# BioReliance® Validation Services Site Quality Self-Assessment

based on

## Rx-360 Supplier Assessment Questionnaire

Module 2 (Site) and Module 4 (Laboratory Appendix)

Relevant for

**Millipore S.A.S**
**39, Route Industrielle de la Hardt**
**67120 Molsheim, France**
**An affiliate of Merck KGaA, Darmstadt, Germany**

The site self-assessment covers our quality management system for the following regulated applications:
- laboratory testing, validation and compliance services

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, Darmstadt, Germany
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany
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Sigma-Aldrich Corporation
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3050 Spruce Street
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EMD Millipore Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive Burlington,
MA 01803, USA
Phone +1 (781) 533-6000

# Information

This document is based on the Rx-360 Consortium's Supplier Assessment Questionnaire template, Module 2 and Module 4. 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.

| SECTION 1. General Site Information | |
|---|---|
| 1.1 | Site or Facility-Specific Name:<br>BioReliance® Validation Services, EUROPE |
| 1.2 | Address:<br>39 Route Industrielle de la Hardt<br>67129 MOLSHEIM Cedex<br>France<br><br>GPS Coordinates: |
| 1.3 | Phone:<br>800-MILLIPORE |
| 1.4 | Email:<br>Please contact your local Sales representative |
| 1.5 | Fax:<br>n/a |
| 1.6 | Website:<br>http://www.sigmaaldrich.com |

| SECTION 2. General Site Operating Information | |
|---|---|
| 2.1 | What year did the site start operating? 1990 |
| 2.2 | What is the primary activity of the site? (e.g. manufacturing, distribution, etc.)<br>Laboratory Testing, Validation and Compliance Services |
| 2.3 | To which, if any, subdivision of the parent company does the site belong?<br>Merck KGaA, Darmstadt, Germany |

| SECTION 2. General Site Operating Information | |
|---|---|
| | |
| 2.4 | Size of site (in sq. ft. or m.):<br>Facility opened October 2005<br>Size of Facility ;<br>Size of laboratory area: 750m2 |
| 2.5 | Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable):<br>Normal Schedule: Monday to Friday, 06:00 - 21:00 |
| 2.6 | Total number of employees on site:<br>Total Employees: 29<br>Laboratory: 14<br>Administrative/Other: 15 |
| 2.7 | Total number of employees in Quality:<br>2 |
| 2.8 | Total number of employees in Manufacturing:<br>n/a |
| 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 |

| SECTION 2. General Site Operating Information | | | | | |
|---|---|---|---|---|---|
| 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>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>DQS | | | | |
| 2.13 | How often, as an annual average, is the site audited by customers or third parties?<br>Five to eight | | | | |
| 2.14 | Has an Rx-360 audit been performed at this site? ☐ Yes ☒ No<br>Please also state the date of the audit if applicable.<br><br>http://rx-360.org/audit-programs/ | | | | |
| 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.):<br>n/a | | | | |
| 2.18 | Does the site outsource any quality-related activity?<br>☒ Yes ☐ No ☐ N/A<br>If answering yes, please specify the activities:<br>Electronic microscopy analysis | | | | |
| 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 | |

| SECTION 2. General Site Operating Information | | | | |
|---|---|---|---|---|
| | | | | |
| 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: | | | | |

| 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):<br>Objectionable materials would only be those being sent to us by our customers to be used in testing. None of these are manufactured at this site. Pesticides are maintained and monitored through our Pest Control program for the facility. | | | |

| 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): | | | |

| Additional Comments: |
|---|

| 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 | ☒ | ☐ | ☐ |
| **SECTION 5. Site Operating Policies** | | | | |
| | | **Yes** | **No** | **Not Applicable** |
| 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: | | | |

| **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 the QA/QM have the authority to assign a disposition to materials? | ☐ | ☐ | ☒ |
| 6.6 | Does the QA/QM review manufacturing and testing records prior to release? | ☒ | ☐ | ☐ |
| 6.7 | Does the facility utilize computerized systems for managing GxP activities or 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? | ☐ | ☐ | ☒ |

