World Health Organization

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WHO Prequalification Team - Inspection services

WHO PUBLIC INSPECTION REPORT (WHOPIR)

In vitro Diagnostic product

Inspected site/s	
Name of Organization	EXBIO Praha a.s.
Address/es of inspected manufacturing site/s	Nad Safinou II 341 25250 Vestec Czech Republic
Inspection details	
Start of inspection	22/09/2025
Inspection duration (in inspector days)	6
Type of inspection	Re-inspection
Introduction	
Brief description of manufacturing activities conducted at the site/s inspected	Purchasing, Production of semi-finished and finished device, Quality control, Warehousing, Management
General information about the organization	EXBIO Praha a.s. is a critical supplier to Sysmex Partec GmbH, legal manufacturer of the product in scope. The EXBIO Praha campus was split across 4 buildings: - Building II hosted the R&D of clinical products, innovations, and QA - Building III was for the manufacturing of research products - Building IV hosted the manufacture of clinical products, QC, and logistics - Building V was considered the HQ and hosted central functions such as HR. Buildings II, IV, and V were visited during this inspection.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	As detailed below, the areas inspected were sampled from the areas of activities performed on site that were relevant to the products in scope. The sampling was performed using a risk-based approach considering, for example, the impact of the area inspected on the product, as well as past inspection findings.
Products in scope	PQDx 0350-081-00 CyFlow® Counter System with CD4 easy count kit and CD4% easy count kit
Criteria	• All applicable clauses of ISO 13485:2016 • WHO PQ requirements • Organization's own requirements

Objective(s)	Verify continued compliance to the inspection criteria.
Limitations	None.
Out of scope	Any processes or activities not related to the products in scope were considered out of scope of this inspection.

Abbreviations	**Meaning**
CAPA	Corrective and Preventive Action
CoA	Certificate of analysis
IQ	Installation qualification
IVD	In vitro device
MR	Management review
MRM	Management review meeting
MSDS	Material safety data sheet
NC	Non-conformity
PPE	Personal protective equipment
OOS	Out-of-specifications test result
OQ	Operational qualification
PM	Preventive maintenance
PMS	Post Market Surveillance
PQ	Performance qualification
PW	Purified water
QA	Quality assurance
QC	Quality control
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure

Summary of the findings and comments

4 Quality management system

4.2 Documentation requirements

4.2.1 General

The quality management system documentation did include:

a) documented statements of a quality policy and quality objectives;

b) a quality manual;

c) documented procedures and records required by the Standard;

d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;

e) other documentation specified by applicable regulatory requirements.

4.2.2 Quality manual

The organization did document a quality manual that included:

a) the scope of the quality management system, including details of and justification for any exclusion or non-application;

b) the documented procedures for the quality management system, or reference to them;

c) a description of the interaction between the processes of the quality management system.

The quality manual did outline the structure of the documentation used in the quality management system.

4.2.4 Control of documents

Documents required by the quality management system were controlled. Records were a special type of document and were controlled according to the requirements given in Clause 4.2.5.

A documented procedure did define the controls needed to:

a) review and approve documents for adequacy prior to issue;

b) review, update as necessary and re-approve documents;

c) ensure that the current revision status of and changes to documents were identified;

e) ensure that documents remain legible and readily identifiable;

f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, were identified and their distribution controlled;

g) prevent deterioration or loss of documents;

h) prevent the unintended use of obsolete documents and apply suitable identification to them.

The organization did ensure that changes to documents were reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions.

The organization did define the period for which at least one copy of obsolete documents was retained. This period did ensure that documents to which medical devices had been manufactured and tested were available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record, or as specified by applicable regulatory requirements.

The nonconformities identified were successfully addressed through a CAPA process.

4.2.5 Control of records

Records were maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

Records did remain legible, readily identifiable and retrievable. Changes to a record did remain identifiable.

The organization did retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.

The nonconformities identified were successfully addressed through a CAPA process.

5 Management responsibility

5.1 Management commitment

Top management did provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:

a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements;

b) establishing the quality policy;

c) ensuring that quality objectives were established;

d) conducting management reviews;

e) ensuring the availability of resources.

5.3 Quality policy

Top management did ensure that the quality policy:

a) was applicable to the purpose of the organization;

b) included a commitment to comply with requirements and to maintain the effectiveness of the quality management system;

c) provided a framework for establishing and reviewing quality objectives;

d) was communicated and understood within the organization;

e) was reviewed for continuing suitability.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management did ensure that responsibilities and authorities were defined, documented and communicated within the organization.

Top management did document the interrelation of all personnel who manage, perform and verify work affecting quality and did ensure the independence and authority necessary to perform these tasks.

