Module 2

Rx-360 Supplier Assessment Questionnaire: Site-Specific Information

Version 14 October 2023

SECTION 1. General Site Information	
1.1	Site or Facility-Specific Name: Thermo Fisher Scientific Baltics UAB
1.2	Address: V. A.Graiciuno 8, LT-02241, Vilnius, Lithuania GPS Coordinates: 54.6246705, 25.1412328
1.3	Phone: (+370) 5 2602131
1.4	Email: info.baltics@thermofisher.com
1.5	Website address: http://www.thermoscientific.com
1.6	If there is an individual contact for the following areas, please provide name and preferred contact information (at a minimum, name and telephone number or email): Quality: Ms.Edita Aukstikalniene, Director, Quality Assurance, edita.aukstikalniene@thermofisher.com Commercial/Bussiness/Sales: lcsvilnius@thermofisher.com Primary Site Contact: info.baltics@thermofisher.com
1.7	Please list the product types manufactured or processed at this site: Reagents, proteins, nucleic acids, nucleotides, antibodies, associated kits and materials intended for ex-vivo separation of human cells for in vitro diagnostics, for further manufacturing and applied market applications, including process under aseptic conditions, bio-sample preparation, cell separation reagents, liquid chromatography (LC) columns and supply of accessories for research or further manufacturing of therapeutics or in vitro diagnostics.

SECTION 2. General Site Operating Information	
2.1	How many years has the site been in business? First sales predate 1994
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc) Manufacturing; R&D
2.3	To which, if any, subdivision of the parent company does the site belong? Life Sciences Solutions Group, Biosciences Division
2.4	Size of site (in sq. ft. or m.): ~34500 m2
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): I-IV 8:00 - 16:30, V 8:00 - 15:30
2.6	Total number of employees on site: >1500
2.7	Total number of employees in Quality Unit? >200
2.8	Total number of employees in Manufacturing: >800
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	
2.10	Does the company have an export license?	Yes
2.11	Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)?	Yes
	If yes, please specify:	FDA registration No 3009573214
2.12	By whom is the site inspected (regulatory or third party) and list inspections within the last three years: BSI -2023-04-17/20, and by Intertek 2023-05-08/11	
2.13	How often, as an annual average, is the site audited by customers or third parties? ~20 customer audits per year.	
2.14	Please list regulatory sanctions impacting the site within the last five years (i.e. warning letters, CEP suspension, import alerts, etc.): N/A	
2.15	Have there been any market withdrawals or consent decrees over the past two years?	No
2.16	Does the site outsource any quality-related activity?	Yes
2.17	If answering yes to question 2.16, are any of the following subcontractor controls in place:	
2.17a	Quality Agreements with suppliers	Yes
2.17b	Subcontractor Qualification/Audit Program	Yes
2.17c	Periodic Review of Supplier Performance	Yes
2.17d	Supplier Feedback Program	Yes
2.17e	Raw Material Supplier List	Yes

SECTION 3. Objectionable Materials on Site		
3.1	Does the site or production plant produce, process or store any of the following:	
3.1a	Beta-Lactam Antibiotics	Yes
3.1b	Pesticides	No
3.1c	Cytotoxins	No
3.1d	Steroids and/or hormones	No
3.1e	Herbicides	No
3.1f	High potency compounds	No
3.1g	Materials of animal origin/Biologics	Yes
3.1h	Live virus or micro-organism	Yes
3.1i	Allergens	No
3.1j	Genetically Modified Organisms (GMO)	Yes
3.1k	Agrochemicals	No
3.2	If yes, are any of the following cross-contamination controls in place?	
3.2a	Dedicated Facilities	Yes
3.2b	Access Controls	Yes
3.2c	Dedicated Personnel	Yes
3.2d	Dedicated Gowning	Yes
3.2e	Procedural Controls	Yes

SECTION 4. Site Operating Policies		
4.1	Does the site utilize the following written policies, programs, or procedures?	
4.1(1)	Environmental, Health, and Safety	Yes
4.1(2)	Facility Environmental Control Policy	Yes
4.1(3)	Quality Control/Quality Management Policy	Yes
4.1(4)	Quality Manual	Yes
4.1(5)	Periodic Product Quality Review	Yes
4.1(6)	Disaster Recovery Plan	Yes

