

Hyderabad, Telangana, India

Process Development and GMP Manufacturing of Vaccines and Biologics/Bio-Therapeutics

Piramal Pharma Solutions offers development and manufacturing services for large molecules through our associate company Yapan Bio. Based in Hyderabad, India's Genome Valley, Yapan Bio has a proven track record of success in developing and manufacturing a variety of large molecules. Yapan provides process development, scale-up, and GMP compliant manufacturing of vaccines and biologics/bio-therapeutics, including high containment product classes (up to BSL-2+), recombinant vaccines, viral vector-based vaccines, gene therapies, monoclonal antibodies, therapeutic proteins, and other complex biologics for Phase I/II human clinical trials.



Product Classes

Vaccines

- Recombinant vaccines
 - Protein antigens
 - Virus-like particles
 - Nano-particles, etc.
- Viral vector-based vaccines
- RNA vaccines
- DNA vaccines

Biologics/Bio-Therapeutics

- Gene therapy
 - Oncolytic viruses
 - Vectors (viral & non-viral), etc.
- Monoclonal antibodies
- Therapeutic proteins and other complex biologics

Services Offered

Process Development

- Cell line development
- Optimization and scale-up for high product titer, stability and consistent manufacturing output
- Upstream and downstream development
- Analytical method development and qualification
- Formulation development
- Stability studies

GMP Manufacturing

- Cell and virus seed banking
- Rocker, stirred tank and adherent cell bioreactors
- Utilization of single-use technologies
- Up to 1,000L bioreactor scale
- Facility for high containment/infectious agents (BSL-2+)
- Fill/finish on-site: aseptic formulation, fill & finish (lyophilization & liquid in vials)
- Stability studies

Process Characterization

- Establishment and qualification of small-scale model for different unit operations for the process
- Classification of process parameters and product Quality attributes-critical, major, minor
- Design of experiments (DoE) to establish the appropriate ranges for the process parameters and product quality attributes
- Execution of experiments and generation of data/reports to support regulatory filings

Expression Systems/Platforms

- Mammalian cell culture
- Insect cell culture
- Microbial fermentation



Facilities

Process Development:

- ~6,800 square feet
- 3 upstream development rooms
- BSL-2 containment
- Downstream development lab
- Analytical development lab
- Common preparation area
- Utility and support areas

GMP (450):

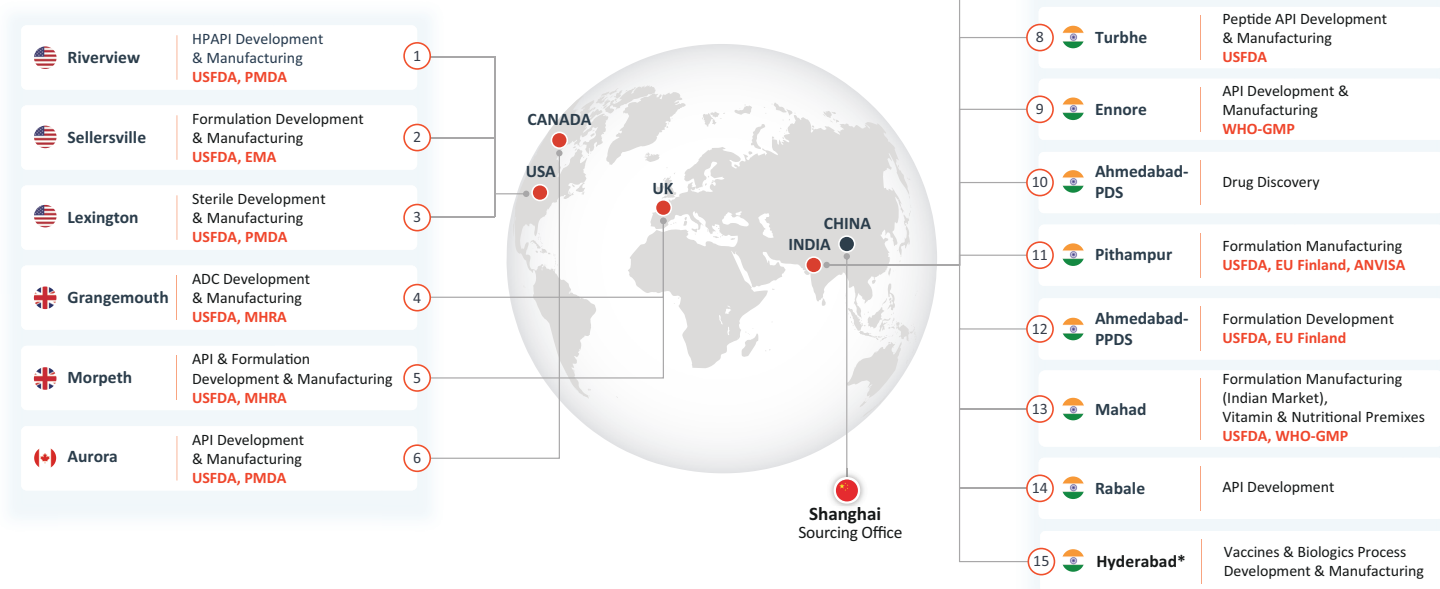
- ~6,400 square feet
- 2 GMP manufacturing suites
- Up to 200L bioreactor scale
- BSL-2+ containment
- Class A/B, C and D areas
- Unidirectional flow
- Quality Control lab

GMP (270):

- ~13,500 square feet
- 2 GMP manufacturing suites
- Up to 1,000L bioreactor scale
- BSL-2 containment
- Class A/B, C and D areas
- Unidirectional flow
- Quality Control lab



OUR GLOBAL PRESENCE



*Yapan Bio: A Piramal Pharma Ltd. Associate Company



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