



Eczacıbaşı



GENSENTA



GENSENTA at A GLANCE

A Pharmaceutical Manufacturing Excellence

**We are a vertically
integrated
manufacturer,
ambitious in sterile
production.**

About us

A Leader Since 1923

Gensenta Pharmaceuticals, established in 1923 in Istanbul, with its 8 employees, was one of the first manufacturers of injectable products in Turkey.

Prioritizing Excellence in Quality

Currently, with its well-trained personnel and modern facilities, Gensenta Pharmaceuticals, is one of the leading manufacturers of finished dosage forms in Turkey.

Gensenta : In Pursuit of Science for Health for +100 Years

From our deep rooted history to the future of healthcare

1957

- The “laboratory” became a joint stock company (1957)
- 1st enteric-coated tablet registration in Turkey (1961)
- 1st production of freeze-dried and onco products (1970s)

1984

- Yenibosna campus was established
- Yenibosna Other Products Plant was established (2003)

2011

- 1st biosimilar contract manufacturing company in Turkey (2011)
- Mustafa Nevzat was acquired by Amgen Inc. (2012)
- 1st mab manufacturing (2012)

2022

- Gensenta was acquired by Eczacıbaşı
- Gensenta is positioned as manufacturing company under Eczacıbaşı Health Group

1923

- Mustafa Nevzat Laboratory was established in Istanbul
- 1st modern quality control system in Turkey
- 1st injectable products in Turkey
- Manufacturing of insulin powder in ampoules (1935)

1974

- API manufacturing started
- 1st antibiotic API production

2009

- Yenibosna onco plant was established
- 1st ANDA file was approved by the US FDA (2005)
- 1st pharmaceutical company in Turkey to receive US FDA approval (2006).
- 1st commercial sales of antibiotics to USA (2007)

2017

- 1st Global API manufacturing agreement signed.
- The GMP & EHS Upgrade Project for \$35M started (2017).
- Mustafa Nevzat trade name was changed to Gensenta (2020)

OUR PURPOSE:

Deliver customer-focused pharmaceutical products with full adherence to quality standards.



We strive to be a leading and preferred manufacturing company with a focus:

