



## **Drug Traceability System** Sinergium Biotech

## ANMAT drug traceability regulatory

### ➤ Resolution No. 435/11 of the Ministry of Health of the Nation

It establishes that the people who intervene in the commercialization, distribution and dispensing of medicinal specialties, included in the ANMAT's **Registry of Medicinal Specialties (REM)**, must implement a **Traceability System** that ensures their control and monitoring, from the production or import of the product until its acquisition by the user or patient. The established traceability system **will consist of the individual and unambiguous identification of each unit of the medicinal specialties to be marketed**, which allows the monitoring of each unit throughout the entire chain of distribution of medicines.

ANMAT will be the enforcement authority of this Resolution.

# ANMAT drug traceability regulatory

➤ <http://anmat.servicios.pami.org.ar/>

Link to the ANMAT National Drug Traceability System page where the data loading is done :



**Trazabilidad de Medicamentos**  
SISTEMA NACIONAL DE TRAZABILIDAD

Si ya es usuario: [Ingresar al Sistema](#) | ¿Aún no es usuario? [Regístrate](#)  
Recuerde cumplimentar los pasos 01 y 02 antes de registrarse aquí.

- LABORATORIO
- DISTRIBUIDOR
- OPERADOR LOGÍSTICO
- DROGUERÍA
- FARMACIA
- ESTABLECIMIENTO ASISTENCIAL
- PERSONA

**Categorías**

- Mapa de Sitio
- Contacto
- Ayuda
- Marco Normativo

**Consulta de Trazabilidad**

**Medicamentos**

**¿Cómo funciona?**

En una primera etapa, se aplicará a especialidades medicinales que contengan en su composición los...

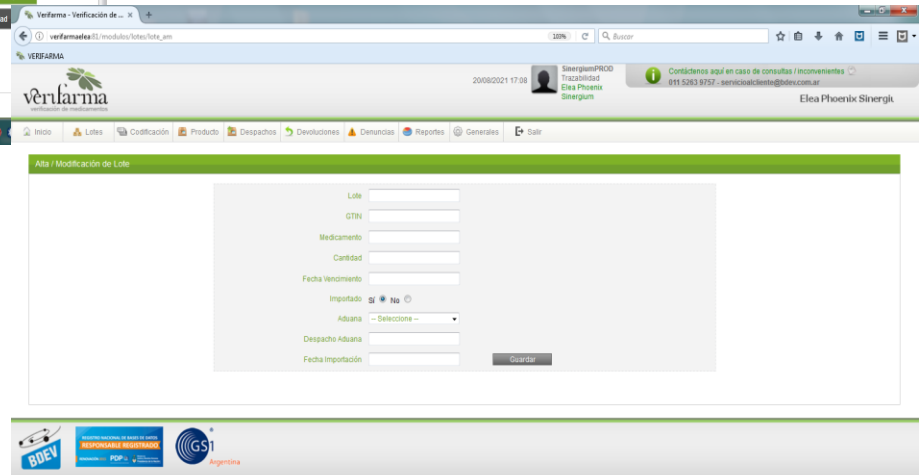
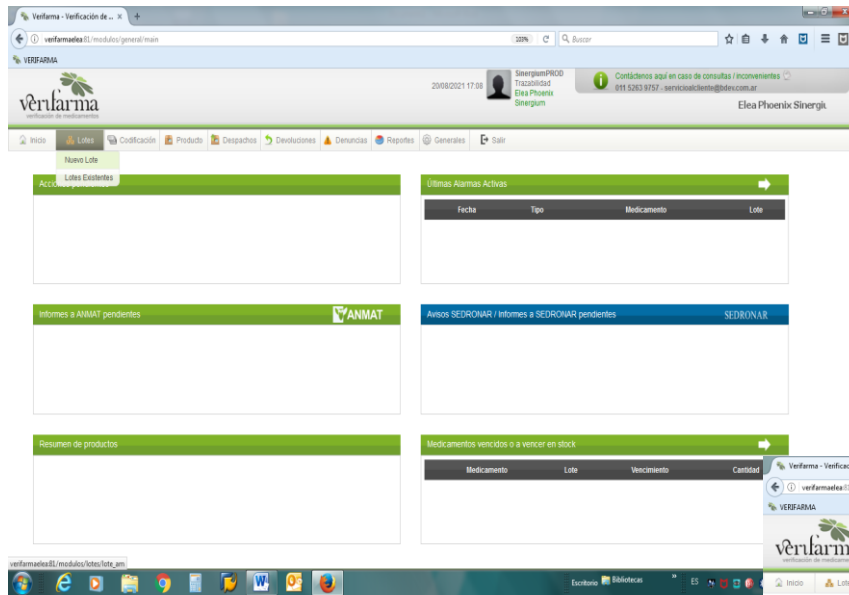
Es un Servicio de Trazabilidad Multifase, que permite el monitoreo en tiempo real de cada uno de los...

