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VENDOR VIEWPOINT

AGILE, INTEGRATED, AND CLIENT-FOCUSED: THE DIPHARMA MODEL FOR MODERN CDMO SERVICES

By Brian Eklov, CEO, Dipharma Inc.

The Dipharma Group is a privately owned Contract Development and Manufacturing Organization (CDMO) with a global footprint, and is a leading manufacturer of Active Pharmaceutical Ingredients (APIs), New Chemical Entities (NCEs), and advanced intermediates for both the worldwide generic and contract manufacturing markets. The Group operates with robust quality systems that meet the rigorous standards set by the global regulatory authorities demonstrated by our inspection records from the FDA, AIFA, PMDA, KFDA and, more recently, ANVISA.


Brian Eklov

With decades of experience in chemical process development, regulatory compliance, and reliable supply chain management, Dipharma has established itself as a trusted partner for the most important pharmaceutical companies worldwide. Its portfolio of high-quality APIs and comprehensive CDMO services reflects a proactive response to evolving market needs, grounded in solid technical know-how and an agile operational capability from discovery to commercial.

Founded in 1949 and headquartered in Milan, Italy, the Group operates four manufacturing sites and two R&D centers across Europe and North America.

One of its key subsidiaries is Dipharma Inc., formerly Kalexsyn, Inc. The site, founded in Kalamazoo, Michigan, in 2003, was acquired by the Dipharma Group in 2018 to enhance the Group's presence in North America.

To explore Dipharma Inc.'s role within the Group and its contribution to accelerating customer projects, we interviewed the company's CEO, Dr. Brian Eklov.

Q: Since joining the Dipharma Group, Dipharma Inc. has significantly expanded its scope. How has the company evolved in terms of infrastructure and capabilities?

A: Since its acquisition seven years ago, Dipharma Inc. has undergone a significant transformation, both in terms of technical capabilities and strategic alignment with the Group's global objectives, enhancing its range of services from that of a world-class contract research organization (CRO) to much more of a full-service CDMO. One of the key milestones has been the implementation of Current Good Manufacturing Practices (CGMP), which allows us to leverage our world-class chemistry services for our clients' clinical-phase projects. This process has been closely tied to a major investment in our Kalamazoo site, most notably the installation of a two-line CGMP Kilolab, designed to accommodate API release for Phase 1 and Phase 2 clinical trials, as well as for small commercial volumes. This suite is supported by a state-of-the-art Quality Control laboratory, designed and equipped to the latest pharmaceutical quality standards, with full 21CFR Part 11 compliance for Data Integrity management.

This transformation culminated in a successful FDA preapproval inspection in January 2024 and receipt of the commercial manufacturing approval in 2025.

Concurrently, we are enhancing Analytical and Solid-State Development capabilities to offer integrated, science-driven solutions that meet evolving customer needs. These investments strengthen our position in the North America market, which represents approximately 40% of the Group's overall turnover, and reflects our commitment to

providing comprehensive CDMO services from pre-clinical and Phase I/II support from Kalamazoo, back integration with our Italian sites, and supporting Phase III and commercial launches from any of the four plants in the Group's portfolio. We operate the Group as a single, unified international team, enabling higher quality and faster project execution—benefits achievable only through this unified approach. Moreover, our close integration into client teams fosters strong connections that translate into long-term, repeated successes built on scientific rigor and transparency.

Our strength lies in the combination of deep and broad scientific know-how, a robust quality culture, long-standing manufacturing excellence, and a deep desire to see our clients' projects move forward and positively impact patients' lives

Q: What are the most common challenges you encounter during early-phase clinical projects, and how does Dipharma Inc. address them?

A: One of the key challenges at the early clinical stages is to remain focused on the deliverables, and what work needs to be completed to achieve the client's goals. Often, projects enter the clinical arena with very limited chemical and analytical knowledge. Moving the synthetic and analytical development forward enough to satisfy regulatory requirements while not over-taxing often complicated budgetary needs on our client's side, is key. To address this, we take a flexible, phase-appropriate, and iterative approach to development. Helping our clients understand the requirements and the risks that are inherent in the available options is critical to our mutual success. This enables us to rapidly identify critical issues and propose pragmatic, efficient solutions that can evolve as development progresses.

Q: How does Dipharma Inc. ensure quality and regulatory compliance during clinical activities?

A: We adopt a proactive, science-based approach to compliance from the very beginning. Our team follows phase-appropriate ICH and FDA guidelines in all clinical programs, and we integrate quality risk management principles in all our processes. Moreover, by leveraging the Group's extensive regulatory experience, we provide clients with full documentation support that is aligned with global standards—essential when moving through the clinical phases and into commercial production.

Q: What distinguishes Dipharma's approach from other CDMOs in the market?

A: Our strength lies in the combination of deep and broad scientific know-how, a robust quality culture, long-standing manufacturing excellence, and a deep desire to see our clients' projects move forward and positively impact patients' lives. As part of a vertically integrated group, we can offer clients a seamless progression from early development to commercial production. At Dipharma Inc., we are committed to providing personalized support, scientific rigor, and the agility required to meet evolving project demands.

Q: How does Dipharma Inc. collaborate with the Group's R&D centers to support innovation?

A: Our relationship with our European team is highly collaborative, often with project development goals shared across sites. Our U.S. team engages in regular technical meetings and shares appropriate data in real-time through common digital platforms. This integrated workflow ensures alignment at every step and accelerates necessary decision making. By combining local responsiveness with global scientific resources, we bring innovation closer to our clients, especially during the early phases of development.

Q: What impact does early development have on the overall cost and timeline of pharmaceutical programs?

A: Strategic investment in early development significantly reduces long-term costs and is a significant factor in avoiding delays in later, and much more expensive, stages of development. A flexible yet robust process design coupled with a phase-appropriate analytical package during the early clinical stages, helps prevent formulation issues or regulatory setbacks. At Dipharma, we embrace a right-size and right-first-time philosophy, which translates into better timeline control and greater confidence as programs move forward.