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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Finished Product Manufacturer
(VACCINES)

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Xiamen Innovax Biotech Co., Ltd.**
Corporate address of manufacturer	50 Shanbianhong East Rd. Xiamen, Fujian, 361000, China
Inspected site	
Name & address of inspected manufacturing site if different from that given above	1. No. 52, Shanbianhong East Road, Haicang District, Xiamen, Fujian, China 2. No. 60, Shanbianhong East Road, Haicang District, Xiamen, Fujian, China 3. No. 130-1 Xinyuan Road, Haicang District, Xiamen, Fujian, China
Inspection details	
Dates of inspection	22 to 26 September 2025
Type of inspection	Routine inspection for Recombinant Human Papillomavirus Bivalent (Types 16, 18) Vaccine Inclusion of a new Finished product production line (C03) of Vaccine Production Workshop C (No. 60 Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province, China)
Introduction	
Brief description of the manufacturing activities	In collaboration with the National Institute of Diagnostics and Vaccine Development in Infectious Diseases (NIDVD), the company has established an E.coli-based platform for development and manufacture of recombinant particulate vaccines. Based on this platform, the world ’s first Recombinant Hepatitis E Vaccine (HEV), Hecolin, was approved in China in December 2011. In addition, the Recombinant Human Papillomavirus Bivalent (Types 16, 18) Vaccine (HPV16/18 bivalent vaccine), Cecolin, was approved in China in December 2019 and prequalified by WHO in October 2021. The Recombinant Human Papillomavirus 9 -Valent (Types 6,11,16,18,31,33,45,52,58) Vaccine (HPV9v vaccine), was approved in China in May 2025.
General information about the company and site	Xiamen Innovax Biotech Co., Ltd. was established in Xiamen, in March 2005. The company is the wholly owned subsidiary of Beijing Wantai Biological Pharmacy Enterprise Co. Ltd., under the Yangshengtang Co., Ltd. in China. There are 3 authorized manufacturing sites in the Manufacturing License: 1. No.130-1 Xinyuan Road, Haicang District, Xiamen, Fujian, China (called “Old site”): Vaccine production workshop A for Hepatitis E Vaccine - Hecolin® vaccine (Prefilled syringe) and Aluminum hydroxide adjuvant manufacturing.

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	2. No.52, Shanbianhong East Road, Haicang District, Xiamen, Fujian, China (called "New site"): Vaccine production workshop B, Production line B01 for the manufacturing of purified monovalent HPV 16 and 18 antigen bulks and production line B02 for manufacturing of the finished product in vials for HPV16/18 bivalent vaccine and prefilled syringe, HPV9v vaccine Prefilled syringe and HEV vaccine* Prefilled syringe. 3. No.60, Shanbianhong East Road, Haicang District, Xiamen, Fujian, China (called "New site"): New finished product workshop C (vials) for HPV16/18 bivalent vaccine, HPV9v vaccine and HEV vaccine*. * HEV vaccine has obtained a manufacturing license but has not yet been approved for marketing for the Vaccine production workshops (B) and (C). The old site is about 3000 m^2, and the new site is about 70000 m^2.
History	The initial and the last WHO inspection for the Recombinant Human Papillomavirus Bivalent (Types 16, 18) took place from 2 to 6 February 2021.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	- Production line B01 for the manufacturing of purified HPV 16 and HPV 18 monovalent antigen bulks - Production line B02 for manufacturing of the finished product in vials - Production line C03 for manufacturing of the finished product in vials - Aluminum hydroxide adjuvant production at the workshop A located at No. 130-1 Xinyuan Road, Haicang District, Xiamen, Fujian, China, 361022 - Warehouses, QC laboratories and Utilities related to the HPV bivalent manufacturing
Restrictions	Due to the limited visibility, the Aluminum hydroxide adjuvant production was not physically inspected but observed by camera.
Out of scope	Other products than the Recombinant Human Papillomavirus Bivalent (Types 16, 18) vaccine
WHO products covered by the inspection	FVP-P-389 - Cecolin® - Recombinant Human Papillomavirus (HPV) Virus-like Particle Vaccine (types 16,18) – single-dose vials
Abbreviations	**Meaning**
AHU	Air handling unit
APR	Annual product review
APS	Aseptic process simulation
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CCS	Contamination control strategy
CFU	Colony-forming unit

