

FORMULATION SERVICES



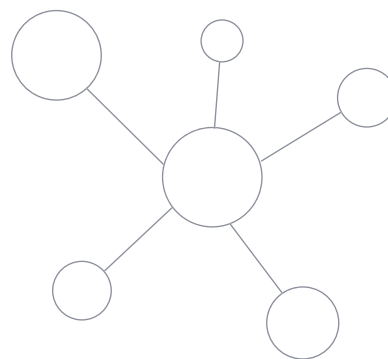
Committed to Quality

Delivering Excellence

Piramal Pharma Solutions is a leading Contract Development and Manufacturing Organization (CDMO) with a global network of facilities in North America, Europe, and India. We offer a comprehensive range of services across all phases of the drug life cycle, including drug discovery and development; manufacturing and packaging of clinical trial supplies; and commercial manufacturing of APIs and finished dosage forms (FDFs). Our deep expertise in developing and manufacturing innovative formulations ensures we can deliver cutting-edge products to meet our client's unique needs, ultimately helping bring life-changing treatments to patients.

PRE-FORMULATION STUDIES AND FORMULATION/PROCESS DEVELOPMENT

- Material characterization
- Physical-chemical attributes
- Excipient compatibility
- Formulation development for testing
- Process development
- Analytical methods development & validation
- Analytical testing
- Stability storage and testing
- CMC support services



CLINICAL TRIAL SUPPORT SERVICES

- Clinical trial manufacturing, packaging, and GMP supply services
- Post-study drug and patient kit returns, reconciliation, and destruction management
- TrakPak®- clinical kit supplies tracking tool
- Regulatory and QP services

COMMERCIAL MANUFACTURING AND PACKAGING

- Oral solids - various dosage forms handled
 - Tablets (film-coated, press-coated, bi-layered, IR, ER, MR)
 - Hard gelatin capsules (powders, granules, and pellets)
 - Controlled release solids
- Sterile injectables
 - Vials - liquid (solutions and suspensions) and lyophilized (aqueous and non-aqueous)
 - Nanoparticles and liposomes
 - Stable emulsions
- Liquids, creams, and ointments
- Cytotoxic and potent compounds
- Bottle, bulk, blister, and sachet packaging
- Serialization and aggregation of packaged OSD products

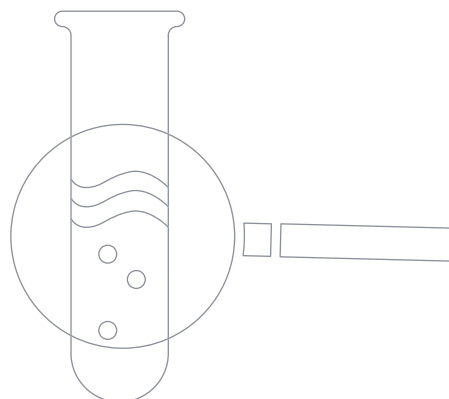


PHARMACEUTICAL DEVELOPMENT SERVICES

- Phase I-III clinical development (NCEs)
 - Oral solids
 - Sterile injectables
 - Liquid-filled capsules
 - Creams and ointments
 - Powder-in-bottle to drug-in-capsule
- Formulation development in various dosage forms
 - Oral solids (e.g. sublingual tablets, modified and delayed release, etc.)
 - Liquid-filled capsules
 - Sterile formulations (e.g. sterile liquids - injectable and ophthalmic, in-situ salt formulations)
 - Creams and ointments
- Specialized formulations
 - Pediatric formulations (mini-tablets, tablet-in-capsule, powders for oral suspension, chewable tablets)
 - Hormonal formulations
 - Liposomal formulations
 - Controlled drug substances
 - Oncology drug products

LATE LIFE CYCLE MANAGEMENT

- Improve the margins of late life cycle products
- Patent extensions by new dosage form development
- Improving operational efficiencies
- Improve supply chain modalities
- API source change/additions
- Regulatory support



SPECIALIZED SERVICES

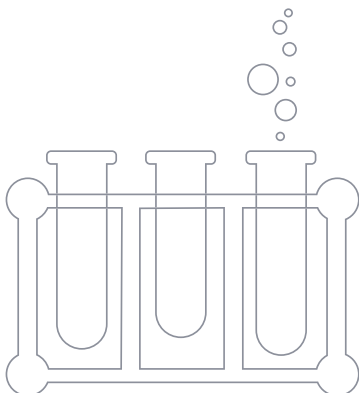
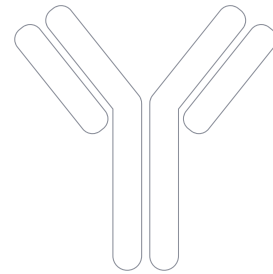
- High potency drugs (cytotoxics, steroids, acutely toxic compounds)
- Controlled substances
- Pediatric formulations
- Hormonal formulations
- Nutritional premixes and vitamins

ANTIBODY-DRUG CONJUGATIONS (ADCs)

