

### **COMPANY PROFILE**

## O.F.I. - PROCEMSA Group

We are one of the leader Group in the creation, development and Contract Manufacturing of:

- Food Supplements,
- Probiotics
- Medical devices
- Dermo cosmetics

In all solid and liquid forms

The Group offers to customers a broad catalogue of products ready for distribution, and medical devices available in out-licensing.

Our work is driven by the desire to anticipate the needs of our customers.

Science, history and imagination at your service. It is passion... it is fantasy...

it is Made in Italy since 1939 and 1946



#### **KEY NUMBERS**

- Stop Shop Group
- 2 Production sites between Bergamo Lombardy and Turin Piedmont
- 6 Manufacturing plants, one dedicated for probiotics, for more than 22.000 square meters
- 25 Researchers innovating and Researching every day in "R&D "departments
- Technicians involved in CQ/QA departments
- Pallet places in our warehouses
- More than 300 customer all around the world, and counting...

100% Made in Italy

#### **CERTIFICATIONS**

- GMP Certification for manufacturing and Packaging of Food Supplements according to Code of Federal Regulation title 21 - FDA (current edition)
- GMP ISO 9001 (Good Manufacturing Practises) philosophy and enforcing a Quality System
- **ISO 14001** Environmental Protection, managment system certification
- ISO 13485 Development and production of Medical Devices
- **ISO 22716** Cosmetics Good Manufacturing pratices (GMP) Guide Lines on good manufacturing pratices
- ISO 45001 Safety Management System
- OHSAS 18001 Safety on workplace management system
- **IFS** Food certification version 6
- HALAL and COSMOS-ECOBIO (ICEA)

  Certification for single products.

CERTIFIED MANAGEMENT SYSTEMS



UNI EN ISO 9001:2015 UNI EN ISO 14001:2015 UNI ISO 45001:2018 IMPLEMENTATION IN GMP GUIDE IN COSMETIC SECTOR



ISO **22716:2007** 

CERTIFIED QUALITY
MANAGEMENT SYSTEM



UNI CEI EN ISO 13485:2016



OHSAS 18001:2007

















#### **SUSTAINABILITY**

Our Group is directly involved in 4 priority areas:

- **Employee's health and safety.** We ensures employees safety with an integrated approach that includes: job organization, safety management, health protection from dangerous substances, advanced industrial processes.
- **Environmental protection.** We act pro-actively to satisfy environmental standards, using environmentally friendly products and processes, with adequate environmental management systems and effective projects aimed to lower emissions and wastes.
- **Safety Processes.** We act in a precautionary, systematic and exhaustive manner: for every production processes and equipment used, risks are identified, evaluated, deleted or reduced, assuring the respect of the highest safety standards.
- "Product stewardship" or Responsible Product management. We act respecting safety, health and environment standards, during all the product lifecycle: from planning to after sales supervision until eventual disposal

# We produce every year our **SUSTAINABILITY REPORT**

## CORPORATE SOCIAL RESPONSABILITY

We are also part of the voluntary international "Responsible Care" programme, which monitors the implementation of principles and conduct regarding the safety and health of employees and environmental protection. The commitment also involves the disclosure of the results achieved towards continuous, significant and tangible improvement.

Responsible Care®



Water without impurities is an essential condition Production standards benefit from a new inverse osmosis plant, which produces extremely pure water, and a technologically advanced water purification system.

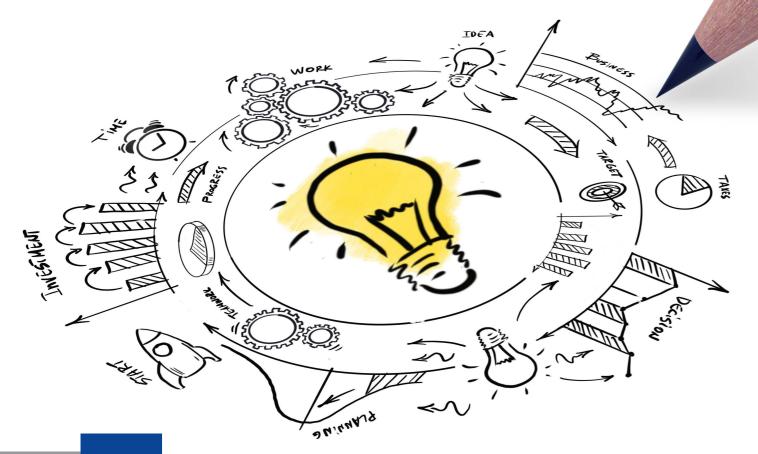
The constant purity of the water is guaranteed by a permanently connected, dedicated emergency system.

We work in a socially responsible way so that the community in which we live and the territory in which we work can look towards a long-term future, to satisfy the needs of the present without compromising the ability of the future generations.





## WHY O.F.I. PROCEMSA GROUP?





- 1) R&D
- 2 Marketing
- **3** Regulatory Affairs
- 4 Production
- **5** Quality Assurance
- 6 Warehouse and Logistics
- 7) After Sales Customer Assistance

#### RESEARCH AND DEVELOPMENT

Formulation, Research of Raw Materials, Innovation

Manufacturing Process Development and Industrial Scale Up

Analytical Development

Technical Dossier

Ich Stability Studies, on-Going Stability Studies

Regulatory Support

— Clinical Trials

Medical Device Development, Dossier

Innovative Textures and New Aromas
Continuous Research

New Packaging and Applications Study and Research

#### **PATENTS**

Research Lab

**25** People

4.000
Research
Projects
per year

**50.000**Formulations
in our Databe









#### MARKETING SUPPORT

Innovative Packaging Research

**Trends** 

Research

Dedicated Marketing Team International Market



Distribuition Channels



Market Analysis

#### REGULATORY SUPPORT

- Registration Assistance Italy and Abroad
- Pre-Registration
  Document Preparation
- (V) Tailored Assistance
- Legislative Compliance Evaluations
- Support to Relevant Institutions and Governative Organizations





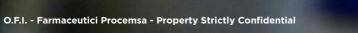
#### **PRODUCTION**

- Technologically Advanced
  Equipment
- High Flexibility:
  All Liquid and Solid Forms
- All Types of Packaging
- Complete Traceability
- Full Service and Customer
  Partnership









#### Production FOOD SUPPLEMENT

We develop, produce and package our products in 4 modern plants, we work with customers all over the world.