5.6 Management review

5.6.1 General

Top management did review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness. The review did include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews were maintained.

The nonconformities identified were successfully addressed through a CAPA process.

6 Resource management

6.1 Provision of resources

The organization did determine and provide the resources needed to:

a) implement the quality management system and to maintain its effectiveness;

b) meet applicable regulatory and customer requirements.

6.2 Human resources

Personnel performing work affecting product quality were competent on the basis of appropriate education, training, skills and experience.

The organization did document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.

The organization did:

a) determine the necessary competence for personnel performing work affecting product quality;

b) provide training or take other actions to achieve or maintain the necessary competence;

c) evaluate the effectiveness of the actions taken;

d) ensure that its personnel were aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;

e) maintain appropriate records of education, training, skills and experience.

The nonconformities identified were successfully addressed through a CAPA process.

6.3 Infrastructure

The organization did document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure included, as appropriate:

a) buildings, workspace and associated utilities;

b) process equipment (both hardware and software);

c) supporting services (such as transport, communication, or information systems).

The organization did document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, could affect product quality. As appropriate, the requirements did apply to equipment used in production, the control of the work environment and monitoring and measurement.

Records of such maintenance were maintained.

The nonconformities identified were successfully addressed through a CAPA process.

6.4 Work environment and contamination control

6.4.1 Work environment

The organization did document the requirements for the work environment needed to achieve conformity to product requirements.

If the conditions for the work environment could have an adverse effect on product quality, the organization did document the requirements for the work environment and the procedures to monitor and control the work environment.

7 Product realization

7.1 Planning of product realization

The organization did plan and develop the processes needed for product realization. Planning of product realization was consistent with the requirements of the other processes of the quality management system.

The organization did document one or more processes for risk management in product realization. Records of risk management activities were maintained.

The nonconformities identified were successfully addressed through a CAPA process.

7.4 Purchasing

7.4.1 Purchasing process

The organization did document procedures to ensure that purchased product conforms to specified purchasing information.
The organization did plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product were monitored.
Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities were maintained.
The nonconformities identified were successfully addressed through a CAPA process.

7.4.3 Verification of purchased product

The organization did establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities were based on the supplier evaluation results and proportionate to the risks associated with the purchased product.
When the organization became aware of any changes to the purchased product, the organization did determine whether these changes affect the product realization process or the medical device.
Records of the verification were maintained.

7.5 Production and service provision

7.5.1 Control of production and service provision

Production and service provision were planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls did include but were not limited to:
a) documentation of procedures and methods for the control of production;
b) qualification of infrastructure;
c) implementation of monitoring and measurement of process parameters and product characteristics;
d) availability and use of monitoring and measuring equipment;
e) implementation of defined operations for labelling and packaging;
f) implementation of product release, delivery and post-delivery activities.
The organization did establish and maintain a record for each medical device or batch of medical devices that provided traceability to the extent specified in Clause 7.5.9 and identified the amount manufactured and amount approved for distribution. The record was verified and approved.

7.5.6 Validation of processes for production and service provision

The organization did validate processes for production and service provision where the resulting output could not be or was not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product was in use or the service had been delivered. Validation did demonstrate the ability of these processes to achieve planned results consistently. Records of the results and conclusion of validation and necessary actions from the validation were maintained. The nonconformities identified were successfully addressed through a CAPA process.

7.5.8 Identification

The organization did document procedures for product identification and identify product throughout product realization.
The organization did identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status was maintained throughout production, storage, installation and servicing of product to ensure that only product that had passed the required inspections and tests or released under an authorized concession was dispatched, used or installed.
The nonconformities identified were successfully addressed through a CAPA process.

7.5.9 Traceability

7.5.9.1 General

The organization did document procedures for traceability. These procedures did define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained.

7.5.10 Customer property

The organization did identify, verify, and protect customer property provided for use or incorporation into the product while it was under the organization's control or being used by the organization. If any customer property was lost, damaged or otherwise found to be unsuitable for use, the organization did report this to the customer and maintained records.
The nonconformities identified were successfully addressed through a CAPA process.

7.5.11 Preservation of product

The organization did document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation did apply to the constituent parts of a medical device.

7.6 Control of monitoring and measuring equipment

The organization did determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.
The organization did document procedures to ensure that monitoring and measurement could be carried out and were carried out in a manner that was consistent with the monitoring and measurement requirements.

8 Measurement, analysis and improvement

8.1 General

The organization did plan and implement the monitoring, measurement, analysis and improvement processes needed to:

a) demonstrate conformity of product;
b) ensure conformity of the quality management system;
c) maintain the effectiveness of the quality management system.