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CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
GMP	Good manufacturing practices
GPT	Growth promotion test
HEPA	High efficiency particulate air
HPLC	High performance liquid chromatography (or high performance liquid chromatography equipment)
HPV	Human Papillomavirus
HVAC	Heating, ventilation and air conditioning
IQ	Installation qualification
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media fill Test
MR	Management review
NC	Non conformity
NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RABS	Restricted access barrier System
RCA	Root cause analysis
RO	Reverse osmosis
SIP	Sterilization in place
SMF	Site master file

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SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer
WFI	Water for injection

Part 2	**Summary of the findings and comments (where applicable)**

1. Pharmaceutical quality system

The Pharmaceutical Quality System (PQS) was described in the site's Quality Manual. The Quality Unit, which encompassed Quality Assurance and Quality Control activities, was found to be functioning with appropriate independence from the production unit. The quality unit was responsible for the implementation of the written quality policy of the sites. The Quality Manual described the quality policy and specified that quality objectives were managed on an annual basis.

Quality objectives were defined as part of the quality system and were managed on an annual basis. Procedures were in place to ensure that quality objectives were established at the beginning of each year, monitored regularly, and reviewed by senior management. Quality performance data were collected on a routine basis and presented during management review meetings. Review of recent management review records confirmed that the process for establishing, monitoring, and documenting quality objectives was implemented as described.

The main elements and processes required for a pharmaceutical quality management system in accordance with WHO GMP were documented and implemented. Overall, the Quality Unit had procedures and systems in place that were functioning to support the consistent manufacture of quality products. Production and control operations were described in written procedures, and managerial responsibilities were defined in job descriptions. Products and processes were routinely monitored, and the outcomes were considered during batch release decisions. Regular quality monitoring and periodic product quality reviews for the recombinant human papillomavirus bivalent vaccine were conducted in accordance with established procedures.

In general, the pharmaceutical quality system and its key elements were in place and operational. Some deficiencies were noted and satisfactory addressed before the publication of this WHOPIR.

Management review (MR):

Procedures were in place to govern management review activities within the pharmaceutical quality system. Management reviews were conducted on a routine basis, including monthly quality reviews and a comprehensive annual management review. Senior management participation was evident, and the reviews involved relevant functions across the organization.

Records of management review meetings were available and included documentation of attendance and topics discussed. The annual management review covered a wide range of quality system elements, including quality objectives, product quality reviews, deviations, change control, corrective and preventive actions, out-of-specification and out-of-trend results, regulatory inspections, audits,

self-inspections, supplier management, recalls, complaints, customer feedback, training, regulatory updates, and follow-up of actions from previous reviews.

Product quality review:

Annual product quality reviews were conducted in accordance with established procedures defining the scope, responsibilities, timelines, and data sources required to ensure continued process control and product quality. Reviews were performed on a yearly basis and covered an appropriate number of manufactured batches. For products manufactured at low volume, batches from preceding periods were included to ensure adequate data for meaningful evaluation.

The product quality review included assessment of batch manufacture and release status, deviations, out-of-specification and out-of-trend results, change control activities, corrective and preventive actions, complaints, recalls, stability data, critical process parameters, in-process controls, and finished product testing results. Batch inclusion was determined based on production date within the review period. Approval timelines defined in the procedure were generally met.

The 2024 PQR for the HPV bivalent vaccine was reviewed during the inspection.

Quality risk management:

A quality risk management system aligned with ICH Q9 R1 and WHO guidelines was established and routinely applied to manufacturing operations, environmental monitoring, changes, and new projects, using appropriate risk assessment tools. Risks were documented, tracked, and subject to periodic review, with control measures implemented to reduce risks to acceptable levels.

