

# Drug Traceability System Project

## Sinergium Biotech

June 2022



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- 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.

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### ***Project design and plan***

- Project design and URS definition.
- Purchase of software and equipments.
- Equipments installation.
- Equipments tests.
- Validation equipments and software system.

### ***Department involved in the Project***

- Engineering and Projects Teams.
- I&T Teams.
- Validation Teams.
- Production Teams.
- Instrumentation and Control system Teams.

### ***The Overall investment***

- Around USD 300.000 (hardware , software, development and Technical support)
- 100% of investment were made by SB

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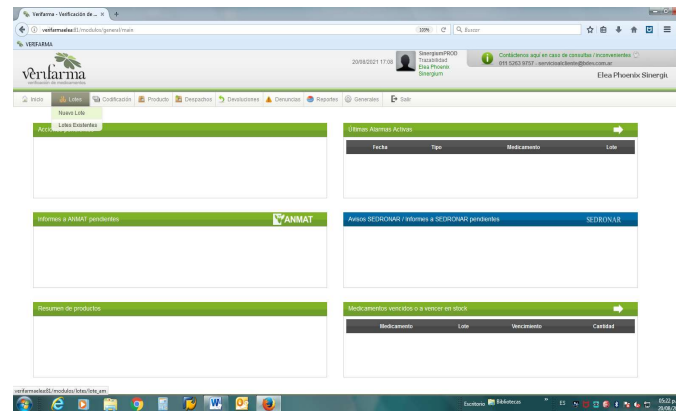
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### *Consultans and external suppliers*

#### **Verifarma**

-Supply Software System  
Data under GS1 standards



#### **LIXIS - SEAVISION**

Hardware solution for track and trace automation in packaging lines  
-Supply Equipments and components

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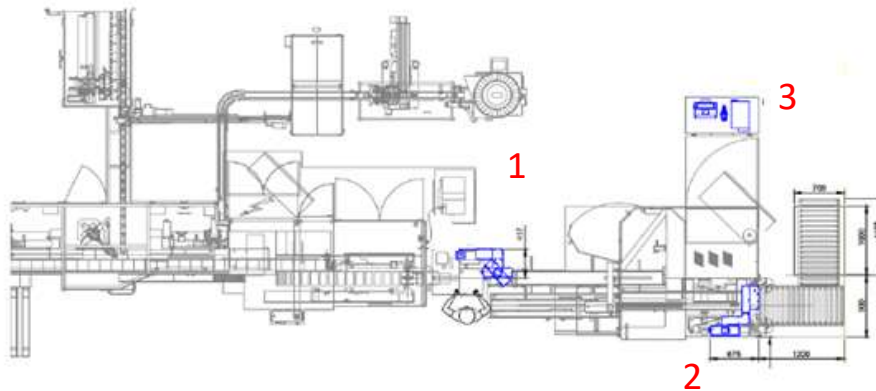


### *Components required for the project, hardware and software*

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

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

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





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### *Components required for the project, hardware and software*

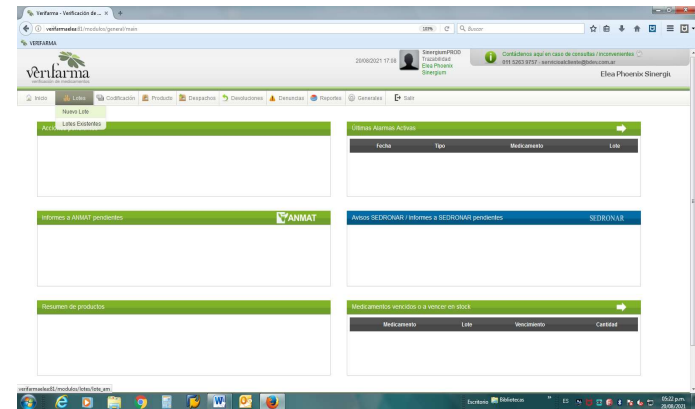


1PVS-T



2 PVS-Mi

3 PVS-P



Verifarma Software System

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### ***Principal challenges encountered***

#### ***- Covid 19 Pandemic***

Delay in manufacturing equipments.

TRAVEL Restrictions (Technicians for installation and Qualification)

Project Rescheduled.

- Technical issues of printing with different formats 1x vs 10 x

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### *Printing tests on the case*





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### ***Schedule and status project***

<i>Description</i>	<i>Status</i>
Equipments installation	Finalized
Equipments tests	Finalized
Equipments validation	Finalized
Verifarma software validation	In process Estimated finish date July 2022
First Batch	Campaign production flu vaccine January 2023

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# Thanks!

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