



Site Quality Self-Assessment

based on

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

Relevant for

Sigma-Aldrich
1302 West Anthony Drive Urbana,
IL 61802, USA

An affiliate of Merck KGaA, Darmstadt, Germany

The site self-assessment covers our quality management system for the following applications:
- Manufacturing of inorganic salts



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
3050 Spruce Street
St. Louis, MO 63103, USA
Phone +1 (800) 521-8956 / +1 (314) 771-5765

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. The contents of this questionnaire are built on the Rx-360 questionnaire version 2.0 intact with no question added or deleted.

Rx-360's CEO/COO gave permission to Life Science to use the Rx-360 logo.



Merck KGaA, 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
3050 Spruce Street
St. Louis, MO 63103, USA
Phone +1 (800) 521-8956 / +1 (314) 771-5765

EMD Millipore Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive Burlington,
MA 01803, USA
Phone +1 (781) 533-6000

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: Aldrich-APL, LLC
1.2	Address: 1302 W. Anthony Dr Urbana, IL 61802 GPS Coordinates: Lat: N 40° 8' 15" W 88° 13' 38"
1.3	Phone: 217-398-2806
1.4	Email: please refer to your Sales representative
1.5	Fax: Not available
1.6	Website: www.Sigmaaldrich.com

SECTION 2. General Site Operating Information	
2.1	What year did the site start operating? 1995
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) manufacturing, packaging, labelling, release testing, warehouse
2.3	To which, if any, subdivision of the parent company does the site belong? Life Science business of Merck KGaA, Darmstadt, Germany

SECTION 2. General Site Operating Information	
2.4	Size of site (in sq. ft. or m.): 36.000 squarefeet
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): 8/5
2.6	Total number of employees on site: Headcount of 26 total (25 positions filled)
2.7	Total number of employees in Quality: 4
2.8	Total number of employees in Manufacturing: 13
2.9	<p>What quality management system is utilized on site?</p> <p><input checked="" type="checkbox"/> ISO 9001 <input type="checkbox"/> ISO 13485 <input type="checkbox"/> 21 CFR Part 210/211 <input type="checkbox"/> 21 CFR Part 820 <input type="checkbox"/> European GMP, Eudralex Volume 4 Part I <input type="checkbox"/> European GMP, Eudralex Volume 4 Part II <input type="checkbox"/> ICH Q7 <input type="checkbox"/> HACCP <input type="checkbox"/> ISO 22000 <input type="checkbox"/> Other</p> <p>Please describe:</p> <p>Which Regulatory Initiatives does the site follow/comply with?</p> <p><input type="checkbox"/> REACH <input type="checkbox"/> RoHs <input type="checkbox"/> Ca Prop. 65 <input type="checkbox"/> WEEE</p>
2.10	<p>Does the company/site have an export license?</p> <p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A</p>

SECTION 2. General Site Operating Information

2.11	<p>Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If yes, please specify. DEA, IEMA, DOT, EPA, IEPA</p>
2.12	<p>By whom is the site inspected (regulatory or third party) and list inspections within the last three years:</p> <p>ISO 9001:2015 certificate valid as of 18-Nov-2020 EPA 23-Feb-2021</p>
2.13	<p>How often, as an annual average, is the site audited by customers or third parties?</p> <p>1 to 2 times</p>
2.14	<p>Has an Rx-360 audit been performed at this site? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Please also state the date of the audit if applicable.</p> <p>http://rx-360.org/audit-programs/</p>
2.15	<p>Are you willing to have Rx-360 conduct an audit on behalf of your customers according to the Rx-360 audit programs on your site?</p> <p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
2.16	<p>Are you willing to have your customers conduct audits on your site?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>
2.17	<p>Please list regulatory sanctions impacting the site within the last five years (i.e. warning letters, CEP suspension, import alerts, etc.):</p> <p>none</p>
2.18	<p>Does the site outsource any quality-related activity?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If answering yes, please specify the activities:</p> <p>QC tests including: [rarely/sometimes] assay, KF, LOD, EDTA, NaOH, HCl, TAG, melt point, trace, GDMS/SSMS [always] KMnO4, I2, gravimetric analysis, hydrogen evolution, KSCN, XRD, NMR, UV-Vis, GC, HPLC, solubility, ATR, CHN, alpha rotation, IC, bioburden, TAMC, enzyme testing</p>
2.19	<p>Please check the supplier controls in place for this facility:</p>

