

SOLVED WITH INVESTMENT & INNOVATION

patheon

Global steriles investment & innovation

The medicines we help develop and deliver for our customers impact one million patients each day. With an increasing demand for our services, expertise and capabilities, comes a commitment to continuously expand our products and services. This is why we have been making unprecedented investments in our network of sites and capabilities around the world.

Our investment is not just about adding capacity—it's about enhancing capabilities across our Pharma Services business. By drawing on the collective expertise from businesses across Thermo Fisher Scientific, expanding our network of best-in-class facilities, and strengthening our workforce with exceptional talent, we provide solutions to our customers that enable them to accelerate innovation and productivity and get medicines to their patients faster.

Pharma services global steriles network



Here are the global investments we are making across our network:

Line	Description	Line Type	Customer dedicated	Equipment	Aseptic Technology	Lyop-hilization	Ready to Use	Vials	Syringes	Cartridges	Batch size	Line speed	In Process Control	Flow path	Timing
Greenville, North Carolina															
Development Suite #3	Flexible development line for vials, PFS and PFC in nest and tub configurations	Development with dedicated capacity for small scale commercial manufacturing	No	IMA INJECTA	Isolator	Yes 2 X 5 m2	Yes, – Vials RTU only – stoppers and over-seals could be RTU or RTS	2R–50R (change parts for Gerresheimer & Schott 2R/6R/8R/10R/20R vials)	1mL–5ml (fill volume > 0.25mL)	1mL – 10mL	10L – 400L (can go < 10L if needed)	3 – 80 objects per min	100% IPC at full-speed	Peristaltic pumping with disposable product pathway (piston pump optional)	GMP ready in Q1 2022
Commercial Line #5	Liquid filling lines	Commercial	No	Optima	Isolator	No	RTU and Atec processing system (Ready-to-Sterilize)	2R – 50R	—	—	1000L (max)	450 vials/ min up to 10mL	100% IPC at full-speed	Rotary piston pumps with CIP/SIP + Peristaltic pumping with disposable product pathway	Media Fill in July 2021
Commercial Line #6			No												Media Fill in Q4 2022
Commercial Line #7			Yes												Media Fill in Q1 2022
Commercial Lines #9, #10	Stand alone building w/ 2 X BSL-2 liq fill lines Incoming sampling/ dispensing area, thaw & compounding areas dedicated QA/QC/ EM/Sterility labs, GMP warehouse	Commercial	No (but reserved supply/ priority access of 150M doses)	IMA XTREMA	Isolator	Future (2) x 30m2 on Line 9	RTU stoppers and over-seals	2R – 100mL (change parts for 10mL)	—	—	1000L (max)	400 vials/ min for 2mL & 300 vials/ min for 10mL	100% IPC at full-speed	Peristaltic pumping with disposable product pathway	Operational in Q3 2022
Flex line	Liquid & lyo filling line	Commercial	Yes (but available for general use)	IMA XTREMA	Isolator	Yes (3) x 15m2 IMA	Yes	2R – 100mL	—	—	1000L (max)	400 vials/ min for 2mL & 300 vials/ min for 10mL	100% IPC at full-speed	Peristaltic pumping with disposable product pathway	Operational in Q2 2023
Ferentino, Italy															
Development Suite #2	Brand new building w/ development capability supporting bulk vials, nested vials, syringes, cartridges, vial tray	Development with dedicated capacity for small scale commercial manufacturing	No	Optima Multiuse	Isolator	Yes 2 X 10 m2	Yes (vials, PFS, PFC) + stoppers and over-seals could be RTU or RTS *	2R – 50mL (change parts for 2R, 6R, 10R & 20R)*	1mL – 10 mL (change parts for 1mL & 2.25mL)	1mL - 10mL (change parts for 3mL)	1L – 400L	6000 objects/hr (max)	100% IPC at full-speed	Peristaltic pumping with disposable product pathway	GMP Ready Q1 2022
Commercial Line #4	Liquid vial filling line VEGA 8 vial washer + tunnel with dry heat sterilization of cold chamber	Commercial	No	IMA XTREMA	Closed RABS + Isolator	No	Yes, for stoppers	2R – 100H (change parts for 3mL, 6R/10R /20R/50H)	—	—	65L – 1000L	400 objects/ min	100% IPC at full-speed	Peristaltic pumping with disposable product pathway (piston pump optional)	Qualified in Q2 2021
Monza, Italy															
Commercial Line #6A	Flexible line for vials, PFS and PFC in nest and tub configurations; automatic debagger; small/medium size batches	Commercial	No	IMA INJECTA Robotic line	Isolator	No	Yes (vials, PFS, PFC) + stoppers and over-seals RTU	2R – 20R	0.5mL – 20 mL (change parts for 1mL)	1.5 mL – 20mL	400L (max)	Up to 60 – 90 objects/min (depending on product)	100% IPC at full-speed	Peristaltic pump and potentially rotary piston pump	Qualified in Q3 2021
Commercial Line #6B	Liquid/Lyo filling line + DA VINCI automatic loading/unloading of freeze dryers + ALU crimping machine for liquid vials	Commercial	No	IMA XTREMA	Isolator	Yes 2 X 20 m2	Yes, for stoppers	2R – 100H, 0.2 – 100ml (liquid) 2R – 50R, 16 – 40mm, h max 95mm (lyo) (change parts for 2R/10R)	—	—	Upto 1200L	400 objects/ min	100% IPC at full-speed	Peristaltic pump and rotary piston pump	Qualified in Q3 2021

