GMP Site Quality Self-Assessment

based on

Rx-360 Supplier Assessment Questionnaire

Module 2, Site Specific Information

Relevant for

MilliporeSigma Sheboygan Falls
Facility 5485 County Road V
Sheboygan Falls, WI 53085, USA
An affiliate of Merck KGaA, Darmstadt, Germany

The site self-assessment covers our quality management system for the following regulated applications:
- manufacturing of Flavours & Fragrances

The site also processes products which do not fall under any of the above mentioned regulated areas. For these products, other quality standards apply. For details, please refer to our non-GMP Quality Site Self-Assessment.

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
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany

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.

SECTION 1. General Site Information	
1.1	Site or Facility-Specific Name: Aldrich Chemical Company, LLC
1.2	Address: 5485 County Road V, Sheboygan Falls, WI 53085-2814, USA GPS Coordinates: Latitude:43.673968 Longitude: -87.781175
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.sigma-aldrich.com/flavors-fragrances

SECTION 2. General Site Operating Information	
2.1	What year did the site start operating? Aldrich began business in 1951, purchased the Sheboygan Falls site in 1977, adding buildings over the 41 year period.
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) manufacturing, quality control and packaging
2.3	To which, if any, subdivision of the parent company does the site belong?

SECTION 2. General Site Operating Information	
	Merck KGaA, Darmstadt, Germany, Life Science division
2.4	Size of site (in sq. ft. or m.): 440,000 sq. ft on 77 acres developed and 515 acres undeveloped.
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): 4 hours a day, 7 days a week Site shutdown 2 days during Thanksgiving (end of November) Site shutdown 2 days during Christmas (end of December)
2.6	Total number of employees on site: Aproximately 630 employees
2.7	Total number of employees in Quality: 80 total in Quality Control and Quality Assurance
2.8	Total number of employees in Manufacturing: 280 in Manufacturing (appr. 40 employees in flavors & fragrances operation), 65 packaging
2.9	What quality management system is utilized on site? ☒ ISO 9001 ☐ ISO 13485 ☐ 21 CFR Part 210/211 ☐ 21 CFR Part 820 ☐ European GMP, Eudralex Volume 4 Part I ☐ European GMP, Eudralex Volume 4 Part II ☐ ICH Q7 ☒ HACCP ☒ ISO 22000 ☒ Other Please describe: ISO 14001, Food defence, HARPC, 21 CFR 117 and (EC) No 852/2004 Which Regulatory Initiatives does the site follow/comply with? ☒ REACH ☒ RoHs ☒ Ca Prop. 65 ☒ 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.)? ☒ Yes ☐ No ☐ N/A If yes, please specify. FDA food facility registration #15537241694 Wisconsin Dept. of Agriculture, Trade and Consumer Protection (#482568) US Environmental Protection Agency (RCRA hazardous waste generator) US Department of Homeland Security	
2.12	By whom is the site inspected (regulatory or third party) and list inspections within the last three years: AIB (FSSC 22000), DQS (ISO 9001:2015), Rabbi Gershon Segal (Kosher), IFANCA (Halal), Homeland Security 2016	
2.13	How often, as an annual average, is the site audited by customers or third parties? 20-30	
2.14	Has an Rx-360 audit been performed at this site? ☐ Yes ☒ No Please also state the date of the audit if applicable. 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? ☒ Yes ☐ No	
2.16	Are you willing to have your customers conduct audits on your site? ☒ 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.): none	
2.18	Does the site outsource any quality-related activity? ☒ Yes ☐ No ☐ N/A If answering yes, please specify the activities: Pest control, selected analytical testing and calibration services.	

SECTION 2. General Site Operating Information				
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
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: Please note that the checks in 2.9, 2.11 and 2.12 refer to GMP processing, The site also processes non-GMP related product. Please refer to non-GMP Site Self-Assessment				

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): 3.1d: yes for GMP production, no for non-GMP production For GMP production we declare: No use of Cytotoxins,			

	No use of APIs, No use of Food allergens (US FDA, EU EFSA, Japan Ministry of Health) ,but toxic, hazardous chemicals,

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): All materials are stored in sealed containers. Containers are opened only in isolated rooms with line clearance after each product is handled.			

Additional Comments:
Some materials derived from highly refined oils or distillates or extracts from allergen sources. Third party analysis verified end products are allergen-free.
Some materials derived from highly refined oils or extracts from animal sources.
Some materials derived from highly refined oils or distillates from GMO plant-sources.

