

# 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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preservamos la vida

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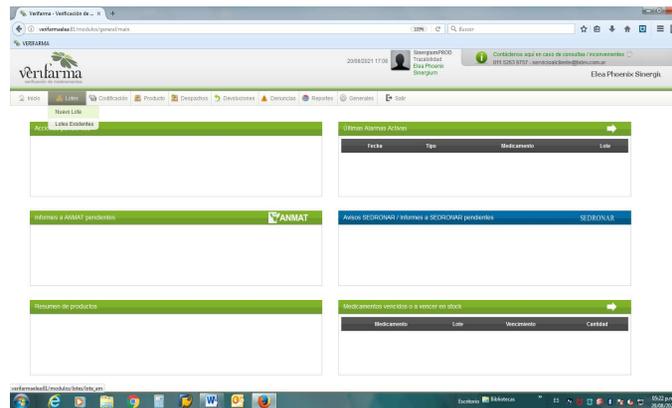
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### *Consultans and external suppliers*

#### **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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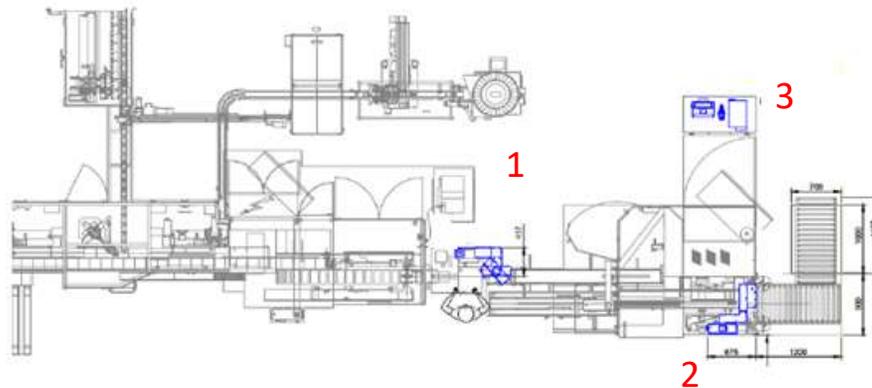


### *Components required for the project, hardware and software*

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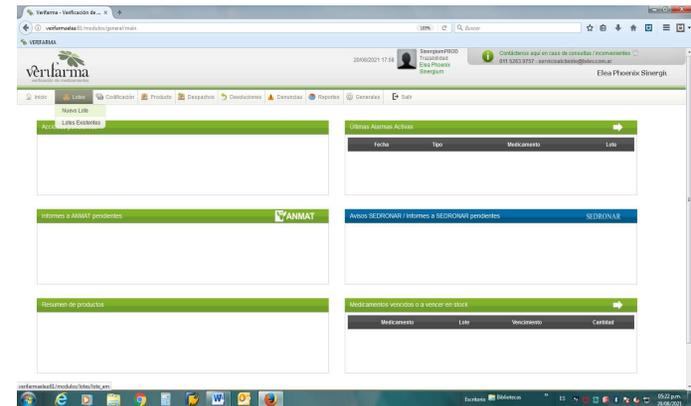
### Components required for the project, hardware and software



1PVS-T



3 PVS-P



Verifarma Software System

2 PVS-Mi

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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

**Thanks!**

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