Contamination Control Strategy (CCS)

A documented contamination control strategy was established in line with WHO guideline and defined the elements to be considered across the product life cycle. The strategy was supported by a governing procedure that specified scope and periodic review requirements, linked to product quality review activities. A contamination control strategy specific to the recombinant human papillomavirus bivalent vaccine was available and presented during the inspection.

Deviation management:

A documented deviation management system was in place, defining the processes for identification, recording, investigation, classification, root cause analysis, impact assessment, and closure of deviations. Deviations were categorized according to their potential impact on product quality and GMP compliance, with separate arrangements established for the handling of out-of-specification and related laboratory events. Quality performance was monitored through routine statistical trending of deviations, and results were reported to management during regular quality meetings.

An electronic quality management system was implemented to support deviation management, replacing the previous paper-based process. Deviations were required to be reported promptly and were

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subject to review and confirmation of classification by the quality function. Records demonstrated that deviations were generally documented, tracked, and closed in a structured manner.

CAPA management:

A corrective and preventive action (CAPA) system was established within the pharmaceutical quality system, defining responsibilities and processes for the initiation, evaluation, implementation, and closure of CAPAs arising from a wide range of quality system inputs, including deviations, laboratory events, trend analyses, complaints, audits, inspections, risk management activities, and product quality reviews. A structured workflow was in place to support CAPA management.

Records demonstrated that CAPAs were routinely initiated and tracked, and management review included analysis of CAPA performance.

Change control (CC):

A documented change control system was in place to manage temporary and permanent changes with potential impact on product quality, regulatory compliance, and GMP. The process included change initiation, impact and risk assessment, classification, approval, implementation, effectiveness verification, and formal closure. Defined responsibilities ensured appropriate quality oversight, and implemented changes were subject to periodic review through product quality review and management review processes. An electronic quality management system was used to track changes, with arrangements in place to ensure continuity and traceability in case of system downtime.

Changes reviewed during the inspection demonstrated that risk-based justifications were applied, including for adjustments to raw material testing strategies and supplier changes. These changes were supported by documented risk assessments, implemented through defined action plans, and approved prior to use.

Overall, the change control system was established and functioning;

Complaints:

A documented system was in place for the handling and investigation of customer complaints, including classification based on potential impact on patient health and product quality, defined timelines for investigation and closure, and requirements for escalation to the qualified person for significant complaints. Complaint investigations included communication of outcomes to complainants prior to closure.

A limited number of complaints related to product presentation were recorded during the review period. These included issues associated with foreign matter and labelling presentation. One complaint, classified as major, concerned the durability of printed batch and expiry information on vials. The issue was promptly investigated, escalated to senior management, and assessed for potential impact on traceability and pharmacovigilance. The investigation concluded that, while normal handling would not readily remove the printed information, the printing material used had limited abrasion resistance under repeated contact.

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Corrective and preventive actions were initiated, including implementation of a more durable printing material and initiation of a change to an alternative printing technology to further mitigate the risk. At the time of inspection, part of the corrective action had been implemented, while additional changes remained in progress.

Product recalls:

A documented product recall system was in place, defining responsibilities and procedures for the management of voluntary and mandatory recalls, including classification according to potential health risk and timelines for regulatory notification, evaluation, reporting, and follow-up. The recall procedure was aligned with regulatory expectations and included requirements for escalation to relevant authorities and ongoing status reporting based on recall classification.

Arrangements were established to ensure recall readiness through periodic mock recall exercises, including more frequent simulations for products supplied to WHO-related markets. Records confirmed that no actual product recalls had been initiated to date.

A recent simulated recall exercise was conducted using a product batch distributed within the same calendar year and a destination country selected to reflect actual distribution complexity.

Self-inspection:

A self-inspection programme was established and implemented as part of the pharmaceutical quality system, with inspections conducted at least annually. The scope of self-inspections was comprehensive and covered organizational arrangements, personnel, facilities, equipment, materials and products, qualification and validation, documentation, production, quality control and quality assurance, contract activities, product shipment and recall, data integrity, and follow-up of previous findings.

