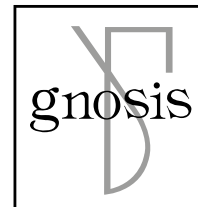


advanced biotech

Knowledge
for a better life

Knowledge for a better life





advanced biotech

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GNOSIS

Knowledge for a better life



Inspired by nature

Gnosis is an Italian biotechnology company specialized in the development, manufacturing and sale of fermentation-derived ingredients and natural finished products for use in the pharmaceutical, nutraceutical, veterinary and cosmetic industries.

With its team of highly qualified and competent experts and thanks to the collaboration between a solid R&D centre and two cGMP approved European manufacturing sites, **Gnosis guarantees high quality bulk APIs and nutraceutical ingredients adapted to market trends and tailored to specific customer needs.**

Since its foundation in 1989 until today, Gnosis has based its strong growth on the innovative and cutting-edge approach in the Research & Development department, where investments in laboratories and equipment are continuously updated and expanded.



OUR CORE COMPETENCES

include microbial fermentation, purification, chemical modification and analysis of molecules derived from yeasts and bacteria

HISTORY



A great number of successes

Gnosis has **over 25 years of experience** in the production of microbial-derived biopharmaceuticals for both oral and injectable use.

With its proprietary technology and sophisticated know-how from strain selection to analytical development, today Gnosis is proud to have supplied a wide range of high quality products to worldwide customers over the years.



**LOOK AT
THE MAIN HIGHLIGHTS
OF GNOSIS EVOLUTION:**

1989

Foundation

2003

Construction
of the R&D
center in Desio
(Italy)

2004

Acquisition
of the first
Manufacturing
Unit
(Sant'Antonino
Operations)

2009

Gnosis
acquires a new
Manufacturing
site
(Pisticci
Operations)

2006
New
manufacturing
areas are built in
Sant'Antonino
to diversify the
production

2011

Gnosis USA
new Branch
opening

2012

Gnosis China
new Branch
opening

2017

New warehouse
and creation of two
dedicated areas
for pharmaceutical
and nutraceutical
products in Pisticci
site

2018

Further expansion
of the R&D
department with
new equipment
and a new Lab
area dedicated to
the formulation
development

2014
US FDA Approval
for both Gnosis
manufacturing
sites

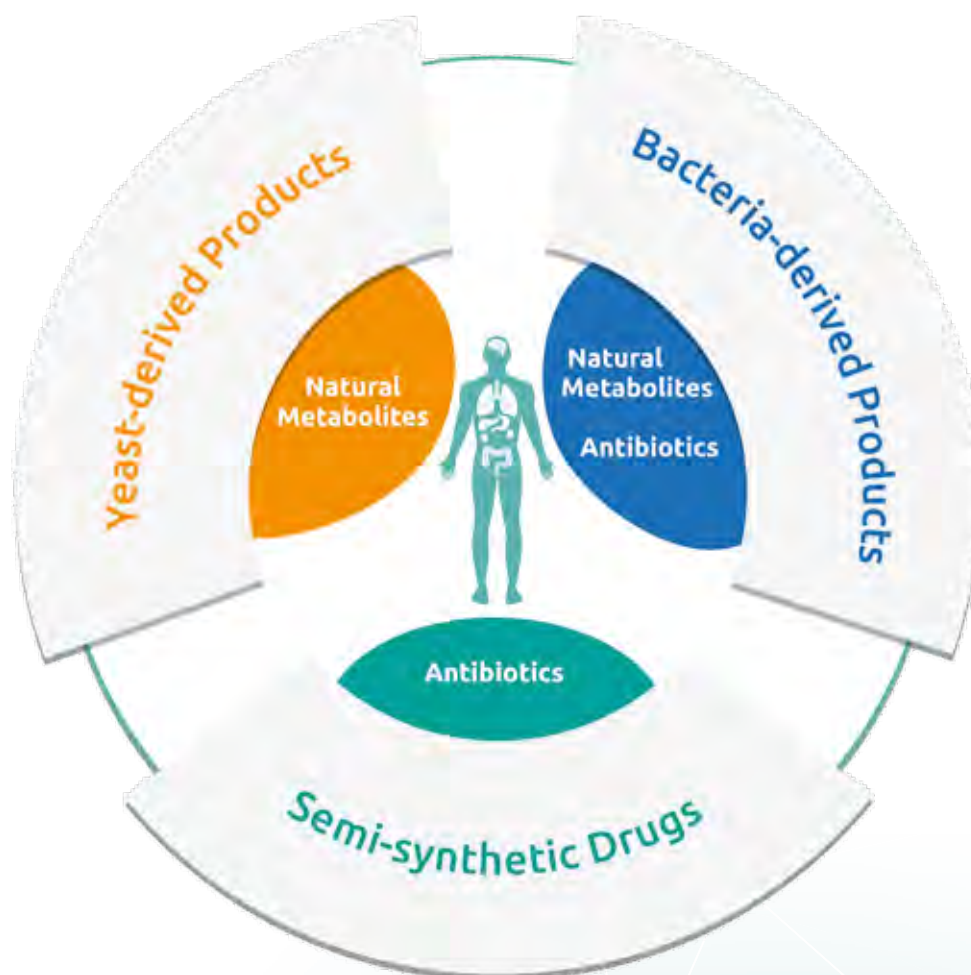
2015
Lesaffre
majority
participation
in Gnosis

