ANTIBODY DRUG CONJUGATION SERVICES

Piramal
Pharma Solutions

Piramal is the world leader in delivering customer-centric solutions in the field of Antibody Drug Conjugates (ADCs) and Bioconjugates to global pharmaceutical companies. Our world-class facilities in the UK & US, backed by a highly experienced team, offer integrated services, from Conjugation Development to Clinical & Commercial ADC GMP Batch Manufacturing & Fill/Finish.

OUR UNIQUE POSITION INCLUDES:

- Integrated service, from Preclinical Development of Conjugated ADC to Sterile Fill/Finish
- >98% GMP Batch success rate
- Global supplier for commercial ADCs
- GMP Manufacture - 600+ batches, 40 bioconjugate entities. Early Phase to commercial. 10+ year commercial manufacture experience.
- Development lab - 500+ batches, 200+ bioconjugate entities.
- Worked with over 60 different Toxin/Toxin-Linker Systems
- Successfully audited by US FDA, UK MHRA, Japan PMDA, Brazil ANVISA & Turkey Ministry of Health

OUR BIOCONJUGATION SERVICES

Piramal offers an end-to-end service, from Conjugation Development through Clinical Trials Supply, to Commercial Manufacture.
Specific service areas include:

- Proof-of-Concept Preclinical Development Studies
- Bioconjugation Process Development & Scale-Up
- ADC/ Bioconjugates Clinical Manufacturing
- Commercial Manufacturing
- ADC/ Bioconjugates Fill/Finish
- Analytical Development Services
- Toxicology, Bulk Drug Substance and Finished Drug Product release testing
- ICH Stability testing

OUR TEAM

People are our biggest asset. Our technical knowledge is what separates us from the pack. We believe that our service is world-class because of our people. Currently, we have a team of over 180 split across our Development, Quality & Manufacturing services functions.

- Technical knowledge
- Empowering creative thought
- Consistent in our thought
- Protecting & enhancing
- Aspiring to be the best
- Striving to be humble

Our R&D team includes world experts in Process Development, Scale-up & Analytical Development, including Cell-killing Assays. Our GMP Manufacturing experience is unparalleled & backed by a strong Quality Assurance Team. Whilst being supported by a global parent company, our ADC services site in Grangemouth maintains that personal touch for our clients, providing tailored client-centric solutions for their projects.

PROOF OF CONCEPT

Cost-effective Proof of Concept Conjugation service to demonstrate the viability of Cytotoxic Drugs or Monoclonal Antibodies for use in Therapeutic ADCs. ADC Standards to benchmark client materials.

TAILORED TO YOUR NEEDS

Core strengths

- Short lead times to start your projects
- Competence to operate at mg-g scale for preparation of Low Endotoxin Conjugates
- Integrated Process & Analytical Development Functions
- Process development & scale up to GMP manufacture

Client Cytotoxic or Linker Technologies

- Piramal can make various Conjugates with Model Antibodies using your Linker or Drug Platforms
- Experience with a range of Novel Linker Technologies

Client Antibodies for suitability for Conjugation

- Programmes tailored to meet your needs
- Comparison of different chemistries (Cysteine, Lysine)
- Range of different Linkers available (Cleavable, Non-cleavable, PEGylated)
- Range of Payloads available (Microtubule-disrupting Drugs, DNA Damaging Compounds, Experience with a range of non cytotoxic payloads
- Preparation of different Drug Loadings
- Analytical Characterisation & Screening of Conjugates

ANALYTICAL SERVICES

Piramal provides on-site analytical services for ADC Characterisation. This includes Analytical Method Development & Validation, Method Transfer & Release/Stability Testing for Bulk Drug Substance & Finished Product.

ANALYTICAL CATEGORY	TYPICAL ASSAYS	
Identity	✓ icIEF Profile ✓ HIC Profile	✓ Dot Blot ✓ ELISA
Strength	✓ Protein Concentration (UV / SEC / SoloVPE)	
Potency	✓ Drug Load ✓ Binding ELISA	✓ Cell Based Assay ✓ Effector Function Assays (ADCP / ADCC)
Purity	✓ SEC ✓ CE-SDS (R and NR) ✓ Charge Profile (cIEF / icIEF / CEX) ✓ % Unconjugated Ab (HIC)	✓ Conjugate Distribution (HIC / PLRP) ✓ Residual Solvent (LC or GC) ✓ Residual Drug-related species
Safety	✓ Bioburden	✓ Endotoxin
Quality	✓ pH ✓ Osmolality	✓ Appearance (Colour and Clarity) ✓ Excipient Levels (Tween)
Characterisation	✓ Peptide Mapping (LC-MS) ✓ Glycan Profiling (LC-MS / CE)	✓ Drug Distribution (LC-MS)

Drug Substance & Drug Product Stability Testing

- State-of-the-art Onsite Analytical Development & Quality Control Laboratories
- Full testing to ICH Guidelines
- Over 80 stability trials conducted for Clinical & Commercial ADC Batches

STATE-OF-THE-ART DEVELOPMENT

Cell-based Assay (CBA) experience

- World leader in the development of Cell-killing Assays
- Tailored development programmes utilising Design of Experiment Approaches
- Experience in Technical Transfer/Optimisation of client methods
- Multiple CKAs Developed & Validated to meet client & regulatory requirements
- Expert knowledge of Validation to Regulatory Standards <USP111>, <1032, <1033> & PhEur 5.3
- Development of Characterisation methods

ADC MANUFACTURING

Multi-product facility for Clinical & Commercial Manufacturing of Antibody Drug Conjugates (ADCs). Process Development, Characterisation, Optimisation & Scale-up expertise supporting successful GMP Manufacturing.

