

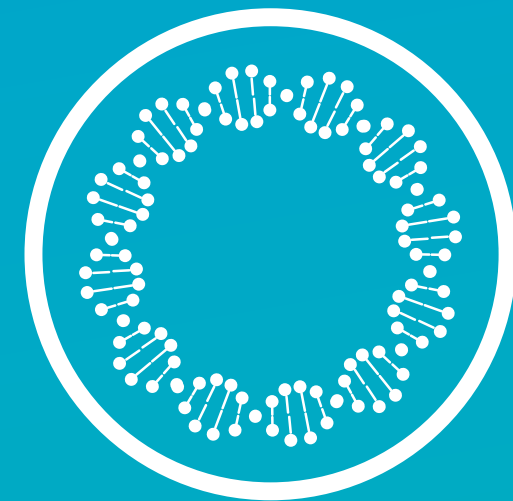
ANEMOOCYTE

Manufacturing
Biotech
Innovation

**COMPANY
PRESENTATION**



Anemocyte is a **Biotech Manufacturing Organization (BMO)**
Offering development and manufacturing services and innovative
solutions from R&D to GMP to address needs in the field of:



pDNA

PLASMIDS FOR VIRAL VECTOR
AND RNA MANUFACTURING



mRNA

mRNA FOR VACCINES AND
IMMUNO-ONCOLOGY THERAPIES

OUR WEALTH OF EXPERIENCE

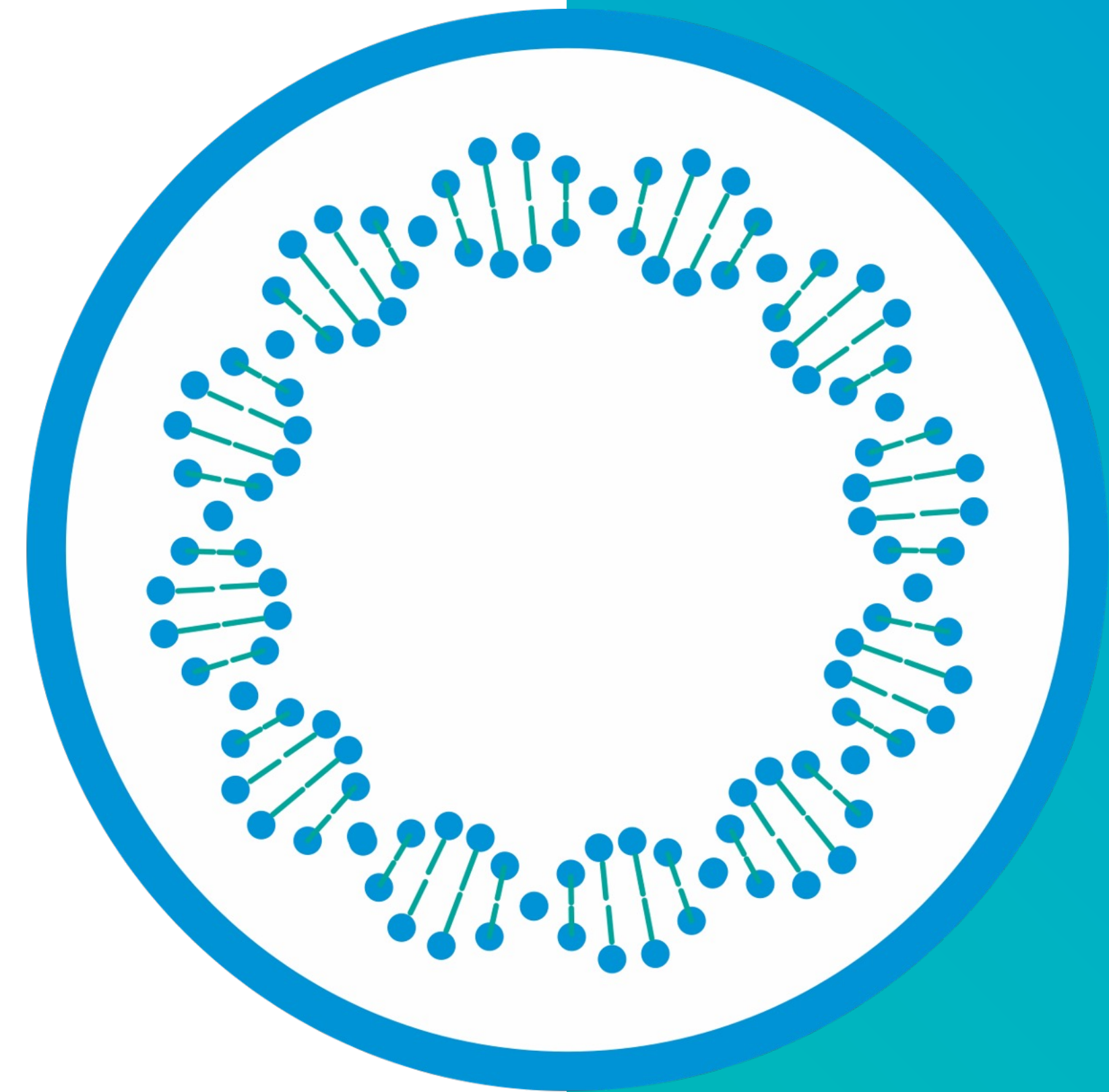
MORE
THAN
20
YEARS

OF GMP MANUFACTURING OF CGTs
AND BIOLOGICAL DRUGS

Plasmid DNA development and manufacturing

Plasmids can be used as ancillary or critical starting material for:

- ∞ AAV or lentiviral vector productions to be applied to the clinical manufacturing of gene and immuno-oncology therapies;
- ∞ mRNA manufacturing;
- ∞ clinical manufacturing of biological drugs.



