

Product development services (PDS) for steriles

Expanded services across North America and Europe

Key resources for clinical development:

We offer a comprehensive range of product development services (PDS) for biopharma sponsors, including formulation development, compounding, lyophilization, analytical services, and Fill-finish. For fill-finish, PDS typically produces smaller clinical batch sizes but can also handle small-scale commercial manufacturing on certain lines. We offer dedicated PDS lines at four of our sites:

- Greenville, North Carolina, US
- Plainville, Massachusetts, US
- Ferentino, Italy
- Monza, Italy

Summary of PDS capabilities by site

	Greenville, NC, US	Plainville, MA, US	Ferentino, Italy	Monza, Italy
Liquid vials	2R–30R	2R-10R	2R–100 mL	2R–50R
Lyophilized vials	2R–30R	N/A	2R–100 mL	2R–50R
Prefilled syringes (PFS)	1–5 mL	N/A	1–10 mL	0.5–2.25 mL
Prefilled cartridges (PFC)	1–10 mL	N/A	1–20 mL	N/A

Greenville, NC

2 PDS lines

Site summary

	PDS 2	PDS 3
Objects processed	Liquid, Iyo	Liquid, Iyo, PFS, PFC
Tox level supported	3B	3A
Equipment	Bosch MLF 3020	IMA INJECTA
Lyo equipment	2 LYOMAX	2 IMA
Qualified vials	2R, 6R, 10R, 20R (OMPI)	2R, 6R, 10R, 20R (Gerresheimer and Schott)
Qualified syringes		1 mL long (BD)
Inspection	Manual and semi-automated. Equipment: Seidenader	

Plainville, MA

1 PDS line, 1 coming soon

Site summary

	PDS 1	PDS 2 (coming soon)
Objects processed	Liquid	Liquid
Tox level supported	3B	3B
Equipment	Optima VFVM 7000 MultiUse	Optima VFVM 7000 MultiUse
Qualified vials	2R, 10R (OMPI); 0.5 mL, 2 mL, 5 mL, 10 mL (CZ)	2R, 6R, 10R (OMPI); 0.5 mL, 2 mL, 5 mL, 10 mL (CZ)
Inspection	Manual light booth	

Ferentino, Italy

2 PDS lines, with 2 more coming soon

Site summary

	PDS 1	PDS 2	PDS 3 (coming soon)	PDS 4 (coming soon)
Objects processed	Liquid, Iyo	Liquid, Iyo, PFS	Liquid, PFS	Liquid, Iyo
Tox level supported	3B	3B	3B	3B
Equipment	Steriline VFM50	OPTIMA MultiUse	B&S KSF 5105	B&S KSF 5105
Lyo equipment	1 IMA 1 BOC Edwards	2 OPTIMA		GEA
Qualified vials	2R, 5 mL, 6R, 8R, 10R, 10 mL, 15R, 20R, 20 mL, 25R, 30R, 50 mL, 100 mL (OMPI, Schott)	2R, 6R, 8R, 10R, 20R, 25R (OMPI, BD)	2R, 6R, 10R, 20R (OMPI)	2R, 6R, 10R, 20R (OMPI)
Qualified syringes		0.5–2.25 mL (OMPI, Terumo, BD)	1 mL long–2.25 mL (OMPI, BD)	
Inspection	Manual			

Monza, Italy

3 PDS lines, with 2 more coming soon

Site summary

	ST2b	PDS 1	PDS 2	PDS 3 (coming soon)	PDS 4 (coming soon)
Objects processed	Liquid, PFS	Liquid, Iyo	Liquid, Iyo, PFS	Liquid, PFS	Liquid, PFS
Equipment	Bosch FXS	IMA SMART	B&S VarioSys 1	B&S VarioSys 2	IMA TILE-X
Tox level supported	2	3B	3B	3B	3B
Lyo equipment	N/A	2 IMA LYOMAX	GEA	N/A	
Qualified vials	2R (OMPI)	2R, 10R, 20R, 30R (OMPI); 6R (Soffieria Bertolini); 50R (Schott)	2R, 6R, 10R, 20R (OMPI)	2R-50R (OMPI) (pending)	2R-50R (Shott) (pending)
Qualified syringes	0.5 mL (Terumo); 1–2.25 mL (BD)	N/A	1 mL long– 2.25 mL (BD)	1mL long -2.25 mL (BD)	1 mL long–2.25 mL (BD) (pending)
Inspection	Manual	Manual (liquid) and semi-automated (Iyo) (Marchesini)			

Greenville, NC, US

PDS capabilities

The Greenville, NC facility features integrated sterile liquid and lyophilized product development for biologics, highly potent compounds, and small molecules.

