GTP Bioways
CDMO
Continuum for biologics

Press Kit

GTP Bioways opens two new production lines, expands its footprint in the French and European bioproduction sector.

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A word from Alain Sainsot

President of GTP Bioways

The group was created in 2019 with the ambition to build, in France, a unique, coherent and flexible offer to support every stage in the clinical development of a new drug, from cell line all the way to aseptic filling.

Bringing multiple businesses under one roof, GTP Bioways has combined their complementary expertise and long-standing experience to provide personalised services for the biopharmaceutical industry. We also have a strategic partnership with Fareva, with whom we operate a superb GMP production platform for monoclonal antibodies.

As a public health player, we bolster European innovation with our leading-edge know-how in bioproduction.

With the opening of two new GMP production lines (microbial and small-volume mammalian) in 2023, our organisation is contributing to the drive to relocate pharmaceutical production in France, by boosting national industrial bioproduction capacities.

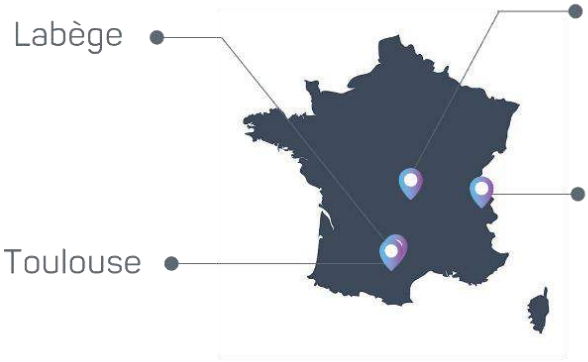
Drawing on our expertise in solving complex problems for our clients, we're unique in our ability to develop agile solutions for ambitious projects and overcome the challenges standing in the way of producing tomorrow's drugs.

GTP Bioways under the microscope

GTP Bioways is a **subcontractor or CDMO** (Contract Development and Manufacturing Organisation). As an expert in the manufacturing of innovative therapies, the company supports biopharmaceutical companies in the transfer of their drug candidates from R&D to clinic or commercial production.

GTP Bioways' expertise and capabilities include the development of manufacturing processes and the manufacturing of biomolecules (in both the mammalian and microbial systems), of antibody-drug conjugates and of nanodrugs, as well as aseptic filling in vials or syringes.

GTP Bioways operates four French production sites



Key figures and ambition of GTP Bioways

130 Employees in France

45% MsC /PhD

20M Euros: expected turnover in 2023

12 12 millions euros invested in 2020

4 GMP production suites

270 Clients worldwide

Between January 2022 and 2023, 20 new positions were created within the Toulouse sites. With increased manufacturing capacities, the group is aiming to double its turnover by 2027-28

The group was created in 2019

2000 – GTP Technology is created
Process development and protein production

2019 – V-Nano is created
Expert CDMO in nanomedicine and aseptic fill and finish

2019 – GTP Bioways absorbs GTP Tech and V-nano
Comprehensive CDMO services for biologics. **V-Nano becomes GTP Nano**

2019 – The GTP Biologics facility is added
Strategic partnership with Fareva

2021 – GTP Bioways acquires IDBiotech
GTP Bioways introduces analytical services. **IDBiotech becomes GTP Immuno**

2023 – GTP Bioways opens two new production lines
Opening of two GMP production lines through a 12M€ investment

GTP Bioways was born out of its founders' ambition to create a CDMO offering integrated pharmaceutical subcontracting services, to respond to the needs of biotech companies developing innovative therapies.

The group was formed out of merging three companies with complementary capabilities: GTP Technology, GTO Nano (ex V-nano) and GTP Immuno (ex ID Biotech). From the outset, GTP Bioways built a strategic partnership with a manufacturer, Fareva, in order to complement its offer with the GTP Biologics site (formerly Pierre Fabre CDMO and acquired by Fareva from Pierre Fabre), located in Saint-Julien-en-Genevois. It now runs this site.

GTP Bioways is still growing and will open two new pharmaceutical production lines in 2023.

A unique continuum of expertise

Few mid-sized CDMOs can offer an integrated offer such as GTP's. Through this offer, the company can support clients from R&D through to clinical trials and bringing their therapeutical molecule to market.

Process development for complex biomoelucules manufacturing

Having gained 20 years' experience in process development for the production of complex proteins, GTP Bioways has a unique expertise in process development. With increasingly complex to produce biomolecules, biopharmaceutical companies are on the lookout for CDMOs that are capable of guiding them through this critical phase in their development.