8.2 Monitoring and measurement

8.2.1 Feedback

As one of the measurements of the effectiveness of the quality management system, the organization did gather and monitor information relating to whether the organization had met customer requirements. The methods for obtaining and using this information were documented.
The organization did document procedures for the feedback process. This feedback process did include provisions to gather data from production as well as post-production activities.
If applicable regulatory requirements require the organization to gain specific experience from post-production activities, the review of this experience did form part of the feedback process.

8.2.2 Complaint handling

The organization did document procedures for timely complaint handling in accordance with applicable regulatory requirements.
These procedures did include at a minimum requirements and responsibilities for:

a) receiving and recording information;
b) evaluating information to determine if the feedback constitutes a complaint;
c) investigating complaints;
d) determining the need to report the information to the appropriate regulatory authorities;
e) handling of complaint-related product;
f) determining the need to initiate corrections or corrective actions.

Complaint handling records were maintained.
The nonconformities identified were successfully addressed through a CAPA process.

8.2.4 Internal audit

The organization did conduct internal audits at planned intervals to determine whether the quality management system:

a) conforms to planned and documented arrangements, requirements of the Standard, quality management system requirements established by the organization, and applicable regulatory requirements;
b) was effectively implemented and maintained.

The organization did document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.
An audit program were planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods were defined and recorded. The selection of auditors and conduct of audits did ensure objectivity and impartiality of the audit process. Auditors did not audit their own work.
Records of the audits and their results, including identification of the processes and areas audited and the conclusions, were maintained.
The nonconformities identified were successfully addressed through a CAPA process.

8.2.5 Monitoring and measurement of processes

The organization did apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods did demonstrate the ability of the processes to achieve planned results.

8.2.6 Monitoring and measurement of product

The organization did monitor and measure the characteristics of the product to verify that product requirements had been met. This was carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures.
Evidence of conformity to the acceptance criteria was maintained. The identity of the person authorizing release of product was recorded. As appropriate, records did identify the test equipment used to perform measurement activities.
Product release and service delivery did not proceed until the planned and documented arrangements had been satisfactorily completed.

8.3 Control of nonconforming product

8.3.1 General

The organization did ensure that product which did not conform to product requirements was identified and controlled to prevent its unintended use or delivery. The organization did document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product.
The evaluation of nonconformity did include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.
Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions were maintained.

8.3.2 Actions in response to nonconforming product detected before delivery

The organization did deal with nonconforming product by one or more of the following ways:

a) taking action to eliminate the detected nonconformity;
b) taking action to preclude its original intended use or application;
c) authorizing its use, release or acceptance under concession.

The nonconformities identified were successfully addressed through a CAPA process.

8.4 Analysis of data

The organization did document procedures to determine, collect and analyse data to demonstrate the suitability, adequacy and effectiveness of the quality management system.
The nonconformities identified were successfully addressed through a CAPA process.

8.5 Improvement

8.5.1 General

The organization did identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the QMS as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post- market surveillance, analysis of data, corrective actions, preventive actions and management review.

8.5.2 Corrective action

The organization did take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions were taken without undue delay. Corrective actions were proportionate to the effects of the nonconformities encountered.
Records of the results of any investigation and of action taken were maintained.

8.5.3 Preventive action

The organization did determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions were proportionate to the effects of the potential problems. Records of the results of any investigations and of action taken were maintained.

Conclusion – Inspection outcome

Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report the company, ***EXBIO Praha a.s.*** located at ***Nad Safinou II 341, 25250 Vestec, Czech Republic*** was considered to be operating at an acceptable level of compliance with ISO 13485:2016 and WHO *Information for Manufacturers on Pre-qualification Inspection Procedures for the Sites of Manufacture of Diagnostics* (PQDx_014).

All the non-compliances observed during the inspection that were listed in the full report were addressed by the organization to a satisfactory level prior to the publication of the WHOPIR.

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.

List of WHO Guidelines referenced in the inspection report

1. WHO Information for Manufacturers on Prequalification Inspection Procedures for the Sites of Manufacture of Diagnostics (PQDx_014). (https://www.who.int/diagnostics_laboratory/evaluations/en/)
2. ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
3. WHO Post-market surveillance of in vitro diagnostics 2020 (ISBN 978 92 4 001532 6)
4. Medical devices - Application of risk management to medical devices - ISO14971:2019
5. GHTF/SG3/N19:2012 “Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange”
6. GHTF/SG4/(99)28 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements
7. GHTF/SG4/N30R20:2006 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy
8. 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.