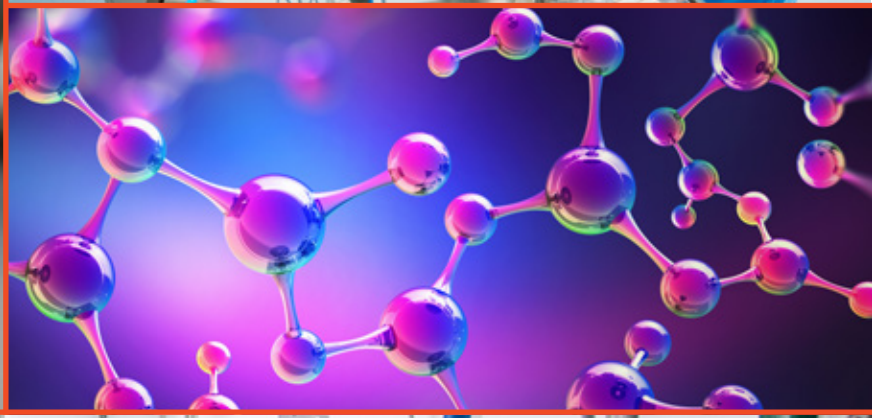
Piramal
Pharma Solutions



INTEGRATED SERVICES: PARTNERSHIPS FOR SUCCESS

Efficiency, speed-to-market, and access to unique expertise are among the key benefits of partnering with a contract development and manufacturing organization (CDMO) offering integrated, end-to-end services.

Piramal Pharma Solutions (PPS) provides customers in the pharmaceutical and biotech space with a fully integrated approach to drug discovery, development, manufacturing, packaging, and more. PPS has a superior record of delivering successful product launches with the seamless transfer of technology, documentation, and materials across global sites. Regulatory know-how and deep experience across a spectrum of projects and categories further solidify the company's standing as an elite integrated CDMO.

Why Integration Matters

In the initial days of integrated services, CDMOs were primarily geared toward early-stage development, helping clients obtain an investigational new drug (IND) application. Today, however, integrated CDMOs like PPS assist companies across the entire development process, including late stage and commercial projects.

From discovery to intermediates, active pharmaceutical ingredients (APIs) and drug products, a CDMO requires expertise across multiple elements of the pharma process to deliver an integrated experience. Through comprehensive project management teams, PPS oversees and executes all elements of this work on behalf of its clients and their patients. By taking ownership of the end-to-end integrated project, we gain in speed while also de-risking transfers between multiple CDMOs.

The PPS organization is uniquely positioned to support its customers from project inception through commercial manufacturing, as well as providing specialized services like high potency APIs (HPAPIs) and antibody-drug conjugates (ADCs). PPS has internal capabilities to assist companies along any aspect of a product development lifecycle. For example, if an innovator company has developed an API but lacks the ability to manufacture it internally, PPS has the capabilities and know-how to spearhead an integrated program of scale up and commercial manufacturing across multiple sites.

To coordinate this complex web, first-class knowledge and customer care are essential. Clear communication and data and tech transfer between facilities in the CDMO are of the utmost importance. PPS's integrated project management provides unmatched oversight across all of its facilities to support a seamless experience for its partners.

How We Can Help

There are numerous advantages to partnering with an integrated CDMO. However, over the company's nearly 40 years of experience, several primary factors continue driving customers to the exceptional services provided by PPS.

Speed—especially during early phase development—is a huge asset for customers relying on a CDMO. "A lot of integrated work comes from biotech or pharma companies with early phase candidates in their pipeline," explained Amar Karandikar, Vice President of Business Development at Piramal Pharma Solutions. Phase I, Phase II, and Phase III tend to be more integrated, he explained. "Companies are coming to us because they want custodianship and someone who will be responsible for the tech transfer between various phases of the product development."

Cost is another clear win when outsourcing to an integrated CDMO. Consider, for example, the steps required to source a high-value API. There are strong regulatory and technical benefits to working with GMP manufacturing sites in Europe or the U.S., while acquiring raw materials in China or India may help reduce the cost of overall production. PPS produces intermediates and starting materials at the company's facility in Ennore, India, and its Shanghai, China procurement center supports customers with raw material sourcing. Technology-rich sites in either India or the West then produce the finished

API or Drug Product, giving the client an end-to-end integrated option for supply.

