

# Kymanox® Announces Low Volume Manufacturing Capabilities Supporting Human Clinical Studies

*The company strengthens its end-to-end service offerings with GMP-compliant manufacturing for medical devices and device constituents of combination products*



KING OF PRUSSIA, PA, UNITED STATES,  
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[Kymanox®](#), a leading provider of device design and product development, quality, regulatory and technical solutions exclusively serving the Life Science industry, is pleased to announce the successful completion of a significant manufacturing project, with clinical devices manufactured at its King of Prussia facility that are now being utilized in human clinical studies. The company

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*Nicholas Ciccarelli, PE, Chief  
Technology Officer*

recently delivered devices that were designed, developed, and assembled in-house and performed as intended during clinical testing. This milestone reinforces Kymanox's position as a comprehensive solutions provider for life science companies that are looking for a partner to accelerate their programs through development and clinical phases.

Kymanox's recent manufacturing success is reflected through the comprehensive support provided to its client, that leveraged the 5,000+ square feet of newly constructed GMP-compliant manufacturing space, the ability to create novel designs and execute design verification onsite,

support sterilization process development, and the full development of a clinical-stage Design History File.

"Our manufacturing capabilities aren't designed as a standalone service, but as an integrated component of our comprehensive development approach," said Nicholas Ciccarelli, PE, Chief Technology Officer at Kymanox. "The successful completion of our recent clinical manufacturing project demonstrates our team's exceptional ability to deliver high-quality, complex devices for

critical applications. I'm incredibly proud of our team's dedication to excellence and the expertise they bring to every project. This achievement solidifies our ability to support our partners throughout the entire product lifecycle, providing seamless continuity that ultimately benefits both our clients and the patients they serve."

The company's manufacturing services operate with rigorous documentation and controls to ensure compliance with Current Good Manufacturing Practices (CGMP), specializing in manufacturing for critical pre-commercial milestones including devices for human factors studies, design verification testing, and clinical trials. This strategic focus allows Kymanox to provide exceptional value for low volume batches while maintaining the quality standards necessary for clinical applications.

As Kymanox continues to enhance its manufacturing capabilities, it remains dedicated to fostering strong relationships with clients and partners, driving advancements in healthcare, and accelerating the development and delivery of modern medicines and technologies for patients worldwide.

For more information about Kymanox's clinical-scale manufacturing capabilities and comprehensive development services, visit [www.kymanox.com](http://www.kymanox.com) or contact [info@kymanox.com](mailto:info@kymanox.com).

#### About Kymanox:

Kymanox has proven, collaborative, end-to-end solutions that help bring Life Science products to the market – and keep them there. We are a global professional services organization that supports comprehensive drug development with integrated science, engineering, compliance (e.g., QA/RA), and technical project management. Our work across small and large molecules, medical devices, and combination products affords us a wholly unique advantage. With our diverse team of experts, Kymanox helps clients navigate commercialization challenges that arise throughout a product's life cycle – from early development to post-market – with optimized safety, quality, efficacy, and accessibility. We strive to advance Life Science innovation through insightful solutions and collaboration...because patients deserve better. Kymanox was founded in 2004 and is headquartered in Morrisville, North Carolina USA. Kymanox is backed by WestView Capital Partners, a Boston-based growth equity firm.

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