



Biologics Services

"Concept to Commercial" for recombinant products including mAbs, bi- & multi-specifics, cytokines, enzymes, and other complex proteins

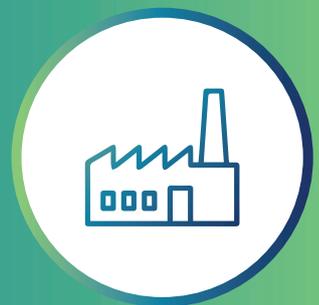
Built on the legacy of developing and commercializing biologic products across 30+ countries over 25+ years, Aurigene offers integrated and standalone services for biologics discovery, process development and CGMP manufacturing to innovator pharma and biotech companies.



Discovery



Process
Development



Commercial
Manufacturing



Discovery Services

Aurigene offers discovery services, from target identification to protein expression and pre-clinical evaluation, for wide range of biotherapeutics with primary focus on recombinant products.

Modalities



Monoclonal Antibodies

Single B-cell culturing and screening | Hybridoma (transgenic, humanized - mouse, rat & rabbit) | Display technologies (yeast & phage)



Bi- & multi-specifics

T cell engagers | T cell activation | Cytokine release assays | *In vitro* & *in vivo* tumor killing assays



Immuno-fusion molecules

Immunotoxin | Immune cytokine | Antibody enzyme fusion



Antibody drug conjugate

Antibody generation | Linker & payload development | Conjugation



Other advanced modalities

mRNA | Viral vectors | CAR-T | Cell mediated drug delivery

Support services

- **Custom Bioreagents:** Tool antibodies, mono and polyclonal | Anti-ID | engineered cell lines | proteins & conjugates
- ***In vitro* Biology:** Immuno oncology | Immunogenicity screening | Effector functional analysis | Potency & mechanistic assays
- ***In vivo:*** Multiple animal and disease models | Mice, rat, dog | AAALAC accredited vivarium

Why Aurigene Discovery Services?

Supported by world-class talent & infrastructure



Global talent pool
of scientists



State-of-the-art
equipment



ISO 9001 certified labs and
AAALAC accredited vivarium

Process Development and Manufacturing Services

Aurigene offers comprehensive process development capabilities that support pre-clinical, clinical, and PPQ/commercial manufacturing services (Drug Substance & Drug Product) for biologics at USA FDA & EMA inspected facilities.

Specialized mammalian services provider

- Monoclonal antibodies
- Engineered antibodies
- Bi- & multi-specifics
- Immuno-fusion molecules
- Enzymes
- Cytokines
- Other recombinant products

Biologics CDMO offerings

- Clone development
- Process design & development (CMC)
- Process optimization & scale-up
- Pilot scale manufacturing for toxicology/ pre-clinical studies
- CGMP manufacturing of Drug Substance & Drug Product for clinical phases through PPQ & commercialization for global markets
 - Fed batch and high density perfusion DS manufacture in single use bioreactor systems
 - Liquid and lyophilized DP formulations in multiple formats

Support services

- Cell line development & characterization
- Analytical development & validation
- Stability studies
- Antibody/protein screening
- Manufacturability assessment
- CGMP cell banking
- Viral clearance studies
- Proven quality & regulatory support
- Customized bioreagent generation



Why Aurigene Biologics CDMO Services?

25+ years of expertise & quality track record

- Commercialized 6 products in 30+ countries
- Global talent pool of scientists
- USA FDA, EMA inspected CGMP facility
- Proven, fully digital Quality Management System

State-of-the art facilities

- Pilot/clinical scale facility for CGMP & non-GMP supplies (200L reactors)
- Large scale commercial CGMP Drug Substance facility with single use bioreactors with capacity of ~25,000 L
- CGMP Drug Product filling vials, pre-filled syringes and cartridge for liquid and lyophilized formulations

ESG / Sustainability

Aurigene as a wholly owned subsidiary of Dr. Reddy's Laboratories adopts the ESG goals of our parent company. Dr. Reddy's has been committed to sustainability, diversity and equality for over two decades and has been honored with numerous accreditations and awards.



Awarded 'Gold Medal' status by EcoVadis, the global sustainability ratings agency, 2023



First Indian pharma firm to earn a place in the Standard & Poor Dow Jones Sustainability World Index (DJSI World) for 2023.



6th year in a row to be featured in the Bloomberg Gender-Equality Index (GEI) 2023.



Achieved "A" rating for supplier engagement, and for climate change & water security in 2023 by Carbon Disclosure Project (CDP)



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