Senior and experienced leadership is yet another key component guiding PPS's integrated offerings. With each of PPS's projects, the client interface and the coordination of activities are handled by a veteran project manager that acts as the primary point of contact for the client. Kevin Duffield, Head of Client Services NA/UK, noted that the staff's global integrated program managers and project managers are customer advocates who shepherd each project through the production process.

The program manager oversees and coordinates complex and time-sensitive tasks on the client's behalf—oftentimes across continents and differing regulatory environments. "When we have an integrated project, there might be three sites working to deliver the project, with the program manager facilitating complex interactions with the client, our research and operations teams and other experts. These complex projects elevate the level of governance, reporting, and expertise needed for the CDMO," explained Mr. Duffield. "Often we're working in parallel, not in series, to deliver on optimal timelines."

Supply chain integrations for small-molecule chemistry is yet another offering bringing clients to PPS. "We are able to take responsibility for these initial API activities, and then backward integrate to produce the intermediates or KSMs internally, leading to reduced supply chain risks and assurance of supply for later stage and commercial products," said Mr. Duffield. PPS is also able to help companies navigate this process from a regulatory standpoint, helping them determine where it makes sense to perform specific aspects of the project, depending on location, cost, and other considerations.

Above all, Mr. Karandikar and Mr. Duffield agreed that the core benefit of using integrated services is helping customers simplify their business. "At the end of the day, if we're making life easier for our clients, we're doing our job well," said Mr. Karandikar. "With our growing network of experts at various stages of the drug development and discovery pipeline, we're confident in our ability to do just that."

Acquisition of Excellence

Over the years, PPS has expanded significantly and obtained a wealth of expertise through acquisition. "As our company has grown, every facility that we've acquired has become its own center of excellence within the network," explained Mr. Karandikar.

Looking ahead, he believes integrated services will continue to be in demand, offering essential services to the pharma and biotech industries. Mr. Karandikar pointed to key acquisitions by major CDMOs as indicative of an industry shift toward integration. Likewise, PPS is continually enhancing its network of first-class facilities throughout the world through expansions and acquisitions to improve the integrated experience for its clients.

The PPS network of integrated service facilities currently includes:

- **Aurora, Canada** for the development and GMP manufacturing of NCEs
- **Lexington, US** for sterile fill/finish of liquid and lyophilized parenterals and injectables
- **Riverview, US** for the development and manufacturing of HPAPIs
- **Sellersville, US** for manufacturing and packaging of oral solid forms, liquids, creams, and ointments
- **Grangemouth, UK** for the development and manufacturing of ADCs
- **Morpeth, UK** for manufacturing, development and packaging of oral solid forms
- **Ahmedabad, India (Development Services)** for the development and manufacturing of GMP oral solid forms
- **Ahmedabad, India (Discovery Solutions)** for early-stage discovery including medicinal chemistry and synthetic chemistry
- **Pithampur, India** for clinical supply and commercial manufacturing of oral solid forms
- **Digwal, India** for late phase APIs and intermediates
- **Ennore, India** for GMP starting materials and intermediate
- **Mahad, India** for manufacturing of vitamins and premixes for human and animal nutrition
- **Mumbai, India** for development of generic APIs

In light of the COVID-19 global pandemic, Mr. Duffield also suggested clients may become interested in working with a single CDMO throughout a project in a specific geographic region(s) depending on where the company and end patients are located. With 13 sites around the globe, Piramal Pharma Solutions is well-equipped to serve the specific needs of its clients and the people they're caring for.

"Will clients continue to be more interested in developing products from beginning to end in one region or country? How will this disrupt the industry and its supply chain? It's unknowable and constantly changing during this crisis. But I feel confident that our diverse offerings around the globe will be able to facilitate our partners in creating life-sustaining and life-saving drugs and drug substances," Mr. Duffield said.

With increased interest in integrated services coming from a variety of customers, including global pharma innovators, biotechs, and virtual pharma companies, the future of this space is looking bright. "Each customer type has a different need, but there is a place for integrated services for each of them," concluded Mr. Karandikar.

