



# Site Quality Self-Assessment

based on

## Rx-360 Supplier Assessment Questionnaire

### Module 2 (Site specific information)

Relevant for

**Warehouse in Ireland 3rd Party  
Logistics service provider (3PL)**

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



As a trusted partner of our customers, we deliver quality  
- always.

Merck KGaA, Darmstadt, Germany  
Corporation with General Partners  
Frankfurter Str. 250  
64293 Darmstadt, Germany  
Phone +49 6151 72-0

Sigma-Aldrich Corporation  
A subsidiary of Merck KGaA, Darmstadt, Germany  
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EMD Millipore Corporation  
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## 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.



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## Rx-360 Supplier Assessment Questionnaire : Site-Specific Information

Please check here if additional documents are attached.

| <b>SECTION 1. General Site Information</b> |  |
|--|--|
| 1.1  | Site or Facility-Specific Name:<br>Warehouse in Ireland for Life Science products<br>Site is 3rd Party Logistics service provider managed by Rhenus Chemical Logistics |
| 1.2  | Address:<br>Damastown Industrial Park, Mulhuddart, Dublin D15 VRH4<br><br>GPS Coordinates:<br>53.41031334450041, -6.412481170961897                                    |
| 1.3  | Phone:<br>Please contact your responsible Sales representative   |
| 1.4  | Email:<br>Please contact your responsible Sales representative   |
| 1.5  | Fax:<br>Please contact your responsible Sales representative   |
| 1.6  | Website:<br>www.sigmaaldirch.com   |

| <b>SECTION 2. General Site Operating Information</b> |   |
|--|---|
| 2.1  | What year did the site start operating? 2020  |
| 2.2  | What is the primary activity of the site? (e.g. manufacturing, distribution, etc.)<br>warehousing and distribution                        |
| 2.3  | To which, if any, subdivision of the parent company does the site belong?<br>Life Science is a business of Merck KGaA, Darmstadt, Germany |

| <b>SECTION 2. General Site Operating Information</b> |   |
|--|---|
| 2.4  | Size of site (in sq. ft. or m.): 30,000sq ft /  |
| 2.5  | Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable):<br>08.30am - 17.30pm Monday to Friday  |
| 2.6  | Total number of employees on site:<br>6   |
| 2.7  | Total number of employees in Quality:<br>2  |
| 2.8  | Total number of employees in Manufacturing:<br>0  |
| 2.9  | <p>What quality management system is utilized on site?</p> <p><input checked="" type="checkbox"/> ISO 9001<br/> <input type="checkbox"/> ISO 13485<br/> <input type="checkbox"/> 21 CFR Part 210/211<br/> <input type="checkbox"/> 21 CFR Part 820<br/> <input type="checkbox"/> European GMP, Eudralex Volume 4 Part I<br/> <input type="checkbox"/> European GMP, Eudralex Volume 4 Part II<br/> <input type="checkbox"/> ICH Q7<br/> <input checked="" type="checkbox"/> HACCP<br/> <input type="checkbox"/> ISO 22000<br/> <input checked="" type="checkbox"/> Other</p> <p>Please describe: GDP Passport</p> <p>Which Regulatory Initiatives does the site follow/comply with?</p> <p><input type="checkbox"/> REACH<br/> <input type="checkbox"/> RoHs<br/> <input type="checkbox"/> Ca Prop. 65<br/> <input type="checkbox"/> WEEE</p> |
| 2.10   | <p>Does the company/site have an export license?</p> <p style="text-align: right;"><input type="checkbox"/> Yes      <input type="checkbox"/> No      <input checked="" type="checkbox"/> N/A</p>   |

## SECTION 2. General Site Operating Information

|       |   |  |
|-------|---|--|
| 2.11  | Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)?<br><input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A<br>If yes, please specify.                                |  |
| 2.12  | By whom is the site inspected (regulatory or third party) and list inspections within the last three years:<br>NSAI, RSA, HAS, Insurers, Customers  |  |
| 2.13  | How often, as an annual average, is the site audited by customers or third parties?<br>8  |  |
| 2.14  | Has an Rx-360 audit been performed at this site? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No<br>Please also state the date of the audit if applicable.<br><br><a href="http://rx-360.org/audit-programs/">http://rx-360.org/audit-programs/</a> |  |
| 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><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No   |  |
| 2.16  | Are you willing to have your customers conduct audits on your site?<br><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.):<br>N/A  |  |
| 2.18  | Does the site outsource any quality-related activity?<br><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A<br>If answering yes, please specify the activities:   |  |
| 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 |

