



USA
Malvern, PA

Focused on early stage & pre-clinical development

Facility Facts

Contact info: 383 Phoenixville Pike
Malvern, PA 19355-9603
Phone: +1 610-621-4900
Workforce: 40
Capacity: 2 m³
Potency Capability: OEL > 0.1 µg/m³

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
- Small scale commercial manufacturing

Summary

Initially dubbed "Flamma-delphia", 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 lines in isolators that can handle an OEL > 0.1 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 as well as additional space for future expansion for any necessary analytical chemistry, process development and/or warehouse needs. 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), provides another option for those looking for a US based CDMO service provider for process development and scale up of intermediates and APIs for clinical supply under cGMP conditions.

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	
Laboratories	Process Development Labs	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	•		•			
			FBRM	•		•			
		In-Situ Monitoring	ReactIR	•		•			
	Standard isolation	ISCO Chromatography	•		•				
	Monitoring	HPLC, KF, GC	•	•	•				
Analytical Lab	Analytical Development	HPLC (UV, CAD, RI detectors, GC liquid injection, GC with Headspace, LCMS (QTOF and QDA), GCMS, KF, DSC, TGA, Melting Point, 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 0.1ug/m ³)	•	•	•	•	•	
		Walk-in Hood with Isolator	1 x Wet Chemistry up to 50 L (hood); all isolations in Isolator (balances, vacuum oven & rotovap; surrogate tested to 0.1ug/m ³)	•	•	•	•	•	
		QC	Dedicated HPLC and GC	•	•	•	•	•	
	Kilo Labs	Synthesis	3 x GMP Kilo labs	•		•			
			5 L to 50 L Glass Jacketed/Lined Vessels	•		•			
			-40 to 150 °C; 20 L rotovaps	•		•			
		Hydrogenation	0.5 to 20 L + 300 L Hastelloy (up 12 bar)	•		•			
		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	•		•				
	Bohle Blender	5 L, 10 L, 20 L & 40 L bins	•		•				
	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 12 bar)			•	•	•	
		Centrifuge	2 x Centrifuges; 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			•	•	•		
ReactIR 45P	Fits all Glass Lined Reactors			•	•	•			