4.1(7)	Pandemic Preparedness Plan	Yes
4.1(8)	Supply Chain Emergency Preparedness Plan	Yes
4.1(9)	Business Continuity/Contingency Plan	Yes
4.1(10)	Master Validation Plan	Yes
4.1(11)	Risk Assessment Program	Yes
4.1(12)	Supplier Approval Procedure	Yes
4.1(13)	Monitoring and Review of Approved Suppliers	Yes
4.1(14)	Mechanism to Reduce Testing	Yes
4.1(15)	Receiving Incoming Inspection	Yes
4.1(16)	Change Control Procedures	Yes
4.1(17)	Document Management Policy	Yes
4.1(18)	Change Notification Procedures for Clients	Yes
4.1(19)	General Facility Cleaning Procedures	Yes
4.1(20)	Hygiene and Sterilization Procedures	Yes
4.1(21)	Validated Equipment Cleaning Procedures	Yes
4.1(22)	Preventative Maintenance Program/Procedures	Yes
4.1(23)	Pest Control Program	Yes
4.1(24)	Master Production Procedure	Yes
4.1(25)	Control of Nonconforming Material	Yes
4.1(26)	Deviation/Investigation Procedure	Yes
4.1(27)	Out of Specification Policy and Procedure	Yes
4.1(28)	Sampling Procedure/Sampling Plan	Yes
4.1(29)	Raw Material Retention Program	Yes
4.1(31)	CAPA Procedure	Yes
4.1(32)	Label Control and Accountability	Yes
4.1(33)	Product Release Procedure	Yes
4.1(34)	Employee Training Program	Yes
4.1(35)	Stability, Expiration, and Shelf-Life Program	Yes
4.1(36)	Product Retention Program	Yes
4.1(37)	Recall Procedure	Yes
4.1(38)	Customer Complaint Handling	Yes
4.1(39)	Equipment Validation/qualification Procedure	Yes
4.1(40)	Internal Audit/self-inspection Program	Yes
4.1(41)	Site Security/Site Access Control Policies	Yes
4.1(42)	New Hire Program/Induction Program	Yes

SECTION 5. Quality Assurance and Production		
5.1	Does the site have an independent and defined Quality Assurance/Quality Management Division?	Yes
5.2	Does QA/QM have authority over the following:	
5.2a	Policies and procedures?	Yes
5.2b	Review of documentation for release?	Yes
5.2c	Release or rejection of incoming materials?	Yes
5.3	Does QA/QM investigate and resolve quality complaints?	Yes
5.4	Does QA/QM investigate and resolve internal deviations?	Yes
5.5	Does the QA/QM have the authority to assign a disposition to materials?	Yes
5.6	Does the QA/QM review manufacturing and testing records prior to release?	Yes
5.7	Does the facility utilize computerized systems for managing GxP activities or data?	Yes