Self-inspections were documented through formal reports, and identified deficiencies were addressed through defined follow-up actions and corrective and preventive actions. Records confirmed that self-inspections were conducted in recent years in accordance with the established schedule.

Quality audits and suppliers' audits and approval:

A supplier qualification and audit system was established to ensure that materials used in production were sourced from approved suppliers and met defined quality and regulatory requirements. Materials were categorized by type and classified according to their criticality to product quality and patient safety, with corresponding qualification and audit requirements applied on a risk-based basis.

Supplier qualification included quality assessments using questionnaires, sample evaluation, and on-site, remote, cooperative, or contracted audits, as appropriate. Critical and moderately critical suppliers were subject to periodic review and audit, while non-critical suppliers were managed through less intensive controls. Annual performance assessments were conducted for selected suppliers and were used to support ongoing supplier approval and, where justified, optimization of incoming material testing strategies.

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Supplier changes followed established qualification and change control processes, including document review, sample testing, suitability assessment, and inclusion in the approved supplier list. Records reviewed during the inspection demonstrated alignment between supplier qualification status and change control documentation.

On-site supplier audits were conducted with multidisciplinary participation and covered manufacturing operations, quality management systems, data integrity, sterility assurance, and equipment qualification. Audit findings were documented, risk-assessed, and managed through corrective and preventive actions. Where audit observations did not indicate high risk, suppliers remained qualified subject to ongoing monitoring of CAPA implementation.

Overall, systems for supplier qualification, quality auditing, and approval were in place and functioning, with risk-based controls applied to ensure the suitability of materials and services used in vaccine manufacture.

Contract production, analysis and other activities and Quality agreements:

Manufacture of the recombinant human papillomavirus bivalent vaccine was performed entirely in-house. Certain analytical testing activities and warehousing services were contracted to external providers under defined quality agreements.

Specialized microbiological identification testing was outsourced to an accredited external laboratory operating in accordance with international standards for testing laboratories. A quality agreement was in place that clearly defined the responsibilities of both parties, including compliance with pharmacopoeial methods, data retention, reporting timelines, and review of test results by the manufacturer.

External warehousing services were used for the storage of selected non-critical materials. The contract defined responsibilities for provision of appropriate storage infrastructure, environmental controls, security, and monitoring systems. The manufacturer maintained operational control through on-site presence of its own personnel and full access to stored materials, ensuring continued oversight and compliance with GMP requirements.

Overall, arrangements for contracted activities were supported by written agreements and appropriate oversight to ensure that outsourced activities did not adversely affect product quality or regulatory compliance.

Personnel

The site was adequately staffed, with personnel distributed across quality, production, and supply chain functions. Personnel met during the inspection demonstrated knowledge of GMP principles and confirmed participation in initial and ongoing training. Written job descriptions defining duties and responsibilities for key positions were available, and an organizational structure was in place demonstrating clear separation between quality and production functions.

A training system was established to manage GMP and role-specific training through annual training plans, defined qualification requirements, assessments, and retraining mechanisms. The training system was in transition from a paper-based approach to an electronic training management system,

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with both systems in use during the review period. Training planning and tracking were generally implemented.

Personnel hygiene and behavior requirements were defined through documented procedures, including controls for gowning, health status, and conduct in production and aseptic areas. Appropriate facilities and controls were in place to support hygienic operations.

Qualification systems for aseptic operators and visual inspectors were established and implemented. Aseptic operators working in classified areas underwent initial and periodic qualification, including training, procedural assessment, and performance simulation, with reviewed records demonstrating satisfactory qualification status. Visual inspectors were subject to structured qualification programs, including theoretical training, practical exercises, and periodic requalification against defined acceptance criteria. Spot checks confirmed that visual inspectors were appropriately trained and qualified.

Documentation:

A document and record management system was established and implemented through an electronic quality document management system. The system supported controlled issuance, revision history, periodic review, and archiving of quality documents, with oversight by the quality function. Document review cycles were managed electronically, and responsibilities for review and approval were defined.

Arrangements were in place for the management of controlled paper, including the use of designated paper types for different GMP purposes and defined contingency measures during system downtime.