PRODUCTS



BioPharma

Through the integration of microbial fermentation with advanced chemical synthesis and purification, Gnosis is able to manufacture highly complex Active Pharmaceutical Ingredients (APIs) in large scale according to the most widely recognized international quality standards.



There are three main areas of development of APIs, where Gnosis' expertise and core competences merge

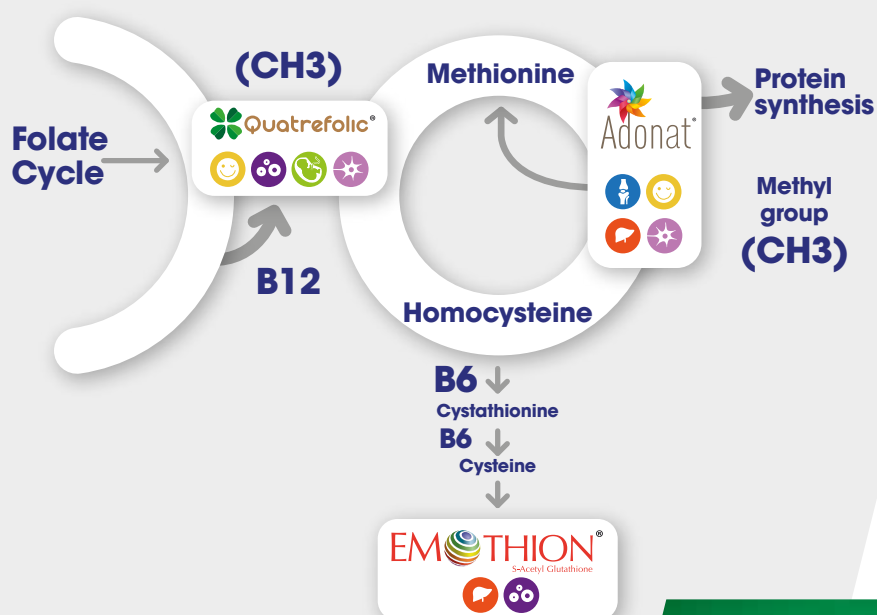
PRODUCTS



Advanced Nutrition

Gnosis Advanced Nutrition redefines the nutrients contained in food to offer customers a wide range of differentiated solutions able to improve and boost human head-to-toe health conditions and compensate for the poor quality of the contemporary diet.

Gnosis offers two interrelated concepts of active ingredients for wellbeing and longevity.

