



Warehouse Management System Project

Linda
June 24th 2022



Group structure and stakeholders

YangShengTang Group (YST)



Beijing Wantai

National Institute of Diagnostics
and Vaccine Development in
Infectious Diseases(NIDVD)

Xiamen University



(ELISA, POCT, diagnostic reagents,
vaccine)



Veterinary
diagnostic
reagents



Reagents



Quality control
materials



Chemiluminescent
reagents



Medical device



Recombinant
subunit vaccine



Xiamen Innovax is the wholly owned subsidiary of Beijing Wantai. It is the only vaccine arm of YST

Founded in

2005

Employees

1000+

Manufacture Sites

2

Products

Hecolin® (HEV) – Launched
Cecolin® (HPV) – Launched



- Floor area: 13,814 m²
 - Building area: 12,734 m²
 - Capacity: 5,000,000 doses/year
- HEV vaccine production facility**

&



- Floor area: 67,834m²
 - Phase I building area : 35,365m²
 - Capacity: 30,000,000 doses /year
- HPV vaccine production facility**

Innovax is dedicated to provide high-quantity and affordable innovative vaccine for people in need to combat infectious disease.

Products



- **Hecolin®**
- Recombinant Hepatitis E Vaccine (*Escherichia Coli*)
- Licensed in 2012
- First vaccine for Hepatitis E worldwide.

- **Cecolin®**
- Recombinant Human Papillomavirus Bivalent (Types 16,18) Vaccine (*Escherichia coli*)
- Licensed in 2019
- China's first domestic HPV vaccine
- China's first WHO PQ receiving domestic HPV vaccine



Pipelines

Vaccine	Development stage					
	R&D	IND	Ph1	Ph2	Ph3	BLA
Cecolin®(HPV2v vaccine)						
Hecolin®(HEV vaccine)						
HPV9v vaccine						
Varicella vaccine (V-Oka)						
Influenza virus vector COVID-19 vaccine for intranasal spray						
2nd generation varicella vaccine(VZV-7D)						
20-valent PCV						
Recombinant COVID-19 vaccine						
JADE (HPV vaccine)						
Herpes zoster vaccine						
20-valent HPV vaccine						
Rotavirus vaccine						



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1 Background

Vaccine production is complex with a number of steps constituting the process flow including the reception of raw material through intermedia products to the vaccine dispatch.

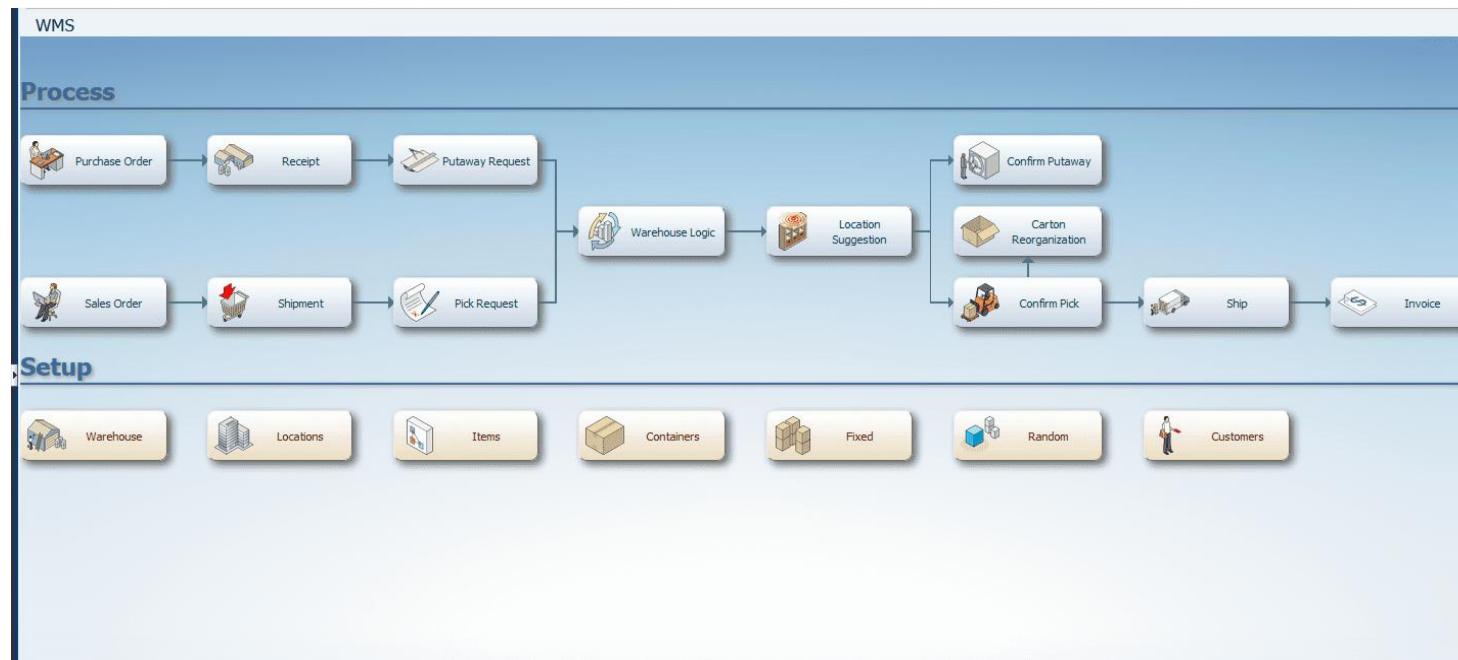
Traceability is being applied to the packaging of vaccines are increasingly considered as the primary level, as recommended by the Vaccine Innovation Prioritization Strategy (VIPS). The premise here is to apply traceability into the production phases starting with the receipt of raw materials, to enable a fully integrated data availability from start to dispatch.

