# Thermo Fisher

## Summary of Capabilities

# Ferentino, Italy

#### **Facility Facts:**

Regulatory Approval (key)	: AIFA, US FDA, EMEA, Health Canada, ANVISA, TMOH (Turkish), Russian MOH, MFDS (Ministry of Food and Drug Safety Korea), Japan PMDA (Pharm. and Med. Dev. Agency), TFDA (Taiwan Food and Drug Administration)
Potency Capability:	Up to Cat 3b (Commercial) / Cat 3b (PDS)
Controlled Drug	
Schedule Registrations:	None
Contact Info:	2° Trav.SX Via Morolense, 03013 Ferentino (FR), Italy
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#### **Specialized Capabilities:**

- Sterile liquid vials (SVP & LVP)
- Prefilled syringes
- Prefilled cartridges
- Biopharmaceuticals, including:
- Monoclonal antibodies
- Other recombinant proteins
- Monoclonal antibodies
- Proteins
- Peptides
- Sterile lyophilized vials
- Secondary packaging (vials)
- Small molecules
- Scale up
- Blood products
- Hormones

#### **Unique Offering:**

Integrated sterile liquid and lyophilized product development and commercial manufacturing, including high potency products, prefilled syringes and cartridges, and LVP.

		Early Development			ate Dev	Commercial Supply		
Dosage Forms	Formulation Development	Analytical Development	Phase I	Phase II	Phase III	Commercial Scale Up	Tech Transfer	Regulatory
Liquid vials	•	•	•	•	•	•	•	•
Lyophilized vials	•	•	•	•	•	•	•	•
Prefilled syringes	•	•	•	•	•	•	•	•
Prefilled cartridges	•	•	•	٠	•	•	•	•

#### Lifecycle by Dosage Form:

#### Ferentino Equipment List – Development Scale (GMP Manufacture for Clinical Trials):

	Equipment (Features / Scale)	Liquid Vials	Lyophilized Vials	Prefilled Syringe/ Cartridge
Compounding	Refrigerating and heating circulator	•	•	•
	Glove box	•	•	•
	Benchtop wand mixer (up to 20 L)	•	•	•
	Floor wand mixer (50 – 100 L)	•	•	•
	Disposable flexible containers (2 – 130 L)	•	•	•
	Glass vessels (2 – 50 L)	•	•	•
Washing	Vial washer	•	•	
Depyrogenation	Depyrogenation tunnel	•	•	
Component sterilization	Autoclave	•	•	•
& Drying	Pass-box UV	•	•	•
Filling & Stoppering	Filling machine	•	•	•
Lyophilization	Lyophilizer (2 x 7 m2)		•	
Capping	Crimping machine	•	•	
Inspection	Manual Inspection	•		•
	Visual Inspection System (semi automated inspection of powders)		•	•

#### Ferentino Key Equipment List – Commercial Scale:

	Equipment (Features / Scale)	Liquid Vials	Lyophilized Vials	Prefilled Syringe/ Cartridge
	Mixing tanks (50 – 2000 L)	•	•	•
Compounding	Mixing tanks (50 – 5550 L)	•	•	•
	Moveable mixing tanks (stainless steel & disposable bag system, 15 – 1000 L, thermoregulation)	٠	•	•
	Ultrafiltration	•	•	•
	Isolator for slurry preparation	•	•	•
	Column lift	•	•	•
Washing	Vial Washer, automatic washer machine for format parts	•	•	
Depyrogenation	Depyrogenation tunnel	•	•	
	Autoclave	•	•	•
Component Sterilization & Drving	Dry Oven	•	•	•
Sterilization & Drying	Pass Box (UV/VIS & VHP) Isolator	•	•	•
Filling & Stoppering	Vial Filler (Filling under nitrogen, piston pumps and peristaltic pumps)	٠	•	•
Lyophilization	Lyophilizers (1 x 33m <sup>2</sup> , 1 x 35m <sup>2</sup> , 1 x 42m <sup>2</sup> Sterile Area 1; 2x20 m <sup>2</sup> fully automated and 1 x 10m <sup>2</sup> Sterile Area 2)		•	
Capping	Vial crimper	•	•	
Laminar Air Flow (LAF)	Transportation of vials (maintenance of grade A continuity)	•	•	•
Inspection & Packaging	Visual Inspection System (semi automated inspection of lyophilized product)		•	•
	Manual inspection	•	•	•
	Visual Inspection System (Fully Automated, by means telecameras for liquid)	٠		
	Printer	•	•	
	Serialization capabilities	•	•	
	Labeling machine	•	•	
	Leaflet folder	•	•	
	Vial packaging	٠	•	

\* Minimum and maximum batch sizes are not necessarily related to scale, batch size requirements are dependent on the project details.

For detailed equipment information please contact your Thermo Fisher Scientific representative.

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