1

Quality Excellence

2

Operational Excellence

3

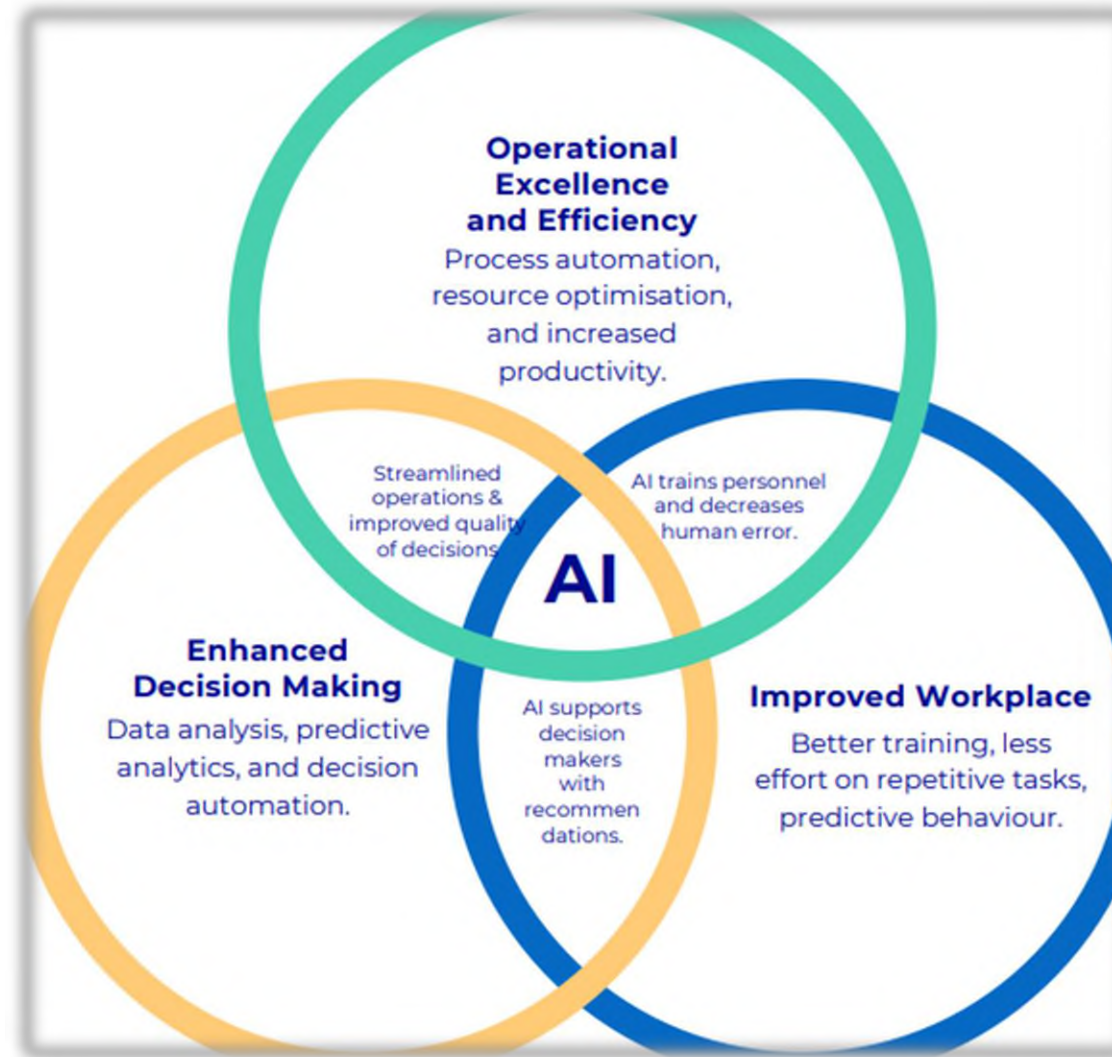
Research & Development

4

Reliability, Satisfaction, Sustainability

OUR PURPOSE:

We are preparing to centralize AI to go beyond excellence.



We prioritize R&D.

One of the first certified R&D CENTERS
by the Ministry of Science , Industry and Technology



Analytical Method Development

Analytical Method Development, CMC and elaboration of monographs for the European Pharmacopoeia.



Sterile Formulation Development

Through meticulous design, we are ensuring the safety and efficacy of injectable drugs.



Value Added Generics Development

R&D professionals highly skilled in developing non-infringing formulations.

QUALITY Overview

Strategy

Deliver high-quality pharmaceutical and OTC products by leveraging digital solutions while ensuring continuous regulatory compliance and driving continuous quality improvement.

GMP Certifications

Successful GMP inspections from 15 different Health Authorities from 2012 to 2025

- Spain (EMA)
 - Russia
 - Brazil (ANVISA)
 - Italy (EMA)
 - Korea (MFDS)
 - Saudi FDA
 - TC Sağlık
 - Japan PMDA
 - Belarus
 - Hungary (EMA)
 - Iran
- Active Certifications**
- Health Canada
 - Colombia (INVIMA)
 - UK (MHRA)
 - US FDA

Cont. Improvement Initiatives

Amgen Quality Integratio

Eczacıbaşı Acquisition

US FDA
FDA

2012

2022

2024

2025

- Paperless Quality Management System (Qmex)
- Digital Environmental Monitoring System (Novatek)
- Digital Microbiological Identification System (Vitek)
- Analytical Data Management System (Empower)

Integrating Gensenta and Eczacıbaşı Quality Systems under a single organization

- Digitalization of Supplier Qualification
- Implementation of Image Processing for Personnel EM Sampling Oversight
- Intelligence check w/ AI
- e-Batch Record
- Investment on lines