| SECTION 6. Quality Assurance and Production | | | | |
|---|---|---|---|---|
| | | **Yes** | **No** | **Not Applicable** |
| 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(R4) solvents used in the manufacturing process of supplied materials? | ☐ | ☐ | ☒ |
| 6.16 | Are stability studies carried out 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: | | | |
| 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? | ☒ | ☐ | ☐ |

| SECTION 6. Quality Assurance and Production | | | | |
|---|---|---|---|---|
| | | Yes | No | Not Applicable |
| 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:<br>Testing performed is microbial retention and physical testing related to Merck KGaA, Darmstadt Germany devices | | | |
| Additional Comments: | | | | |

| 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 re-testing 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 product 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 | ☐ | ☐ | ☒ |

| SECTION 7. Laboratory Procedures | | ☐ N/A for this Site | | |
|---|---|---|---|---|
| | | **Yes** | **No** | **Not Applicable** |
| | Conformation/Compliance (CoC) for each lot or batch? | | | |
| 7.12 | Does the CoA/CoC contain the manufacture name and location? | ☐ | ☐ | ☒ |
| 7.13 | Does 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:<br>Testing performed is microbial retention and physical testing related to Millipore devices. the BioReliance site does not manufacture anything that would require a CoA or CoC | | | |
| 7.16 | Additional Comments: . | | | |

| 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? | ☒ | ☐ | ☐ |

| SECTION 8. Packaging, Storage, and Transport | | ☐ N/A for this Site | | |
|---|---|---|---|---|
| | | **Yes** | **No** | **Not Applicable** |
| 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: | | | | |

**Rx-360 Supplier Assessment Questionnaire**
**Module 4 : Service Supplier**
**Laboratory Appendix**
**Version 2.01**

☒ Please check here if additional documents are attached.

| SECTION 1. General Site Information | |
|---|---|
| 1.1 | Site or Facility-Specific Name:<br>BioReliance® Validation Services, Europe |
| 1.2 | Address:<br>39 Route Industrielle de la Hardt<br>67129 MOLSHEIM Cedex<br>France<br><br>GPS Coordinates (Map Coordinates/Longitude & Latitude): |
| 1.3 | Phone:<br>800-MILLIPORE |
| 1.4 | Email:<br>Please contact your local Sales representative |
| 1.5 | Fax:<br>n/a |
| 1.6 | Website:<br>www.sigmaaldrich.com |
| 1.7 | If there is an individual contact for the following areas, please provide name and preferred contact information (at a minimum, name and telephone number or email):<br>Quality:<br>Please contact your local Sales representative<br>Technical Services:<br>Please contact your local Sales representative<br>Commercial/Business/Sales:<br>Please contact your local Sales representative<br>Primary Site Contact: |

| Section 2. Laboratories ☐ N/A | | | | |
|---|---|---|---|---|
| 2.1 | Type of laboratory testing offered?<br>☐ Chemical<br>☒ Microbiological<br>☐ Biological<br>☒ Physical<br>☐ Instrumental (e.g. ICP; AAS, LC-MS, HPLC, GC)<br>☐ Virology<br>☐ Other<br>☐ See attached | | | |
| 2.2 | Types of Services Offered?<br>☐ Compendial (e.g. USP, EP, JP, ACS etc.)<br>☐ Environmental<br>☐ Stability testing<br>☒ Other Laboratory testing, validation and compliance services<br>☐ See attached | | | |
| 2.3 | Are the following programs in place: | | | |
| 2.3a | Internal Audits | ☒ Yes | ☐ No | ☐ N/A |
| 2.3b | Calibration | ☒ Yes | ☐ No | ☐ N/A |
| 2.3c | OOS (Out-of-Specification) Procedure | ☒ Yes | ☐ No | ☐ N/A |
| 2.3d | Preventive Maintenance | ☒ Yes | ☐ No | ☐ N/A |
| 2.3e | GLP (Good Laboratory Practices) | ☐ Yes | ☒ No | ☐ N/A |
| 2.3f | GDP (Good Documentation Practices) | ☒ Yes | ☐ No | ☐ N/A |
| 2.3g | Periodic Quality/Management Review Meeting | ☒ Yes | ☐ No | ☐ N/A |
| 2.4 | Does your laboratory use a LIMsSystem? | ☐ Yes | ☒ No | ☐ N/A |

