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	Chembio Diagnostics, Inc.
Address/es of inspected manufacturing site/s	3661 Horseblock Road, Medford, NY 11763, USA 1560 5th Avenue, Bay Shore, NY 11706, USA
Inspection details	
Start of inspection	08/04/2024
Inspection duration (in inspector days)	6
Type of inspection	Re-inspection
Introduction	
Brief description of manufacturing activities conducted at the site/s inspected	Design & Development, Process Scale Up, Manufacturing Operations, Distribution & Warehousing, Regulatory Affairs, Sales & Marketing, Finance & Administration of in vitro diagnostic tests.
General information about the organization	The Medford site was ~36,000 square feet and hosted the manufacturing activities. The Bay Shore site was ~30,000 square feet and hosted warehousing and customer services.
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 0210-006-00 - DPP HIV 1/2 Assay (oral fluid) - PQDx 0053-006-00 - DPP HIV 1/2 Assay - PQDx 0054-006-02 - SURE CHECK HIV 1/2 Assay (variant name) SURE CHECK HIV 1/2 SELF-TEST (original name) - PQDx 0007-006-00 - HIV 1/2 STAT-PAK - PQDx 0054-006-01 – SURE CHECK 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 (where applicable)

4. Quality management system

4.1 General requirements

The organization and management structure of the facility was documented and defined within the organisational chart. Roles and responsibilities were available with the overall reporting structure available with clear delineation for release of product.

4.2 Documentation requirements

4.2.2. Quality manual

The organization`s Quality Manual adequately addressed and reflected the intended practices of the organization, with clear commitment from top management for the continual improvement and support of the QMS. It contained a description of the interaction between the processes of the QMS and defined the structure of the documentation system. The procedures were referenced in the quality manual. The nonconformities identified were addressed through a CAPA plan.

4.2.4. Control of documents and records

There were documented procedures for document and record control which met the requirements of the standard. There were no significant changes to the previously inspected document control system that had been implemented to manage QMS documentation, including procedures, work instruction, records, CAPAs including quality incidents and NCs and other documents. Document control practices were compliant where the procedures and the records reviewed provided evidence of conformity and

completion of requirements. Generally, records and documents were readily available. Record retention was confirmed as being at least equivalent to the lifetime of the device. The nonconformities identified were addressed through a CAPA plan.

5. Management responsibility

5.1. Management commitment

Top management provided evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by communicating to the organization the importance of meeting customer as well as applicable regulatory requirements; establishing the quality policy; ensuring that quality objectives were established; and conducting management reviews.

5.4. Planning

5.4.1. Quality objectives

Quality objectives, including those needed to meet applicable regulatory requirements and requirements for product. Quality objectives were measurable and consistent with the quality policy.

5.5. Responsibility, authority and communication

5.5.1. Responsibility and authority

Responsibilities and authorities were defined, documented, and communicated within the organization. The interrelation of all personnel who managed, performed, and verified work affecting quality were documented and ensured the independence and authority necessary to perform these tasks.

5.5.2. Management representative

The VP Quality & Regulatory was the management representative. Their responsibility and authority included ensuring that processes needed for the quality management system were documented; reporting to top management on the effectiveness of the quality management system and any need for improvement; and ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

5.6. Management review

5.6.1. General

The organization had an established process for regular management reviews that met the requirements of the standard. Records from management reviews were maintained. The review included assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

5.6.2. Review input

The input to management review included feedback; complaint handling; reporting to regulatory authorities; audits; monitoring and measurement of processes; monitoring and measurement of product; corrective action; preventive action; follow-up actions from previous management reviews; changes that could affect the quality management system; recommendations for improvement; and applicable new or revised regulatory requirements.

5.6.3. Review output

The output to management review were documented and included decisions and actions related to improvement needed to maintain the suitability, adequacy, and effectiveness of the quality

management system and its processes; improvement of product related to customer requirements; changes needed to respond to applicable new or revised regulatory requirements; and resource needs.

6. Resource management

6.1. Provision of resources

The facility was well resourced, with trained personnel and adequate but ageing facilities for the function and activities that were performed. This largely ensured the QMS was implemented, and its effectiveness maintained, and that applicable regulatory and customer requirements were met.

6.2. Human resources

The facility was staffed with personnel who had the necessary education, training, technical knowledge, and experiences for their assigned functions. Staff questioned were open and forthcoming with information. The organization had an established and well documented training procedure, including refresher training for staff. Training files for staff were maintained and available for review during the inspection. The nonconformities identified were addressed through a CAPA plan.

6.3. Infrastructure

The Medford facility showed signs of ageing. Pest control management procedure was implemented. The Bay Shore facility was well maintained, clean, orderly, and clearly sign posted.
The organization had documented requirements for the maintenance activities that applied to equipment used in production, to the control of the work environment, and to monitoring and measurement. The nonconformities identified were addressed through a CAPA plan.

6.4. Work environment and contamination control

6.4.1. Work environment

Production was planned to be carried out in rooms with controlled environments, with recordings available. Staff were observed to be wearing appropriate PPE, with access to appropriate coats, shoes, masks, and hair nets that were provided by the organization. There were pictorials when entering an area on the gowning requirements. A mirror was available to ensure appropriate PPE was properly downed. The nonconformities identified were addressed through a CAPA plan.

6.4.2. Contamination control

Procedures for the cleaning of the facility and infrastructure were available to prevent contamination of the work environment, personnel, or product. Cleaning validations for selected equipment were available. The nonconformities identified were addressed through a CAPA plan.