Early identification of regulatory trends

Unified quality language across all organizational levels

Integrated digital quality ecosystem

Talent Excellence

Health Authority Approvals

	TR MoH	EMA AEMPS	Russia	ANVISA	Saudi Arabia MoH	Korea MFDS	TGA Australia	Japan PMDA
Vial-1	Local Authority	CTP13 (Infliximab) Inspection Date: Sep 2024 Certificate is valid for 3 years	Texared-L Inspection Date: Feb 2024 Valid for 3 years	CTP13(Infliximab) & CTP6(Trastuzumab) Inspection date: Sep 2023 Extended in 11.2025 Valid for 2 years, until Nov 2027			GMP Clearance Sterile Products Without inspection Valid until March 2028	
Vial-2	Local Authority	The line was inspected by EMA/AEMPS and mentioned in the inspection report. However there is no submitted product in EU. EU GMP certificate does not cover this line. As it is discussed with the authority, the line will be remotely reviewed with the scope of Caspofungin and the certificate will be revised including Vial-2						
Vial-3	Local Authority	CTP13(Infliximab) CTP6(Trastuzumab) CTP43 (Ustekinumab) Caspofungin, Daptomycin, Anidulafungin Inspection Date: Sep 2024 Certificate is valid for 3 years		CTP13(Infliximab) & CTP6(Trastuzumab) Inspection date: Sep 2023 Extended in 11.2025 Valid for 2 years, until Nov 2027	Caspofungin Inspection date: Oct 2023 Valid for 5 years Inspection was product specific but the certificate is generic for all facility	CTP43(Ustekinumab) Inspection Date: March 2024 Specific for CTP43 submission	GMP Clearance Sterile Products Without inspection Valid until March 2028	GMP Clearance Sterile Products Inspection Date: December 2025 Valid until : December 2028
Ampoule	Local Authority							
OSD	Local Authority	Apixaban Inspection Date: Sep 2024 Certificate is valid for 3 years	Texared tablet Inspection Date: Feb 2024 Valid for 3 years					

