

Innovation Shaping the Future



COMPANY PROFILE INTRODUCTION

• WHO WE ARE

• IDENTITY

• INNOVATION

• SECTORS

• SERVICES

• ACCOUNTABILITY

• CONTACTS



The CDMO that grows *by innovating*

We are the new Italian leader in the international market for the development, manufacturing and packaging of food supplements, medical devices, probiotic-based drugs and cosmetics. Our CDMO philosophy is to turn ideas into finished products, in order to offer different and ready-to-sell solutions to our customers, allowing them to fully exploit market opportunities, thanks to our ability to *innovate*.



WHO WE ARE

BIOFARMA GROUP



Our manufacturing *sites*

200 million *Euros in sales*

500 *clients*

2,000 *products*

5,000 *articles*

800 *employees*

4 *manufacturing sites*

3 *R&D Labs*

100,000 m² *dedicated to manufacturing and logistics*

170 *production and packaging lines*

**Mereto
San Pietro Viminaro
Gallarate
Cusano Milanino**



WHO WE ARE

BIOFARMA GROUP

Our *mission*

In a changing world, we develop innovative solutions and technologies to *improve people's health and well-being.*



IDENTITY

BIOFARMA GROUP

Our *vision*

Pioneers in a future where innovation is at the service of personalised and sustainable prevention.

Our *values*

Respect and Trust, Responsibility, Team spirit, Innovation, Courage.



IDENTITY

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Our daily challenge consists in developing ***unprecedented*** and ***distinctive solutions***. Innovation is the unfaltering engine that allows us to make our research a reality, by generating technologies and patents that support our clients' business.



INNOVATION

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R&DLabs

We contribute to innovation through ongoing research, analysis of new starting materials and the **development of new formulae** that translate into exclusive, customised solutions. A wealth of experience that translates into products with tested and validated effectiveness supported by **clinical studies**, to provide our clients with **ready-to-market products**.

50 specialists
2,000 projects developed every year
32 patents in Italy
56 patents in the rest of the world

Quality and control laboratories

Our Chemistry & Physics and Microbiology Labs are staffed by **highly-skilled professionals** who work in concert with prestigious research institutes and universities; the labs can count on **sophisticated analytical equipment**. *The Quality Control Laboratory of the Mereto site has been AIFA-certified since 2016.*



INNOVATION

BIOFARMA GROUP

Technology and **patents**



Multilayer tablets

Technology for the oral administration – in a single product – of formulations with active substances or mixtures of active ingredients for diversified sustained and controlled release, for a more efficacious action in the body.



Microencapsulation

We are the first CDMO in the Italian nutraceutical field to use this innovative, patented German technology, which is suitable for powders, capsules and tablets, to coat and protect an ingredient while keeping it active and stabilised, until it is released.



Dry-Cap and M-Cap

Based on a special two-phase packaging technology making it possible to enclose and at the same time separate in the same main pack, the solid component (powder) and liquid component of the product. It is particularly well-suited to probiotic-based drugs, but it can also be used for vitamins, minerals and other micronutrients.





T-Win

T-Win is a powder packaging system that has been patented in Italy and is pending international patent. A sachet with two separate chambers makes it possible to package different but mixable powders that need to be kept separate until use. The two chambers can be opened at the same time with a single gesture.



ODT – Orally Disintegrated Tablet

ODTs are tablets with a solid form that disintegrate in the mouth without water in approximately 30 seconds, to guarantee greater convenience and better compliance for a vast range of therapeutic indications and patient types.



BOV - Bag on Valve

This technology has revolutionised the production of aerosols pressurised with liquid or compressed gases. The product is contained inside a bag connected to the valve, that is immersed in a non-chemical, non-flammable compressed air-based propellant that guarantees absolute safety and does away with emissions that are harmful for the environment.





Food *supplements*

At Biofarma Group, we are committed to developing and formulating nutraceuticals and supplements in solid and liquid forms for different areas of application, strong in the conviction of their inestimable and noble value.

Our therapeutic *areas*

- Immune system
- Cough and cold
- Beauty from inside
- Metabolic System
- Mental Wellness
- Active Ageing
- Genitourinary System
- Gastronitestinal Function
- Vitamins and minerals
- Pain
- Oral Hygiene
- Sport
- Clinical studies

47 production lines

61 packaging lines

847 million capsules manufactured every year

1.71 billion tablets manufactured every year

75,000 kg of fluid bed granules a year

615 million stick packs a year

342 million sachets a year

61 million blisters a year



SECTORS

BIOFARMA GROUP



Probiotic-based *drugs*

We manufacture products containing probiotics that are released as supplements and medicinal products. At our Mereto site, these products are manufactured in a dedicated, AIFA-certified, 3,500-square metre ISO 8 facility with controlled temperature and humidity conditions and a nitrogen atmosphere.

