

# Aurora, Ontario, Canada Development & GMP Manufacturing of APIs for Complex NCEs

The Aurora site specializes in process/route selection, process development and cGMP and non-GMP manufacturing of APIs. The site is comprised of Research and Development, Analytical Development, Analytical Services, Quality Control labs and three manufacturing areas with 18 plant scale reactors ranging from 200-4000L and is supported by 200 highly qualified and dedicated employees operating on a 24/7 basis. We have a long-standing regulatory history with US FDA, Health Canada and PMDA Japan and are fully compliant with all applicable regulations, safety, and environmental standards. The site is conveniently located 1 hour from the Toronto International Airport.



## Featured Services

- Process/route selection
- Process development for GMP scale-up
- Analytical method development, validation, and stability studies
- GMP manufacturing from grams to 100s kg scale
- Commercial API launch and commercial API manufacturing
- Potent API manufacturing (OEL  $\geq 1\mu\text{g}/\text{m}^3$ )
- CMC consulting & filing support
- Transfer early-stage intermediates and large volume APIs between Piramal Pharma Solutions sites

## Research & Development

- Impurities and reference standards preparation
- Process development for pre-clinical and clinical supplies
- Pre-clinical (non-GMP) manufacturing (10s grams to kilograms)
- NMR (400 MHz), GCs, Lasentec FBRM, Calorimetry, Easy Max, bench-top XRPD, HPLCs, UPLCs and Crystal16
- Process safety lab
- Factorial experimental design (JMP)
- 50-100L scale-up labs



## Analytical Services

- Analytical method development
- Analytical method validation
- Stability studies as per ICH guidelines
- Reference standard qualification
- Third party sample analysis

## Manufacturing Capacities

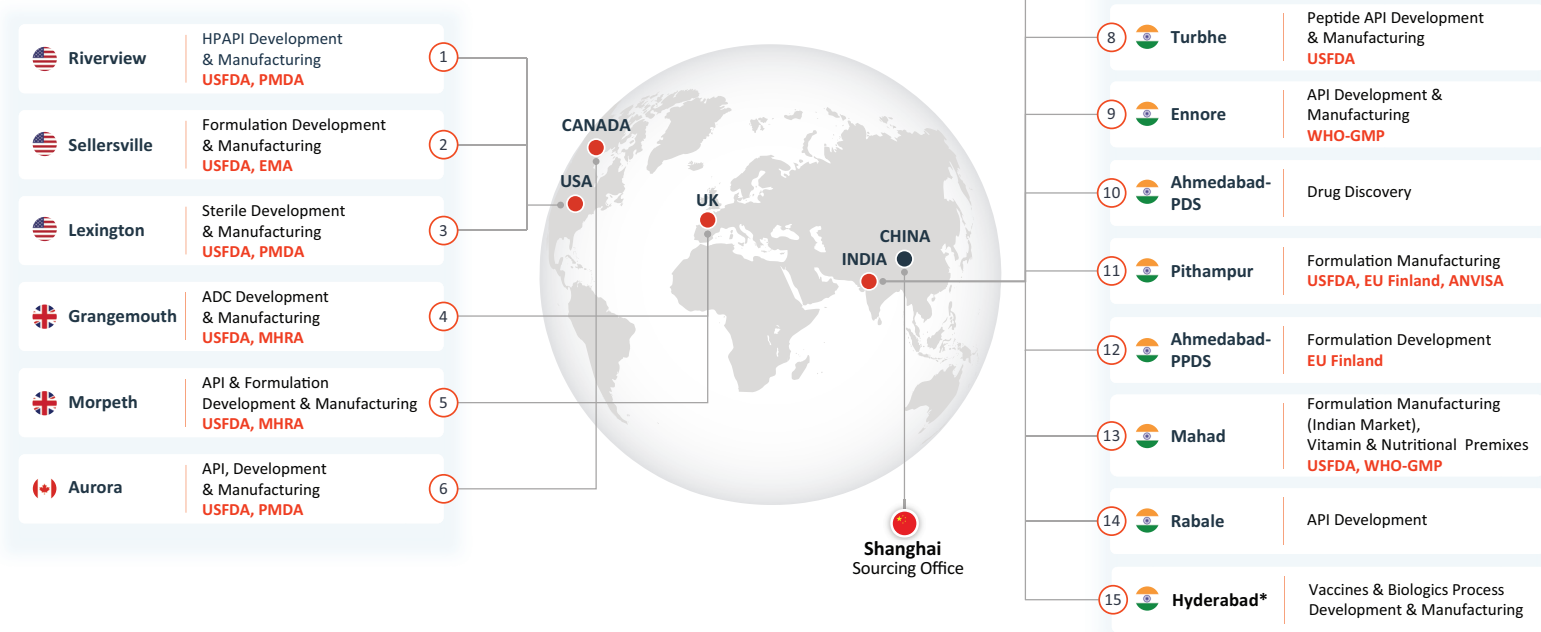
- Potent API manufacturing (OEL  $\geq 1\mu\text{g}/\text{m}^3$ )
- Pre-clinical (non-GMP) Kilo Labs (50-100L capacity)
- GMP Kilo labs (50-100L capacity)
- 3 GMP plants (200 – 4000L capacity)
- Hydrogenation facility (200L 9 bar and 800L 5.8 bar)
- Wet milling
- Biotage Flash 400 chromatography



The Aurora site recently expanded with the launch of new, state-of-the-art API manufacturing suites. The three-story building expansion includes two reactor suites (2 x 2KL, 1 x 3KL and 1 x 4KL reactors), a filter dryer room, and wet milling capability. Contact us to plan your visit!



## OUR GLOBAL PRESENCE



\*Yapan Bio: A Piramal Pharma Ltd. Associate Company



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