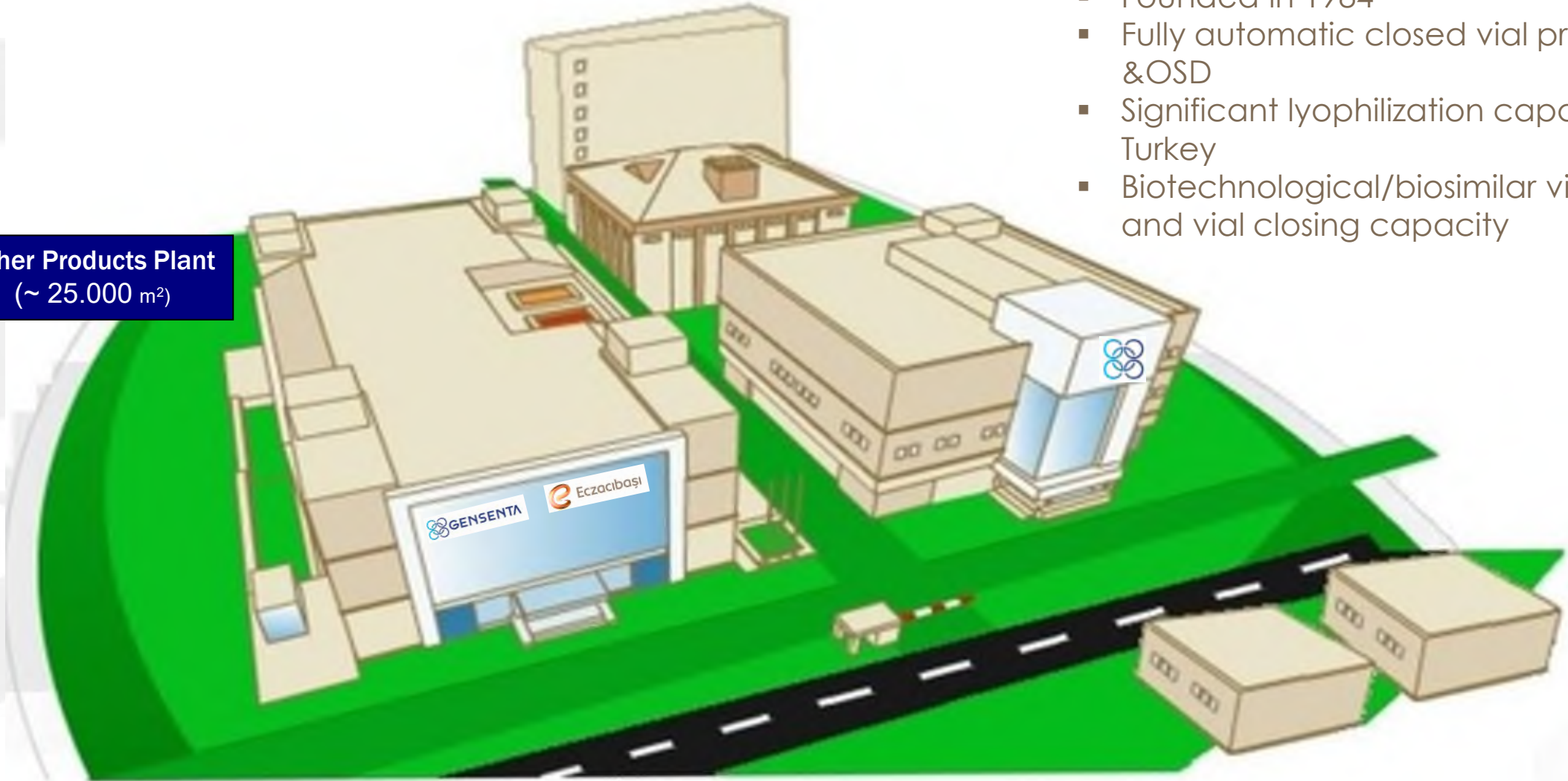
CMO Business Strategic Partnership With World Leaders



Gensenta – Yenibosna FDF Campus

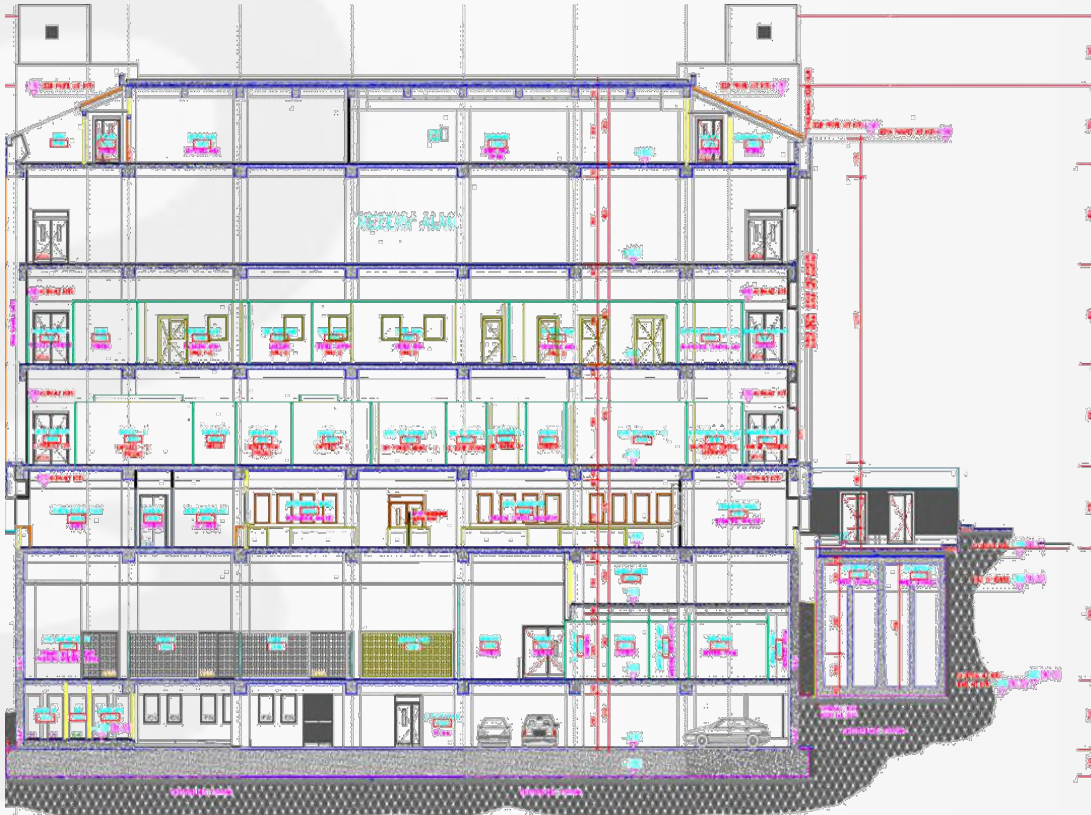
- Founded in 1984
- Fully automatic closed vial production & OSD
- Significant lyophilization capacity in Turkey
- Biotechnological/biosimilar vial filling and vial closing capacity