Data integrity was governed by documented procedures covering the full data lifecycle and aligned with internationally recognized principles. Electronic and paper-based systems were used across manufacturing, laboratory, warehouse, training, and quality management activities. Review of selected records indicated that data integrity principles were generally understood and applied.

Batch Release Process and Lot Summary Protocol:

A documented system was in place to govern batch and lot release activities, defining responsibilities and procedures for review and authorization. Batch release involved review of manufacturing, packaging, and testing records by the quality function, followed by submission of required samples and documentation to the national control laboratory for official release, in accordance with regulatory requirements. Final release of finished product by the qualified person was performed only after receipt of the relevant regulatory authorization.

Product-specific procedures were established to cover batch release activities for drug substance, intermediates, and finished product. Review of selected batch and lot release records confirmed that the required documentation was complete and that release decisions were made in line with established procedures. Batches intended for specific international markets were appropriately identified and released in accordance with defined requirements.

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2. Production system

Good manufacturing practices were generally implemented. Necessary resources were provided, including qualified and trained personnel, adequate premises, suitable equipment and services, appropriate materials, containers, approved procedures and instructions, laboratories and equipment for in-process and other controls. Manufacturing steps were monitored and recorded in batch manufacturing record (BMR) and packaging records. Deviations from procedures were recorded and investigated. Product was being released by the qualified person in accordance with written procedures.

The production lines of HPV16/18 bivalent vaccine (Vial) include the bulk production line B01 for preparing purified antigen bulk (PB), and two formulation and finished product filling lines (B02 and C03).

Manufacturing operations for drug substance, adjuvant preparation, formulation, filling, and visual inspection were observed and generally complied with GMP requirements. Production was supported by qualified personnel, validated processes, and appropriate in-process controls. Batch manufacturing records were maintained electronically and reviewed prior to release.

Seed lot and cell bank systems were appropriately managed, with controlled storage, monitoring, and segregation of production and backup materials.

Drug substance manufacturing processes were well defined, and purification and filtration steps were appropriately controlled.

Fill and finish operations were conducted using barrier systems and controlled environments. Environmental monitoring, in-process controls, and aseptic process simulations supported assurance of sterility.

Visual inspection was performed by qualified inspectors under controlled conditions.

3. Facilities and equipment system:

Manufacturing facilities were appropriately designed and sized for the activities performed, with defined material and personnel flows and segregation of cleanroom grades.

Floor plans including layouts, manufacturing rooms' classification, AHU zoning, material flow, product flow, personnel flow, waste flow and air flow were presented.

Both filling lines were equipped with a vial washing machine, a depyrogenation tunnel, a filling line into a RABS with an extended LAF, and a sealing machine.

The site had a Validation Master Plan in place. This document outlined the general provisions for qualification and validation activities across the facility. It served as a foundational reference for ensuring that equipment, systems, and processes consistently meet predefined specifications and regulatory requirements.

Equipment used in production, sterilization, and environmental control was generally well maintained, calibrated, and qualified.

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Utilities supporting sterile manufacturing, including water systems, HVAC, compressed air, and clean steam, were established and monitored.

Water and Pure Steam systems:

The water system comprised purified water and water for injection, with purified water used as feed for water for injection and pure steam generation, as well as for cleaning and preparation activities in lower-grade areas. Water for injection was used for final rinsing and critical sanitation activities. Both systems were designed with appropriate storage, distribution, continuous circulation, online monitoring of critical quality attributes, and defined diversion of out-of-specification water. Sanitization of water systems and integrity testing of critical components were performed at defined intervals, and reviewed records demonstrated compliance with established procedures.

HVAC

The HVAC system was designed to maintain controlled environmental conditions in classified areas, with defined pressure differentials, air change rates, temperature and humidity limits, and use of HEPA filtration. Periodic qualification and requalification were performed based on cleanroom classification. Environmental parameters were continuously monitored, and airflow visualization studies were conducted to support contamination control.

Compressed air and gases

Clean compressed air was supplied through qualified distribution systems and monitored based on criticality of points of use. Monitoring included physical, chemical, and microbiological parameters.