Here are the global investments we are making across our network (continued):

Line	Description	Line Type	Customer dedicated	Equipment	Aseptic Technology	Lyop-hilization	Ready to Use	Vials	Syringes	Cartridges	Batch size	Line speed	In Process Control	Flow path	Timing
Swindon, UK															
Commercial Line #6A	Liquid and lyo filling line under isolator with vial washer and tunnel	Commercial	No	Bausch + Ströbel	M+P Isolator	Yes 2 x 15m2 Optima 1 x 30m2 Optima	Not as of now	2R – 50R (lyo) 2R – 100H (liquid) Change parts for 2mL, 6R/10R/20R (not ISO)	—	—	Determined by client req	Nominal speed 300 objects/min with 2mL vials	100% IPC at full-speed	Peristaltic pumping with disposable product pathway	Qualified in Q3 2021
Commercial Line #6B	Liquid filling line under isolator with vial washer and tunnel	Commercial	No	Optima	M+P Isolator	—	Not as of now	2R – 100H Change parts for 2mL, 10R, 50mL	—	—	Determined by client req	Nominal speed 450 objects/min with 2mL vials	100% IPC at full-speed	Rotary piston pumps with CIP/SIP + Peristaltic pumping with disposable product pathway	Qualified in Q3 2021
Singapore															
Commercial Line #1	BSL II line for life virus filling	Commercial	No	IMA	Isolator	No	RTU stoppers and over-seals	1mL – 100mL	—	—	1000L (max)	400 VPM (2R), 300VPM (10R)	100% IPC at full-speed	?	Operational Q3 2022
Commercial Line #2	Standard sterile filling line	Commercial	No	IMA	Isolator	"Yes (2) 30m2 IMA"	RTU stoppers and over-seals	1mL – 100mL	—	—	1000L (max)	240 VPM	100% IPC at full-speed	Peristaltic pumping with disposable product pathway	Operational Q1 2023
Hangzhou, China															
Development Suite #1	JV w/ Innoforce Pharmaceuticals Liquid filling line; cGMP PD capabilities onsite Re-filling & re-stoppering capabilities on the line	Development	No	Optima	M+P Isolator	No	RTU Stoppers, seals and vials – RTU vials in tray – RTU vials in nest and tub – RTU syringes – RTU cartridges	2R – 50R (change parts for 6R, 10R, 20R)	0.5mL – 10 mL (change parts for 1mL long)	3mL – 10 mL (change parts for 3mL)	250L (max)	30 objects/min or 1,800 objects/hr	100% IPC	Peristaltic pumping with disposable product pathway	Operational in Q4 2022
Commercial Line #1	JV w/ Innoforce Pharmaceuticals Liquid & lyo filling line; cGMP PD capabilities onsite Re-filling & re-stoppering capabilities on the line	Commercial	No	Optima	M+P Isolator	"Yes 2 x 10 m2"	RTU Stoppers, seals and vials – RTU vials in tray – RTU vials in nest and tub – RTU syringes – RTU cartridges + vials in bulk	2R – 50R (change parts for 6R, 10R, 20R)	0.5mL – 10 mL (change parts for 1mL long)	3mL – 10 mL (change parts for 3mL)	1000L (max)	100 objects/min or 6,000 objects/hr	100% IPC	Peristaltic pumping with disposable product pathway	Operational in Q1 2023
Plainville, MA (VVS)															
Commercial Line #1	RTU fill line for small batches of gene therapy products	Commercial	No	Optima	Isolator	No	RTU stoppers, seals, and trayed vials	0.5 mL Crystal Zenith – 10 mL Crystal Zenith 2R – 10R glass	—	—	< 5,000	40 Vials per Minute	100% IPC, redosing feature	Peristaltic pump, single use flowpath	Operational Q1 2022
Commercial Line #2	RTU fill line for small batches of gene therapy products	Commercial	No	Optima	Isolator	No	RTU stoppers, seals, and trayed vials	0.5 mL Crystal Zenith – 10 mL Crystal Zenith 2R – 50R glass	—	—	< 5,000	40 Vials per Minute	100% IPC, redosing feature	Peristaltic pump, single use flowpath	Order placement Q2 2021 FAT Q3 2022

About us

Thermo Fisher Scientific provides industry-leading pharma services solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With more than 55 locations around the world, we provide integrated, end-to-end capabilities across all phases of development, including API, biologics, viral vectors, cGMP plasmids, formulation, clinical trials solutions, logistics services and commercial manufacturing and packaging. We give pharma and biotech companies of all sizes instant access to a global network of facilities and technical experts across the Americas, Europe, Asia and Australia. Our global leadership is built on a reputation for scientific and technical excellence. We offer integrated drug development and clinical services tailored to fit your drug development journey through our Quick to Care™ program. As a leading pharma services provider, we deliver unrivaled quality, reliability and compliance. Together with our customers, we're rapidly turning pharmaceutical possibilities into realities.