Other Products Plant
(~ 25.000 m²)



Gensenta – Other Products (OPP) Plant

OPP* BUILDING



FLOORS

(3) Packaging, Cafeteria

(2) RESERVE AREA & technical spaces

(1) Injectable manufacturing

(0) Solid dosage manufacturing

(-1) Labs, Water treatment, Offices

(-2) Dispensing, Warehouse

(-3) Car park, Workshops

Capacity Overview



SOLID PRODUCTION

Tablet Forms

750 million tablets
/year

Capsule Forms

160 million capsules
/year



STERILE PRODUCTION

3 Bosch (Syntegon)
Filling Lines
up to 15k vials/hr

6 Freeze Dryer

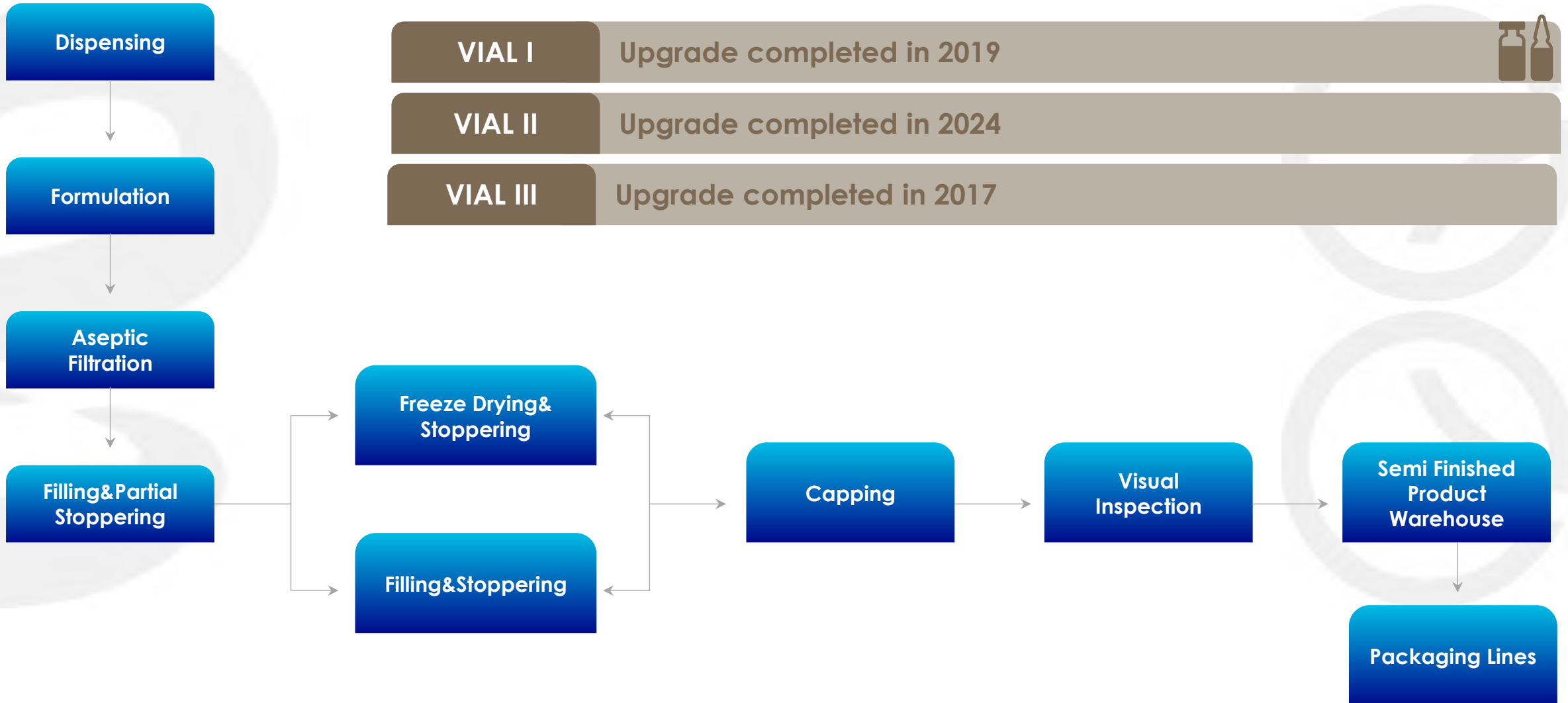
168 m2 Capacity

10 M Vial

Free Capacity

Over 50 Years of Excellence in High Capacity Lyophilization

Sterile Injectable - Process Flow & Capabilities



VIAL I	Upgrade completed in 2019	
VIAL II	Upgrade completed in 2024	
VIAL III	Upgrade completed in 2017	

Injectable Production Lines' Equipment & Capability

Vial I, Vial II, Vial III –
Total Lyo Capacity * 20 Mn Vial; Total Liquid Capacity * 10 Mn Vial.

Production Line	Filling Machine		Freeze-Dryer Capacity	Capability/ Product Types/ Category
	Brand/Model Technology	Speed		
Vial I	Bosch FLC 3060 Open RABS Technology	12K vials/hr (5 mL)	37 m ² + 37 m ²	Liquid & Lyo filling Non-beta lactam products, small molecules and biologics (fill & finish)
Vial II	Bosch FLC 3040 Open RABS Technology	12K vials/hr (5 mL/4R)	17 m ² + 27 m ²	Liquid & Lyo filling Non-beta lactam products, small molecules and biologics (fill & finish)
Vial III	Bosch FLC 3080 Open RABS Technology	15K vials/hr (5 mL)	25 m ² + 25 m ²	Liquid & Lyo filling Non-beta lactam products, small molecules and biologics (fill & finish)

* Capacity based on current product portfolio.

We are leading experts in Sterile Production.



Among the **highest volume** vial lyophilization capacities.



Automated lyophilizers for high-quality, safe production of sensitive drugs.



Flexible single-use Technologies reduce contamination risk and cost.



Sterile vial lines with RABS technology meet **international standards** (AIFA,EMA,etc.)

Vial IV New Investment Project

The new sterile Vial-4 production line aims for top quality, safety and efficiency in drug production with high tech equipment, technology and software for digitalization and automation.

