World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Prequalification Unit Inspection Services
WHO INSPECTION REPORT

WHO Public Inspection Report (WHOPIR)

Part 1	**General information**
Company information	
Name of manufacturer	Beckman Coulter Life Sciences (Blue Ocean Biomedical LLC)
Corporate address of manufacturer	11800 SW 147th Ave, Miami, Florida 33196 United States of America
Manufacturing site(s) under assessment	
Address of manufacturing site if different from that given above	Hebron MFG Facility: 2295 Progress Drive, Hebron, Kentucky, 41048, USA Lattitude: 39.078441619873; Longitude: -84.6543884277344 Kendall Facility: 11800 SW 147th Ave, Miami, Florida, 33196 USA Latitude: 25.658037; Longitude: -80.434944 Hialeah Facility: 740 W 83rd St, Hialeah, Florida, 33014, USA Latitude: 25.897396; Longitude: -80.298637
Desk assessment details	
Date of review	23-27 April 2026
Last WHO inspection	Beckman Coulter Life Sciences has been inspected by WHO on the following occasions: • I-03521 – 17-19 Feb 2015. Compliant (On-site inspection). • I-03582 – 25 May 2021. Compliant (Desk assessment). • I-03859 – 15-19 August 2022. Compliant (On-site Inspection)
Introduction	
History of the site	Beckman Coulter was founded in 1935 with the manufacturing of the first commercial pH meter. Since then, the company has expanded its laboratory instruments focus to include healthcare applications in clinical diagnostics. The company have more than 150 facilities around the world. After several acquisitions over the years, in 2012 the company was divided into two – Diagnostics and Life Sciences. Beckman Coulter Life Sciences primarily serves the academia and pharma markets in scientific research instruments.

	The company also serves the clinical research market as well as applied markets such as agricultural, food and beverage, gas and oil, aerospace, among several others.	
WHO Product(s) to be covered by this desk assessment	• PQDx 0156-053-00 – Aquios CL flow cytometer	
Abbreviations	**Meaning**	
NC	Non-conformity	
NCR	Non conformity Report	
OOS	Out-of-specification	
QC	Quality control	
QMS	Quality management system	
SCAR	Supplier Corrective Action Request/Report	
Part 2	**Summary of the assessment of ISO evidence submitted**	
Inspection Report 1		
Competent authority names	bsi	
Dates of inspection	9-12 September 2025 (Miami, Florida site) 16-18 September 2025 (Hialeah, Florida site) 07 October 2025 (Hebron, Kentucky site)	
Type of inspection	Continuing Assessment (Surveillance audit)	
	Products:	A number of products and components were samples at the time of the above audits. The specific WHO prequalified product was not named within the reports provided. However, similar components were listed.
	Scope:	**MD 670607** The design and development, manufacture, distribution, installation, service and customer support of automated instruments, software, reagents, calibrators, controls, and other consumables for use in in-vitro diagnostic medical devices. **MDSAP 678344** The design and development, manufacture, distribution, installation, and service of automated instruments, software, reagents, calibrators, controls, and other consumables for use in in-vitro diagnostic medical devices. **FM 663564**

		The Design and Development, Manufacture, Installation, Service and Customer Support of Particle Characterization Systems, and the Design, Development, Manufacture and Service of Cytometry Systems for Research Use Only.
	Activities:	Management, Device Marketing Authorization and Facility registration, Measurement, Analysis and Improvement, Medical Device Adverse Events and Advisory Notices, including complaints, Reporting to regulatory authorities, Design and Development including changes, Production and Service Controls, Corrective and Preventive Actions (CAPA), Internal audits, Supplier control and purchasing.
	Standard(s):	ISO 9001:2016 ISO 13485:2016 MDSAP IVDR 2017/746
Final conclusion of the inspection report	The report concluded that "the management system has been effectively implemented. The system addresses the scope of registration and is in accordance with the company objectives, applicable requirements of the management standard and BSI Terms of Service. The result of this audit is a recommendation for continued certification" and that "based on the objective evidence, this audit enables a recommendation for continued certification to ISO 13485:2016 MDSAP, including the requirements of Australia, Brazil, Canada, Japan, USA."	
Inspection Report 2		
Competent authority names	WHO	
Dates of inspection	15-18 August 2022	
Type of inspection	Routine inspection	
	Products:	PQDx 0156-053-00 – Aquios CL flow cytometer
	Scope:	ISO 13485:2016 and WHO requirements
	Activities:	Management, Device Marketing Authorization and Facility registration, Measurement, Analysis and Improvement, Medical Device Adverse Events and Advisory Notices, including complaints, Reporting to regulatory authorities, Design and Development including changes,

		Production and Service Controls, Corrective and Preventive Actions (CAPA), Internal audits, Supplier control and purchasing.
	Standard:	IISO 13485:2016
Final conclusion of the inspection report	The sites were found to meet the criteria of the inspection and therefore the requirements were considered to be adequately implemented.	