Unique manufacturing capacities

GTP Bioways is also the only French and one of few European CDMOs to offer manufacturing services for biotherapeutics in both the microbial and mammalian systems, thus being able to adapt to the manufacturing needs of a range of proteins.

Aseptic filling capacities

Finally, the company owns its own aseptic filling lines for syringes or vials. Offering this key stage in the manufacturing process in-house means minimised project risks and shortened timelines.

GTP Bioways awarded investment

Under the France 2030 [1] investment plan 'Capacity Building » call for proposals

France 2030 is **a French government investment programme**, taking over from the 2020 France Relance recovery plan, launched to address the economic consequences of COVID-19 . France 2030 aims to invest 54 billion euros into accelerating the transformation of key French economic sectors and positioning France as a leader in emerging fields. 761 million euros were dedicated to the healthcare sector – of which **GTP Bioways was awarded 5,9 million euros to open two pharmaceutical production lines in Toulouse**, following its submission under the 'Capacity Building' call for proposals.

[1] Gouvernement. Plan France 2030 https://www.economie.gouv.fr/france-2030#

€12m invested in the opening of two new production lines, including €5.9m funded under the France 2030 programme

GTP Bioways is a pharmaceutical business

GTP Bioways produces experimental **drugs destined for clinical trials in humans.** Production units are therefore certified and subject to extremely strict regulations.

These regulations are governed by **Good Manufacturing Practice** (GMP) defined by WHO as 'the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.' [2]

[2] Organisation Mondiale de la Santé G*uide OMS des normes relatives aux bonnes pratiques de fabrication (BPF), Partie 1 : Modes opératoires normalisés et formules originales de fabrication.* (Ref WHO/VSQ/97.01)

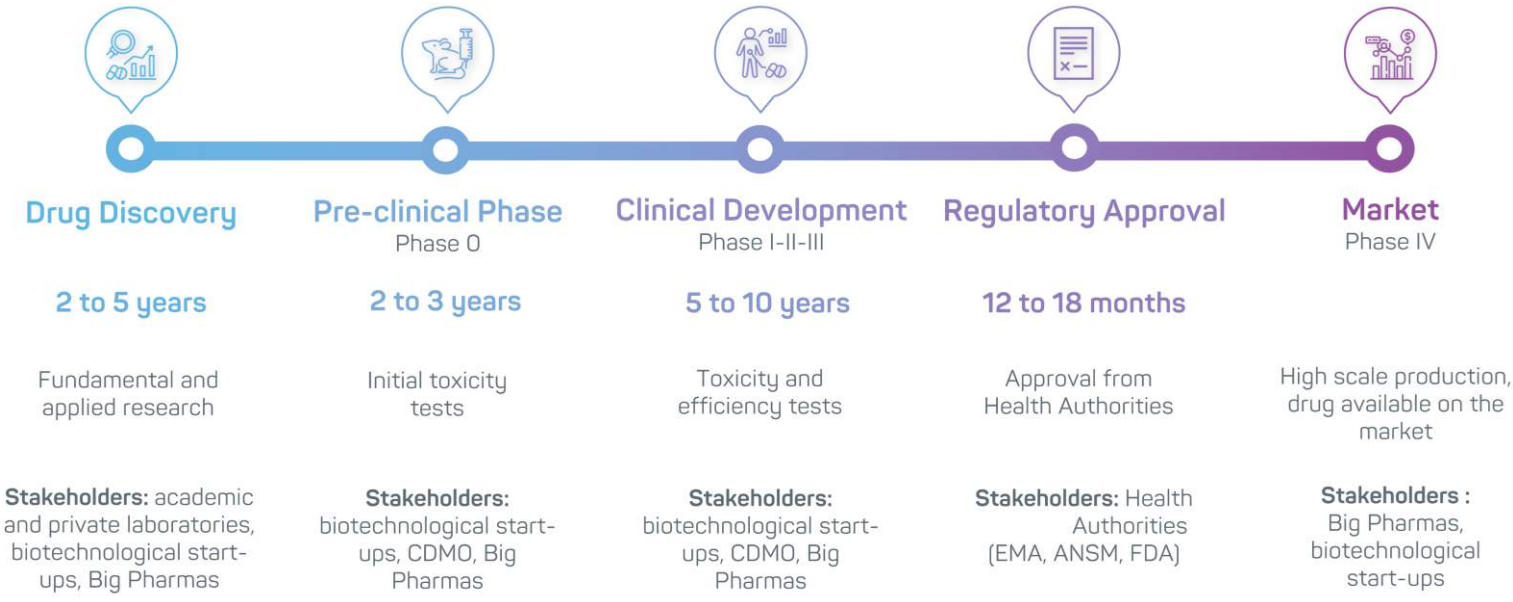
2

Biological drugs:
current context and outlook

Innovation and the development of new therapeutical molecules are now largely carried out by biotech companies, without the in-house capabilities or the means to produce drug batches for clinical trials.