| | | | | |
|---|---|---|---|---|
| 2.5 | Do you have a qualification program for instruments used in critical analytical testing? | ☒ Yes | ☐ No | ☐ N/A |
| 2.6 | Does the company have a procedure that defines the need to requalify laboratory instruments based upon certain activities/changes? | ☒ Yes | ☐ No | ☐ N/A |
| 2.7 | Does the company have a process for verification of the ability to conduct compendial tests? | ☐ Yes | ☐ No | ☒ N/A |
| 2.8 | Does the company have a procedure for validating compendial methods that are modified by the company in order to ensure that all tests are still valid? | ☐ Yes | ☐ No | ☒ N/A |
| 2.9 | Does the company have a procedure for method validation/method transfer for non-compendial methods? | ☒ Yes | ☐ No | ☐ N/A |
| 2.10 | Does the site have standard procedures for sample handling? | ☒ Yes | ☐ No | ☐ N/A |
| 2.11 | Does the site have standard procedures for retaining samples? | ☐ Yes | ☐ No | ☒ N/A |
| 2.12 | Does the site have standard procedures for re-testing samples? | ☒ Yes | ☐ No | ☐ N/A |
| 2.13 | Does the site have written and approved specifications and test methods? | ☒ Yes | ☐ No | ☐ N/A |
| 2.14 | Are laboratory instruments calibrated regularly? | ☒ Yes | ☐ No | ☐ N/A |
| 2.15 | Is there a standard procedure in place for analytical method development? | ☐ Yes | ☒ No | ☐ N/A |
| 2.16 | Does the company qualify and/or validate analytical test procedures? | ☐ Yes | ☒ No | ☐ N/A |

| | | | | |
|---|---|---|---|---|
| 2.17 | Does the site perform stability testing on materials and/or products? | ☐ Yes | ☒ No | ☐ N/A |
| 2.18 | Are retention samples of key raw materials maintained? | ☐ Yes | ☐ No | ☒ N/A |
| 2.19 | Are standards traceable to their preparation and reagents used? | ☒ Yes | ☐ No | ☐ N/A |
| 2.20 | Are retention samples of finished product maintained? | ☐ Yes | ☐ No | ☒ N/A |
| 2.21 | Are shelf life/retest/expiration dates available and standardized? | ☐ Yes | ☐ No | ☒ N/A |
| 2.22 | Does the company provide a certificate of analysis (CoA) and/or a Certificate of Conformation/Compliance (CoC) for each lot or batch? | ☐ Yes | ☐ No | ☒ N/A |
| 2.23 | Is the CoA/CoC signed/e-signed by a quality representative? | ☐ Yes | ☐ No | ☒ N/A |
| 2.24 | Does the company have a procedure for notifying customers of preliminary OOS results? | ☐ Yes | ☐ No | ☒ N/A |
| 2.25 | Does the company have a procedure for notifying customers of a confirmed OOS result? | ☒ Yes | ☐ No | ☐ N/A |
| 2.26 | If answering ‘not applicable’ for any of the above, please elaborate: | | | |
| **Comments**<br>**(Please reference appropriate question number for any additional comments)** | | | | |
| | | | | |

# Additional Site-Specific Information
# BioReliance® Validation Services, Europe
# (not based on Rx 360 Supplier Assessment Questionnaire)

## 1. General Information

### a) Site Information

| | |
|---|---|
| 1. How is access to facility controlled? | Badge access |
| 2. SIC Code(s) | 43469119200018 |
| 3. DUNS Number | 434 691 192 |

### b) Regulatory/Certification Information

| | Yes | No |
|---|---|---|
| 1. Initial date of ISO 9001 certification. | 1991 | |
| 2. Date of last ISO 9001 certification inspection. | Sep-2016 | |
| 3. ISO 14001 Certified? | ☒ | ☐ |
| 4. Initial date of ISO 14001 certification. | 1997 | |
| 5. Date of last ISO 14001 certification inspection. | Oct-2020 | |
| 6. Is the laboratory GMP or GLP certified? | ☐ | ☒ |