Part 3	**Review of additional documents**

1. Certification and audit reports:

The manufacturer provided a copy of the bsi Certificate, ISO 13485:2016 (Certificate number MDSAP 678344, effective date 2024-08-30 until 2027-03-12).
The main site was listed as:

Beckman Coulter, Inc
250 Sith Kraemer Blvd, Brea, California, 92921, USA.

A total of 10 sites were listed, including the three sites listed above.

The following jurisdictions were included within the certification: Australia, Brazil, Canada, Japan, and the USA.

The scope of certification was as follows:
Scope (MDSAP 678344 and FM 663564):

The Design and Development, Manufacture, Installation, Service and Customer Support of Particle Characterization Systems, and the Design, Development, Manufacture and Service of Cytometry Systems for Research Use Only.

Scope (MD 670607):

The design and development, manufacture, distribution, installation, service and customer support of automated instruments, software, reagents, calibrators, controls and other consumables for use in in-vitro diagnostic medical devices.

2. Quality Manual:

The company has sites throughout the world and has implemented a global Quality Management System with an overarching Quality Manual - Quality Management System (QMS) Manual. The company has offices in many countries, and where Beckman Coulter does not have an office, a sales channel partner is appointed to handle local business activities.

The high-level quality manual was set out according to the requirements of ISO 13485:2016 with endorsement from top management on the effectiveness and maintenance of the QMS. Top

management was committed to the development and continual improvement of the quality management system.

Top management was responsible for implementing the Quality Policy. Beckman Coulter QMS polices were described as broad, high-level statements that provided general criteria for acceptable behaviour and practices. All documents were available to staff via Beckman Coulter's intranet.

This high-level document briefly described the role that Beckman Coulter takes in the product life cycle to include design controls, device marketing authorisation, risk management, purchasing controls, production and process controls, traceability and measurement, analysis, and improvement, to just name a few.

The manufacturer provided a copy of the organogram with clear separation of roles and reporting responsibilities.

It was noted that all high-level /global procedures provided were available in multiple languages.

3. List of current quality management procedures:
A list of the relevant Quality Management Procedures was available, containing document number, title, and effective date.

4. Standard operating procedures for:

i. Complaint handling and vigilance:
The manufacturer provided a copy of the Complaints Management Policy. All safety-related complaints were to be communicated within 48 hours of the event if it was related to possible death or serious injury and 2 business days for all other types of complaints. All complaints were recorded in the SmartSolve Simplified Intake form and were handled by a dedicated team within Beckman Coulter.

The Complaint Handling and Investigation was provided and described in detail roles and responsibilities, including the adverse event evaluator. All complaints were assessed for Adverse Events and Vigilance Reporting.

All complaints were categorised as follows:

- Level 1 – Safety – resulting in or the potential to result in injury or death or an event that could result in the deterioration of health to a patient, operator, or any other person.
- Level 1 – Quality – an alleged deficiency that does not pose death, injury, or deterioration of health.
- Level 2 – Quality – complaints that require additional investigation, including customer follow-up, investigation or return of parts or products
- Level 3 – Quality – Complaints resolved without requiring any further investigation.

Timelines for the closure of complaints was available with 60 days for Safety – level 1 complaints and 90 days for Quality – level 1 complaints.

Trending was to be performed to establish if a similar complaint had been received within 14 days, and where three events had occurred within a 14-day period, further investigation would be conducted, including consultation with Subject Matter Experts (SME).

ii. Post Market Surveillance:

The manufacturer provided a copy of the Event and Incident Reporting for Medical Devices procedure. The procedure described how an adverse event or incident could be escalated for a medical, scientific, or legal review and when management would be notified. Assessment of risk to determine the probability and severity of the hazard was to be performed.

Although WHO was not specifically listed in the notification list, all applicable IVDR countries, MDSAP jurisdictions and many other countries were listed with appropriate reporting timelines and requirements.

iii. Control of nonconforming goods/processes:

The manufacturer provided a copy of the Non-Conforming Product in Manufacturing procedure. The procedure described the process of segregation of nonconforming products upon discovery, the evaluation process, CAPA assessment and outcome. Roles and responsibilities were clearly defined. Timelines for closure was available (i.e., 90 calendar days for the completion of the investigation phase).

iv. Document Control:

The manufacturer provided a copy of the Quality System Documentation Management procedure. This procedure described the handling and control of all Beckman Coulter global documents. The procedure described situations when a document was reviewed with changes and when further training would be triggered. All documents were to be reviewed no later than 2 or 3 years after release depending on the type of document. All documents were retained for a period of 10 years.

v. Change control/change notifications (products and processes):

The manufacturer provided a copy of the Design Change. Roles and responsibilities were clearly defined, with members of all teams being involved in the design change process. A process flowchart was available that included the review of risk at all stages. References to other documents were available including the risk management plan documents.