- Proof-of-concept studies
- Bio conjugation development
- GMP clinical/commercial manufacturing
- Fill/finish
- Analytical development services

REGULATORY SERVICES

- IND, NDA, ANDA filing in USA, Europe, and Asia Pacific
- DMF, ASMF, and CEP/COS filing
- eCTD submissions for US and EU



OUR FORMULATION SITES

Lexington Kentucky, USA



Liquid & Lyophilized Sterile Fill/Finish
ADC Fill/Finish

Sellersville Pennsylvania, USA



Solid Oral Dosage Forms
Liquids, Creams, & Ointments

Morpeth Northumberland, UK



Integrated API & Drug Product Site,
Solid Oral Dosage Forms

Ahmedabad Gujarat, India



Solid Oral Dosage Forms and
Clinical Scale GMP Manufacturing

Pithampur Madhya Pradesh, India



Commercial Manufacturing &
Packaging of Tablets & Capsules

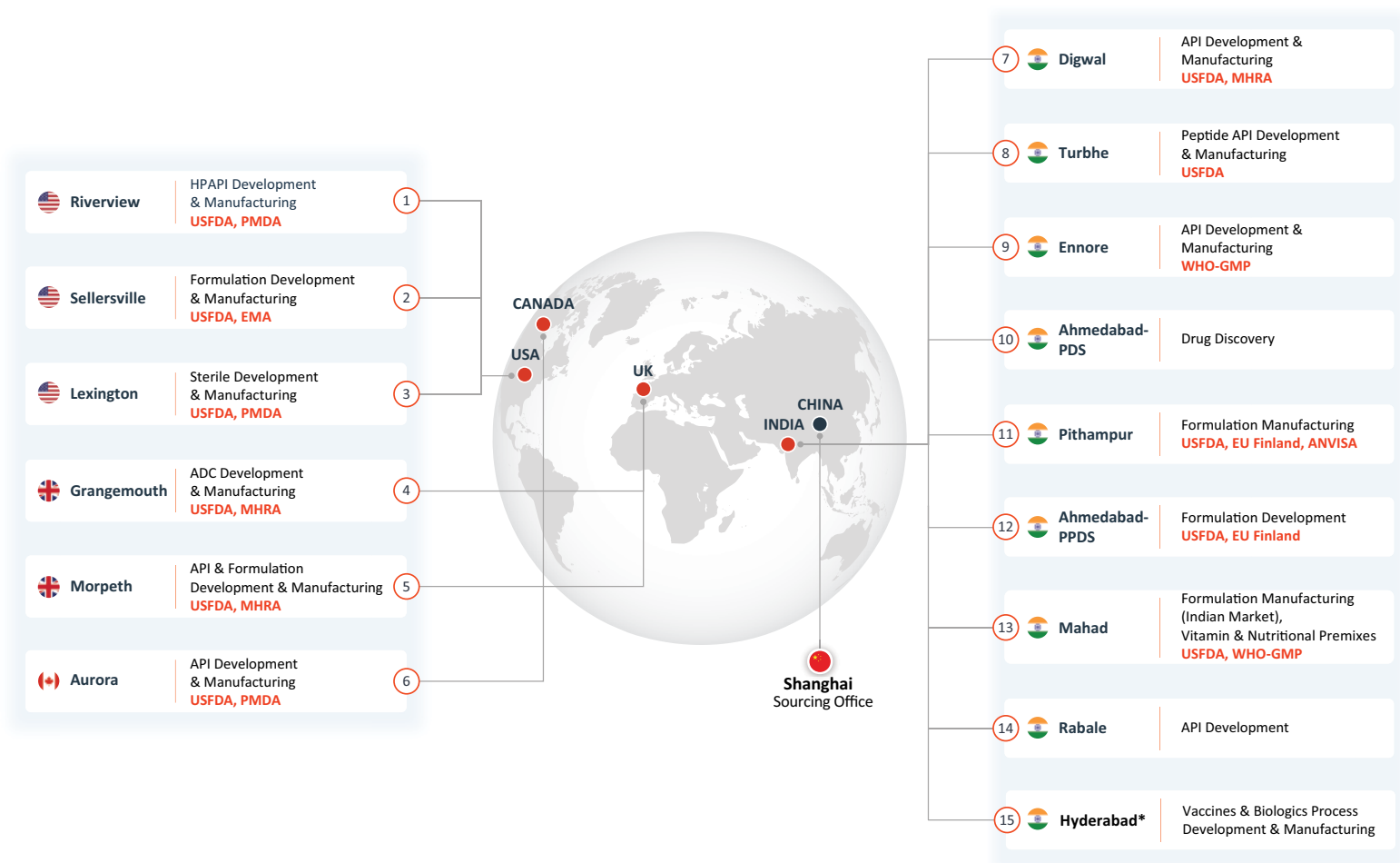
Mahad Maharashtra, India



Solid/Liquid Drug Products
Nutritional Premixes & Vitamins



OUR GLOBAL PRESENCE



*Yapan Bio: A Piramal Pharma Ltd. Associate Company



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