### c) Change Control

| | Yes | No |
|---|---|---|
| 1. Do you have a computerized Change Control process? | ☒ | ☐ |
| 2. Does the Change Control Procedure include equipment, facilities, materials, utilities, documentation, and testing? | ☒ | ☐ |
| 3. Are you willing to enter into a change notification commitment with customers? | ☒ | ☐ |

### d) Buildings/Utilities

| | Yes | No |
|---|---|---|
| 1. Do backup power systems exist for critical equipment? | ☒ | ☐ |
| 2. Is there a defined schedule for housekeeping in service areas? | ☒ | ☐ |
| 3. Is there a floor plan for the lab? | ☒ | ☐ |

### e) Equipment/Utilities

| | Yes | No |
|---|---|---|
| 1. Are environmental conditions controlled in locations where the environment can affect service operation? | ☒ | ☐ |
| 2. Have compressed air and vacuum systems been validated? | ☐ | ☒ |
| 3. Are the compressed air and vacuum systems monitored periodically? | ☒ | ☐ |
| 4. Is the HVAC system monitored periodically? | ☒ | ☐ |
| 5. Does the laboratory have HEPA filtered air, and are the filters on a defined frequency for testing/recertification? | ☐ | ☒ |

## 2. Quality Organization

### a) General

| | Yes | No |
|---|---|---|
| 1. Is there an Organizational Chart available to customers during on-site audit? | ☒ | ☐ |
| 2. Can the Quality Unit escalate quality issues outside operations to life science (LS) or Merck KGaA, Darmstadt Germany Quality Unit? | ☒ | ☐ |
| 3. Does the training program require an annual GMP refresher? | ☒ | ☐ |
| 4. Are there requirements for when retraining should be conducted? | ☒ | ☐ |
| 5. Do you have a validation master plan? | ☒ | ☐ |
| 6. How long are records of test results kept? | 11 years | |

## 3. Laboratory Controls

### a) General

| | Yes | No |
|---|---|---|
| 1. Are there controls to avoid use of expired reagents and reference standards? | ☒ | ☐ |
| 2. Are there controls to prevent the mix-up of controls, standards, and samples? | ☒ | ☐ |
| 3. Are there controls to prevent inadvertent use of rejected materials? | ☒ | ☐ |
| 4. Does the laboratory have validated refrigerators, cold rooms and freezers for the storage of customer product and laboratory materials**?** | ☒ | ☐ |
| 5. Is access to the material and sample storage area(s) limited to authorized personnel? | ☒ | ☐ |
| 6. Are laboratory personnel notified in the event of a temperature excursion during non-business hours**?** | ☒ | ☐ |

### b) Standards and Measuring & Testing Equipment (MTE)

| | Yes | No |
|---|---|---|
| 1. Are calibration standards and MTE kept in a secure area? | ☒ | ☐ |
| 2. Is maintenance/calibration coordinated by an electronic system? | ☒ | ☐ |
| 3. Are there systems to prevent inadvertent use of rejected standards and MTE? | ☒ | ☐ |
| 4. Are storage areas for calibration standards and MTE restricted to authorized personnel? | ☒ | ☐ |
| 5. Is there a procedure in place to notify customers of non-conforming standards? | ☒ | ☐ |
| 6. Are there requirements for environmental conditions for the use of standards and MTE? | ☒ | ☐ |
| 7. Are there controls in place to maintain defined environmental conditions? | ☒ | ☐ |
| 8. Is a 4:1 (TUR) uncertainty ratio between the standard and instrument calibrated maintained for all calibrations? | ☒ | ☐ |
| 9. Are standards and MTE labeled with a unique number? | ☒ | ☐ |
| 10. Are standards and MTE labeled with calibration that contain the date calibrated and calibration due date? | ☒ | ☐ |

### c) Traceability, Uncertainty and Calibration Methods

| | Yes | No |
|---|---|---|
| 1. To which standards organization is the instrumentation traceable? | NIST or LINE | |
| 2. Is there an Out of Tolerance procedure? | ☒ | ☐ |
| 3. Are calibration labels placed on all equipment that is calibrated? | ☒ | ☐ |
| 4. Are customers notified in the event of an OOT that impacts their testing? | ☒ | ☐ |

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

Date: 04NOV2020
Title: Quality manager BioReliance Validation Services