# Current Traceability process in Biopharmaceutical products.

- **Manual process** Verifarma software, using standard SG1
- The label (with GTIN number) is pasted by an operator in the unit. Then the units are stored in a box (case). Finally the boxes are placed on a pallet
- Traceability steps:
  - 1- Serialization of units with GTIN number (global trade item number).
  - 2- Each unit is associated with a case.
  - 3- Each case is associated with a pallet.



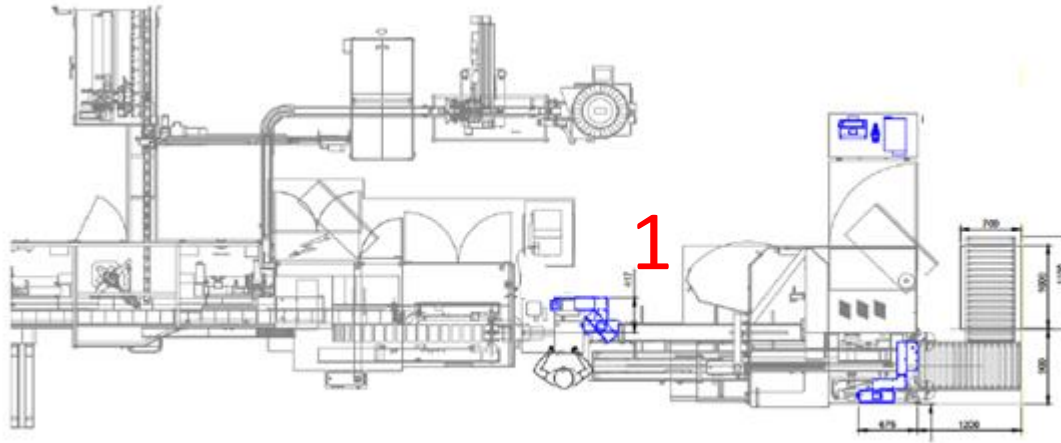
# Manual process Verifarma Software



# Automatic Traceability Project

## Automatically secondary packaging line

- Automatic process using Verifarma software. (standard SG1)
- The GTIN number is printed in the unit by a automatic printer. Then the units are automatically stored in a carton box (case). Finally the boxes are placed on a pallet
- Traceability steps:
  - 1- Serialization of units with GTIN number (global trade item number).
  - 2- Each unit is associated with a case.
  - 3- Each case is associated with a pallet.



2



**SINERGium Biotech**

*Cuidamos la salud, preservamos la vida*

# Automatic Traceability Project

## Schedule

<b>Automatic Traceability Project</b>	<b>September - 2021</b>
<b>Description</b>	<b>Schedule date</b>
<b>1</b> PVS-T equipment installation (GTIN number and SN printing and reading on the case)	Sep - 2021- Finalized
<b>2</b> PVS-Mi equipment installation (Reading GTIN numbers and SN associated carton box)	Sep - 2021- Finalized
<b>3</b> PVS-P equipment installation (Pallet label printing associated cartons boxes)	Sep – 2021 - Finalized
<b>4</b> Case Packer Adequacy	Sep – 2021- Finalized
Equipment tests	Sep – 2021 - Finalized
IQ/OQ	Sep - 2021 -Finalized
Verifarma software validation	May 2022

<b>Production with Automatic Traceability</b>	<b>Schedule date</b>
First Batch	TBD By the client



# Automatic Traceability Project

## Equipments

1 PVS-T equipment installation (GTIN number printing and reading on the case)

2 PVS-Mi equipment installation (Reading GTIN numbers associated carton box)



1PVS-T (GTIN number and SN printing and reading on the case)

