

Piramal invests \$10M to expand API capability in U.S.

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Expansion enhances the company's ability to serve the growing ADC market



Piramal Pharma Solutions (PPS), a leading Contract Development and Manufacturing Organization (CDMO) has announced the Grand Opening of a new wing at the Riverview site dedicated to the production of high potency active pharmaceutical ingredients (HPAPIs) with low Occupational Exposure Levels (OELs).

The total investment required to upgrade the site was approximately \$10 million USD. This includes the new QC/analytical lab and two kilo-labs, as well as a doubling of the office space, which was needed to support the dramatic growth at the Riverview site.

Local dignitaries participated in the event, including Riverview Mayor Andrew Swift, Wayne County Executive Warren C. Evans and other officials representing the City of Riverview, Wayne County and Michigan Economic Development Corporation (MEDC).

To date, the Riverview site has had the containment capability and engineering controls to safely handle HPAPIs with OELs down to 1mcg/m³, at scales ranging from grams to ~250 kilos. The new wing, which consists of two kilo-labs and a QC/analytical lab, brings more to the table. It was designed with the required engineering controls and containment solutions to handle HPAPIs with OELs <1mcg/m³ and as low as ~20ng/m³. Materials will primarily be produced in this new wing at kilo-lab scales; lots of <5 kilos can be produced in this new state-of-the-art facility.

Vivek Sharma, CEO, Piramal Pharma Solutions said, "We are one of only a few companies in the contract development and manufacturing market that have the capability to produce HPAPIs at such low OELs. It's another example of how we remain committed to partnering with our customers to serve the patient community and reduce the burden of disease."

Historically, the site operated as one shift, five days a week. Today, the site operates twelve hours a day, seven days a week, and is headed towards being a full 24/7 site. The Riverview site expansion also provides significant benefits to the local economy, including the addition of new high-tech jobs. The local staff has increased from 80 to 127 people, with a projected total of approximately 150 employees in the near future. This includes high-tech staffing of PhD and BS degreed scientists, plus manufacturing operators and other skilled workers.

Vince Ammoscato, Vice President and Riverview Site Head, added "This new, enhanced capability opens the site up to a new base of customers, including the antibody drug conjugate (ADC) market. We are equipped to offer ADC customers a seamless end-to-end solution, since we can develop the HPAPI payloads and linkers here in Riverview, send them to our site in Scotland for the antibody conjugation, then back to our Lexington, Kentucky site for sterile fill and finish."

The ability to offer a fully integrated solution for the ADC market – from proof-of-concept studies to conjugation development, clinical and commercial ADC GMP batch manufacturing and fill/finish – represents a significant strategic advantage for Piramal Pharma Solutions.

According to Ammoscato, more expansions are forthcoming. There is additional real estate available on the site for added capacity and new capability enhancements that will be designed to match the market needs of the pharmaceutical industry.