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: can be disclosed in an audit			

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?	☒	☐	☐
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: ☒ City/potable water ☐ Distilled water ☒ Dionized water ☐ Water for injection (WFI) ☒ Reverse Osmosis ☐ Clean steam ☒ Ultra-filtrated water (purified water) ☐ Other:			

SECTION 6. Quality Assurance and Production				
		Yes	**No**	**Not Applicable**
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?	☒	☐	☐
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: 6.6 The site does not release the F&F products, release is done at other site 6.19a: Site potoable water is used for cleaning and the water quality is checked 6.26 - 6.28: in the means of ISO 2200, not in the means of pharma IQ,OQ,PQ 6.30,6.31: for rework and reprocessing: documented cleaning between uses is perfomed			
Additional Comments: Section 6.14 -all GMP batches tested for As, Cd, Hg, Pb Section 6.18a - well/potable water				

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?	☒	☐	☐

SECTION 7. Laboratory Procedures		☐ N/A for this Site		
		Yes	**No**	**Not Applicable**
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 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: 7.4: analytical method developed at other sites. 7.8: Prepared standards not used at the site.			
7.16	Additional Comments: N/A is checked for the section 7 as the site does not release F&F products, release testing is done at another site, the checks in section 7 describe laboratory procudure for F&F products Name/Address on CoA contains 24 hr contact information and owning site address			

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?	☒	☐	☐
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: Third party distributors used in select regions				

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

Date:20th February 2023

Title:QA Supervisor

Additional Site-Specific Information

(not based on Rx 360 Supplier Assessment Questionnaire)

9. Food Safety Management System		**Yes**	**No**
9.1	Does the facility have a documented food safety management system?	☒	☐
9.2	Is a food safety plan maintained at the site?	☒	☐
9.3	Is there a designated food safety and/or HACCP team?	☒	☐
9.4	Does the food safety/HACCP team meet regularly to review the food Safety management system?	☒	☐
9.4.a	How often?	1/month	
9.5	Is any non-food production performed at the site?	☒	☐
9.5.a	Is the non-food production segregated from the food facility?	☒	☐
9.6	Is organoleptic testing performed?	☒	☐
9.7	Are any of the following added to the product:		
9.7.a	Artificial colors?	☐	☒
9.7.b	Silicon dioxide (SiO_2)	☐	☒
9.7.c	Monosodium glutamate (MSG)	☐	☒
9.7.d	Guanylates and/or Inosinates?	☐	☒
9.9	Are any materials treated with the following:		
9.9.a	Chemical treatment:		
9.9.a.i	Fumigation?	☐	☒
9.9.a.ii	Ethylene oxide (EtO)?	☐	☒
9.9.a.iii	Methyl bromide?	☐	☒
9.9.b	Irradiation?	☐	☒
9.9.c	Steam treatment?	☐	☒
9.9.d	Heat treatment?	☐	☒
9.9	Indicate which internal audits are performed and their frequency:		
	GMP audit (monthly), ISO 9001 (annually), ISO 22000/22002 (annually)		
9.10	Is there a written recall procedure?	☒	☐
9.11	Is there a lot traceability system that allows for traceability backwards to materials received and forwards to lots shipped?	☒	☐
9.11.a	Does the traceability system include packaging supplies?	☒	☐
9.12	Are traceability exorcises performed?	☒	☐
9.12.a	How often?	2/year	
9.12.b	Indicate acceptable recover:	100%	
9.12.c	Indicate acceptable recovery time:	4 hours	
9.12.d	Do traceability exorcises include direct-contact packing supplies?	☒	☐
9.13	Is there a packaging supply supplier selection and approval process?	☒	☐
9.13.a	Are there established specifications and/or conformity requirements for packaging supplies?	☒	☐
9.13.b	Are packaging supplies inspected for cleanliness and integrity prior to being approved for use?	☒	☐
9.13.c	Is there a process for managing non-conforming packaging supplies	☒	☐

		Yes	No
9.14	Is there a pest control program for all areas including raw material and packaging supply storage areas?	☒	☐
9.14.a	Are toxic pest baits or pesticides used in any areas?	☐	☒
9.14.b	Is there a pesticide usage log?	N/A	
9.14.c	Is there a pest sighting log available to employees?	☒	☐
9.14.d	Are the grounds maintained so there are no excessive weeds or plant growth?	☒	☐
9.15	Is there a documented master cleaning schedule?	☒	☐
9.16	Are cleaning chemicals stored in non-production areas?	☒	☐
9.17	Does the facility have a glass/brittle plastic program?	☒	☐
9.17.a	Is the facility regularly inspected for glass/brittle plastic and how often?	☒	☐
9.17.b	How often?	1/month	
9.19	Are diesel power vehicles used anywhere in the facility?	☐	☒
9.19	Are only food grade lubricants used with the food processing equipment?	☒	☐
9.20	Is latex used anywhere in the facility?	☐	☒
9.21	Are incoming and outgoing vehicles inspected for cleanliness prior loading or offloading?	☒	☐
9.22	Are metal detectors used?	☐	☒
9.23	Is there a documented food defense program?	☒	☐
9.23.a	Are security cameras used?	☐	☒
9.23.b	Are all site entrances monitored and/or locked and alarmed?	☒	☐
9.23.c	How often is the food defense program reviewed?	annually	

10.	**Fair Trade / Sustainability**	**Yes**	**No**
10.1	Is the site registered to any fair trade and/or sustainability organization?	☒	☐
	SEDEX registered – Sedex number S000000045396		
10.2	Has the site undergone any fair trade and/or sustainability audits?	☒	☐
	SMETA 4-Pillar audit		

For more information on fair trade and sustainability minerals visit us at:
emdgroup.com/en/sustainability-reportHere you will find information including:

Environmental Policy		Supplier Code of Conduct	
Social Policy	Bioethics Policy	Fiscal Policy	Labor Policy
Statement on Conflict Minerals		Annual Global Citizenship Reports	
UN Global Compact Communication on Progress			