

Traceability Pilot Project in CDIBP



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- WHO PQed Vaccine: Japanese encephalitis vaccine, live
 - 2 ml vial, 10 vials/box
 - GS1 barcoding from secondary package – mandatory requirements from UNICEF/Gavi procurement to be implemented since Jan. 1, 2022
- Going to comply with UNICEF guidelines, July 2021: preferred characteristics:

Data element	Application Identifier	Example
Global Trade Item Number	01	01234567890123
Expiry date	17	210131
Batch/ Lot	10	abc123
Serial number	21	a1b2c3000987654

Project goal

- GS1 Data Matrix on secondary package
- GS1-128 barcode after the secondary package
- Aggregate information on each level of package
- Make the packaging line ready for use by March 1, 2022



Working group

- Members from Production Management Dept., Filling & Packaging Dept., Warehouse & Logistics Dept., Engineering Dept., QCM, IT, International Business and Cooperation Dept.
- Leader: Manager of Production Management Dept.

Decision of the project

- Traceability of vaccines have been implemented in China from secondary packaging since 2008
- 128 coding system of 9 digitals, different from GS1 data matrix
- Upgrade a packaging line for implementing GS1 bar coding
- Upgrade software to configure the GS1 barcoding system
- Apply DCVMN traceability pilot projects consortium support

Work Procedures

- Project initiated in Sep. 2021 and completed in April 2022
- Vendor selection: Shanghai Minze Information & Technologies Co., Ltd.
- Site investigation with vendor and discussion the packaging line upgrading plan
- URS drafting and consultation UNICEF team
- Design the procedure flow for implementing GS1 barcoding
- Equipment procurement and software development
- Installation and qualification
- Process validation
- Training along the project progress, SOPs

Total costs

- Equipment: about 150,000 USD
- Software: about 50,000 USD
- Consultation and training services – funds from DCVMN to vendor: 50,000 USD

Equipment for packaging line upgrading

- Control panel and screen
- Cameras
- Scanners
- Printers
- Labelers for secondary and tertiary packages

Software for GS1 barcoding

- Generating software for GS1 Barcoding
 - Vendor consulted GS1 China office as well as the GS1 headquarters
 - CDIBP consulted UNICEF about the readable display of GS1 barcode
 - Considered UNICEF guidelines and standard GS1 identifications

Training provided by Vendor

- Engineers of Minze stayed on site for nearly half years
- Training given at beginning of the project, through URS drafting, project planning, commissioning, qualification, during and after performance validation
- Minze also helped to consult GS1 offices to confirm the requirements and implementation

Regulatory actions

- Consult UNICEF about the GS1 barcode readable part design
- Submit the implementation of GS1 barcoding for JE vaccine to UNICEF and WHO PQ team when the project completed

Challenges

- Delay of equipment arrival due to impact of Pandemic. The project delayed totally 1.5 months, but still meet the demand
- Understanding the coding logics and optimizing the design coding system
- Considering sampling issue
- Considering integrity with warehousing system
- Fine printing on small box

Project target achieved

- JE vaccine for UNICEF this year are produced and labeled with GS1 barcoding



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THANK YOU