7. Product realization

7.1. Planning of product realization

The organization’s approach to the planning of production and service provision was adequately documented in the QMS, with procedures for document management, risk management, product production, material verification, process validation, monitoring, inspection, and test activities.
The nonconformities identified were addressed through a CAPA plan.

7.2.2. Review of requirements related to product

The organization reviewed the requirements related to the products. This review was conducted prior to the organization's commitment to supply the products to the customer. The nonconformities identified were addressed through a CAPA plan.

7.2.3. Communication

The organization was collecting customer feedback via different means, including some appropriate to resource-constrained settings. Where relevant, advisory notices, recalls, and other communication with customers were documented.

7.3. Design and development

7.3.1. General

The organization had an established process for design and development. This was not reviewed at this inspection as the products were reviewed in detail at the initial inspection.

7.3.9. Control of design and development changes

The organization had an established and well documented procedure for the control of design and development that incorporated a determination of any necessary regulatory affairs actions. The nonconformities identified were addressed through a CAPA plan.

7.4. Purchasing

7.4.1. Purchasing process

The organization had an established and well documented process for the purchasing of materials and services that included verification of critical incoming material. Supplier management and qualification procedures were available and implemented. Criteria for selection, evaluation, approval, and re-evaluation of suppliers were available. The nonconformities identified were addressed through a CAPA plan.

7.4.2. Purchasing information

Purchasing information described the product to be purchased. The nonconformities identified were addressed through a CAPA plan.

7.4.3. Verification of purchased product

The organization had implemented processes for the verification of purchased products to ensure that they met specified purchasing requirements. The extent of verification activities was proportionate to the risks associated with the purchased product. Records of these activities were maintained. The nonconformities identified were addressed through a CAPA plan.

7.5. Production and service provision

7.5.1. Control of production and service provision

Production and service provision was carried out, monitored, and controlled to ensure that product conformed to specifications. The organization had a documented process for the control of production that included, but was not limited to, qualification of infrastructure and monitoring and measuring equipment. Batch manufacturing records were available and identified the amount manufactured and amount approved for distribution. Records were verified and approved. The nonconformities identified were addressed through a CAPA plan.

7.5.6. Validation of processes for production and service provision

The organization had validated processes for production and service provision that followed procedures that included the equipment qualification and qualification of personnel; the use of specific methods, procedures, and acceptance criteria; the criteria for revalidation; and the approval of changes to the processes.

7.5.8. Identification

There was a documented procedure for product identification and segregation of released and nonconforming products within the facility. The nonconformities identified were addressed through a CAPA plan.

7.5.9. Traceability

7.5.9.1. General

The manufacturer had documented provisions for traceability in its procedures and batch records. The nonconformities identified were addressed through a CAPA plan.

7.5.10. Customer property

The organization identified and verified customer property provided for use. This included a segregation of customer property from other products. The nonconformities identified were addressed through a CAPA plan.

7.6. Control of monitoring and measuring equipment

The organization had implemented procedures for the control of monitoring and measuring equipment. Measuring equipment was calibrated and/or verified, at specified intervals, or prior to use; had identification indicating its calibration status; and was safeguarded from adjustments that would invalidate the measurement result. Calibration records were available, and a sample was reviewed.
The organization had procedures in place to assess and record the validity of the previous measuring results when the equipment was found out of tolerance. These included taking appropriate actions regarding the equipment and any product affected.

8. Measurement, analysis and improvement

8.2. Monitoring and measurement

8.2.1. Feedback

The organization had procedures in place to gather and monitor information relating to whether the organization has met customer requirements. Data were gathered from production as well as post-production activities and served as input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

8.2.2. Complaint handling

The organization had implemented a procedure for the timely handling of customer complaints. The procedures included requirements and responsibilities for investigating complaints; determining the need to report the information to the appropriate regulatory authorities; handling of complaint-related product; and determining the need to initiate corrections or corrective actions. Corrections and corrective actions were documented. Complaint handling records were maintained.

8.2.4. Internal audits

The organization had implemented an internal audit program and was conducting internal audits at planned intervals (about ten per year). The audit program was planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval, and methods were defined and recorded. Auditors were selected to ensure objectivity and impartiality of the audit process. Auditors did not audit their own work. All nonconformities identified were captured and followed using the organization`s CAPA process.

8.2.6. Monitoring and measurement of product

The organization had implemented procedures to 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 identity of the person authorizing release of product and the test equipment used to perform measurement activities were recorded.
Product release 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 had a process in place for the segregation of nonconforming product. The nonconformities identified were addressed through a CAPA plan.

8.3.3. Actions in response to nonconforming product detected after delivery

The organization had implemented procedure to deal with nonconforming product detected after delivery by taking action appropriate to the effects, or potential effects, of the nonconformity. Procedure for issuing advisory notices were in place.

8.5. Improvement

8.5.2. Corrective action

The organization had procedures in place to take action to eliminate the cause of nonconformities to prevent recurrence. The procedures defined the requirements for reviewing nonconformities (including complaints); determining the causes of nonconformities; evaluating the need for corrective action; planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; and reviewing the effectiveness of corrective action taken.
Records of investigation and actions taken were maintained. The nonconformities identified were addressed through a CAPA plan.

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, ***Chembio Diagnostics, Inc.*** located at ***3661 Horseblock Road, Medford, NY 11763, USA*** and ***1560 5th Avenue, Bay Shore, NY 11706, USA*** 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.