Document Owned by [INSERT NAME]
Updated on [INSERT DATE]

SECTION 1. General Site Information

| | |
|-----|--|
| 1.1 | Site or Facility-Specific Name: Merck Millipore Ltd. An affiliate of Merck KGaA, Darmstadt, Germany |
| 1.2 | Address: Tullagreen, Carrigtwohill, Cork, Ireland T45 KD29 GPS Coordinates: Latitude: 51.9, Longitude: -8.28 |
| 1.3 | Phone: +3531890924645 |
| 1.4 | Email: iecustomerservice@millipore.com |
| 1.5 | Fax: +3531890924884 |
| 1.6 | Website: http://www.sigmaaldrich.com |

SECTION 2. General Site Operating Information

| | |
|-----|---|
| 2.1 | What year did the site start operating? 1988 |
| 2.2 | What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) Membrane and Device Manufacturing |
| 2.3 | To which, if any, subdivision of the parent company does the site belong? Life Science Division of Merck KGaA, Darmstadt, Germany |
| 2.4 | Size of site (in sq. ft. or m.): 224,965 sq.ft |
| 2.5 | Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): 08:30 - 17:00 GMT, holiday shut down and facility maintenance schedule is agreed annually |
| 2.6 | Total number of employees on site: approx. 740 |
| 2.7 | Total number of employees in Quality: approx. 90 |

| | |
|------|---|
| 2.8 | Total number of employees in Manufacturing: approx.520 |
| 2.9 | <p>What quality management system is utilized on site?</p> <input checked="" type="checkbox"/> ISO 9001 <input checked="" type="checkbox"/> ISO 13485 <input type="checkbox"/> 21 CFR Part 210/211 <input checked="" 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 type="checkbox"/> Other Please describe: |
| | <p>Which Regulatory initiatives does the site follow/comply with?</p> <input checked="" type="checkbox"/> REACH <input type="checkbox"/> RoHs <input type="checkbox"/> Ca Prop. 65 <input checked="" type="checkbox"/> WEEE |
| 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> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| | <p>If yes, please specify. FDA registration number: 8020892 HPRA Registration Number: IE/CA01/M/IV/0699</p> |
| 2.12 | By whom is the site inspected (regulatory or third party) and list inspections within the last three years: Annual GMED Notified Body inspection – ISO 13485, CE and MDSAP audits |
| 2.13 | How often, as an annual average, is the site audited by customers or third parties? approx. 12 |
| 2.14 | <p>Has an Rx-360 audit been performed at this site?</p> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |
| | <p>Please also state the date of the audit if applicable.</p> <p>Learn more about the Rx-360 Joint Audit Program® here.</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> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |
| 2.16 | <p>Are you willing to have your customers conduct audits on your site?</p> <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.): N/A |
| 2.18 | <p>Does the site outsource any quality-related activity?</p> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

| | | | | |
|-------|---|---|-----------------------------|------------------------------|
| | If answering yes, please specify the activities: Sterilization Service, Sterility Testing | | | |
| 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:

Supplier Controls are as per applicable site procedures

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 checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3.1e | Live virus or micro-organism | <input checked="" type="checkbox"/> | <input 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): 3.1e: microorganisms are only used in laboratory testing | | | |

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 checked="" type="checkbox"/> | <input 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): | | | |

Additional Comments:

SECTION 5. Site Operating Policies

| 5.1 | Does the site utilize the following written policies, programs or procedures? | Yes | No | Not Applicable |
|-----------------------|---|-------------------------------------|--------------------------|--------------------------|
| Site Specific: | | | | |
| 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: Available for review during onsite audits | | | |

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? | <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"/> |
| 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 type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.15 | Are ICH Q3C solvents used in the manufacturing process of supplied materials? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.15a | If Yes, what class of solvent is used? N/A | | | |
| 6.16 | Are stability studies carried out according to ICH guidance? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.17 | Are solvents and mother liquor reused/recycled? | <input checked="" type="checkbox"/> | <input 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 checked="" type="checkbox"/> Reverse Osmosis <input type="checkbox"/> Clean steam <input type="checkbox"/> Ultra-filtrated water (purified water) <input type="checkbox"/> Other: | | | |
| 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 checked="" type="checkbox"/> | <input 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 type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 6.31 | Is reprocessing allowed? | <input type="checkbox"/> | <input checked="" 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: Site does not manufacture products that are governed by these ICH guidances | | | |

Additional Comments:

Site refers to suppliers as critical and does not use the term GxP in site supplier system

| SECTION 7. Laboratory Procedures | | <input type="checkbox"/> N/A for this Site | | |
|---|---|--|--------------------------|-------------------------------------|
| | | Yes | No | Not Applicable |
| 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 type="checkbox"/> | <input type="checkbox"/> | <input checked="" 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 checked="" type="checkbox"/> | <input type="checkbox"/> | <input 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 checked="" type="checkbox"/> | <input 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: Method development not completed on site and repackers not used | | | |
| Additional Comments: | | | | |
| CoA/CoC are provided on request | | | | |

| SECTION 8. Packaging, Storage and Transport | | <input type="checkbox"/> N/A for this Site | | |
|--|--|--|-------------------------------------|-------------------------------------|
| | | Yes | No | Not Applicable |
| 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 checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8.4 | Are barcode readers in use and challenged regularly? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8.5 | Are vision systems in use? | <input checked="" type="checkbox"/> | <input 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 checked="" type="checkbox"/> | <input 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 type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 8.15 | Are good distribution policies implemented? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 8.16 | Are transport mechanisms dedicated? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8.17 | Does the company validate shipping method? | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 8.18 | Does the company validate packaging methods? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Additional Comments:

Controls are as per applicable site procedures

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

Title: Quality Manager - Compliance & Supplier Quality

Date: 10Apr2025