Line Name	PDS 2	PDS 3
Dose forms	Liquid, Iyo	Liquid, Iyo, PFS
Readiness	Ready	Ready (PFS 1 mL long qualified) (Q4 2025) (2.25 mL Q4 2025)
Theoretical annual output in M units (1 mL PF or 10R vials)	5	10
Equipment	Bosch MLF 3020 with RABS, bulk vials	IMA INJECTA with isolator
Ready-to-use materials	Yes (stoppers/caps)	Yes
Tox level	3B	3A
Liquid vials	Size range qualified and parts available: 2R, 6R, 10R, 20R (OMPI)	Vials change parts available: 2R, 6R, 10R, 20R (Gerresheimer and Schott)
Lyophilized vials	Size range qualified and parts available: 2R, 6R, 10R, 20R (OMPI)	Vials change parts available: 2R, 6R, 10R, 20R (Gerresheimer and Schott)
Lyophilization equipment	2 LYOMAX (6300–23,400 max vials per run)	2 IMA (4500–16,714 vials per run)
Nitrogen overlay	Yes	Yes
Prefilled syringe	N/A	Size range qualified: 1 mL long (BD) Change parts available: 1 mL long and 2.25 mL
Prefilled cartridge	N/A	Range capable: 1–10 mL
Inspection	Manual and semi-automated Equipment: Seidenader Speed: 2 per min (MVI), variable (AVI)	

Plainville, Massachusetts, US

PDS capabilities

Located 50 miles (80 km) southwest of Boston, the Plainville, MA site supports clinical sterile injectable fill-finish, specializing in smaller 1,000–5,000-unit batches.

Line Name	PDS 1	PDS 2
Readiness	Ready	Q1 2026
Dose form	Liquid	
Theoretical annual output in M units (10R vials)	5	
Equipment	Optima VFVM 7000 MultiUse with isolator	
Ready-to-use materials	Yes	
Tox level	3B	
Liquid vials	Qualified: 2R, 10R (OMPI); 0.5 mL, 2 mL, 5 mL, 10 mL (CZ) Change parts available: 4R, 6R, 8R (OMPI); 5 mL (CZ)	
Inspection	Manual light booth Speed: 2.5 vials per min per operator	

Ferentino, Italy

PDS capabilities

The Ferentino site features integrated sterile liquid and lyophilized product development, as well as commercial manufacturing, including for high-potency products.

Line Name	PDS 1	PDS 2
Dose forms	Liquid, lyo	Liquid, lyo, PFS
Readiness	Ready	Ready
Theoretical annual output in M units (1 mL PF or 10R vials)	5	15
Equipment	Steriline VFM50 with RABS, and bulk vial	OPTIMA MultiUse with isolator and bulk vials
Ready-to-use materials	Yes	Yes
Tox level	3B	3B
Liquid vials	Size range qualified 2R, 5 mL, 6R, 8R, 10R, 10 mL, 15R, 20R, 20 mL, 25R, 30R, 50 mL, 100 mL (OMPI, Schott)	Size range qualified: 2R, 6R, 8R, 10R, 20R, 25R (OMPI, BD)
Lyophilization equipment	1 IMA 1 BOC Edwards (6,400–24,000 max vials per run)	2 OPTIMA (12,000–40,000 max vials per run)
Lyophilized vials	Size range qualified: 2R, 5 mL, 6R, 8R, 10R, 10 mL, 15R, 20R, 20 mL, 25R, 30R, 50 mL, 100 mL (OMPI, Schott)	Size range qualified: 2R, 6R, 10R, 20R (OMPI, Schott)
Nitrogen overlay	Yes	Yes
Prefilled syringe	N/A	Size range qualified: 0.5–2.25 mL (OMPI, Terumo, BD)
Prefilled cartridge	N/A	Range capable: 1–20 mL (OMPI)
Inspection	Manual	Manual