2 PVS-Mi (Reading GTIN numbers and SN associated carton box)

3 PVS-P equipment installation (Pallet label printing associated cartons boxes)



3 PVS-P Pallet label printing associated cartons boxes



# Automatic Traceability Project

## Equipments

### 4 Case Packer Adequacy



# Automatic Traceability Project

*Example of traced cases*

Example of traced cases



GTIN: Global Trade Item Number

SN: Alphanumeric Serial Number

VTO: Expiry date

LOTE: Number batch (test)

# Automatic Traceability Project

*Example of traced Final boxes*

## Example of Final Boxes Label

**PRODUCTO FINAL**

 **SINERGium  
Biotech**

**DESCRIPCIÓN:**  
PRODUCTO LIXIS-AR

**CÓDIGO:** 17790440485917

**LOTE:** LOTE01      **VENCIMIENTO:** 01/01/2030

**CANTIDAD:** 300      **ESTUCHES**

**PREPARADO POR:** .....

**FECHA:** 01/12/2021      **HORA:** 15.40

  
00100000000000000020

**MANTENER ENTRE 2° Y 8°C**



**SINERGIUM Biotech**

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# GS1 Project Progress

Linda  
Jan.18, 2022



# Contents

- 01 | Objectives
- 02 | Main actions of the pilot
- 03 | Current status
- 04 | Consultancy
- 05 | Challenge

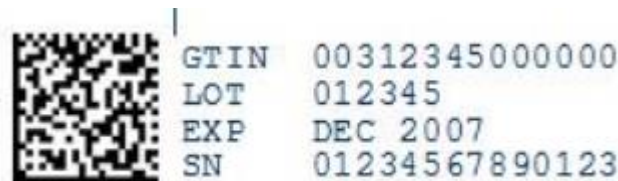


# 1 Objective

To complete implementation of barcoding on secondary packaging using standard GS1 barcodes for HPV16/18 bivalent vaccine before end of 2021. The barcoding for secondary package will contain **GTIN, lot number, and expiry date**.

The pilot will focus on: **secondary packaging**

eg:



## 2 Main actions of the pilot

### Project

- To establish a GS1 implementation project, pulling together associated personnel from different departments.
- To further study the relevant requirements.

May.1st,2021-  
Jun.30th,2021

### Vendor

- Obtain GTIN for HPV16/18 bivalent vaccine;
- Vendor selection
- Equipment manufacture
- Implement the protocol (including equipment adjustment and qualification, additional hardware and software application).

Jun.1st,2021-  
Aug.31th,2021

### Document

- Formulate validation report on the new barcoding and traceability system.
- **Formulate/revise the relevant SOPs**, including main process of labelling, cartoning, etc.

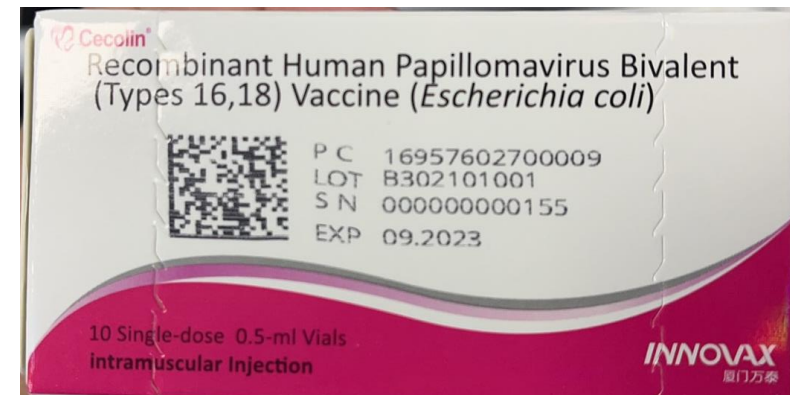
Sept.1st,2021-  
Feb.15th,2022

## 4 Current status of the pilot

- ✓ Vendor selection
- ✓ Confirm the style, content and place on the secondary packaging
- ✓ Equipment manufacturing

✓ **Equipment FAT, SAT, qualification, etc.**

● Validation **on going**



**Pilot run**

①

②

③

④

⑤

⑥

- ✓ Formulate the project
- ✓ Study the requirement of GS1

✓ Apply for GTIN

**on going**

- Formulate/revise the relevant SOPs

- The whole validation is planned to be completed before Chinese Spring Festival.
- Pilot run might be completed until Jul. depending on the international business progress.