Disinfection, Decontamination and Cleaning Validation

A comprehensive system was in place for validation of disinfectants, facility decontamination, and cleaning processes to support contamination control in sterile vaccine manufacture.

Disinfectant efficacy was validated using a range of disinfectants applied in classified areas, supported by studies addressing efficacy over time and compatibility with production surface materials. A defined disinfectant rotation programme was implemented for classified clean areas.

Facility decontamination using vaporized hydrogen peroxide was qualified and validated for critical manufacturing areas and pass-through chambers. Validation included assessment of sterilant distribution, biological and chemical challenge indicators, residue clearance, and worst-case loading configurations, based on risk assessment.

Cleaning validation was performed in accordance with documented procedures using a risk-based approach. All product-contact equipment for HPV16/18 manufacture was dedicated. Validation activities demonstrated effective removal of product residues, detergents, and microbial contaminants using appropriate analytical methods. Historical performance data supported validated usage limits for chromatography columns, and cleaning effectiveness was confirmed for fermentation and chromatography systems.

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Computerized systems validation

The manufacturer had implemented and maintained a range of computerized systems to support GMP activities, including document management, electronic batch records, laboratory operations, environmental monitoring, warehouse and equipment management, training, and quality management processes. These systems were integrated where appropriate and operated on a common platform to support data consistency and workflow management.

A validation programme was in place for computerized systems used in GMP-critical activities. Validation activities were conducted using a risk-based approach and included testing of system functionality, user roles and permissions, and key workflows relevant to quality events, such as deviations, laboratory investigations, corrective and preventive actions, and change control. Issues identified during validation testing were documented, investigated, and resolved prior to routine use of the systems.

Access to computerized systems was controlled through defined authorization processes, with user roles and privileges assigned based on job responsibilities. Records demonstrated that system use was monitored and that data generated were attributable, legible, contemporaneous, original, and accurate.

Overall, the computerized systems supporting the pharmaceutical quality system were validated and operational.

4. Laboratory control system

Quality control laboratories for physicochemical, biological, and microbiological testing were established with appropriate segregation of personnel access, sample receipt, storage, and distribution. Laboratory activities were managed through a laboratory information management system, with defined controls for data entry, review, and supervision. Although analytical instruments were not fully integrated with the system, data were securely stored on servers and appropriately reviewed. Microbiological laboratories, including sterility testing facilities, were found to be suitable for their intended use, with appropriate controls for media management, incubation, environmental monitoring, and microbial identification, including outsourcing of species-level identification where required.

Animal testing activities were conducted in dedicated facilities with controlled environmental conditions and defined procedures for animal care, immunization, observation, and investigation of adverse outcomes. Arrangements demonstrated appropriate segregation, monitoring, and oversight of animal testing used to support product quality control.

A documented system was in place for the management of out-of-specification, out-of-trend, and out-of-expectation results, applying a phased, hypothesis-driven investigation approach. Investigations reviewed demonstrated structured assessment of laboratory and process factors, implementation of corrective actions, and confirmation of system integrity. Management of laboratory events was supported by a computerized quality management system, and records indicated timely investigation and closure.

Procedures were established for the management of reference standards, including classification, qualification, storage, use, and monitoring. A wide range of reference standards was used to support physicochemical, biochemical, potency, and microbiological testing.

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Stability studies were conducted in accordance with defined procedures covering cell banks, intermediates, finished products, and adjuvants. Stability samples were stored under controlled conditions with continuous temperature monitoring. Review of ongoing stability studies for finished product and drug substance demonstrated that testing was performed according to established schedules, with results remaining within specifications.

Retention sample systems were established and well maintained, with appropriate storage conditions, documentation, and periodic examination. Records reviewed did not identify any issues with retention sample management.

Water system monitoring was performed based on a risk-based sampling strategy, with defined testing frequencies, routine trend analysis, and review through quality systems. Monitoring data demonstrated overall system control, with alert-level excursions appropriately investigated and managed without impact on product quality.