That's why they call on the services of CDMOs to support them through the pre-clinical and clinical development of their drug candidate.

Stages of drug development [3]



[3] USA Food and Drug Administration, *The Drug Development Process*, 2018 & Les Entreprises du Médicament (LEEM), *Recherche et Développement*, 2023

Small molecules vs biologics

For most drugs currently on the market, their active ingredients are molecules obtained through chemical synthesis. They're also called 'small molecules' because of their size (under 100 atoms), in contrast to biological molecules (up to 25,000 atoms). Biological molecules are obtained through a biotechnological process through the use of reprogrammed living cells or organisms which act as 'factories' for the production of the desired protein. The production of biological molecules involves complex processes made up of various stages (cell expression, in some instances cell lysis, purification) with production costs far superior to those of a chemical molecule.

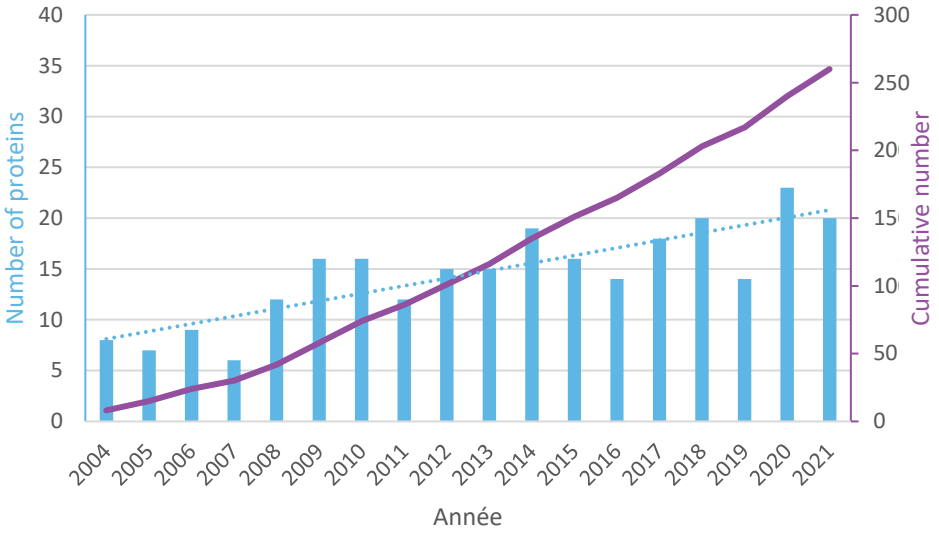
Biotherapies are targeted therapies and they're particularly prominent in the fields of oncology, inflammation and immunity, infections and metabolic and cardiovascular diseases. [4]

[4] Labtoo, *Bioproduction: le grand enjeu des biotechnologies*, 2020

The rise of biological drugs

Dozens of biotherapies are put on the market every year. Between 2010 and 2020, a quarter of newly authorised drugs were biologics. [5]

Number of recombinant protein-based biologics brought to market, Europe and North America *GlobalData, April 2023*



Even though the market is still dominated by chemical molecules, biological drugs are burgeoning. 571 clinical trials of biological drugs with a protein as their active principle are currently underway .

When it comes to biomanufacturing, France is lagging behind

In 2021, 5 biotherapies were produced domestically in France. There's an objective of 20 by 2030. [6]
Through the France 2030 programme, aiming to close the gap in the emerging industrial fields, the government has granted funding to players in the field of 'Biotherapy and Biomanufacturing', thus giving a fresh boost to the country's biomanufacturing sector.