- **Capability:** Lyophilized and Liquid vial Filling and Packaging
 - High speed Line (24.000 units/hour)
 - State of Art Technology
 - Full automatic Loading and Unloading System Lyophilizer with Capacity of 40 m2
-
- **Capacity:** 23,5 mn units/year Liquid; 4,1 mn units/year Lyo
- First product PV target date:** 2027 Q1

State of the
Art Isolator
Technology



Capacity

5 M units/year - Lyo Vial

25 M units/year - Liquid Vial



Capability

**Lyophilizer & liquid filling
Packaging**

Optima Filling and Closing Machine-VFVM 1800 w/Optima Freeze Dryer S39



Vial IV Investment Project- High Speed Line & Lyo

Large scale
commercial batch
manufacturing

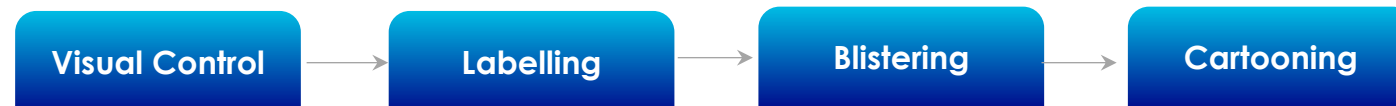
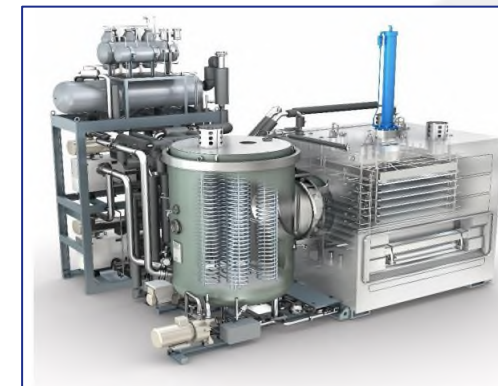
Clinical batch
manufacturing