Core strengths

- Fully licenced by MHRA
- Approved for Commercial ADC Supply by FDA & other worldwide authorities
- >98% GMP Batch success rate
- Over 30 years experience of working safely with High Potency Materials
- Over 15 years experience of working safely with ADCs & Potent Payloads
- Batch sizes up to 2.5 kg input mAb
- Up to 1000L Reactive Volume Capability depending on the complexity
- Three ADC manufacturing suites based on Isolator Technology
- Two commercial-scale manufacturing suites
- Dedicated or single-use Product-contact Manufacturing Components
- 100% Batch Shipping success rate

Unparalleled experience

- Over >1100 ADC/Bioconjugates batches manufactured
- Over >600 GMP batches manufactured
- Over 200 Different conjugates from 120 antibodies
- Over 60 different toxin/toxin-linker system
- Over 40 different ADCs manufactured to GMP
- Over >250 commercial batches manufactured

ADCelerate
Rapid, Integrated ADC to IND

Accelerated Phase I GMP Delivery of Antibody-Drug Conjugates

- Shortens timelines, because speed matters
- Solutions that are customized to the scope of your project
- Take advantage of our experience in ADC problem solving
- Includes first clinical supply of drug substance and drug product

State-of-the-art Antibody-Drug Conjugate (ADC) manufacturing and aseptic fill/finish facility in Grangemouth, Scotland

Two new ADC manufacturing suites have been added to the existing three.

GLOBAL SUPPLIES

Supply Chain Management

- Well established relationship with World Courier or Pharmafreight
- Temperature Logging on all shipments
- Typically 2-3 days shipment time
- Shipping in small Insulated Boxes, Cryocontainers & Drums

FILL/FINISH OF ADC

Piramal offers Aseptic Filling of ADC Drug Product through our FDA-approved state-of-the-art manufacturing facility in Lexington, KY. Our facility is centred around Mobile Isolator Technology, providing an ISO 5 environment during processing, as well as Product Containment for Potent & Cytotoxic Products.

Aseptic filling capabilities include:

- Pre-formulation & Formulation of Liquid & Lyophilised Drug Products
- Liquid & Lyophilised Drug Product Manufacturing
- Vial sizes from 2-50ml
- Dispensing volumes from 0.5ml to 50ml
- Batch sizes up to 50,000 vials, for Liquid-filled Products (size dependent)
- Batch sizes up to 15,000 vials, for Lyophilised Products (size dependent)

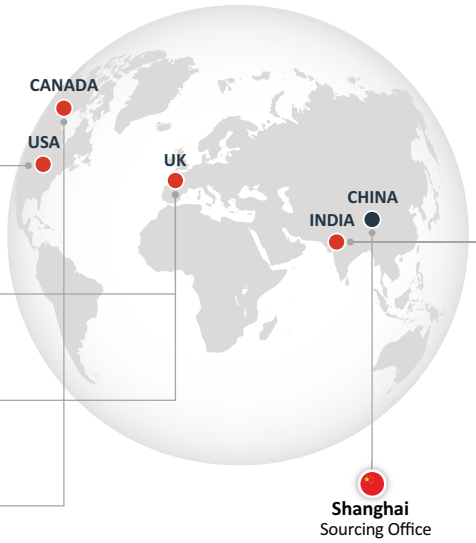
PROJECT MANAGEMENT

Piramal prides itself in its world-class project management, designed in partnership with its clients.

- Virtual extension of your company
- Flexible & tailored to meet clients' needs
- Single point of contact to champion your project
- Project management ensures continuity for entire program of activities & remains with projects from Technology Transfer to GMP Manufacture

OUR GLOBAL PRESENCE

1	Riverview	HPAPI Development & Manufacturing	USFDA, PMDA
2	Sellersville	Formulation Development & Manufacturing	USFDA, EMA
3	Lexington	Sterile Development & Manufacturing	USFDA, PMDA
4	Grangemouth	ADC Development & Manufacturing	USFDA, MHRA
5	Morpeth	API & Formulation Development & Manufacturing	USFDA, MHRA
6	Aurora	API Development & Manufacturing	USFDA, PMDA



7	Digwal	API Development & Manufacturing	USFDA, MHRA
8	Turbhe	Peptide API Development & Manufacturing	USFDA
9	Ennore	API Development & Manufacturing	WHO-GMP
10	Ahmedabad-PDS	Drug Discovery	
11	Pithampur	Formulation Manufacturing	USFDA, EU Finland, ANVISA
12	Ahmedabad-PPDS	Formulation Development	USFDA, EU Finland
13	Mahad	Formulation Manufacturing (Indian Market), Vitamin & Nutritional Premixes	USFDA, WHO-GMP
14	Rabale	API Development	
15	Hyderabad*	Vaccines & Biologics Process Development & Manufacturing	

*Yapan Bio: A Piramal Pharma Ltd. Associate Company

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