| <b>SECTION 2. General Site Operating Information</b> |   |   |  |   |
|--|---|---|--|---|
| 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 type="checkbox"/> Yes            | <input checked="" type="checkbox"/> No | <input type="checkbox"/> N/A            |
| 2.19e  | Approved Material Supplier List         | <input type="checkbox"/> Yes            | <input type="checkbox"/> No            | <input checked="" 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:                                 |   |   |  |   |

| <b>SECTION 3. Objectionable Materials on Site</b> |   |                          |                                     |                          |
|---|---|--------------------------|-------------------------------------|--------------------------|
| 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):   |                          |                                     |                          |

| <b>SECTION 4. Cross Contamination Control</b> |   |                                     |                          |                          |
|---|---|-------------------------------------|--------------------------|--------------------------|
| 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:                          |   |                                     |                          |                          |

| <b>SECTION 5. Site Operating Policies</b> |  |                                     |                          |                                     |
|---|--|-------------------------------------|--------------------------|-------------------------------------|
| 5.1                                       | Does the site utilize the following written policies, programs, or procedures? |                                     |                          |                                     |
| <b>Site Specific:</b>                     |  | <b>Yes</b>                          | <b>No</b>                | <b>Not Applicable</b>               |
| 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 type="checkbox"/>            | <input type="checkbox"/> | <input checked="" 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 type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| <b>Quality:</b>                           |  |                                     |                          |                                     |
| 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 type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 5.1l                                      | Master Validation Plan   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" 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 type="checkbox"/>            | <input type="checkbox"/> | <input checked="" 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 type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 5.1y                                      | Sampling Procedure/Sampling Plan   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 5.1z                                      | Raw Material Retention Program   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 5.1aa                                     | CAPA Procedure   | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            |
| 5.1bb                                     | Label Control and Accountability   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 5.1cc                                     | Product Release Procedure  | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" 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 type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 5.1ff                                     | Product Retention Program  | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" 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"/>            |

| <b>SECTION 5. Site Operating Policies</b>    |   |                                     |                          |                          |
|--|---|-------------------------------------|--------------------------|--------------------------|
|  |   | <b>Yes</b>                          | <b>No</b>                | <b>Not Applicable</b>    |
| 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"/> |
| <b>Business Continuity/Contingency Plan:</b> |   |                                     |                          |                          |
| 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:<br>Yes |                                     |                          |                          |

| <b>SECTION 6. Quality Assurance and Production</b> |  |                                     |                          |                                     |
|--|--|-------------------------------------|--------------------------|-------------------------------------|
|  |  | <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 type="checkbox"/>            | <input type="checkbox"/> | <input checked="" 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 the QA/QM have the authority to assign a disposition to materials?                        | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.6  | Does the QA/QM review manufacturing and testing records prior to release?                      | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.7  | Does the facility utilize computerized systems for managing GxP activities or data?            | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.8  | Are relevant computerized systems 21 CFR part 11 and EU GMP annex 11 compliant?                | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" 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 type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |



| <b>SECTION 6. Quality Assurance and Production</b> |  |                                     |                          |                                     |
|--|--|-------------------------------------|--------------------------|-------------------------------------|
|  |  | <b>Yes</b>                          | <b>No</b>                | <b>Not<br/>Applicable</b>           |
| 6.12   | Is any environmental monitoring conducted in production/finishing areas?   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.13   | Does the site supply BSE/TSE declarations?   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" 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?   |                                     |                          |                                     |
| 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 type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.18   | Does the site have a process water treatment system?   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.18a  | Please check all that apply to the system:<br><input type="checkbox"/> City/potable water<br><input type="checkbox"/> Distilled water<br><input type="checkbox"/> Dionized water<br><input type="checkbox"/> Water for injection (WFI)<br><input type="checkbox"/> Reverse Osmosis<br><input type="checkbox"/> Clean steam<br><input type="checkbox"/> Ultra-filtrated water (purified water)<br><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 type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.19c  | Is batch/lot manufacturing continuous?   | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            |
| 6.19d  | Is manufacturing batch by batch?   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.20   | Does the site perform on-plant audits prior to approving critical GxP suppliers?   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.21   | Does the site audit critical GxP suppliers after initial approval?   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" 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 type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.24   | Does the site establish purchase specifications for raw materials?   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.25   | Is the equipment multi-use?  | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.26   | Does the site qualify equipment installation?  | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.27   | Does the site qualify equipment operation?   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.28   | Does the site qualify equipment performance?   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.29   | Are production critical use instruments calibrated regularly?  | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

