

Grangemouth, Scotland, UK

Antibody-Drug Conjugate Services

Piramal's Grangemouth site is the facility of choice for antibody-drug conjugate (ADC) development, manufacture, and integrated solutions. Growing from a legacy as pioneers in contract development and manufacturing services in ADCs, we have become a global leader, with hundreds of unique ADCs developed and more than a thousand ADC batches manufactured. We provide a complete conjugation offering from mg scale Proof of Concept (POC) studies, process development, and scale-up through to clinical and commercial supply.



Featured Services

- Proof of Concept studies
- Process development, optimization and scale-up
- Analytical and bio-analytical method development and validation
- Preclinical and Toxicology batch preparation
- GMP manufacture of clinical and commercial supplies
- Supporting commercialization studies (e.g. process characterization & process performance qualification [PPQ])
- Integrated ADC development programs: mAb > payload/linker > conjugation > fill/finish

Specialized Capacities

- Five dedicated GMP production suites for clinical and commercial manufacturing
- Multi-product manufacturing facility characterized by specialized or single-use product-contact manufacturing components
- ISO 7 processing area and ISO 5 filling area
- Quality management system to ICH Q7

Cytotoxics & High Potency Molecules

- Capable of handling compounds with OEL <math><0.01 \mu\text{g}/\text{m}^3</math>
- >18 years experience with various cytotoxics, including manufacture of over 700 GMP batches
- Batch sizes up to ca. 8kg (dependent on process volumetrics)
- Experience of working with numerous payloads including auristatins, camptothecins, maytansines, PBDs, immunostimulators, protein degraders, chelators and dyes

The Grangemouth site recently expanded with the launch of a multipurpose state-of-the-art ADC manufacturing and aseptic fill/finish facility. Two new suites have been added, along with a new customer experience center. Reach out to us to plan your visit!