Within Europe, France ranks fourth among the producers of newly authorised drugs, behind Germany, Ireland and Italy. 80% of this production is still chemical drugs. The France 2030 programme aims to make the country more competitive on the European stage for the production of biodrugs. The Council of European BioRegions (CEBR) observed that bioproduction CDMOs needed higher amounts of seed money. Meeting the goal of self-sufficiency defined by the EU will rely on the development of European CDMOs, as they are the ones to prop up innovation. An Important Project of Common European Interest (IPCEI) has been initiated to fund healthcare-related infrastructure projects, in order to limit American and Asian investment into European CDMOs. [7]

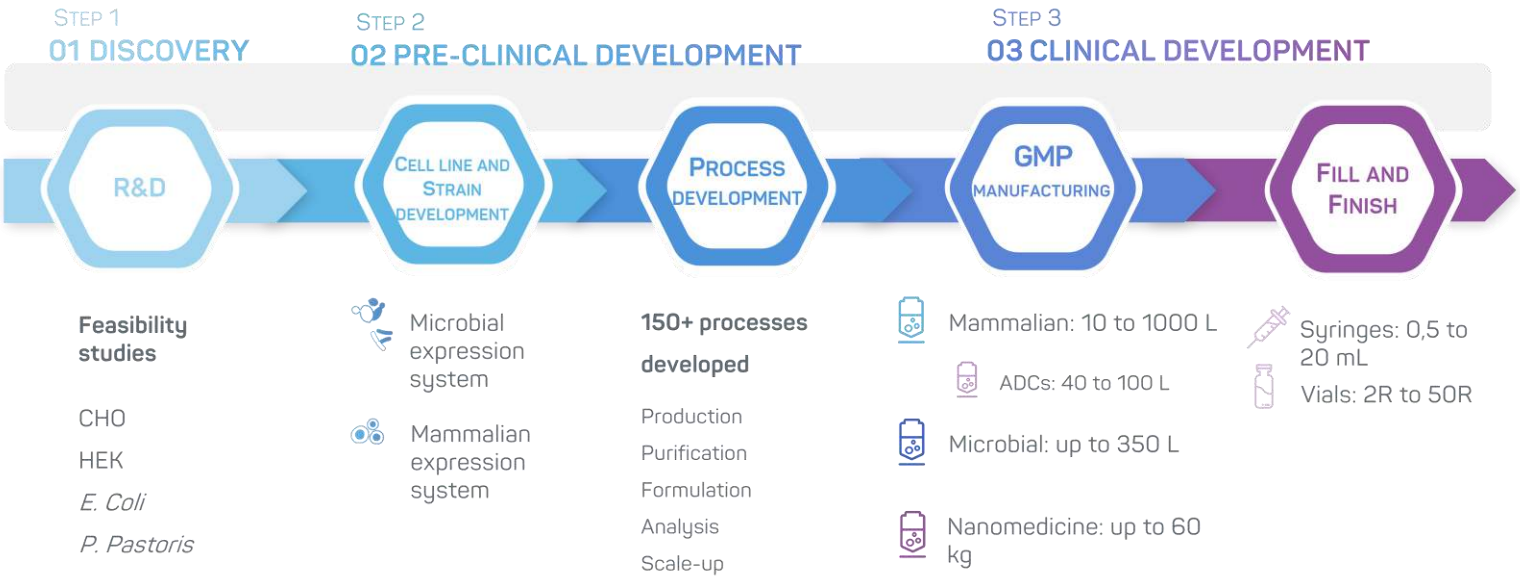
[5] Andrii Buvailo, *A fresh viewpoint on drug discovery, pharma and biotech*, BioPharmaTrend, 2022
[6] Emmanuel Dequier, Elodie Pliquet et al. « *Biothérapie et Bioproduction* », France 2030, 2022
[7] CEBR, EIT Health, *Together for tackling the biomanufacturing & breakthrough technologies challenges in Europe*, 2021

The part played by GTP Bioways

GTP Bioways' service offering and manufacturing capabilities perfectly cater to the needs of biotechnology companies in the preclinical and clinical development stages of their drug candidate.

With mammalian production capacities ranging from 10 to 1,000 L, we can respond to production needs of ancillary proteins for cell and gene therapies, vaccines, and monoclonal antibodies used in the treatment of cancer or infectious diseases.

GTP Bioways is the only French and one of few European CDMOs to also offer microbial production. There are still many molecules produced in microbial systems, which have the particular advantage of much lower production costs than mammalian systems.



With these new production lines,

GTP will fill a gap in the French landscape and help reach the goals of the France 2030 programme.

