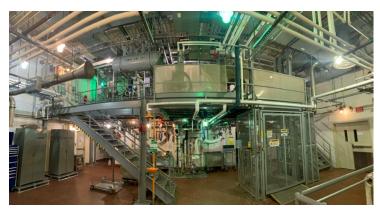


# USA Malvern, PA



# 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 m <sup>3</sup>
Potency Capability:	OEL > 0.1 μg/m <sup>3</sup>

#### 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 m<sup>2</sup>) 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 >  $0.1 \mu g/m^3$ . 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	<b>Pre-clinical</b>	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 MI	Phase III	Commercial
		EZ Max (50 mL to 400 mL)	٠		•			
	abs	Organic Synthesis Development	OptiMax (up to 1L)	•		•		
Solid See Standard	Development	Jacketed reactors (50 mL to 3L)	•		•			
	ner	Reaction	HF Cal	•		•		
	lopr	Calorimetry/Safety	HEL TSU	•		•		
ŝ	eve	Calid Otata	Polarized Light Microscope	•		•		
Laboratories	° D	Solid State	FBRM	•		•		
rato	Ses	In-Situ Monitoring	ReactIR	•		•		
lod	roc	Standard isolation	ISCO Chromatography	٠		•		
La	-	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	•	•	•	•	•
	Ana	QC	In addition to above, there are Stability chambers (CRT, 2-8°C, Freezer)	•	•	•	•	•
Suite	Benchtop Hoods with Isolators	2 x Wet Chemistry up to ~3 L in hood; Isolator (surrogate tested to 0.1ug/m <sup>3</sup> )	٠	•	•	•	•	
	Benchtop Hoods with Isolators	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/m³)	•	•	•	•	•
	Hig	QC	Dedicated HPLC and GC	•	•	•	•	•
			3 x GMP Kilo labs	•		•		
Synthesis	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)	•		•		
	abs	Nutsche Filter	Glass w/ polypropylene basket	•		•		
uo			14 inch Hastelloy w/ poly propylene pad	•		•		
loti		Centrifuge	10 & 14 inch Baskets	•		•		
odl		Wet Mill	IKA DRS 2000/5	•		•		
Pr		Kilo Fitz Mill	L1A Model	٠		•	1	
		Bohle Blender	5 L, 10 L, 20 L & 40 L bins	٠		•	1	
		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	<u> </u>		•	•	•
	Harden Her Dryon Divide Her Harden Her Dryon   Hydrogenation 300 L Hastelloy (up 12 bar)   Centrifuge 2 x Centrifuges; 20, 26, 30, & 36 inch Basket   Tray Dryer 22 to 90 °C   CUNO Filter 6 & 12 inch   Sparker Filter 8 & 12 inch					•	•	•
			-	1	•	•	•	
						•	•	•
						•	•	•
					İ	•	•	•
	Pilot Fitz Mill	M5A Model			•	•	•	
		ReactIR 45P	Fits all Glass Lined Reactors			•	•	•