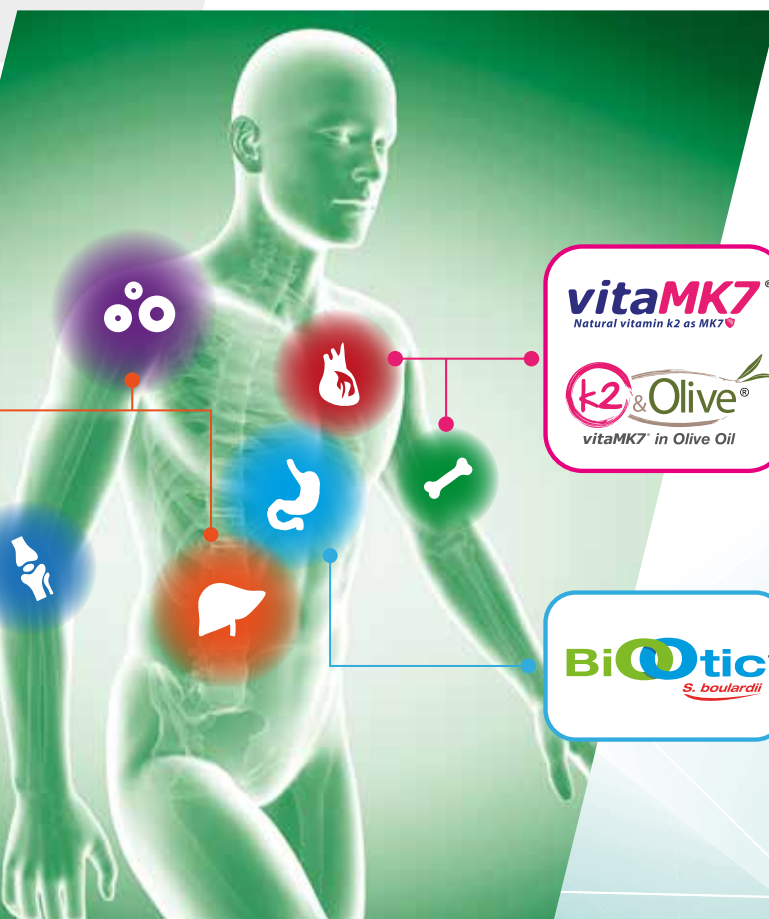


ONE CARBON:

The key network of biochemical reactions that involves the transfer of **one-carbon methyl groups** from one compound to another, essential to sustain human life for the whole body health condition.

BIOACTIVES:

Naturally occurring functional compounds with a **variety of physiological functions** that promote a healthy balance and wellness.



TECHNOLOGY



Innovative and green

Gnosis produces Pharmaceutical and Nutraceutical active ingredients **through a fermentation process** using specially developed microorganisms and integrates a well-established know-how and expertise in **5 main areas**:



STRAIN SELECTION

With decades of expertise in refining strain productivity through both mutagenesis and recombinant DNA techniques, Gnosis dedicates three separate microbiology laboratories to the isolation, development and maintenance of proprietary industrial strains including: *Escherichia coli*, *Bacillus subtilis*, *Saccharomyces cerevisiae*, *Actinomycelates*.



FERMENTATION

After an accurate selection and isolation of microbial strains, fermentation processes are designed using different scale fermenters, resulting in reproducibility and reliability, once the process is scaled up to commercial manufacturing, and enhancing the quality of the bio-ingredients produced.



DOWNSTREAM PROCESSING

The active compounds produced by a microorganism during fermentation can be contained inside the cell or be transferred outside the cell in fermentation media. The downstream processing is focused on the identification and design of purification methodologies to extract and optimize the active ingredients derived from fermented biomasses.



SYNTHESIS

The synthesis unit is responsible for defining and evaluating the innovative synthetic routes applied to modify the structure of the natural metabolites achieved through the purification of biomasses and to obtain new chemical entities.



ANALYTICAL DEVELOPMENT

Analytical Development provides the definition and the validation of the analytical procedures developed in-house, as well as the application of validated methods for in-process controls for the complete characterization of finished products, including impurities profile.

LOCATIONS



We operate all over the world

With over 300 employees, a headquarters organized with a valued and equipped R&D centre, two overseas commercial offices and two cGMP approved production sites, Gnosis Group is able to operate all over the world.

*Over **25**
Years of
Experience*

*More than **35**
Patents*

***5**
Centers*

***40**
Countries*

***300**
Customers
Worldwide*



Gnosis S.p.A.
Headquarters
and R&D Centre
Desio - Italy



Gnosis Bioresearch S.r.l.
Manufacturing Site
Pisticci - Italy



Gnosis Bioresearch S.A.
Manufacturing Site
Sant'Antonino - Switzerland



Gnosis USA Inc.
Branch Office
Doylestown - USA



Gnosis China
Branch Office
Shanghai - China



Headquarters and R&D Centre Desio - Italy

The corporate headquarters in Desio drives commercial operations across Europe and around the world, and provides support to its facilities with great commitment to quality, safety, health and environmental responsibility.

The highly innovative and sophisticated R&D centre, built in 2003 and equipped with the most modern research laboratories, represents the hearth of Gnosis activities, where biologically active products come to life and are scaled-up to be transferred to our cGMP approved manufacturing plants.

