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CONTRACT MANUFACTURING ORGANIZATION EDITION

Dipharma

Accelerating Drug Development with Comprehensive CDMO Services

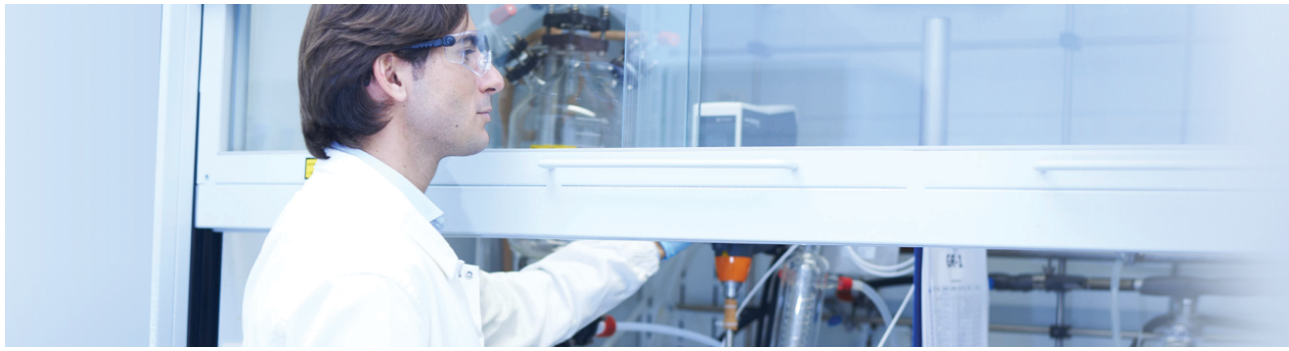
Andrea Confetti,
Exclusive Synthesis Business Unit Leader

Adept at delivering a symphony of reliability, experience and innovation, Dipharma is not just a contract development and manufacturing organization (CDMO) but a trusted orchestrator of success for pharmaceutical companies worldwide. Celebrating its 75th anniversary in 2024, it leverages vast chemistry and advanced technology expertise to optimize drug production processes amid the growing pressure to optimize costs and accelerate high-quality drug development.

Today, many pharma businesses face regulatory hurdles, supply chain disruptions and strict guidelines, which hinder their production schedules. Dipharma effectively addresses these challenges with its widespread geographical presence, which adapts to changing requirements and enables seamless cross-border collaborations while maintaining compliance with quality and safety standards.

Through a comprehensive and CGMP services suite, Dipharma supports customers throughout a molecule's lifecycle with a commitment to product manufacturing excellence of the highest benchmarks. From active pharmaceutical ingredient (API) development to commercial production, its technical expertise gives clients the peace of mind to focus on their end goals. It also delivers in-depth insights into potential material-related risks to help them strategically channel resources, achieve regulatory compliance and boost scalability.

"Our widely recognized technical capability proactively identifies customer needs to tailor solutions that fit their complex syntheses and drug analysis requirements and helps them navigate their way out of the various process-related challenges," says Andrea Confetti, Exclusive Synthesis Business Unit Leader.



Exemplifying its competency in addressing supply chain disruptions is the success story of supporting a multinational pharma company. Since they initially scouted for API suppliers to tailor their study material, which was unavailable off the shelf, Dipharma received timely samples for product familiarization. However, when it was time to begin production, the client's supplier cancelled their high-volume delivery, disrupting the project timeline. Dipharma's R&D team quickly identified alternate synthesis routes by converting a commercially available compound into suitable materials, bypassing the supplier shortage with a guaranteed API source that delivered uninterrupted production and enabled access to effective medication for end-users.

Successes like these are a testament to Dipharma's highly qualified offer. Staffed by more than 550 highly skilled employees, today, Dipharma is equipped with R&D hubs, one near Milan, Italy, and another one in Kalamazoo, Michigan, USA. These hubs fortify the company adeptness at scaling a client's project as the manufacturing process evolves from small- to large-scale production. An added benefit of these vast R&D capabilities is the ability to support the entered product development, working closing with process technology experts. Dipharma's offering includes a state-of-the-art kilo laboratory, designed for managing small drug quantities and early clinical assessments. At higher scale, Dipharma can offer a larger footprint, with two pilot plants, offering customers access to state-of-the-art pilot testing for better product scalability and optimized compound analytics. Finally, the industrial-sized production lines at all three Italian facilities enable to manage commercial volumes spanning up to several tens of tons per year.

From a regulatory standpoint, Dipharma's facilities in Italy have long-standing regulatory compliance with the major Regulatory Agencies, such as the FDA, the European Medicines Agency (EMA), represented by the Italian Medicines Agency, the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), the Korean FDA and the Brazilian Health Regulatory Agency (ANVISA). Even in the U.S., its facility has received this year a pre-approval inspection by the FDA. This globally recognized compliance helps its customers to confidently market their products across many target geographies.

Dipharma is also dedicated to helping clients adapt to the evolving sustainability standards. It leverages efficient cogeneration and third-generation equipment to minimize the environmental impact and carbon footprint of their operations. At the same time, it strives to embrace eco-friendly raw materials, green solvents, and energy-saving alternatives to optimize process yields with limited resources and lower the release of toxins. In compliance with the GMP regulations, Dipharma recovers and reuses solvents to reduce waste generation and new solvent requirements, implements waste management programs and partners with upcycling companies to decrease external biological treatments.

The forward-looking attitude of our people, supported by our widely recognized technical capability, proactively identifies customer needs to tailor solutions that fit their complex syntheses and drug analysis requirements and helps them navigate their way out of the various process-related challenges

Since its inception, Dipharma has constantly focused on innovation to broaden its service capabilities. Recently, the company expanded the analytical services and lab space of its Italy-based R&D center by 130 percent to simultaneously manage multiple projects and improve customer experience. On the manufacturing front, it has quadrupled the reactor capacities within its kilo lab, which is set to extend its capabilities to more diverse client requirements.

An industry-leading CDMO player, Dipharma aims to become a beacon for those seeking manufacturing excellence, service reliability and transformative solutions for drug development. Above all, it remains a partner that drives client success one molecule at a time. Ph