USA
Malvern | PA

Early Stage and Low Volume Commercial API Development and Manufacture

FACILITY FACTS

Contact info: 383 Phoenixville Pike
Malvern
PA 19355-9603, USA
Phone: +1 610-621-4900
Workforce: ~50
Capacity: 2 m^3
Potency Capability: OEL > 1 µg/m^3

OFFERINGS

- Small molecule cGMP scale-up and manufacturing
- Production scales ranging from grams to 10's of kilos
- Process development/optimization
- Process safety studies
- Analytical method development and validation
- HPAPI & Controlled Substance (II-IV) manufacturing
- Low-Volume commercial manufacturing
- FDA Inspected

SUMMARY

The Flamma USA site in Malvern is 40,000 sq. ft. (3,700 m2) of lab and manufacturing space. The site contains a cGMP Pilot Plant along with 5 cGMP kilo lab suites and an ISO-8 (Class 100,000) clean room. The cGMP HPAPI kilo lab suite has 3 separate isolator lines that can handle an OEL > 0.01 µg/m3. The site is equipped with 22 fume hoods, an analytical development lab, QC lab, on-site NMR, LC-MS QTOF, and LC-MS QDA. Flamma USA is currently in the first phase of a pilot plant expansion that would see an increase in processing capacity. This expansion will add two larger volume reactors (1000 L and 1600L) as well as additional isolation capabilities. This expansion will increase the total manufacturing capacity to 4.6 m3. The expansion is estimated to be completed in late 2027. Flamma USA also has a license for handling controlled drug substances (schedule II to IV). Having close proximity to Boston/Cambridge (1.5 h flight), as well as the greater New York/ New Jersey area (1.5 h drive), Flamma USA provides a world-class option for those looking for a US based CDMO with the flexibility of a global footprint.

Initial & Early Development				Late stage	
Analytical Development	Pre-clinical	Phase I	Phase II	Phase III	Small scale Commercial
■	■	■	■	■	■

MALVERN 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
Process and Anal. R&D Labs	Process Development	Organic Synthesis Development	EZ Max (50 mL to 400 mL)	■		■	■	■
			OptiMax (up to 1L)	■		■	■	■
			Jacketed reactors (50 mL to 3L)	■		■	■	■
		Reaction Calorimetry/Safety	HF Cal	■		■	■	■
			HEL TSU	■		■	■	■
		Solid State	Polarized Light Microscope	■		■	■	■
			Crystal 16	■		■	■	■
		In-Situ Monitoring	ReactIR	■		■	■	■
		Standard isolation	ISCO Chromatography	■		■	■	■
		Monitoring	HPLC, KF, GC, NMR	■	■	■	■	■
	Analytical Lab	Analytical Development	HPLC (UV, CAD, RI detectors), GC liquid injection, GC with Headspace, LCMS (QTOF and QDA), KF, DSC, TGA, ROI, USP type I water unit	■	■	■	■	■
		QC	In addition to above, there are Stability chambers (CRT, 2-8 °C, Freezer)	■	■	■	■	■
Production	Highly Potent Suite	Benchtop Hoods with Isolators	2 x Wet Chemistry up to ~3 L in hood; Isolator (surrogate tested to 0.01 µg/m^3)	■	■	■	■	■
		Walk-in Hood with Isolator	1 x Wet Chemistry up to 50 L (hood); all isolations in Isolator (balances, vacuum oven; surrogate tested to 0.01 µg/m^3)	■	■	■	■	■
		QC	Dedicated HPLC and GC	■	■	■	■	■
	Kilo Lab	Synthesis	5 x GMP Kilo labs	■		■		
			5 L to 100 L Glass Jacketed/Lined Vessels –(40 to 150°C)	■		■		
			20 L rotovaps	■		■		
		Purification	75 L and 150 L Biotage	■		■		
		Hydrogenation	0.5 to 20 L	■		■		
		Nutsche Filter	Glass w/ polypropylene basket	■		■		
		Aurora Filter Dryer	14 inch Hastelloy w/ poly propylene pad	■		■		
		Centrifuge	10 & 14 inch Baskets	■		■		
		Wet Mill	IKA DRS 2000/5	■		■		
		Kilo Fitz Mill	L1A Model	■		■		
	Pilot Plant	Glass Lined Reactors	1 x 250 L, 2 x 500 L (-20 to 130°C)			■	■	■
		Hastelloy Reactor	1 x 250 L (-80 to 130°C)			■	■	■
		Aurora Filter Dryer	2 x 26 inch Hastelloy w/ polypropylene pad			■	■	■
		Hydrogenation	300 L Hastelloy (up 10 bar)			■	■	■
		Centrifuge	20, 26, 30, & 36 inch Baskets			■	■	■
		Tray Dryer	22 to 90°C			■	■	■
		CUNO Filter	6 & 12 inch			■	■	■
		Sparker Filter	8 & 12 inch			■	■	■
		Pilot Fitz Mill	M5A Model			■	■	■

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