# 3 Consultancy situation

Consultation company: Beijing Accture Technology Co., Ltd.

## ● GS1 Standard Training

Two training were held by Accture on June and July.

Focus on :

- GS1 introduction
- GS1 implementation flow
- How to apply GS1 barcode
- GS1 barcoding system
- Barcoding principles and methods

## ● GS1 barcoding system and equipment operation

- ESC coding system and related operation training (template printing, coding rules, etc.)
- Operation of layer scanning camera
- Camera operation of detecting secondary package and tertiary package
- Coding process and handling of obnormal situation.

文件编号: 11R-03-001-R01  
Doc Code  
版本号: 10  
Rev.  
实施日期: 2021.06.01  
Implementation Date: Jun.01.2021

培训签到记录表  
Training Attendance Record Form

INNOVAX 万泰疫苗

TRA\_D\_20170112  
2017-01-12

□ Other Methods/其他方式  
6: 3h  
(版、码规则、工位设置)

培训日期 Date	培训课程 Training Course	培训方式 Training Method	应到人数 Required Attendance	实到人数 Actual Attendance
2021.06.18	GS1标准实施	□ 课堂培训 classroom training □ 自学培训 self-learning training □ 一对一培训 one-on-one training □ 岗位操作培训 OJT	13	13
部门/Department	工号/Employee ID	姓名/Print Name	签名/Signature	
1 国际销售部	21450	蒋德冰	蒋德冰	
2 国际销售部	20700	邹力	邹力	
3 物流部	20537	叶善青	叶善青	
4 质量部	21406	林辉宇	林辉宇	
5 质量部	20609	樊杰	樊杰 2021.06.18	
6 质检部	21416	陈金球	陈金球	
7 注册部	20389	肖利兴	肖利兴	
8 设备工程部	20973	戴德福	戴德福	
9 设备工程部	21690	肖平	肖平	
10 设备工程部	21100	王明	王明	
11 销售部	20161	林建明	林建明	
12 销售部	20339	周礼新	周礼新	
13 设备工程部	20917	林维树	林维树	
14				

评估方式 Evaluation method:  
☐ 培训试卷 Training test paper  
☐ 课堂问答 Class Q&A  
☐ 操作技能评估 Operational skills evaluation  
☐ 自学、已阅读并理解该培训内容 Self-learning training, have read and understood the training content  
☐ 其它评估方式, 请注明 Other evaluation method, please indicate:

培训师签名/日期 (If training is provided by external trainer, indicate trainer's company): 刘永 (泰创) 代

229166 27502

Traning records

## 5 Current experience&Challenges

### Current experience:

- Keep close contact with the vendor
- Need to train internal personnel to better master the equipment operation principle, in order to deal with the emergency situation.



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

– *Xiamen Innovax Biotech*







***Biological E. Limited***

*Celebrating Life Every Day*



# Objective of the traceability pilot

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Implementation of unique 2D barcode on primary packaging.

- This will be at product level and does not have serial number of the primary pack.
- Artworks need to be revised with the unique product code as per the GS1 data matrix.
- Planning to implement with 15 mL (COVID Vaccine) vial presentation.

**Data Matrix** : GS1-128 barcode Symbology encoded with:

- GTIN 14
- Expiry Date
- Batch Number



## Present Status - Secondary/Tertiary level barcoding & serialization capabilities at BioE



- We have membership with GS1 since 2012 & membership number: 8901415

PACKAGING LEVEL	BARCODING REQUIREMENT	Data Requirements	TIME LINE as per DGFT	STATUS
Tertiary Level	GS1-128 barcode Symbology encoded with: <ul style="list-style-type: none"><li>▪ GTIN 14</li><li>▪ Expiry Date</li><li>▪ Batch Number</li><li>▪ SSCC</li></ul>	Information printed in human readable format: <ul style="list-style-type: none"><li>▪ GTIN 14</li><li>▪ Expiry Date</li><li>▪ Batch Number</li><li>▪ SSCC</li></ul>	Implemented (2012 as per DGFT notification).	Implemented
Secondary Level	<b>GS1 DataMatrix</b> or a GS1-128 barcode Symbology encoded with: <ul style="list-style-type: none"><li>▪ GTIN 14</li><li>▪ Expiry Date</li><li>▪ Batch Number</li><li>▪ Unique Sr. No.</li></ul>	Information printed in human readable format: <ul style="list-style-type: none"><li>▪ GTIN 14</li><li>▪ Expiry Date</li><li>▪ Batch Number</li><li>▪ Unique Sr. No.</li></ul>	Implemented (2012 as per DGFT notification).	Implemented
Secondary & Tertiary Level Aggregation	Public notice No.:13/2015-2020 dated 22/05/2015 the dates for implementation of Track & Trace system for export of drug formulations along with maintaining the Parent-Child Relationship in packaging have been extended to 01/04/2016 for non SSI manufactured drugs and 01/04/2017 for SSI manufactured drugs.			Implemented