Piramal Pharma Solutions

INTEGRATED MEANS FASTER

Excellent track record of 39 successful product launches,

Successful execution of over 85 integrated projects between discovery, drug substance, and drug product

Proven Track Record of Regulatory Success

Seamless transfers of technology, documentation, knowledge, material and people between sites

Global Vision. Local Execution - Sites in North America, Europe and Asia

Piramal Pharma Solutions is a contract development and manufacturing organization (CDMO), offering end-to-end development and manufacturing solutions across the drug life cycle. We serve our clients through a globally integrated network of facilities in North America, Europe and Asia. This enables us to offer a comprehensive range of services including Drug Discovery Solutions, Process & Pharmaceutical Development services, Clinical Trial Supplies, Commercial supply of APIs and Finished dosage forms. We also offer specialized services like development and manufacture of Highly Potent APIs and Antibody Drug Conjugation. Our capability as an integrated service provider & experience with various technologies enables us to serve Innovator and Generic companies worldwide. For more information and updates, please visit: www.piramalpharmasolutions.com | Social Media: Twitter, LinkedIn

OUR GLOBAL PRESENCE

1 LEXINGTON, USA
Sterile Development & Manufacturing
USFDA

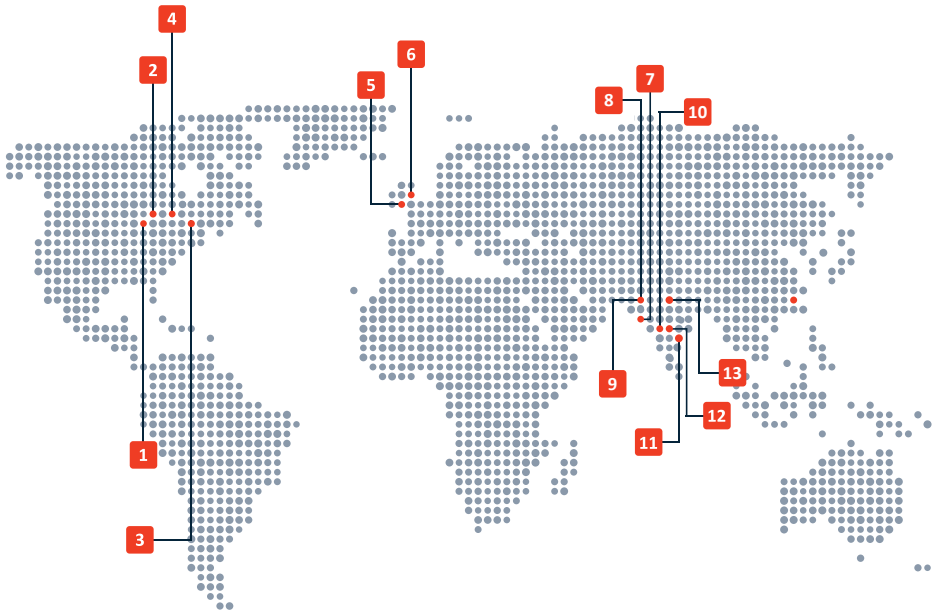
2 RIVERVIEW, USA
HPAPI Development & Manufacturing
USFDA, PMDA Japan

3 SELLERSVILLE, USA
Formulation Development & Manufacturing
USFDA, EMA

4 AURORA, CANADA
API Development & Manufacturing
USFDA, PMDA Japan

5 MORPETH, UK
API & Formulation Development & Manufacturing
USFDA, MHRA

6 GRANGEMOUTH, UK
ADC Development & Manufacturing
USFDA, MHRA



7 MUMBAI, INDIA
API Development

8 AHMEDABAD - PDS, INDIA
Drug Discovery

9 AHMEDABAD - PPDS, INDIA
Formulation Development
EU Finland

10 MAHAD*, INDIA
Vitamins & Minerals Premixes
USFDA, WHO-GMP

11 ENNORE, INDIA
API Development & Manufacturing
WHO-GMP

12 DIGWAL, INDIA
API Development & Manufacturing
USFDA, MHRA

13 PITHAMPUR, INDIA
Formulation Manufacturing
USFDA, EU Finland

SHANGHAI, CHINA
Sourcing Office

Note: *Dietary Ingredient

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