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Flamma USA Successfully Passes FDA Inspection

Malvern, PA, USA – February 23, 2026 – The **Flamma Group** (“Flamma”), a global, fully integrated, Contract Development and Manufacturing Organization (CDMO) of New Chemical Entities (NCEs) and late stage intermediates for Innovator Companies, announces that its Flamma USA site, located in Malvern, PA, has successfully passed its first US Food and Drug Administration (FDA) inspection.

The pre-approval inspection (PAI) took place over the course of four days for an API that the Flamma USA site will manufacture for a global pharmaceutical company. The inspection covered the entire facility including the manufacturing equipment and quality system, and the site was found to be compliant with all FDA GMP requirements.

The Malvern, PA site was acquired by Flamma in late 2019. Since the acquisition, the site has seen investments over \$3M in order to align it with Flamma’s manufacturing and quality standards. The site is focused on early-stage small molecule drug development and manufacture of APIs whether they be small volume, orphan and niche indication APIs.

“This is a tremendous achievement for Flamma USA. Since day one, the site’s goal has been to help customers move their molecules into the clinic for Ph. I studies and onward as quickly as possible,” states Gianmarco Negrisoni, President of Flamma USA. “Our team has worked very hard to bring the site to this level. This milestone serves as a testament to our enduring commitment to the highest standards of quality and regulatory compliance. It affirms our continued capability to strengthen our global presence as a trusted, stable, and dependable partner.”

The Flamma USA site consists of 5 GMP kilo-labs, GMP HPAPI suite, GMP pilot plant, GMP clean room along with an R&D lab with 16 hoods. The site allows our team to work efficiently and effectively for customers looking to leverage the entire Flamma global network. Flamma recently hired Craig Dixon as its Site Director. With over 25 years of experience in the industry, Craig brings extensive understanding of the CDMO marketplace, across development, commercial and operations.

About Flamma:

Founded in 1950, Flamma is a global, fully integrated CDMO specializing in small molecule development and manufacturing. With facilities in Italy, China, and the USA, we deliver **Chemistry with a Human Touch**—combining scientific precision, strategic thinking, and a deeply collaborative approach.



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