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	Pacific Biotech Co. Ltd.
Address/es of inspected manufacturing site/s	Hi-Tech Industrial Estate 136-137 Moo 1, Tambol Baanlane Amphur Bangpa-In, Ayutthaya Province 13160, Thailand
Inspection details	
Start of inspection	16/01/2025
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, Monitoring and Measurement, and Preservation of the products in scope.
General information about the organization	The site is manufacturing the products in scope for OraSure Technologies, Inc., a US-based company. Pacific Biotech CO. LTD is an affiliate of BRIA that manufactures a range of rapid test kits. It has multiple manufacturing sites in Thailand.
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 0244-055-00 - OraQuick Hepatitis C Self-Test PQDx 0159-055-00 - OraQuick HIV 1/2 Rapid Antibody Test PQDx 0159-055-01 - Oraquick HIV Self-Test
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;

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;
d) ensure that relevant versions of applicable documents were available at points of use;
e) ensure that documents remain legible and readily identifiable.

The nonconformities identified were successfully resolved through a CAPA process.

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

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.
The organization did document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.
Records did remain legible, readily identifiable and retrievable. Changes to a record did remain identifiable.
The nonconformities identified were successfully resolved 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.

5.5 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.
The nonconformities identified were successfully resolved through a CAPA process.

5.5.2 Management representative

Top management did appoint a member of management who, irrespective of other responsibilities, had responsibility and authority that included:

a) ensuring that processes needed for the quality management system were documented;

b) reporting to top management on the effectiveness of the quality management system and any need for improvement;

c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

The nonconformities identified were successfully resolved through a CAPA process.

5.6 Management review

5.6.1 General

The organization did document procedures for management review. Top management did review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness.

Records from management reviews were maintained.

The nonconformities identified were successfully resolved through a CAPA process.

5.6.2 Review input

The input to management review did include, but was not limited to, information arising from:

a) feedback;
b) complaint handling;
c) reporting to regulatory authorities;
d) audits;
e) corrective action;
f) preventive action;
g) follow-up actions from previous management reviews;
h) changes that could affect the quality management system;
i) recommendations for improvement;
j) applicable new or revised regulatory requirements.

5.6.3 Review output

The output from management review was recorded and included the input reviewed and any decisions and actions related to:

a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes;

b) improvement of product related to customer requirements;

c) changes needed to respond to applicable new or revised regulatory requirements;

d) resource needs.

6 Resource management

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 nonconformities identified were successfully resolved 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 resolved 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.
The nonconformities identified were successfully resolved through a CAPA process.

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 resolved 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 establish criteria for the evaluation and selection of suppliers. The criteria were:

a) based on the supplier's ability to provide product that meets the organization's requirements;
b) based on the performance of the supplier;
c) based on the effect of the purchased product on the quality of the medical device.

The organization did plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product were monitored. The results of the monitoring did provide an input into the supplier re-evaluation process. 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.

7.4.2 Purchasing information

Purchasing information did describe or reference the product to be purchased, including as appropriate:

a) product specifications;
b) requirements for product acceptance, procedures, processes and equipment;
c) requirements for qualification of supplier personnel;
d) quality management system requirements.

Purchasing information did include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements. To the extent required for traceability given in Clause 7.5.9, the organization did maintain relevant purchasing information in the form of documents and records.

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. Records of the verification were maintained. The nonconformities identified were successfully resolved through a CAPA process.

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.

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.

The nonconformities identified were successfully resolved through a CAPA process.

7.5.8 Identification

The organization did document procedures for product identification and identify product by suitable means throughout product realization.

The organization did identify product status with respect to monitoring and measurement requirements. Identification of product status was maintained throughout production and storage 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 resolved 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 and verify customer property provided for use or incorporation into the product while it was under the organization's control or being used by the organization.
The nonconformities identified were successfully resolved 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.
The nonconformities identified were successfully resolved through a CAPA process.

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. As necessary to ensure valid results, measuring equipment:

a) was calibrated or verified, or both, at specified intervals, or prior to use;
b) had identification in order to determine its calibration status.

The organization did perform calibration or verification in accordance with documented procedures.
Records of the results of calibration and verification were maintained.
The nonconformities identified were successfully resolved through a CAPA process.

8 Measurement, analysis and improvement

8.2 Monitoring and measurement

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.
Evidence of conformity to the acceptance criteria was maintained.
The nonconformities identified were successfully resolved through a CAPA process.

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. Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions were maintained.

8.4 Analysis of data

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

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, ***Pacific Biotech Co., Ltd.*** located at ***Hi-Tech Industrial Estate 136-137 Moo 1, Tambol Baanlane, Amphur Bangpa-In, Ayutthaya Province 13160, Thailand*** 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.