This principally focus on the integration of warehouse management systems, where the warehouse encompasses the complete production process. This is a production modernization approach resulting in increased efficiency in production operations and leading to cost savings.

INNOVAX are now engaged in the first steps in the planning of improved warehouse management.

2 Objective

To ensure the sustainable high quality and safety of vaccine through intelligent management, the WMS are establishing to monitor whole process of warehouse management from receipt of raw materials for antigen development through intermediate products to vaccine stockpiling and final dispatch.



3 Main Actions

Project

- Formulate URS
- Project establishment
- Formulate quality and project plan (QPP)

Validation Preparation

- Project configuration development
- Formulate validation plan (VP)
- Formulate Function specification
- Formulate software design specification
- Formulate hardware design specification
- Formulate risk assessment result
- Formulate design qualification report

Acceptance Test

- Install WMS system for try out.
- Formulate FAT protocol and specification, implement the protocol and formulate FAT report.
- Formulate SAT protocol and specification, implement the protocol and formulate SAT report.
- Formulate I/OQ protocol and specification, implement the protocol and formulate I/OQ report.

Document

- Conduct acceptance and formulate validation acceptance report.
- Formulate relevant SOP, including warehouse management system for material and finished product.

Q1 2022

Q2 2022

Q3 2022

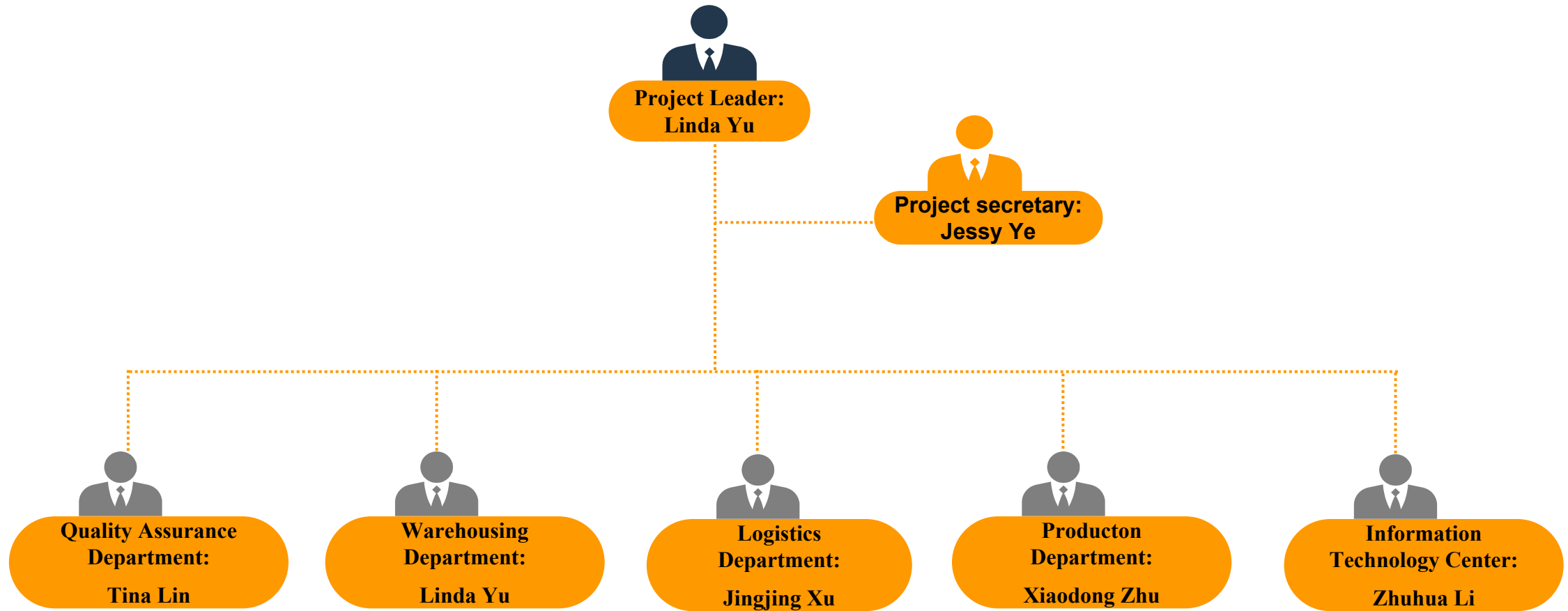
Q4 2022

4 Costs

Hardware	Software	Validation	Consultation	Totally
	\$190,000		\$30,000	\$220,000

Consultation company: Siemens AG

5 Team composition



5 Team composition--roles and responsibilities

Role	Responsibilities	staffs
Project leader	Responsible for the overall project promotion, project planning, staffing planning, etc Responsible for the coordination of the relationship between functional departments involved in the project Responsible for regular report on the project progress Responsible for the management of project team members	Linda Yu