Our therapeutic *areas*

- Immune system
- Cough and cold
- Beauty from inside
- Metabolic system
- Mental wellness
- Active ageing
- Genitourinary system
- Gastrointestinal function
- Pain
- Oral care
- Sport
- Pediatrics
- Clinical studies



Medical *devices*

Our market trend analysis expertise and know-how, combined with on-going partnerships with leading research centres, have allowed us to develop medical devices that we produce under private label manufacturing and in-/out-licensing agreements. We manufacture more than 70 ready-to-market products, many of which are patented.

Private-label manufacturing of medical devices: therapeutic *areas*

Immune system	Genitourinary system
Cough and cold	Gastrointestinal System
Beauty from inside	Pain
Metabolic system	Oral care
Mental wellness	Sport
Active ageing	Pediatrics

In-/out-licensing of medical devices: therapeutic *areas*

Cough and cold
Genitourinary system
Gastrointestinal system
Oral care
Proctology

Our *medical devices*

classes I, IIa, IIb and III – in a wide range of therapeutic areas - solid and liquid forms – for internal oral and topical use - manufactured in ISO 13485-certified facilities.



Cosmetics

24 bulk production lines
38 packaging lines
17.6 million kg of bulk (annual capacity)

Our experience and professional expertise regarding the way in which metabolic processes influence our body, both inside and out-, allows us to work synergistically with the supplement and skin care world, with products intended to satisfy specific skin and body needs, for people of different ages and that are suitable for all lifestyles.

Our therapeutic *areas*

Beauty
Feminine Hygiene
Dermocosmetics
Pediatrics
Sport



SECTORS

BIOFARMA GROUP

Our consolidated experience and the constant nurturing of expertise guarantee our clients a turnkey service and a supply chain that is monitored and guaranteed from start to finish – from development through to delivery of the finished product.

1. PRODUCT DEVELOPMENT

We develop novel solutions and formulations that are able to satisfy needs, by putting ourselves to the test with pioneering studies even in unexplored territory. We have contributed to and intend to continue contributing to our clients' success by creating infinite opportunities for growth.

The phases of product development

- Selection of the starting materials
- Galenic development
- Pilot productions
- Stability protocol design
- Primary and secondary packaging compatibility
- Definition of release specifications for industrialisation



SERVICES

BIOFARMA GROUP

2. REGULATORY ACTIVITIES AND FUNCTIONS

- Preparation of technical files
- Issuance of technical documentation for starting materials
- Issuance of technical documentation for packaging materials
- Development of category-specific Technical Files
- Declarations of conformity with applicable regulations
- Issuance of documentation required for foreign marketing authorisation applications

3. PRODUCTION

Our production system is the result of three factors: advanced technology, human expertise and product quality. Our premises include spacious facilities for the implementation of new production processes, in response to our clients' needs and in step with the Biofarma Group's development project aimed at consolidating its position as a leader in the CDMO sector.

Manufacturing phases

Weighing, pre-mixing and mixing
of the starting materials
In-process controls on the mixtures
Compressing and encapsulation
Primary and secondary packaging

Our Galenic formulations

Liquids
Powders
Coated and non-coated hard capsules
Tablets
Topical products



4. PACKAGING

We are specialised in the manufacture of products in a vast array of forms requiring different types of packaging, and are particularly attentive to process and product sustainability, whilst guaranteeing absolute quality and safety.

Packaging types

Liquids: glass and plastic bottles; Single-dose vials with reservoir caps; stick packs; sachets; Bottles with spray pump; Ampoules; Applicator pens; Vials with droppers.

Solids + Liquids: Single-dose vials with Dry-Cap or M-Cap patented technology; Vials with two-/three-phase kits; ampoules with two-/ three-phase caps

Pressurised solutions: Pressurised aerosols with flammable or non-flammable propellents; BOV

Powders: Jars; Stick pack; T-Win stick; Sachet

Capsules and tablets: Blister (alu-alu, alu-PVC); Bottles; Active vials with desiccants.

5. LOGISTICS

The Biofarma Group logistics function offers a product traceability and availability service and guarantees prompt delivery.

The opening of our new Logistics Centre at the Mereto site (July 2019) provided the Biofarma Group with a highly automated, computerised logistics and dispatch facility.