| <b>SECTION 6. Quality Assurance and Production</b> |  |                          |                          |                                     |
|--|--|--------------------------|--------------------------|-------------------------------------|
|  |  | Yes                      | No                       | Not Applicable                      |
| 6.30   | Is rework allowed?   | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.31   | Is reprocessing allowed?   | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.32   | Are manufacturing and packaging activities traceable to the equipment, areas, and materials used?  | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.33   | Are production materials handled and stored in a manner to prevent degradation, contamination and cross-contamination?                   | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6.34   | If answering 'not applicable' for any of the above, please elaborate:<br>This site is only providing warehousing & distribution services |                          |                          |                                     |
| Additional Comments:                               |  |                          |                          |                                     |

| <b>SECTION 7. Laboratory Procedures</b>               |   |                          |                          |                                     |
|---|---|--------------------------|--------------------------|-------------------------------------|
| <input checked="" type="checkbox"/> N/A for this Site |   |                          |                          |                                     |
|   |   | Yes                      | No                       | Not Applicable                      |
| 7.1   | Does the site have standard procedures for sample handling/tracking?  | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 7.1a  | Does the site have standard procedures for retaining samples?   | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 7.1b  | Does the site have standard procedures for re-testing samples?  | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 7.2   | Does the site have written and approved specifications and test methods?  | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 7.3   | Are laboratory instruments calibrated regularly?  | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" 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 type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 7.6   | Does the site perform stability testing on materials and/or products?   | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 7.7   | Are retention samples of key raw materials maintained?  | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" 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 product maintained?   | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 7.10  | Are shelf life/retest/expiration dates available and standardized?  | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" 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 type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

| <b>SECTION 7. Laboratory Procedures</b> |   | <input checked="" type="checkbox"/> N/A for this Site |                          |                                     |
|---|---|---|--------------------------|-------------------------------------|
|   |   | Yes   | No                       | Not Applicable                      |
| 7.12                                    | Does the CoA/CoC contain the manufacture name and location?   | <input type="checkbox"/>                              | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 7.13                                    | Does the CoA/CoC signed/e-signed by a Quality representative?   | <input type="checkbox"/>                              | <input type="checkbox"/> | <input checked="" 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:<br>.  |   |                          |                                     |
| 7.16                                    | Additional Comments: CoAs controlled by Merck KGaA, Darmstadt, Germany  |   |                          |                                     |

| <b>SECTION 8. Packaging, Storage, and Transport</b> |  | <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 type="checkbox"/>                   | <input type="checkbox"/>            | <input checked="" 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 type="checkbox"/>            | <input checked="" 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 type="checkbox"/>            | <input checked="" 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 type="checkbox"/>                   | <input checked="" 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"/>            |

| <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>               |
| 8.16  | Are transport mechanisms dedicated?          | <input checked="" type="checkbox"/>        | <input type="checkbox"/> | <input type="checkbox"/>            |
| 8.17  | Does the company validate shipping method?   | <input checked="" type="checkbox"/>        | <input type="checkbox"/> | <input type="checkbox"/>            |
| 8.18  | Does the company validate packaging methods? | <input type="checkbox"/>                   | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Additional Comments:                                |  |  |                          |                                     |

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

Date: 11<sup>th</sup> March 2022

Title: Distribution Manager Ireland

## Additional Site-Specific Information

(not based on Rx 360 Supplier Assessment Questionnaire)

| <b>9. Warehousing</b> |   | <b>Yes</b>                          | <b>No</b>                           |
|-----------------------|---|-------------------------------------|-------------------------------------|
| 9.1                   | Are warehouse rooms with different temperature conditions in place?   | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| 9.2                   | Is the temperature monitored  | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| 9.2.1                 | What kind of storage temperatures are in place?   |                                     |                                     |
|                       | For the storage on general conditions?  | Ambient                             |                                     |
|                       | For cool storage?   | N/A – currently no requirement      |                                     |
| 9.3.                  | Are dangerous goods stored separately   | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| 9.3.1                 | Describe dangerous goods storage<br>Dangerous goods stored as per Hazard Class Segregation requirements. Some DG products stored at 3rd Party Warehouse. No explosive or radioactive hazard classes stored on site. |                                     |                                     |