As a part of this cutting-edge approach, in early 2018 the Analytical Development and Synthesis departments were updated with new equipment and a new lab area was created totally dedicated to the formulation development.

The R&D centre is responsible for new product development through the integration of industrial microbiology, biofermentation, chemical synthesis and downstream processing.



We operate all over the world

Approx **90**
employees

15%
Gnosis people
employed
in R&D centre

2,800 m²
area dedicated to
R&D laboratories

New
department
dedicated to
formulations

RESEARCH & DEVELOPMENT



LOGISTICS & PROCUREMENT



QUALITY & REGULATORY



PRE-CLINICAL AND CLINICAL STUDIES



SALES & MARKETING



GNOSIS Bioresearch S.r.l.



Manufacturing Site Pisticci - Italy

Pisticci Operations is the most recent manufacturing site and integrates a multipurpose plant used for the production of fermentation-derived and chemical synthesis-derived bulk Active Pharmaceutical Ingredients (APIs).

The plant, which is cGMP certificated, is fully controlled by DCS (Distributed Control Systems), a modern computerized system enabling management of manufacturing activities in remote mode.



We operate all over the world

Approx **100**
employees

133,000 m²
of total plant
area

Over **200 m³**
of fermentation
capacity

Fully controlled
by DCS
(Distributed
Control
Systems)

PRODUCTION OF BULK APIs

from fermentation and chemical synthesis



SCALING-UP/SCALING-DOWN PROCESSES



MODULAR STRUCTURE

for modern multi-product manufacturing



PROCESS CONTROL SYSTEM (DCS)

for management of manufacturing in remote mode



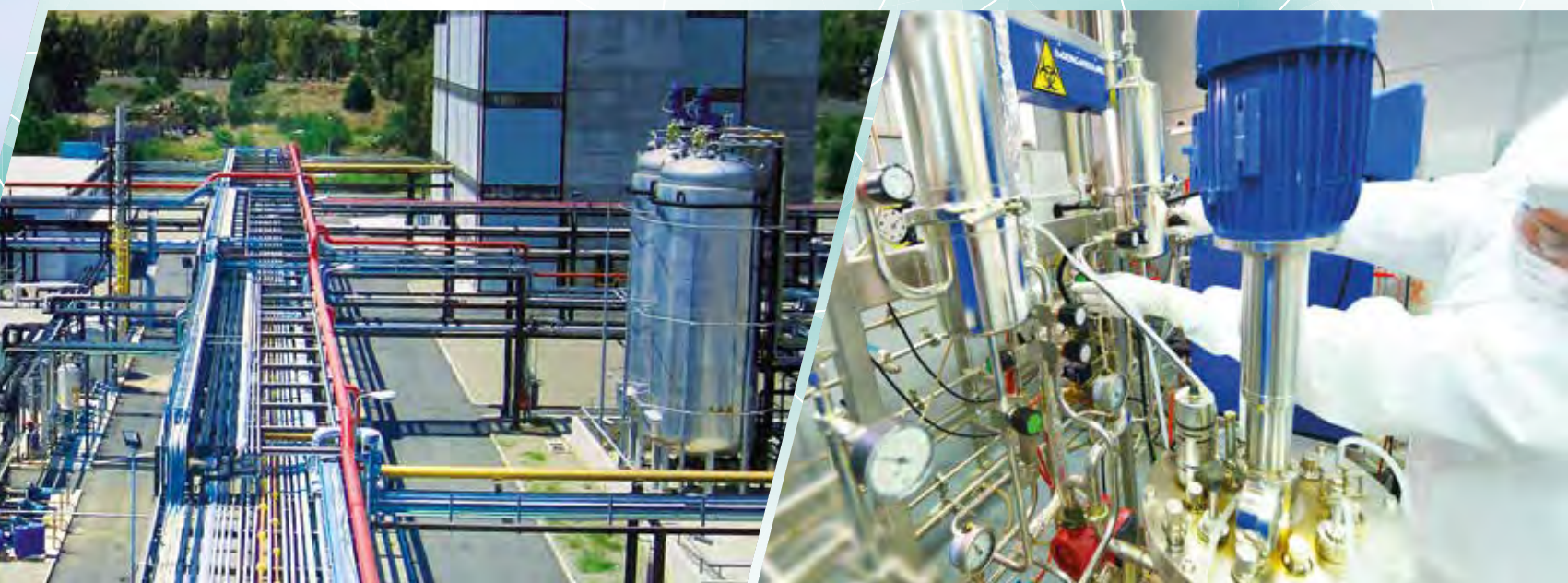
FDA, AIFA

approved



HACCP, ISO 22:000, KOSHER, HALAL

certifications



GNOSIS Bioresearch S.A.