Upon the identification of the need for change, the change was classified, with major changes typically being large-scale changes, including changes to the user needs or intended use of the product or significant redevelopment or additional clinical data. The regulatory team was to be

consulted on all changes to ensure there was no impact affecting other jurisdictions or regions where the product was sold.

vi. Quality Control and Batch release:
The manufacturer provided a copy of the Finished Product Acceptance procedure. This high-level procedure described the requirements as per ISO 13485 and that all finished products must meet all acceptance criteria before release. Specific acceptance criteria for the above prequalified product were not provided.

The Incoming Inspections procedure described at a general level the requirement of sampling plans based on AQL requirements.

vi. Risk management:
The manufacturer provided a copy of the Product Safety Risk Management procedure. This comprehensive high-level procedure described the various tools or methodology used to determine and assess risk, including preliminary hazard analysis, safety, and system risks, as well as post-launch risks. The probability of harm and severity were identified as per the requirements of ISO 14971:2019.

The reduction or control of risk was to be considered after review of current practices or State of the Art (SOTA) review of harmonised standards or nationally/internationally recognised standards or publications.

Details as to how to perform verification and effectiveness checks were available with post-market surveillance data or validation activities (e.g., clinical or usability studies) used to verify the effectiveness of the risk control measures that had been implemented.

Upon completion of the verification and validation activities (both product and process design were performed), and that they were still in accordance with design control procedures, the level of risk would be determined, and a final decision of acceptability would be decided upon.

vii. Supplier evaluation and control, verification of purchased product:
The manufacturer provided a copy of the Supplier Selection, Product Qualification, Monitoring and Communication procedure. All suppliers were categorised into three types, with all category 1 suppliers or service providers requiring an on-site audit and a supplier quality agreement. All suppliers were monitored and scored annually for performance, including annual supplier risk assessments.

viii. Design and development:
The verification procedure described how design verification activities were to be in accordance with the design outputs and satisfy the design requirements. Planning of design verification was required, which included identification of resources required; appropriate risk control measures

were to be established; and statistical techniques were to be used including acceptance criteria. If failure during the verification process was detected, the root cause was to be established and this information was to be documented in the Design History file.

The design validation procedure described the activities required to be performed to ensure that the product conforms to user needs and satisfies the intended use. There was reference to the ongoing review of risk.

The purpose of the design outputs was to ensure that the verification process met the design requirements. The information provided to achieve this was detailed, with reference to other required documents.

5. Manufacturing flowchart including in-process control points:
The manufacturer provided detailed document. This document did not have a unique identifier or effective date. QC testing points were available within the document.

6. List of critical raw materials (including details of the supplier of each material):
The manufacturer stated that "BEC confirms that, in accordance with BEC's established processes, there are no critical raw materials or critical suppliers associated with the products included in the scope of this desk inspection."

7. List of outsourced processes with direct product impact (e.g. outsourced manufacturing of components, outsourced laboratory testing, packaging, printing, etc.) including details of the supplier for each process:
The manufacturer stated that the finished product manufacturing for the AQUIOS Sodium Hypochlorite and the AQUIOS Lysing Reagent Kit were outsourced to CLINICAL DIAGNOSTICS SOLUTIONS, INC. 1750 NW 65th Ave, Plantation, FL, 33313, USA.

Part 5	**Desk assessment conclusion**

Based on the QMS evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection The site ***Beckman Coulter Life Sciences (Blue Ocean Biomedical LLC)*** located at ***118oo SW 147th Ave, Miami, Florida, 33196 United States of America*** is considered to be operating at an acceptable level of compliance with ISO 13458:2016 and WHO requirements.

This WHOPIR will remain valid for 3 years, provided the outcome of any WHO pre-qualification inspection or other audit from regulatory authorities that WHO relies on conducted during this period provides evidence of current compliance with the audit criteria.

Part 6	List of guidelines referenced in this inspection report

1. Overview of WHO's prequalification procedure for in vitro diagnostics (ISBN 978-92-4-011802-7)

2. ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

3. Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics. (ISBN 978 92 4 001531-9)

4. Reportable changes to WHO prequalified and emergency use listed in vitro diagnostics – Application guide (ISBN 978 92 4 010984-1)

5. Medical devices - Application of risk management to medical devices - ISO14971:2007

6. GHTF/SG3/N19:2012 "Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange"

7. GHTF/SG4/(99)28 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements

8. GHTF/SG4/N30R20:2006 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy

9. GHTF/SG4(pd1)/N33R16:2007 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 3: Regulatory Audit Reports ISO 13485:2016, Commitments to WHO PQ