



Italy

Bulciago, Lecco

Facility Facts

Contact info: Strada Statale, Via Briantea, 83
23892 Bulciago
(LC) Italy

Phone: +39 0363 1810211

Workforce: ~ 60

Capacity: 650 m³

Potency Capability: OEL > 1 µg/m³

Offerings

- cGMP large scale and commercial manufacturing
- Production scales from 100's of kgs to MTs
- Internal back-up for Flamma network
- Average reactor size: 12,000 L
- Largest reactor size: 25,000 L
- Regulatory Submission
- FDA and AIFA Inspected
- Japanese Pharmacopoeia accredited

Summary

Flamma Bulciago was acquired in 2022. This GMP facility brings Flamma's total manufacturing capacity in Italy to 900 m³. This site is dedicated to commercial products including APIs, RSMs, NCEs, and other materials. By transferring various products to Bulciago, Flamma is able to free up capacity for earlier stage projects at its Chignolo and Isso facilities.

This site provides the supply chain security as it is an internal back-up for customers working at our Flamma Honkai location. For those preferring the flexibility of adding an alternative manufacturing site based in Europe, Flamma Bulciago also provides an excellent option to consider when looking to add Flamma to your CDMO network.

Flamma continues to investment in Bulciago site in order to improve its offering. Recent upgrades include the revamping of reactors as well as the DCS system. There continues to be improvements made in the production areas along with utility upgrades. There will be an increase in the level of investment in order to improve various areas of the site.

Initial & Early Development					Late stage	Commercial Supply		
Analytical Development	Process Development	Pre-clinical	Phase I	Phase II	Phase III	Tech Transfer	Commercial Scale-up	Regulatory
					•	•	•	•

BULCIAGO EQUIPMENT OVERVIEW				Initial & Early Development			Late stage	
Location on-site	Detailed location	Activity or Equipment Overview	Further Detail	Process Development	Analytical Development	Pre-clinical to Phase I/II	Phase III	Commercial
Production Plant	Glass Lined Reactors	8 reactors from 1,600 L to 12,000 L 12 reactors from 4,000 L to 12,000 L 4 reactors from 12,000 L to 12,400 L					•	•
	Stainless Steel Reactors	15 reactors from 1,500 L to 22,000 L 11 reactors from 3,000 L to 12,000 L 14 reactors from 4,000 L to 25,000 L					•	•
	Centrifuges	4 centrifuges AISI 316 from 980 L to 1,500 L 1 centrifuge (Rilsan) 340 L 5 centrifuges (Halar) from 340 L to 1,500 L					•	•
	Press Filter Dryers	6 SS filter dryers from 5,000 L to 10,500 L					•	•
	Dryers	2 dryers from 1,000 L to 2,100 L 2 dryers from 3,180 L to 5,000 L					•	•
	Other dryers	4 paddle dryers and 1 fluid bed dryer					•	•
	Milling/Blending	Miller, granulator and sieve available (AISI 316L)					•	•
	Mixer	2 Mixers (AISI 316L) from 600 L to 1,000 L					•	•
	Containment Equipment	Glove box available for HPAPI (1,500 L)					•	•
	Special technology	Hydrogenation & HCl loading station Pneumatic system (ASP1 AISI 316L)					•	•
	Temperature range & vacuum	From -15°C to 120°C, full vacuum 6 barg					•	•
QC	Analytical	Analytical Equipment	HPLCs (UV, DAD), GCs (HS-FID), FTIR, Potentiometric titrators, KF Volumetric, Polarimeter, UV-VIS				•	•