9.261 m² logistic area

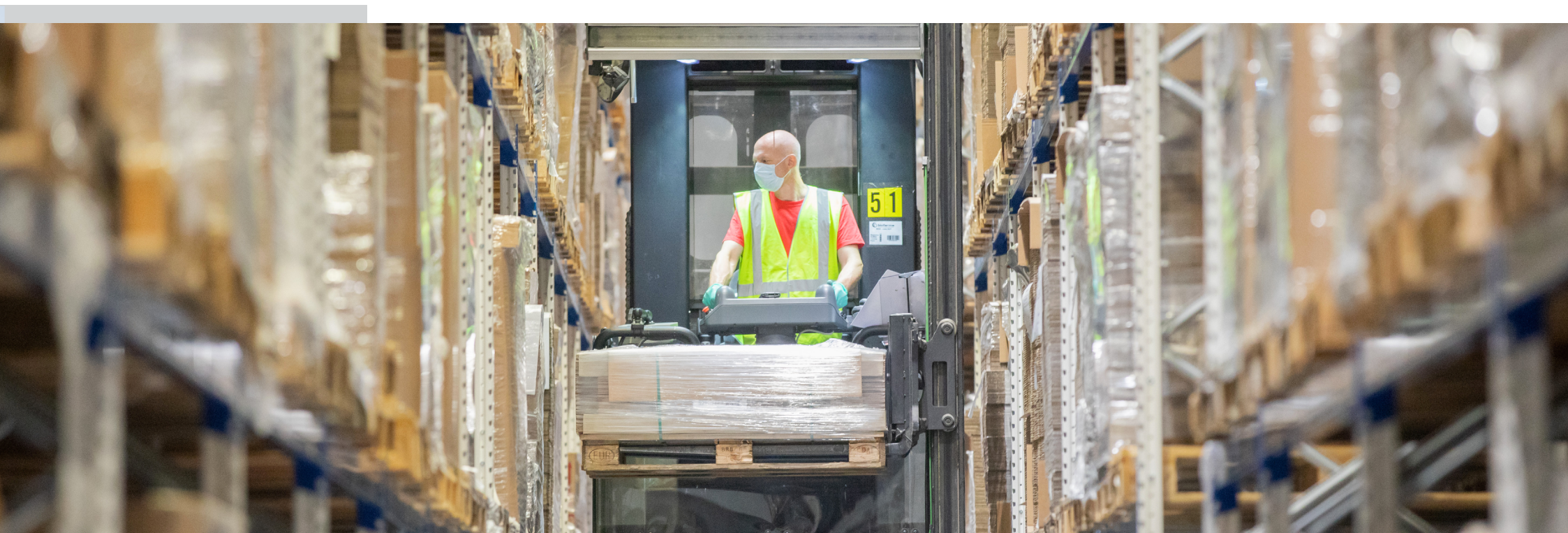
3.058 m² dispatch area

25,000 m² outdoor area

20,205 pallet spaces

777 cold room pallet spaces (between +5° and – 20°)

4,366 controlled – temperature pallet spaces for finished products



6. CERTIFICATIONS AND LICENSES

ISO 13485 (medical devices) / Mereto / Gallarate / S. Pietro Viminario

ISO 22716 (cosmetics) / Mereto / S. Pietro Viminario

ISO 9001 / Gallarate / S. Pietro Viminario

GMP CRF TITLE 21, VOL.2, PART 111 (supplements) / Mereto

GMP CRF TITLE 21, PART 111 (supplements) / Gallarate / Cusano Milanino

GMP PHARMA AIFA / Mereto

PET FOOD SUPPLEMENT AUTHORIZATION (ART 10 OF REG. 183/2005/CE) / Gallarate

KOSHER / Mereto

HALAL / Mereto

COSMOS / Mereto

RSPO MASS BALANCE (cosmetics) / Mereto

ISO 45001:2018 (safety) / Mereto

BIOLOGICO / Gallarate / S. Pietro Viminario

FDA REGISTRATION / Mereto / Gallarate

SMETA (SEDEX) | CODICE ZC409499788 / Mereto

ISO 22000:2018 / Cusano Milanino

IFS HPC-HOUSEHOLD AND PERSONAL CARE / Mereto



SERVICES

BIOFARMA GROUP



Sedex Members

In 2020 the Mereto site joined **Sedex**, the international organisation that helps companies to promote the accountable and sustainable business practices adopted and use responsible procurement sources.

Safety and health

Workers' health and safety and occupational hygiene are essential requirements for planning sustainable, effective and lasting development for our Group. To demonstrate this on-going commitment, our Mereto site has obtained voluntary certification in accordance with **ISO 45001:2018** (Occupational health and safety management systems).



Environment

We believe it is our duty to protect and promote the environment. This shared conviction translates into increasingly sustainable development projects, especially in building construction. With its 420m³ of PEFC-certified spruce wood, the Biofarma Group's site and headquarters in Mereto is an example of sustainable building.

Even the energy-efficient manufacturing facilities are in perfect harmony with the surrounding landscape and are equipped with a efficient process water purification system and mechanisms that restrict emissions into the atmosphere, limit consumption and save energy.





Our goodwill projects

Our goodwill projects reflect our commitment to being socially accountable and actively involved in improving people's lives.

We have supported the **Progetto Madagascar** since 2016, with the intention of producing the medicines and providing the healthcare required to guarantee the treatment and survival of local children and families.

Our contribution has made it possible to build a Galenic laboratory for the on-site production of medicinal products to treat common health problems resulting from poor sanitary conditions and a shortage of clean water.

In January 2019, Biofarma Group teamed up with **Cooperativa Arte e Libro** in Udine to launch a scheme to promote the employment of people with significant physical and mental disabilities, involving them in a professional project able to restore their self-esteem, dignity, motivation and sense of participation.



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