PLASMID MANUFACTURING

HIGHLIGHTS

With more than **500 sqm** (about 5,000 sqft), the Plasmid Unit of Anemocyte addresses the manufacturing needs of **Plasmid DNA from R&D to GMP**.

All manufacturing steps are available in **classified clean rooms**.
Multiple **segregated areas** allow the performance of parallel manufacturing processes.

Flexible sizing of upstream fermentation 5-200 L (higher volumes are possible) performed using **animal-free medium**.

State-of-the-art equipment allows the highest downstream flexibility.

PLASMID MANUFACTURING

HIGHLIGHTS

MANUFACTURING Highlights

Starting from **1 mg batch size**.

QUALITY Highlights

- ∞ Production and analysis are performed in ISO-certified laboratories.
 - ∞ Most relevant features of cGMP manufacturing are applied (e.g., traceability, document control and materials segregation).
 - ∞ All the **equipment** for production and analyses are **validated** (IQ/OQ protocols).
 - ∞ All the starting materials and **single-use components** are certified as **TSE-BSE free**.
 - ∞ Majority of analytical assays are performed **in-house**.
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REGULATORY LANDSCAPE FOR PLASMID MANUFACTURING

Example Products	Application of GMP to manufacturing steps is shown in dark grey GMP Principles should be applied where shown in light grey Starting material – active substance – finished product				
In vivo gene therapy: mRNA	Plasmid, manufacturing and linearization	In vitro transcription		mRNA Manufacturing and purification	Formulation, filing
In vivo gene therapy: non-viral vector (e.g. naked DNA)	Plasmid, manufacturing	Establishment of bacterial bank (MCB, WCB)		DNA Manufacturing, fermentation and purification	Formulation, filing
In vivo gene therapy: viral vectors	Plasmid, manufacturing	Establishment of a cell bank (MCB, WCB) and virus seeds when applicable		Vector Manufacturing and purification	Formulation, filing
Ex-vivo: genetically modified cells	Donation procurement and testing of tissues / cells	Establishment of a cell bank (MCB, WCB) for plasmid and/or vector expansion and viral seeds when applicable	Plasmid Manufacturing Vector Manufacturing	Genetically modified cells manufacturing	Formulation, filing

Source: Questions and answers on the principles of GMP for the manufacturing of starting materials of biological origin used to transfer genetic material for the manufacturing of ATMPs.

PLASMID MANUFACTURING

OTHER SERVICES



Process development

Process optimization and development for different phases of Plasmids and mRNA production, and for Tech Transfer.



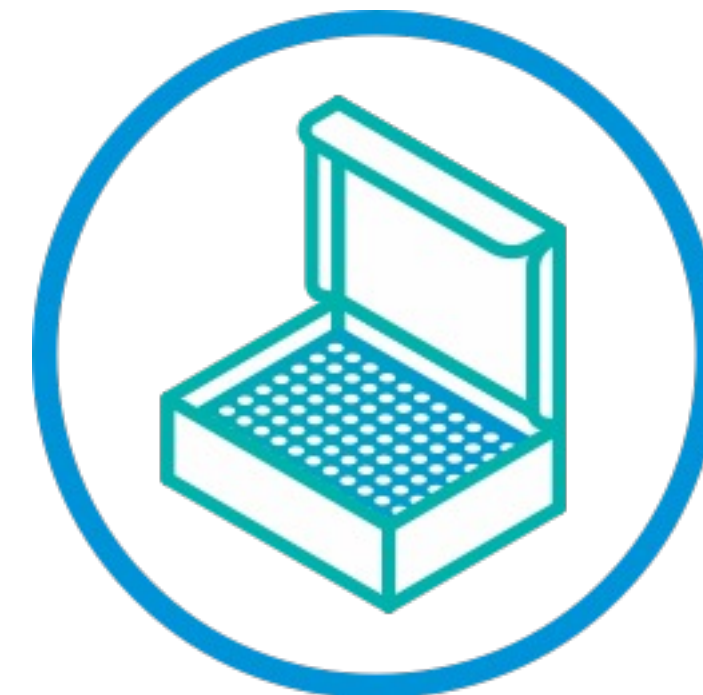
Cryopreservation

Storage and cryopreservation under different conditions.



Stability studies

Long-term and accelerated studies at different temperatures.



Secondary packaging

Anti-tampering dedicated boxes.

mRNA development and manufacturing

mRNA can be used for:

- ∞ Vaccines;
- ∞ Immuno-oncology therapies;
- ∞ Protein replacement therapies;
- ∞ Genetic diseases.





mRNA MANUFACTURING

HIGHLIGHTS

MANUFACTURING Highlights

Starting from **0.2 mL batch size (IVT)**.

QUALITY Highlights

-  Production and analysis are performed in **ISO-certified laboratories**.
-  Majority of analytical assays are performed **in-house**.

ANEMOCYTE

Manufacturing Biotech Innovation

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