## Experience so far with barcoding on secondary and tertiary packaging

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Implemented unique 2D barcode/Serilisation on secondary and tertiary packaging:

So far we have successfully implemented with barcoding on secondary and tertiary packaging. Secondary and tertiary level will have unique serial number of the secondary pack and Linear barcode will be printed on Tertiary level packing.

### Secondary Bar-coding:

- Carton Coding with following details will be printed (Offline) as per DGFT guidelines.
  - GTIN 14
  - Expiry Date
  - Batch Number
  - Unique Sr. No.

### Tertiary Bar-coding:

- Shipper label printing & Inspection implemented, and following details will be printed on Label
  - GTIN 14
  - Expiry Date
  - Batch Number
  - SSCC



## **Actions of the pilot and consultancy arrangements with GS1 solution providers**

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### **Required Equipments for Primary level sterilization:**

- Auto Winder with Printing, Inspection & Web Rejection/ Labelling machine for online integration
- Carton Coding Machine
- Software Integration (PCR System)

### **Current status of the pilot:**

- We have received carton coding Machine
- Implemented unique product code
- Ordered for Auto Winder with Printing, Inspection & Web Rejection (Also planning to order one labelling machine for online integration)
- Consultancy for Primary Serialization and Training completed for technology and all in consultation with URL.
- Artworks developed as per the requirement for COVID Vaccine
- Discussion for Mail Actions of the pilot and consultancy arrangements with GS1 solution providers:
- GS1 compliances for serialization
- Documentation of product wise SOPs and qualification of machinery to be done.



We are planning take trials for pilot with following strategy:.

- We have a bigger vial size of 15 mL for 20 Dose presentation with a Label size of 62x26 mm.
- We have chosen the best case scenario pilot study based on label size in Phase-I.

**Tentative Project kick start:** Under Progress

**Target date for completion:** Q2 2022 (considering machinery lead time)



# Introduction to Traceability Pilot Project in CDIBP



# Traceability Pilot Project in CDIBP

- WHO PQed Vaccine: Japanese encephalitis vaccine, live
  - 2 ml vial, 10 vials/box
  - GS1 barcoding from box (secondary package)
- Going to comply with UNICEF guidelines: preferred characteristics:

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

# Considerations and target

- 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 2022 vaccines supply (March 31, 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.
- Integrate the demands from international and domestic regulatory requirements, current working conditions and procedures, target results.
- Decision: update one packaging line to implement GS1 barcoding

# Corrent progress

- Existing conditions: already upgraded the system to be compatibility for drug supervision and control codes in China and GS1 barcodes
- Search and select vendor: Shanghai Minze Information & Technologies Co., Ltd.
- Site investigation with vendor and discussion the packaging line upgrading plan – done
- Design the procedure flow for implementing GS1 barcoding – done
- URS drafting - done

# Progress from Nov. 2021

- Consulted UNICEF for GS1 barcode sample
  - Detailed upgrading plan confirmed
  - Formal URS signed
- 

PC 06915797820004  
EXP 10.2021  
LOT 202111C020-1  
SN 4683159048864818
- Delays caused by pandemic situation and year end work load
  - One equipment need imported and estimated arrival date will be in middle of Feb. All other equipment already on the sites.



# Next steps

- Upgrading the packaging line, SAT and commissioning: By Feb 28, 2022
- Drafting SOPs: by Feb 28, 2022
- IQ/OQ/PQ: by March 15, 2022, meanwhile personnel training
- Training completion: by Mar. 20, 2022
- Validation the connection of GS1 barcoding with main server of company: by Mar. 25, 2022
- Ready for use: since March 31, 2022
- Delay for one month than previous plan

THANK YOU