

## Summary of capabilities

## Ridgefield, NJ, USA

#### **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 the global pharmaceutical supply chain, with products manufactured here distributed to 67 countries across all continents.

#### **Expertise**

- Viscous product filling
- Formulation
- Aseptic processing
- Terminal sterilization
- Filling: 2 syringe lines + 1 vial line
- Integrated AVI and packaging: 2 syringe lines + 1 vial line
- Global distribution



#### Summary of current filling capabilities

	Semi-auto 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)
	1 mL long syr, staked needle	• 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-auto line	Automated syringe line	Automated vial line
No in-line inspection (manual)	Seidenader VI-60S+HV Denester/renester	Syntegon AIM-2022 Nikka HDB-II-AST HV leak detector
<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>
Manual serialization and aggregation	Serialization and aggregation	Serialization and aggregation
Flexible 0.5 mL-10 mL syringes     Flexible 2 mL vial (serialization and hand pack)	• 0.5 mL to 10 mL	• 2 mL to 10 mL
<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
<ul><li>2.25 mL syringe</li><li>10 mL syringe</li><li>2 mL vial</li></ul>	O.5 mL long I mL long I mL short	<ul><li>2 mL (commercial)</li><li>5 mL (feasibility)</li><li>10 mL (qualified)</li></ul>
~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>
	Preventis safety device capable Inspection and packaging in-line or decoupled	Inspection and packaging in-line
	No in-line inspection (manual)  Optima sh110 denester Optima EKM-331 assembly machine Alloyd rotary blister sealer Fabrima VP120 cartoner Manual case packer Manual serialization and aggregation Flexible 0.5 mL-10 mL syringes Flexible 2 mL vial (serialization and hand pack) 2.25 mL 5 mL 10 mL syringes Blisters Cartons Cases 2.25 mL syringe 10 mL syringe 2 mL vial - ~40 syr/min depending on	No in-line inspection (manual)  Seidenader VI-60S+HV Denester/renester  Optima sh110 denester Optima EKM-331 assembly machine Alloyd rotary blister sealer Fabrima VP120 cartoner Manual case packer  Manual serialization and aggregation Flexible 0.5 mL-10 mL syringes Flexible 2 mL vial (serialization and hand pack)  2.25 mL 5 mL 10 mL syringes Blisters Cartons Cases  2.25 mL syringe 10 mL syringe 11 mL long 11 mL long 11 mL long 11 mL long 11 mL short  Preventis safety device capable Inspection and packaging in-line

### From molecule to medicine:

# An integrated partner for every step in your drug development journey.

Thermo Fisher Scientific provides industry-leading pharma services for drug development, clinical trial logistics, and commercial manufacturing through our Patheon™ brand. We partner with customers in the pharmaceutical, biotech, and life sciences industries as their trusted CDMO to deliver medicine to patients faster. With more than 60 facilities around the world, we provide end-to-end pharma services across all phases of development and commercial manufacturing, including API, oral solid dose, biologics, cell therapy, mRNA, viral vectors, formulation, clinical trial solutions, logistics services, and packaging. We couple our scientific and technical excellence in these areas with a strategic partnership to provide customers of all sizes access to a global network of facilities and dedicated experts across the Americas, Europe, Asia, and Australia. Through our integrated service offerings, we provide tailored solutions to fit your unique drug development journey, accelerating your time to market.

Discover the power of our global network.

For detailed capabilities and capacity information, please contact your Thermo Fisher Scientific representative.

Learn more at thermofisher.com/patheon or email us at pharmaservices@thermofisher.com or call +1 919 226 3200