Ferentino, Italy

PDS capabilities, continued

Line Name	PDS 3	PDS 4
Dose forms	Liquid, PFS	Liquid, lyo
Readiness	Liquid vials (Q1 2026) PFS (Q4 (2026)	Q3 (2026)
Theoretical annual output in M units (1 mL PF or 10R vials)	10	10
Equipment	B&S KSF 5105 with isolator	B&S KSF 5105 with isolator and bulk vials
Ready-to-use materials	Yes	No
Tox level	3B	3B
Liquid vials	Size range qualified: 2R, 6R, 10R, 20R (OMPI)	Size range qualified: 2R, 6R, 10R, 20R (OMPI)
Lyophilization equipment	N/A	1 GEA (12,200–43,400 max vials per run)
Lyophilized vials	N/A	Size range qualified: 2R, 6R, 10R, 20R (OMPI, Schott)
Nitrogen overlay	Yes	Yes
Prefilled syringe	Size range qualified: 1 mL long 2.25 mL (OMPI, BD)	N/A
Prefilled cartridge	Range capable: 1–10 mL	N/A
Inspection	Manual	Manual

Monza, Italy

PDS capabilities

The Monza site specializes in the manufacturing and fill-finish of prefilled syringes, cartridges, and liquid and lyophilized products. It also offers mRNA drug substance manufacturing and development services.

Line name	ST2b	PDS 1	PDS 2
Dose forms	Liquid, PFS	Liquid, lyo	Liquid, lyo, PFS
Readiness	Ready	Ready	Ready
Theoretical annual output in M units (1 mL PF or 10R vials)	8.5	18	10.5
Equipment	Bosch FXS with RABS, bulk	IMA SMART with isolator, bulk	B&S VarioSys 1 with isolator, bulk
Ready-to-use materials	Yes	Yes	Yes
Tox level	2	3B	3B
Liquid vials	Size range qualified and parts available: 2R (OMPI)	Vials change parts available and qualified: 2R, 10R, 20R, 30R (OMPI); 6R (Soffieria Bertolini); 50R (Schott)	Vials change parts available and qualified: 2R, 6R, 10R, 20R (OMPI)
Lyophilized vials	N/A	Vials change parts available and qualified: 2R, 10R, 20R, 30R (OMPI); 6R (Soffieria Bertolini); 50R (Schott)	Vials change parts available and qualified: 2R, 6R, 10R, 20R (OMPI)
Lyophilization equipment	N/A	2 IMA Lyomax (4,200–32,400 max vials per run)	GEA (5,000–20,000 vials per run)
Nitrogen overlay	No	Yes	Yes
Prefilled syringe	Size range qualified and available: 0.5 mL (Terumo); 1–2.25 mL (BD)	N/A	Size range qualified and available: 1 mL long–2.25 mL (BD)
Inspection	Manual	Manual (liquid) and semi-automated (lyo) Equipment: Marchesini	Manual (liquid) and semi-automated (lyo) Equipment: Marchesini

Monza, Italy

PDS capabilities, continued

Line name	PDS 3	PDS 4 (Gloveless)
Dose forms	Liquid, PFS	Liquid, PFS
Readiness	Liquid (2026) PFS (2027)	Liquid (2027) PFS (2027)
Theoretical annual output in M units (1 mL PF or 10R vials)	10	5
Equipment	S VarioSys 2 with isolator, bulk	IMA TILE-X with isolator
Ready-to-use materials	Yes	Yes
Tox level	3B	3B
Liquid vials	Range capable: 2R–50R (OMPI)	Range capable: 2R–50R (Shott)
Lyophilized vials	N/A	N/A
Lyophilization equipment	N/A	N/A
Nitrogen overlay	TBD	TBD
Prefilled syringe	Range capable: 1 mL long–2.25 mL	Range capable: 1 mL long –2.25 mL
Inspection	Manual	Manual

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