High Speed Filling Line

Capability : Lyophilized and Liquid Vial Filling and Packaging

Technology: Aseptic Isolator

Line Speed: 24.000 Vials/h & **Freeze Dryer:** 38.7m²



Vial IV Investment Project- Small Scale Combo Line

Clinical batch
manufacturing

Small scale
commercial batch
manufacturing

Small Scale Volume Combo Line

Capability : Nested Cartridge, Syringe, Vial Filling

Technology: Aseptic Isolator

Line Speed: 450 Units/h

Formulation

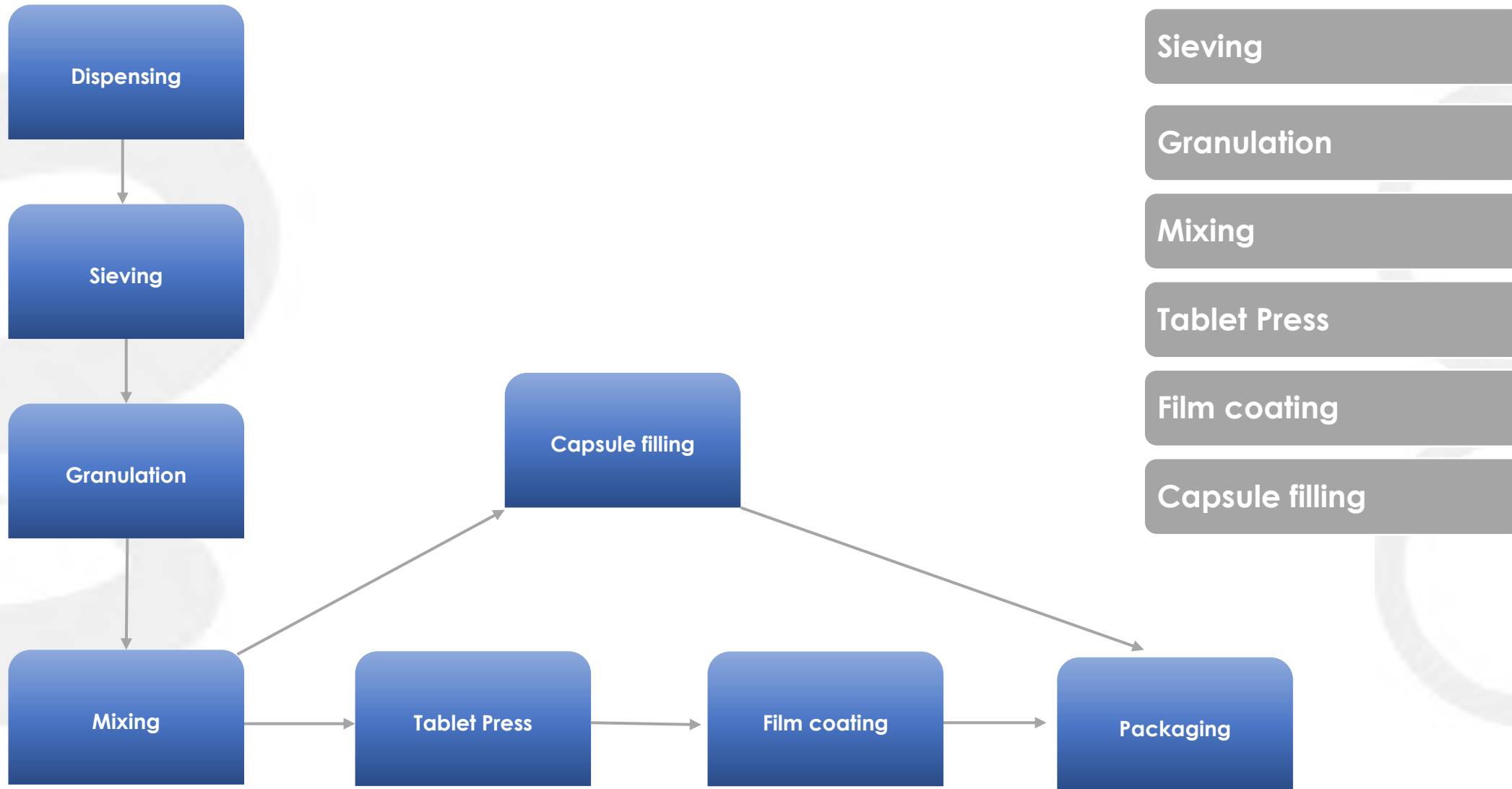
Aseptic Filtration

Filling &
Stoppering

Capping



Oral Solid Production – Process Flow & Capabilities



Yenibosna FDF - Warehouse



2/8°C

15/25°C

-70°C & -20°C



250 PALLET ROBOTIC COLD WAREHOUSE

40 PALLET 2 COLD ROOMS W/ DOUBLE FAN

1,500 PALLET INTERNAL WAREHOUSE

2 RAW MATERIAL CABINETS

SAP

RF Terminals

BMS Temperature Control

WM Stock System

Vacuum Cleaners

Fire Protection System

Remote temperature monitoring system (20 probes)

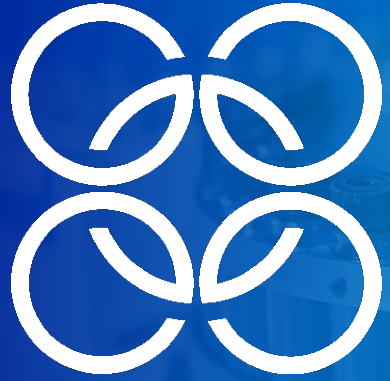
Sustainability



Sustainability Report



- Gensenta commits to reduce **Scope 1 & 2 & 3 emissions 58.8%** by 2034 (2023 baseline)
- Gensenta commits to reduce **Scope 1, 2 & 3 emissions 90%** by 2050 (2023 baseline)



Thank you

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