We develop innovative products, safe and effective, for all ages, starting from a few months of life.

**Search** for the best raw materials, proprietary technologies, patents, industrial competence, accurate controls and stability plans conducted internally, make us the ideal partner.







## **Production TABLETS**

- Swallowable single, double, triple layer tablets
- Chewable Tablets
- Normal, fast, modified release Tablets
- Coated tablets by aesthetic film; taste masking film; gastroprotected film

NEW: Big Size Tablets, Effervescent Tablets In Blister, Strips





## **Production CAPSULES**

- Hard gelatin capsules in sizes:00, 0 long, 0,1, 2
- Vegetable gelatin capsules (HPMC)
  00, 0 long, 0,1, 2
- Low humidity (LH) capsules specific for probiotics and hygroscopic or moisture sensitive active ingredients 00, 0 long, 0,1, 2
- (V) Gastro-resistant capsules
- Capsules without titanium dioxide

**NEW**: Hard Gelatine Capsules with One Beadlet, 2 Type of Beadlet, 1 Type of Beadlet and Powder







## **Production POWDERS**

- Single-dose maxi format sachet (over 8 gr)
- Single and twin sachets up to 8gr, from 60x90 mm to 60x110 mm
- Sticks from 26x90 mm to 26x110 mm
- Strips

Various polylaminate wrapping for different protection needs, barrier to light, oxygen and humidity. Specific wrapping for probiotic-based products, in wrapping with molecular desiccants; Possibility of inserting nitrogen during packaging.

### Sachets Sticks Strips



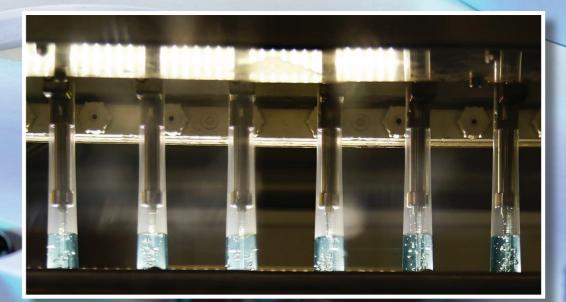


## Production LIQUIDS

- Vials with plug system (reservoir caps) 7,10,15, 25, 30, 60 ml
- With plug system (reservoir caps) 7,10,15, 25, 30, 60 ml
- Vials with dropper 10, 20, 30, 50 ml for aqueous or oily solutions
- Single dose shots of 25, 50, 60 ml
- ( ) 10, 25 ml vials screen-printed or labeled or sleeve

NEW: Stick Pack for liquid (Solutions, Syrups, Gel, Food Emulsion)





## **Production COSMETICS**

Tubes
Jars
Airless Tube
Ampoulles
Bottle
Spray
Sachets
Innovative forms
Sustainable and reusable packaging

FACE CARE
BODY CARESUNPRO TECTION
HAIR CARE PRODUCTS
PERSONAL CARE, CLEANSER PRODUCTS
NEW INNOVATION AND HYBRID
FORMULATIONS





NERATING ANTI-WRINKLE NIGHT



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#### **PRODUCTION & FILLING**

- 1000 Liters Turbo Emulsifier
- **2** 500 Liters Turbo Emulsifier
- **300 Liters** Turbo Emulsifier
- 150 Liters Turbo Emulsifier
- **50 Liters** Pilot Turbo Emulsifier
- 10 Liters Pilot Turbo Emulsifier
- **Tube Filling** Machine: Plastic and Laminate Tubes
- **Line for Filling** jars
- **2** Ampoules Filling Machine
- **Volumetric Filler:** Small quantity Matches

## **QUALITY ASSURANCE**& QUALITY CONTROL

#### **QA and QC laboratories**

perform daily chemical, physical and microbiological controls.

UNI EN ISO 2859 European Pharmacopoeia Samples
Management (Raw
materials and products)

**Equipment Setting and Controls** 

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**Stability Control of Production Batches** 

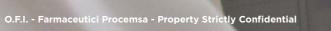
TOTAL PRODUCTS
TRACEABILITY

**Environmental Management** 

#### **100% QUALITY**

- Microbiological analysis on raw materials, semi-finished and finished products
- Chemical and physico-chemical analyzes on incoming raw materials
- Chemical and physico-chemical analyzes on semi-finished and finished products
- Determination of allergens by Elisa test

High qualified staff members of the QA & QC dep. guarantee that each product manufactured complies with all requirements and is suitable from every point of view to meet the expectation of our customer and consumers.



FARMACEUTICI



SIL-30AC

## WAREHOUSE & LOGISTIC

- 6.500 Mq Warehouse
- **2** Computerised management of warehouses
- **3** Completely robotic warehouses
- 4 Humidity and temperatures control
- **5** Customer packaging storage service
- 6 Automatized change pallet system in compliance to pharmaceutical standard



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#### AFTER SALES SUPPORT

#### **Total Products traceability**

from raw materials to the finished product even after market launches

**Customs documents** production

#### **Total After-Sales assistance**

Back Office activity Re-orders planning

#### **QA and QC laboratories**

perform daily chemical, physical and microbiological controls





#### CONTACTS

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