Regulatory Approvals

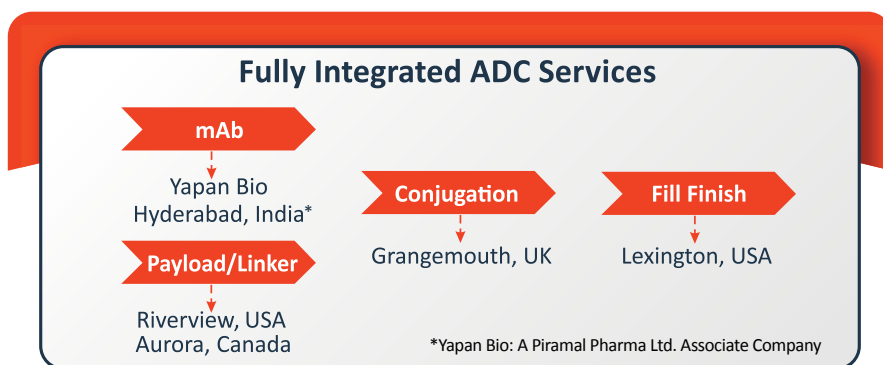




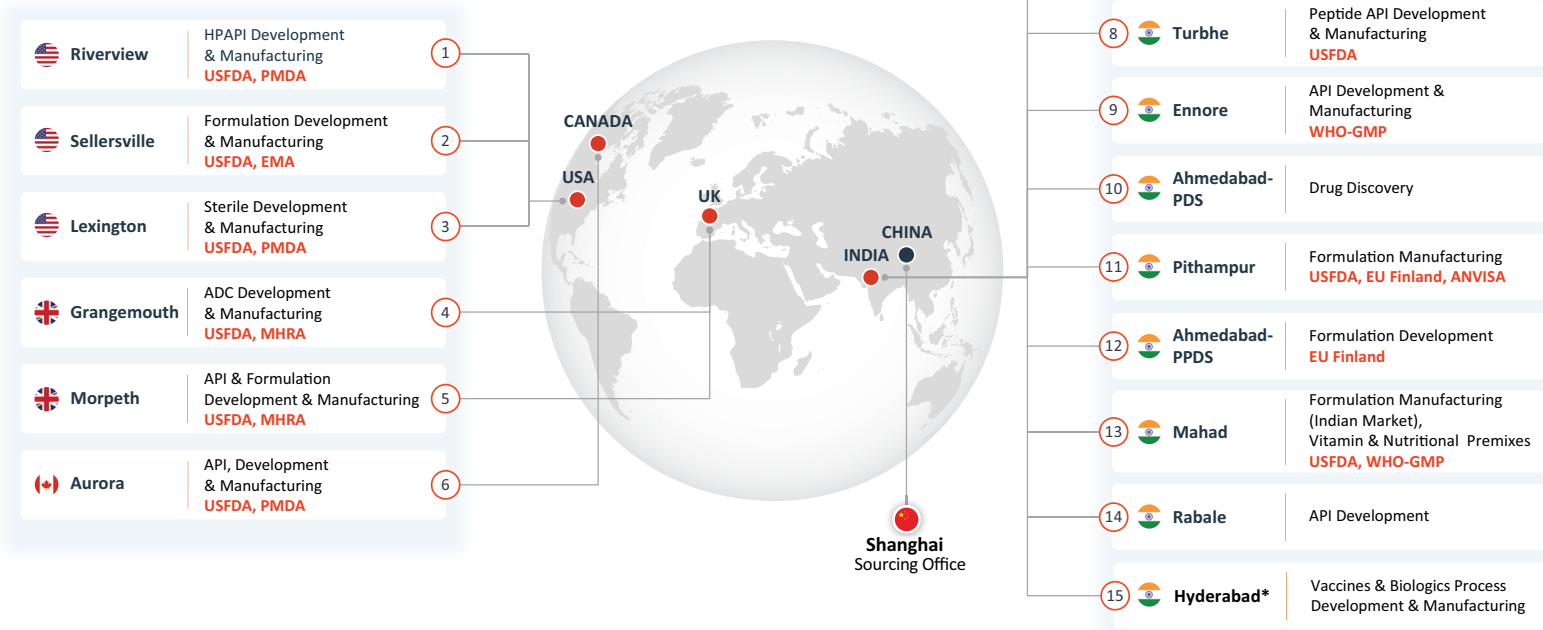
ADCelerate

Rapid, Integrated ADC to IND

ADCelerate is Piramal Pharma Solutions' rapid approach to delivering Phase-I appropriate ADC drug substance and drug product, so that you can accelerate the delivery of your product to patients in the clinic.



OUR GLOBAL PRESENCE



Riverview	HPAPI Development & Manufacturing USFDA, PMDA	1
Sellersville	Formulation Development & Manufacturing USFDA, EMA	2
Lexington	Sterile Development & Manufacturing USFDA, PMDA	3
Grangemouth	ADC Development & Manufacturing USFDA, MHRA	4
Morpeth	API & Formulation Development & Manufacturing USFDA, MHRA	5
Aurora	API, Development & Manufacturing USFDA, PMDA	6
Shanghai Sourcing Office		
7 Digwal	API Development & Manufacturing USFDA, MHRA	7
8 Turbhe	Peptide API Development & Manufacturing USFDA	8
9 Ennore	API Development & Manufacturing WHO-GMP	9
10 Ahmedabad-PDS	Drug Discovery	10
11 Pithampur	Formulation Manufacturing USFDA, EU Finland, ANVISA	11
12 Ahmedabad-PPDS	Formulation Development EU Finland	12
13 Mahad	Formulation Manufacturing (Indian Market), Vitamin & Nutritional Premixes USFDA, WHO-GMP	13
14 Rabale	API Development	14
15 Hyderabad*	Vaccines & Biologics Process Development & Manufacturing	15

*Yapan Bio: A Piramal Pharma Ltd. Associate Company



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