

## Summary of capabilities

## Ridgefield, NJ, US

#### **Facility facts**

Established in 2008, ~240 employees

#### **Facility overview**

**Total site:** ~360,000 sq. ft.

Manufacturing: ~80,000 sq. ft.

Office space: ~50,700 sq. ft.

Warehouse + cold storage: ~65,200 sq. ft. + 2,800 sq. ft.

Packaging: ~8,800 sq. ft.



#### Overview

Our Ridgefield, New Jersey sterile fill-finish and packaging facility is strategically located to optimize logistics while attracting top talent from along the East Coast.

This site is fully integrated into our global pharmaceutical supply chain, with products manufactured here distributed to 67 countries across all continents.

#### **Expertise**

- Viscous product filling
- Aseptic processing
- Terminal sterilization
- ISO 13485 for medical devices
- Filling: 2 syringe lines + 1 vial line
   (2 new PFS lines planned for 2027 and 2028)
- Integrated AVI and packaging: 2 syringe lines + 1 vial line
- Global distribution



#### Summary of current filling capabilities

	Semi-automated syringe line	Automated syringe line	Automated vial line
Equipment	Inova H6-10V RABS	Inova H3-5V RABS	Vfvm27310 RABS
Filling technology	10 x rotary piston	5 x rotary piston	12 x rotary piston
	<ul> <li>10 x peristaltic pump</li> </ul>		• (12 x peristaltic pump capable)
Format capability	0.5 mL to 10 mL	0.5 mL to 10 mL	2 mL to 20 mL
Format parts	None	• 1 mL short	• 2 mL
available*		• 1 mL long	• 5 mL
		5 mL rotary piston	• 10 mL
Formats currently	0.5 mL long	• 1 mL short	2 mL (commercial)
filled	• 1 mL short	• 1 mL long	• 5 mL (feasibility)
	<ul> <li>1 mL long syr, staked needle</li> </ul>	5 mL rotary piston	10 mL (qualified)
	• 1 mL long, PRTC		
Line speed	600 syr/min	150 (viscous product) syr/min	400 vials/min
		300 (liquid product) syr/min	
Additional info	E-beam	Proven capability of filling	In-line IPC
	In-line IPC	viscous products	Vials washed and sterilized
		No in-line IPC	on-site

<sup>\*</sup> Available parts are format parts in inventory that are not currently in use and require passivation before use. Parts for other formats would need to be procured.

#### Summary of current packaging capabilities

	Semi-automated syringe line	Automated syringe line	Automated vial line
Inspection	No in-line inspection (manual)	Seidenader VI-60S+HV Denester/renester	Syntegon AIM-2022 Nikka HDB-II-AST HV leak detector
Equipment	<ul> <li>Optima sh110 denester</li> <li>Optima EKM-331 assembly machine</li> <li>Alloyd rotary blister sealer</li> <li>Fabrima VP120 cartoner</li> <li>Manual case packer</li> </ul>	<ul> <li>2x VSM 2031</li> <li>Korber CP500 thermoformer</li> <li>Korber P1600 cartoner</li> <li>IMA CP18/flex2p case pack/palletizer</li> </ul>	<ul> <li>IMA libra sens A/V labeler</li> <li>IMA FR60 cartoner</li> <li>IMA vertical</li> <li>Cartopallet case packer/palletizer</li> </ul>
Serialization	Manual serialization and aggregation	Serialization and aggregation	Serialization and aggregation
Format capability	<ul> <li>Flexible 0.5 mL to 10 mL</li> <li>Flexible 2 mL vial (serialization and hand pack)</li> </ul>	• 0.5 mL to 10 mL	• 2 mL to 10 mL
Format parts available	<ul><li>2.25 mL</li><li>5 mL</li><li>10 mL syringes</li><li>Blisters</li><li>Cartons</li><li>Cases</li></ul>	<ul><li>0.5 mL long</li><li>1 mL long</li><li>1 mL short</li></ul>	• 2 mL • 5 mL • 10 mL
Formats currently packed	<ul><li>2.25 mL syringe</li><li>10 mL syringe</li><li>2 mL vial</li></ul>	<ul><li>0.5 mL long</li><li>1 mL long</li><li>1 mL short</li></ul>	<ul><li>2 mL (commercial)</li><li>5 mL (feasibility)</li><li>10 mL (qualified)</li></ul>
Line speed	~40 syr/min depending on format/lot size	600 syr/min	<ul><li>400 vials/min for 2 mL</li><li>150 vials/min for 10 mL</li></ul>
Additional info		Preventis safety device capable     Inspection and packaging in-line or decoupled	Inspection and packaging in-line

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