



# Site Quality Self-Assessment

based on

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

Relevant for

**Sigma-Genosys of Texas LLC**  
**9186 Six Pines Drive, Suite 100,**  
**The Woodlands, TX 77380**  
**USA**

The site self-assessment covers our quality management system for the following applications:  
- manufacturing of DNA; siRNA, AQUA and PEPscreen peptides



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  
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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: MilliporeSigma
1.2	Address: 9186 Six Pines Drive, Suite 100, The Woodlands, TX 77380  GPS Coordinates: Latitude: 30.1752983, Longitude: -95.4602374
1.3	Phone: Please contact your local Sales representative
1.4	Email: Please contact your local Sales representative
1.5	Fax: Please contact your local Sales representative
1.6	Website: www.sigmaaldrich.com

<b>SECTION 2. General Site Operating Information</b>	
2.1	What year did the site start operating? 1987
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) Manufacturing of custom oligonucleotides and peptides (non catalogue products)
2.3	To which, if any, subdivision of the parent company does the site belong? Life Science business of Merck KGaA, Darmstadt, Germany

<b>SECTION 2. General Site Operating Information</b>	
2.4	Size of site (in sq. ft. or m.): 37,000 sq.ft.
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): Manufacturing Hours: Monday to Friday, 3 shifts; Monday 06:00 to Saturday 06:30 Shutdown: New Years Eve and Day, Memorial Day, Labor Day, Independence Day, Thanksgiving Day (Thursday and Friday), Christmas Eve and Day.
2.6	Total number of employees on site: 100
2.7	Total number of employees in Quality: 8
2.8	Total number of employees in Manufacturing: 66
2.9	<p>What quality management system is utilized on site?</p> <input checked="" type="checkbox"/> ISO 9001 <input checked="" type="checkbox"/> ISO 13485 <input type="checkbox"/> 21 CFR Part 210/211 <input type="checkbox"/> 21 CFR Part 820 <input type="checkbox"/> European GMP, Eudralex Volume 4 Part I <input type="checkbox"/> European GMP, Eudralex Volume 4 Part II <input type="checkbox"/> ICH Q7 <input type="checkbox"/> HACCP <input type="checkbox"/> ISO 22000 <input type="checkbox"/> Other Please describe:
2.10	<p>Does the company/site have an export license?</p> <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

## SECTION 2. General Site Operating Information

2.11	Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A If yes, please specify.		
2.12	By whom is the site inspected (regulatory or third party) and list inspections within the last three years: DQS for ISO 9001:2015, August 2019. Lloyd's Register for ISO 13485:2016, January 2021		
2.13	How often, as an annual average, is the site audited by customers or third parties? Approximately 2 audits per year.		
2.14	Has an Rx-360 audit been performed at this site? <input type="checkbox"/> Yes <input type="checkbox"/> No Please also state the date of the audit if applicable.  <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? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
2.16	Are you willing to have your customers conduct audits on your site? <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.): none		
2.18	Does the site outsource any quality-related activity? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A 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 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:				

<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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4.1b	Access Controls	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4.1c	Dedicated Personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4.1d	Dedicated Gowning	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4.1e	Procedural Controls	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input checked="" 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"/>
<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 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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.1z	Raw Material Retention Program	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.1aa	CAPA Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1bb	Label Control and Accountability	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1ff	Product Retention Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1gg	Recall Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1hh	Customer Complaint Handling	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ii	Equipment validation/qualification procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<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 type="checkbox"/>	<input checked="" 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 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: yes, in an audit			

<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 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 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"/>
6.9	Does the site use statistical methods for consistency and uniformity?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.10	Does the site use controlled documents for following and recording manufacturing instructions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.11	Does the company qualify and/or validate manufacturing procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



<b>SECTION 6. Quality Assurance and Production</b>				
		<b>Yes</b>	<b>No</b>	<b>Not 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? n/a			
6.16	Are stability studies carried out according to ICH guidance?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.17	Are solvents and mother liquor reused/recycled?	<input type="checkbox"/>	<input checked="" 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 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 type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.24	Does the site establish purchase specifications for raw materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.25	Is the equipment multi-use?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.26	Does the site qualify equipment installation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.27	Does the site qualify equipment operation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.28	Does the site qualify equipment performance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.29	Are production critical use instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<b>SECTION 6. Quality Assurance and Production</b>				
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
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 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: The site does not manufacture to GMP			
Additional Comments:				

<b>SECTION 7. Laboratory Procedures</b>				
<input type="checkbox"/> <b>N/A for this Site</b>				
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
7.1	Does the site have standard procedures for sample handling/tracking?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1a	Does the site have standard procedures for retaining samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1b	Does the site have standard procedures for re-testing samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2	Does the site have written and approved specifications and test methods?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.3	Are laboratory instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.4	Is there a standard procedure in place for analytical method development?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input 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 type="checkbox"/>	<input checked="" 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"/>
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 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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<b>SECTION 7. Laboratory Procedures</b>		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
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: We manufacture non-regulated custom oligo orders, non catalog products.			
7.16	Additional Comments:			

<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 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 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 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 type="checkbox"/>
8.14	Does the site distribute products via a third party?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.15	Are good distribution policies implemented?	<input 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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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:14 June 2021

Title:Quality Assurance and Quality Control Manager