Project secretary	Assist the project manager in project management Responsible for project progress tracking and coordination Responsible for organizing regular project management meetings Responsible for archiving project management data	Jessy Ye
Team member	Assist in supplier selection and subsequent coordination Assist in URS formulation Review technical protocol Lead the implementation of WMS project hardware and software with supplier Plan system network Participate in system validation	Zhuhua Li
Team member	Lead the compliance audit Assist vendor to adjust and validate the system	Tina Lin
Team member	Participate in the system planing of material management module Assist in URS formulation Guide SOP formulation for material management in warehouse management system Participate in system try-out and system acceptance	Linda Yu
Team member	Participate in the system planing of finished product management module Assist in URS formulation Guide SOP formulation for finished product management in warehouse management system Participate in system try-out and system acceptance	Jingjing Xu

6 Current Status

- ✓ Vendor selection
- ✓ Formulate URS
- ✓ Confirm the scope of work

- FAT/SAT protocol (on-going)
- Validation

- Third-party Interface Interconnection



- ✓ Formulate the project
- ✓ Study the requirement of WMS

- ✓ System configuration development
- ✓ Function design (FS\DS\HDS)

- Location/pallet label making
- Hardware selection

- Formulate/revise the relevant SOPs

7 Current Experience & Challenges

Current experience:

- Project establishment
- Study the requirement of WMS
- Select the vendor (right person to do the right thing)
- Keep close contact with the vendor

Challenges:

- Influenced by the global COVID-19 epidemic, spare parts of the equipment are in short supply, may affect the project progress.
- Cross to another rebuildment of automatic warehouse which may delay the WMS establishment.



Making A Safe, Effective and Cost-Conscious Vaccine, Available
for More Females Worldwide.....

– *Xiamen Innovax Biotech*