SECTION 2. General Site Operating Information				
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 type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.19c	Periodic Review of Supplier Performance	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.19d	Supplier Feedback Program	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.19e	Approved Material Supplier List	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.19f	Approved Service Supplier List	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Additional comments: 2.19b: this is not handled locally				

SECTION 3. Objectionable Materials on Site				
3.1	Does the site or production plant produce, process or store any of the following:	Yes	No	Not Applicable
3.1a	Beta-Lactam Antibiotics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1b	Steroids and/or hormones	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1c	High potency compounds	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1d	Materials of animal origin/Biologics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1e	Live virus or micro-organism	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1f	Allergens	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1g	Genetically Modified Organisms (GMO)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1h	Agrochemicals (Pesticides, Herbicides, Fungicides, etc.)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1i	Other (Please specify):			

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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4.1b	Access Controls	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4.1c	Dedicated Personnel	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4.1d	Dedicated Gowning	<input type="checkbox"/>	<input checked="" 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?			
Site Specific:		Yes	No	Not Applicable
5.1a	Environmental, Health, and Safety	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1b	Facility Environmental Control Policy	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.1c	General Facility Cleaning Procedures	<input type="checkbox"/>	<input checked="" 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 checked="" 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 type="checkbox"/>	<input checked="" 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 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 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 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
SECTION 5. Site Operating Policies				
		Yes	No	Not Applicable
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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.1nn	Pandemic Preparedness Plan	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.1oo	Supply Chain Emergency Preparedness Plan	<input type="checkbox"/>	<input checked="" 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:			

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 the QA/QM have the authority to assign a disposition to materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.6	Does the QA/QM review manufacturing and testing records prior to release?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input 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"/>

SECTION 6. Quality Assurance and Production				
		Yes	No	Not Applicable
6.9	Does the site use statistical methods for consistency and uniformity?	<input type="checkbox"/>	<input checked="" 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 checked="" 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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.14	Does the site supply a declaration of Elemental Impurities?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.15	Are ICH Q3C(R4) solvents used in the manufacturing process of supplied materials?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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 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 checked="" type="checkbox"/>	<input 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 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 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"/>

SECTION 6. Quality Assurance and Production				
		Yes	No	Not Applicable
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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.27	Does the site qualify equipment operation?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.28	Does the site qualify equipment performance?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.29	Are production critical use instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.30	Is rework allowed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.31	Is reprocessing allowed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.32	Are manufacturing and packaging activities traceable to the equipment, areas, and materials used?	<input checked="" type="checkbox"/>	<input checked="" 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 is not GMP, GxP, or ICH			
Additional Comments: 6.6 review of manufacturing records, no review of testing records 6.11 yes for qualify no for validate, 6.32 product dependant				

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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7.1b	Does the site have standard procedures for re-testing samples?	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7.7	Are retention samples of key raw materials maintained?	<input type="checkbox"/>	<input checked="" 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"/>

SECTION 7. Laboratory Procedures		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
7.9	Are retention samples of finished product 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 checked="" 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	Does the CoA/CoC signed/e-signed by a Quality representative?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.14	If a repacker performs analyses, will the CoA reflect both the original manufacturing site data as well as the repacking site data?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.15	If answering 'not applicable' for any of the above, please elaborate: 7.4: site does not develop its own analytical tests 7.14: program repacking is not performed			
7.16	Additional Comments: 7.10 Shelf life applicable for a limited number of products at the Urbana site.			

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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.6	Is product ever packaged without a label being initially applied (i.e. bright stocking)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.7	Do labels include shelf life/expiration dates?	<input checked="" 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 type="checkbox"/>	<input checked="" 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"/>

SECTION 8. Packaging, Storage, and Transport		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.13	Does the site make available a description of storage and/or warehouse conditions?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.16	Are transport mechanisms dedicated?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.17	Does the company validate shipping method?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.18	Does the company validate packaging methods?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Additional Comments: 8.7 Shelf life applicable for a limited number of products at Urbana. 8.12: a risk assessment has been performed and demonstrates that monitoring of storage conditions is not necessary 8.14: majority of products are distributed through the Milwaukee facility				

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

Date:08-Feb-2022

Title:Quality Assurance Specialist