Site Quality Self-Assessment

based on

Rx-360 Supplier Assessment Questionnaire

Module 2, Site Specific Information

Relevant for

Merck Life Science Technologies (Nantong) Co., Ltd
No.39, Jianggang Road, NETDA, Nantong, Jiangsu, P.R. China
An affiliate of Merck KGaA, Darmstadt, Germany

The site self-assessment covers our quality management system for the following regulated applications:
- Manufacturing of cell culture media

The site also processes other products: For details, please refer to our GMP Quality Site Self-Assessment for Pharmaceutical Inorganic Salts (PIS) , the Site also processes non-GMP products: For details, please refer to our Non-GMP Site Quality Self-Assessment for Ready to use Media (RTU)

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: Merck Life Science Technologies (Nantong) Co., Ltd An affiliate of Merck KGaA, Darmstadt, Germany
1.2	Address: No.39, Jianggang Road, NETDA, Nantong, Jiangsu, P.R. China GPS Coordinates: 31°50′36.79″N, 120°58′7.56″E
1.3	Phone: +86 513-69917000
1.4	Email: Please refer to your local Sales representative
1.5	Fax: +86 513-69917200
1.6	Website: http://www.emdmillipore.com

SECTION 2. General Site Operating Information	
2.1	What year did the site start operating? 2019
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) Manufacturing of CCM(Cell Culture Media) products Manufacturing of RTU(Ready to Use Media) products- see RTU site Self-Assessment Manufacturing of PIS(Inorganic Salt) products- see PIS site Self-Assessment

SECTION 2. General Site Operating Information	
2.3	To which, if any, subdivision of the parent company does the site belong? Life Science is a business of Merck KGaA, Darmstadt, Germany
2.4	Size of site (in sq. ft. or m.): 44,414 square meters
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): 5 days a week, 2 shifts, 8h per shift, shutdown date during public holiday
2.6	Total number of employees on site: 236
2.7	Total number of employees in Quality: 39
2.8	Total number of employees in Manufacturing: 58
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: We apply EXCiPACT GMP for Cell Culture Media with M-Clarity level MQ500. For Cell Culture Media with M-Clarity MQ200 to MQ400 we apply ISO 9001 QMS Standards only. For sterile filtered liquid media we apply appropriate elements of European GMP, Eudralex Volume 4 Annex 1 (Manufacture of Sterile Medicinal Products) with the exception of sections 4.13 and 9.41. Which Regulatory Initiatives does the site follow/comply with? ☐ REACH

SECTION 2. General Site Operating Information		
	☐ RoHs ☐ Ca Prop. 65 ☐ WEEE	
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. NA	
2.12	By whom is the site inspected (regulatory or third party) and list inspections within the last three years: DQS: ISO9001:2015 We are aligning with a third-party certifier to get our certification for EXCiPACT GMP for cell culture media. We will notify our customers when a certification for CCM is available	
2.13	How often, as an annual average, is the site audited by customers or third parties? Average 40 audits per year	
2.14	Has an Rx-360 audit been performed at this site? ☐ Yes ☒ No Please also state the date of the audit if applicable. NA 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: Qualified, approved contract test facilities utilized for select Quality Control testing not able to be performed on site.	

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: The service supplier list combines material supplier list together.				

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): 3.1e Cell and strains in our microbiology lab for QC testing 3.1h The sporicide is used in production area for cleaning			
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): NA			
Additional Comments: NA				

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: Releasing test: For downfilling product, just test items which impact by Nantong production process, and others follow the test results from giving site (other Life Science affiliates).			

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?	☒	☐	☐

SECTION 6. Quality Assurance and Production				
		Yes	**No**	**Not Applicable**
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 solvents used in the manufacturing process of supplied materials?	☐	☐	☒
6.15a	If Yes, what class of solvent is used? NA			
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:			
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?	☒	☐	☐

SECTION 6. Quality Assurance and Production				
		Yes	No	Not Applicable
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: 6.24 matrial is specified by other Life Science site, not need to establish purchase specification.			
Additional Comments: NA				

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?	☒	☐	☐

SECTION 7. Laboratory Procedures		☐ N/A for this Site		
		Yes	No	Not Applicable
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 no analytical method development actives happened in our site 7.14: No repacker in Nantong site			
7.16	Additional Comments: 7.1b Retesting procedure defined in OOS procedure. 7.6. Nantong site doesn't perform stability studies for materials, but for final CCM products 7.11 CoC is not applicable and not available.			

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)?	☐	☒	☐

SECTION 8. Packaging, Storage, and Transport		☐ N/A for this Site		
		Yes	**No**	**Not Applicable**
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: 8.4 Barcode was used in site. but challenge test not performed, due to this function was validated in system validation.				

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

Date: 2023 November 24

Title:Quality Manager

Additional Site-Specific Information

(not based on Rx 360 Supplier Assessment Questionnaire)

9. Additional information for cleanrooms		**Yes**	**No**
9.1	Are different cleanliness classes installed in the manufacturing-and Laboratory building/area installed?	☒	☐
9.2	Are the different cleaning classes zones monitored according to SOPSs?	☒	☐
9.2.1	Are maximum airborne particles defined for the different Cleanliness classes in release and operation?	☒	☐
9.2.2	Are maximum levels of Airborne Microbe defined for the different Cleanliness classes?	☒	☐
9.2.3	Are maximum settling Microbe levels defined for the different Cleanliness classes?	☒	☐
9.2.4	Are maximum surface Microbe monitoring defined for the different Cleanliness classes?	☒	☐
9.3	Is there a monitoring frequency for the cleaning class zones defined in SOPs?	☒	☐
9.4	Cleanroom is used in the preparation, filling, primary packaging for CCM products.		

10. Warehousing		**Yes**	**No**
10.1	Are warehouse rooms with different temperature conditions in place?	☒	☐
10.2	Is the temperature monitored	☒	☐
10.2.1	What kind of storage temperatures are in place?		
	For the storage on general conditions?	15~25°C	
	For cool storage?	2~8°C	
10.3.	Are dangerous goods stored separately	☒	☐
10.3.1	Describe dangerous goods storage Different rooms for alkali materials, for precursor chemicals, for explosive chemicals, for Toxic material(Cl2)		

9. Lot Numbering Information

Example lot number	1234567890

1234567890: Processing 10 digits number generated automatically by ERP System, unique per batch.