5.8	Are relevant computerized systems 21 CFR part 11 and EU GMP annex 11 compliant?	Yes
5.9	Does the site use statistical methods for consistency and uniformity?	Yes
5.10	Does the site use controlled documents for following and recording manufacturing instructions?	Yes
5.11	Does the company qualify and/or validate manufacturing procedures?	Yes
5.12	Is any environmental monitoring conducted in production/finishing areas?	Yes
5.13	Does the company supply BSE/TSE declarations (if applicable)?	Yes
5.14	Does the company supply a declaration of Elemental Impurities (if applicable)?	No
5.15	Are ICH Q3C(R6) solvents used in the manufacturing process of supplied materials (if applicable)?	Yes
5.16	Are stability studies carried out according to ICH guidance, if applicable?	Yes
5.17	Are solvents and mother liquor reused/recycled?	No
5.18	Does the site have a process water treatment system?	Yes
5.18a	Please check all that apply to the water treatment system:	
	City/potable water	☑
	Distilled water	☑
	Water for injection (WFI)	☑
	Clean steam	☑
	Ultra-filtrated water (purified water)	☑
	Other:Water for Molecular Biology (WMB)	☑
5.19	Does the site have a batch/lot system?	Yes
5.19a	Is the system traceable?	Yes
5.19b	Is it unique?	Yes
5.19c	Is batch/lot manufacturing continuous?	No
5.19d	Is manufacturing batch by batch?	Yes
5.20	Does the company perform on-site audits prior to approving critical GxP suppliers?	Yes
5.21	Does the company audit critical GxP suppliers after initial approval?	Yes
5.22	Does the company inspect incoming materials?	Yes
5.23	Does the company test incoming materials to defined specifications?	Yes
5.24	Does the company establish purchase specifications for raw materials?	Yes
5.25	Is the equipment multi-use?	Yes
5.26	Does the company qualify equipment installation?	Yes
5.27	Does the company qualify equipment operation?	Yes
5.28	Are production critical use instruments calibrated regularly?	Yes
5.29	Is rework or reprocessing allowed and documented appropriately?	Yes
5.30	Are manufacturing and packaging activities fully traceable to the equipment, areas, and materials used?	Yes
5.31	Are production materials handled and stored in a manner to prevent degradation, contamination and cross-contamination?	Yes

SECTION 6. Laboratory Procedures		
6.1	Does the site have standard procedures for handling, retaining and re-testing samples?	Yes
6.2	Does the site have written and approved specifications and test methods?	Yes
6.3	Are laboratory critical use instruments calibrated regularly?	Yes

6.4	Is there a standard procedure in place for analytical method generation?	Yes
6.5	Does the company qualify and/or validate analytical test procedures?	Yes
6.6	Does the site perform stability testing on materials and/or products?	Yes
6.7	Are retention samples of key raw materials maintained?	Yes
6.8	Are standards traceable to their preparation and reagents used?	Yes
6.9	Are retention samples of finished product maintained?	Yes
6.10	Are shelf life/retest/expiration dates available and standardized?	Yes
6.11	Does the company provide a certificate of analysis (CoA) and/or a Certificate of Conformation/Compliance (CoC) for each lot or batch?	N/A
6.12	Does the CoA/CoC contain the manufacture name and location?	Yes
6.13	Does the CoA/CoC signed/e-signed by a Quality representative?	Yes
6.14	If a repacker performs analyses, will the Certificate reflect both the original manufacturing site data as well as the repacking site data?	Yes
6.15	If answering 'not applicable' for any of the above, please elaborate: 6.11 For catalog products certificates are published in http://www.thermoscientific.com For custom products certificates can be provided according to the agreement with the customer.	

SECTION 7. Packaging, Storage & Transport		
7.1	Does the site have a validated or qualified labeling system?	No
7.2	Is the labeling system 100% verified?	Yes
7.3	Are batch production records retained and available?	Yes
7.4	Are packaging and labeling areas separate from production?	Yes
7.5	Are barcode readers in use and challenged regularly?	Yes
7.6	Are adequate in-process controls performed?	Yes
7.7	Is product ever packaged without a label being initially applied (i.e. bright stocking)?	No
7.8	Do labels include shelf life/expiration dates?	Yes
7.9	Do labels include lot/batch number?	Yes
7.10	Do labels include requirements for storage conditions?	Yes
7.11	Is tamper evident seal used for each container of supplied materials?	No
7.12	Does the company use a First-In-First-Out or First-Expiration-First-Out system?	Yes
7.13	Does the company maintain and monitor specialized storage conditions?	Yes
7.14	Does the site make available a description of storage and/or warehouse conditions?	Yes
7.15	Does the company distribute products via a third party?	Yes
7.16	Are good distribution policies implemented?	Yes
7.17	Are transport mechanisms dedicated?	No
7.18	Does the company validate shipping method?	Yes
7.19	Does the company validate packaging methods?	Yes

I (Supplier) confirm that the information provided in this questionnaire is correct and can be verified.	
Printed Name:	Edita Aukštikalnienė
Signature:	Electronically signed by: Edita Aukštikalnienė Reason: Approver of the GxP document Date: Oct 12, 2023 14:37 GMT+3
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