

Riverview, Michigan, USA

Drug Substance Development & Manufacturing

With more than 60 years experience in API manufacturing, Riverview is recognized as a world-class facility for drug substance manufacturing. The site has been fully inspected by numerous regulatory agencies, including USFDA, Health Canada, PMDA Japan, COFEPRIS Mexico, MFDS Korea, TGA Australia, and the Russian Ministry of Health. The Riverview site also has extensive experience in safely delivering high potency APIs (HPAPIs) and has advanced several HPAPIs from early development to commercial manufacture.



Site Capabilities

- Up to 4,000L glass-lined reaction and Hastelloy vessels with a temperature range of -10 °C to 200 °C
- Product isolation capabilities: extraction, filtration, and distillation
- Drying/finishing capabilities: Rosenmund agitated filter dryers with glovebox isolators
- Reactor bays equipped for large scale HPAPI manufacturing (OEL $\geq 1 \mu\text{g}/\text{m}^3$)
- Kilo lab with cryogenic temperatures to -70 °C (up to 100L scale)
- Hydrogenation capability up to 60 psi and 200L scale
- High potency manufacturing suites with airlocks and barrier isolation systems for handling of compounds with occupational exposure limit (OEL) of $< 1 \mu\text{g}/\text{m}^3$ at kilo-lab scale (as low as $10 \text{ ng}/\text{m}^3$)

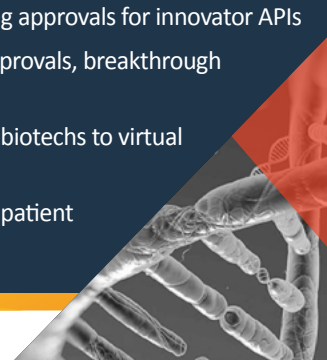


Services Offered

- Process research, development, optimization, and scale-up
- Manufacture of non-clinical tox batches
- cGMP manufacturing for clinical trials
- Process validation (PPQ)
- Commercial API manufacturing
- Analytical method development and qualification/validation
- Impurity identification, characterization, and synthesis
- Solid state characterization (XRPD, DSC, TGA, Crystal 16, PVM, FBRM, and PSD)
- QbD services consistent with ICH guidelines (QRA, FMEA, DoE, parametric studies)
- Development and manufacture of high potency APIs
- Reference standard qualification
- Forced degradation and stability studies
- Preparation of documentation for regulatory submissions (IND, NDA, DMF, CTD)

Site Strengths

- 60+ years experience in API manufacturing
- Experienced in all therapeutic areas
- Focused on core competencies – small molecule APIs
- API from gram scale to 250kg batches
- High potency APIs
- Exceptional record of FDA manufacturing approvals for innovator APIs
- Significant experience with fast-track approvals, breakthrough status and orphan diseases
- Range of clientele from large pharma & biotechs to virtual start-ups
- Customer centric project management, patient centric service

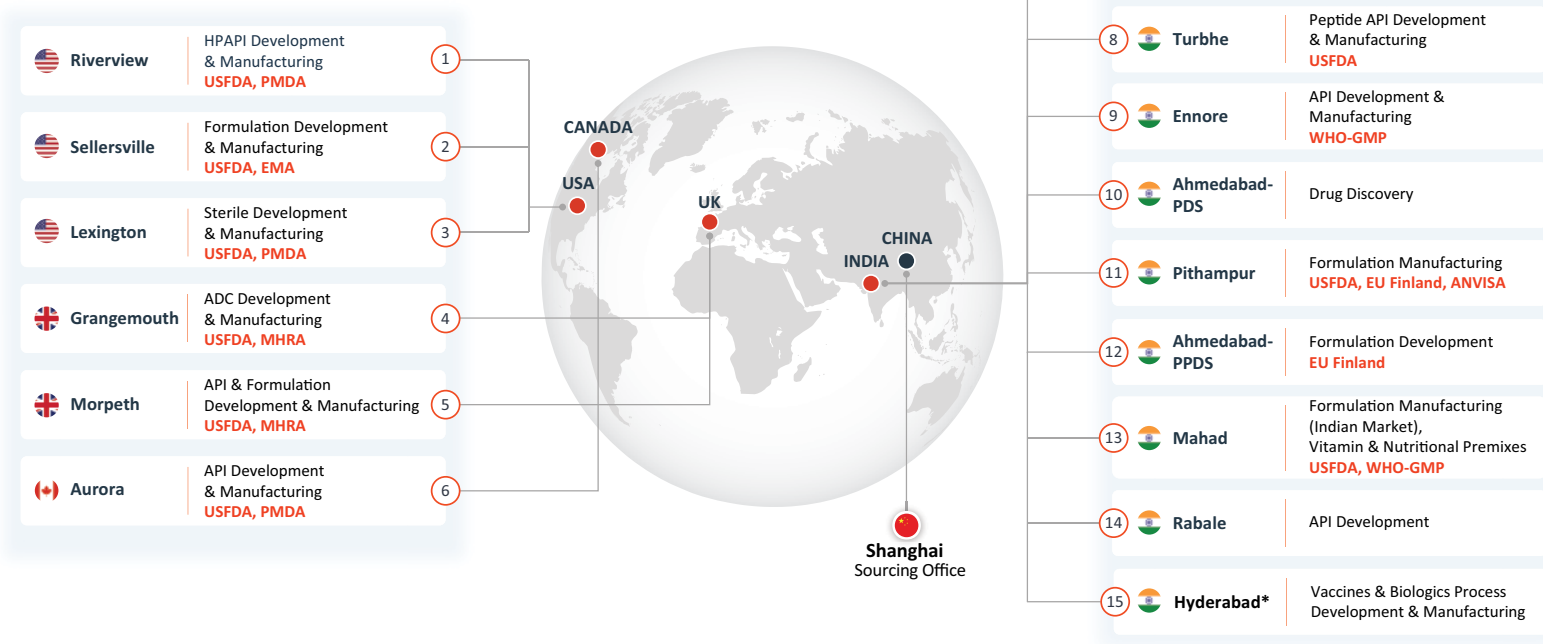


Project PRIME (Piramal Riverview Integrated Manufacturing Expansion)

A \$38 million expansion was recently completed at the site dedicated to the production of APIs and HPAPIs. The featured technology in the new facility is 10,000 L of reactor capacity accompanied by an agitated filter dryer. The new reactor suite is capable of producing high potent APIs with Occupational Exposure Levels (OELs) of $>1 \mu\text{g}/\text{m}^3$. The facility adds 25,000 square feet including production, warehousing, and supporting utilities. The new facility is readily scalable to accommodate additional reactor suites.



OUR GLOBAL PRESENCE



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