Manufacturing Site Sant'Antonino - Switzerland

Through extensive know-how and remarkable experience in biotech operations, the Sant'Antonino plant provides process development, scale-up and manufacturing of fermentation based compounds including Active Pharmaceutical Ingredients (APIs) and Nutraceuticals.

The downstream processes are designed to meet environmental, health and safety challenges by using water-based purification technologies.

Since 2005, Gnosis Bioresearch SA is cGMP approved and is authorized by Swissmedic for the production of non-sterile APIs.



We operate all over the world

Approx **110**
employees

24,000 m²
of total plant
area

Over **150 m³**
of fermentation
capacity

Over **350 m²**
laboratories
analysis
(microbiological
and chemical)

FERMENTATION PROCESS



SCALING-UP/SCALING-DOWN PROCESSES



DOWNSTREAM PROCESSES

with water-based purification technology



PROCESS CONTROL SYSTEM (DCS)

for management of manufacturing in remote mode



SWISSMEDIC, ANVISA, FDA

approved



KOSHER, HALAL

certifications



GNOSIS USA Inc.



North American Branch Office Doylestown - USA

The North American Branch Office (in Pennsylvania, USA) is responsible for providing client-oriented services and developing Gnosis marketing plans in the United States and Canada.

With a long and well-established presence on the market, the Branch Office is responsible for distribution and logistics services throughout all North America territories.

Gnosis USA Inc. integrates the Global Commercial Operations of Gnosis Group located in Italy, creating cross-functioning links between our broad client portfolio and Gnosis European technical and manufacturing network.

GNOSIS CHINA



Asia-Pacific Branch Office Shanghai - China

Gnosis China is part of Gnosis' expanding strategy towards new emerging markets and the wish to respond to market needs with effective and timely services, to enhance the performance of product innovations. Flexible, customer-driven and well integrated in the territories, it recognizes the key driving influencing forces through business planning and analysis, offering a competitive market positioning of the products.

The Branch Office is responsible for defining effective entry strategies to meet countries' regulations to guarantee a competitive advantage to its present and future client portfolio and consolidation of local business relationships.

Gnosis China is located in Shanghai, the largest and most vibrant city of China, the industrial, commercial and financial centre of one of the world's most influential and fast-growing market.

QUALITY AND SUSTAINABILITY



We understand that we have a global responsibility to minimize our environmental footprint and create greater sustainability in everything we do.

To underline our commitment to quality, employee health & safety and our attention to the environment, all Gnosis sites have agreed to adhere to strict global quality standards, backed by first-class worldwide quality control and quality assurance teams.

To achieve this important goal, we have put in place procedures to facilitate our continuous improvement and we are focusing on **biofermentation**, which is **one of the most promising technologies to reduce raw material consumption and waste in the manufacture of active ingredients**.

OUR INSPIRATION



The constant demand for new, safe, effective and natural ingredients from the global pharmaceutical and supplement industry inspires us to discover, develop and provide innovative products.

In the future, more and more natural ingredients will be produced by microbial fermentation; and these ingredients will replace products that are chemically synthesized or extracted from plants or animals.

Gnosis is committed to being a research-intensive biopharmaceutical company providing advanced active ingredients.



OUR PARTNERS



A customer-driven mission

Gnosis places customers at the centre of its strategic choices. Every business decision is driven to give customers what they really need and expect, and to ensure their satisfaction.

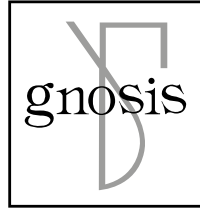
This commitment is reflected in everything Gnosis does:

- **INFORM** and update customers about Gnosis new products and solutions
- **PROVIDE** a scientific marketing support to efficiently promote customers' products
- **INCREASE** customer awareness about physical health, well-being and mood

This "educational plan" project is achieved through the regular release of information through Newsletters, product websites, social media activities.

Connect to our official website www.gnosis-bio.com to learn more.





advanced biotech



www.gnosis-bio.com
www.quatrefolic.com
www.vitamk7.com
www.mythocondro.com



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