An environmental monitoring programme was implemented for classified areas, supported by risk-based selection of sampling locations, defined alert and action limits, routine trending, and microorganism identification in critical areas. Review of monitoring data showed no adverse trends or excursions affecting product quality.

5 Materials management:

Systems were in place for the receipt, storage, control, and distribution of raw materials, excipients, consumables, packaging materials, and finished products. Materials were received in a dedicated warehouse, where checks were performed to verify supplier information, order accuracy, packaging integrity, transportation conditions, shelf life, and, where applicable, sterilization status. Receipt data were recorded in a computerized warehouse management system, and materials were labelled and transferred to storage using automated handling systems.

Materials were stored under defined environmental conditions appropriate to their classification, including controlled room temperature, cool storage, and refrigerated areas, with environmental parameters monitored through an automated system. Raw materials, consumables, and primary packaging materials were stored in designated areas, and additional external warehousing was used for certain non-critical materials under contractual arrangements.

Material status control was managed electronically, with quarantine and rejected materials blocked in the system to prevent unintended use. Material issuance and return were also controlled through the computerized system, which was demonstrated to function as intended. Overall, materials observed in the warehouses were appropriately stored, clearly labelled, and the facilities were maintained in a clean and orderly condition.

Finished products were stored in dedicated cold storage facilities under monitored conditions. Physical segregation was applied for finished products, and storage conditions were appropriate for the products observed.

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Distribution of vaccine products was supported by qualified cold-chain shipping systems. Cold-chain containers were subjected to independent thermal and mechanical performance qualification under worst-case environmental and logistical conditions, including extended transit times, extreme temperatures, multiple transfer points, and handling stresses. Qualification demonstrated that temperature control and container integrity could be maintained throughout distribution. Worst-case locations for temperature monitoring were identified and applied during routine shipments.

6 Packaging and labeling system:

The packaging and labelling system for vialled finished product was inspected and found to be appropriately designed, maintained, and controlled. Packaging operations were governed by documented procedures defining environmental conditions, material handling, equipment operation, and in-process controls. Vials were required to be equilibrated under controlled temperature and humidity conditions prior to labelling to prevent condensation, with checks performed before the start of operations.

Labelling equipment was supported by operating procedures covering setup, parameter control, label configuration, and precautions to ensure correct application and legibility. A recently installed alternative coding technology was observed on the packaging line as part of improvements to labelling robustness. Controls were in place for the storage, handling, and disposal of specialised labels, including those with temperature-sensitive requirements.

Overall, the packaging and labelling system was found to be suitable for its intended purpose and operated in accordance with established procedures.

Part 3	**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, **Xiamen Innovax Biotech Co., Ltd.**, located at **No. 52 and 60, Shanbianhong East Road, Haicang District, Xiamen, Fujian, China** and **No. 130-1 Xinyuan Road, Haicang District, Xiamen, Fujian, China**, was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

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Part 4	List of WHO Guidelines referenced in the inspection report

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
   https://www.who.int/publications/m/item/trs986-annex2

2. WHO good manufacturing practices for biological products. WHO Expert Committee on Biological Standardization. Sixty-sixth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 999), Annex 2. ***Short name: WHO TRS No. 999, Annex 2***
   https://www.who.int/publications/m/item/annex-2-trs-no-999-WHO-gmp-for-biological-products

3. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4. ***Short name: WHO TRS No. 929, Annex 4***
   https://www.who.int/publications/m/item/annex-4-trs-929

4. Good manufacturing practices: guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third report. Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3. ***Short name: WHO TRS No. 1019, Annex 3***
   https://www.who.int/publications/m/item/trs1019-annex3

5. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
   http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

6. WHO good practices for pharmaceutical quality control laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-seventh report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052, Annex 1. ***Short name: WHO TRS No. 1052, Annex 4***
   https://www.who.int/publications/m/item/who-good-practices-for-pharmaceutical-quality-control-laboratories

7. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
   Short name: WHO TRS No. 957, Annex 3
   https://www.who.int/publications/m/item/trs957-annex3

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