€12m invested in Toulouse

5,9 M€ *from the France 2030 programme*
6,1 M€ *from GTP Bioways' own funds*
500 000€ *from the Occitanie regional council*

3 M€ *were needed for the creation of the mammalian production line*
9 M€ *were needed for the creation of the microbial production line*

Press review

PharmaNetwork, 6th April 2023

PHARMAnetwork®
WORLD PHARMACEUTICAL & CDMO BUSINESS NEWS

GTP Bioways increases its mammalian production capacity

By Editors - 6 April 2023

production capacity GTP Bioways extends its mammalian capabilities dedicated to the production of biotherapeutics (Photo credits: Arnaud Spani)/DR

GTP Bioways, CDMO for biologics, extends its existing capabilities through the opening of a new mammalian bioproduction suite. These new capabilities are completing the existing bioproduction lines that enable the manufacturing of innovative therapies from CHO cells.

L'Usine Nouvelle, 1st February 2023

L'USINENOUVELLE

s - Recherche Traitements Covid-19 Equipements Laboratoires pharma

CDMO : GTP Bioways, nouvel acteur de la bioproduction en France

Organisée par entités, la CDMO GTP Bioways se positionne sur toute la chaîne de valeur des biomédicaments, de la production de lignées cellulaires jusqu'aux lots cliniques. De quoi répondre aux besoins croissants des territoires français et européen.

Réservé aux abonnés

Mathilde Lemarchand

Pharma

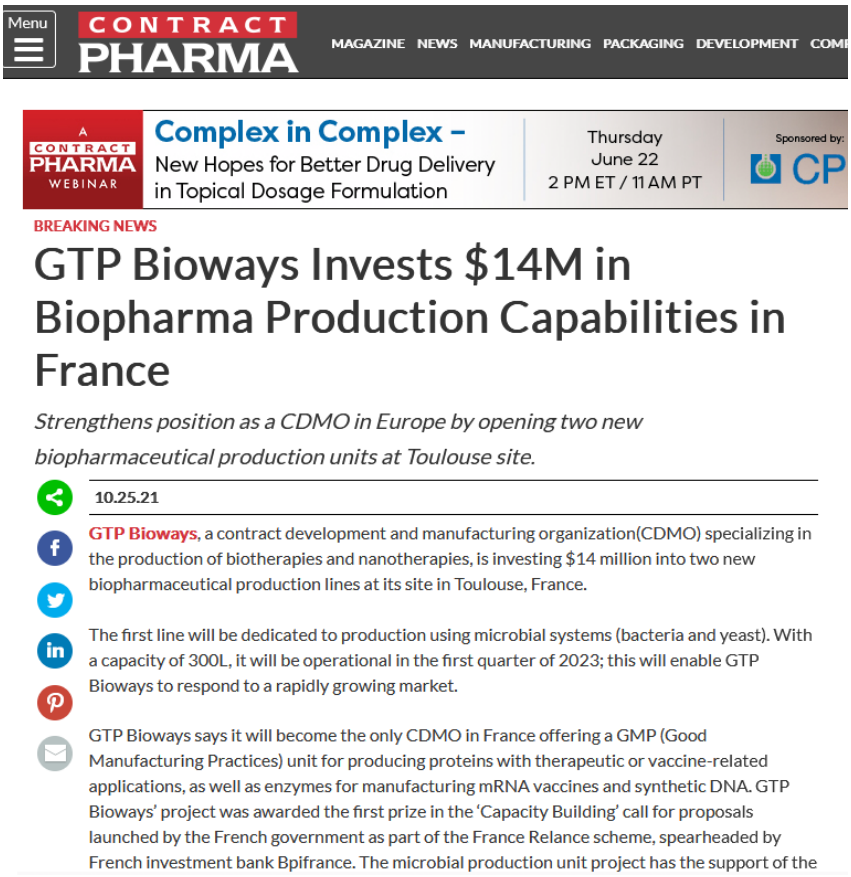
01 février 2022 | 13h00

4 min. de lecture

La CDMO se spécialise dans le développement de procédés et dans le scale-up.

En 2019, GTP Tech, fondée en 2000, opérait une métamorphose dans son organisation. Elle se s'associait à GTP Biologics et GTP Nano, ces trois entités étant spécialisées dans la production de biothérapies et nanothérapies, pour construire GTP Bioways, une CDMO proposant ses services, allant

ContractPharma, 25th October 2021



BioProcess International, 13th March 2023

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