

Capsules  are  
the very essence  
of Qualicaps®

# Capsule core competency

As a company dedicated to capsules, we have a unique perspective on how to contribute to health.

**Qualicaps®** delivers pharmaceutical grade capsules to the pharmaceutical and consumer healthcare industry, together with a **comprehensive service** along the product life cycle through our global team of commercial, scientific and technical experts.

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**+125 years experience**

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**Capsule innovation**

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**Personalized customer support**

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**Excellent scientific & technical support**

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**Equipment and technology synergies**



**As a business,  
what we think, see, and create,  
is born from the capsule**

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#### **DID YOU KNOW?**

We are the first company  
in bringing to the  
pharmaceutical market  
a capsule of vegetal origin

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Qualicaps® is a responsible company dedicated to the supply of two-piece hard capsules and related services **that takes pride in producing each capsule with the aim of promoting the basic principles of wellbeing.**

As one of the principal suppliers to the pharmaceutical industry, we bring a wealth of expertise to the consumer health market:

- Over 125 years of capsule manufacturing **experience.**
- Proven track record in **capsule innovation** and custom capsule applications.
- **Capsule, equipment and technology synergies** to meet nutritional product manufacturing needs.
- Commitment to **personalized customer service.**
- Excellent **scientific & technical support.**



# Contributing to the betterment of individuals



# Contributing to the betterment of individuals.

We're dedicated to enhancing individuals' well-being through innovative pharmaceutical and nutraceutical **solutions**. Our unwavering commitment is to understand and meet customer needs, delivering the highest-quality services.

We continuously push the boundaries of capsule technology and production, refining processes and **introducing pioneering solutions**.

**Sustainability is vital** in our operations; we aim to minimize our environmental impact while supporting local communities.

Our culture fosters collaboration within our organization, with partners and customers. **We strive to build lasting relationships and contribute to advancing the pharmaceutical and nutraceutical industries.**







# Global presence

# Highly prepared to produce and deliver quality products and services

With **capsules manufacturing sites in five locations around the globe** (Japan, Spain, Romania, Brazil, the United States) and teams comprised of capsule subject matter experts, **Qualicaps® is highly prepared to produce and deliver quality products and services** to multi-national companies with several capsule filling sites and R&D centers located in different regions.

**Qualicaps® is a long-term capsule partner for most of the leading global pharmaceutical companies, as well as for many relevant local and regional ones.**

In addition, our expertise cultivated through the years and over geographical boundaries affords the company insight into both existing and emerging markets, and thus the demands of cross-country compliance.





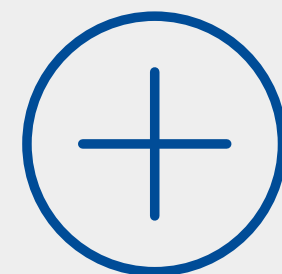
# Continually working to guarantee the highest-quality product



# Delivering quality gives peace of mind

Producing capsules for pharmaceutical and wellbeing purposes is about quality of life, and life itself. Qualicaps® thrives in producing each individual capsule with the objective of delivering superior performance. We analyze performance from many perspectives: pharmaceutical-grade quality, productivity in filling machines, stability through the product shelf-life, functional properties of delivery, and patient ease-of-use.

**With a mindset of continuous improvement, our Quality teams work to strengthen our control processes in order to guarantee the highest-quality product.** Always striving to exceed the most challenging standards and certifications within the market, these professionals drive company excellence and will help maintain optimal performance in capsule filling operations.



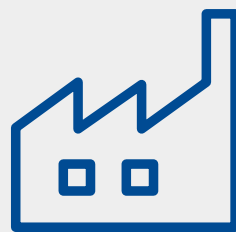
Pharmaceutical  
grade



Local health authorities  
/ FDA certified



ISO 9001-14001  
certified



Manufactured in a  
cGMP compliant facility

## PROPRIETARY TECHNOLOGY

Qualicaps® is engineered with the high standards of the pharmaceutical industry in mind:

- Award-winning<sup>1</sup> artificial vision systems in production for quality assurance
- Laser printing machine for solid dosage forms that allows for the imprinting of extraordinarily fine details, and also acts as an effective anti-counterfeiting measure

1. 2014 R&D+i award winner from Center for the Development of Industrial Technology



# Looking forward to the future of healthcare innovation



# 1st

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In incorporating a **self-locking structure** to capsules.

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In applying the **Rotoprint™ imprinting** techniques.

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In creating a **preservative-free formula** in gelatin capsules.

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In bringing to the pharmaceutical market a **capsule of vegetal origin**.

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In producing a gelatin capsule for use in dry powder inhalers, then subsequently a hypromellose capsule with superior **functional properties specific to inhalation**.

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In developing and marketing a **cellulose capsule with an extremely low moisture content** specifically dedicated to hygroscopic and moisture-sensitive pharmaceutical drugs.





## We are pioneers, we are innovators in vegetal capsules

Looking back at the history of capsules, you will find that many milestones are directly related to our scientists and their research. **Many significant developments are closely linked to the name Qualicaps®.** Whether the first capsule with self-locking features developed in the 1960s, the first capsule developed for Dry Powder Inhalers, the first formulations filled as semi-solid matrices (SSM) in the 1970s, or the first high-speed automatic band-sealing machines in the 1980s.

In the 1990s, **Qualicaps® set a new standard with the first pharmaceutical grade hypromellose (HPMC) capsule**, used nowadays by many leading companies in their strategy to avoid raw materials of animal origin. Since then, **our R&D departments, are in constant pursuit of adding value to vegetal capsule solutions that help to boost therapeutic effects.**

Our latest innovative product demonstrates our work: the new plant-based capsule with highly innovative components contributes to the formulation of active ingredients with highly hygroscopic complex compositions or very moisture-sensitive formulations.



# Why HPMC capsules?

Significant pharmaceutical research shows that gelatin capsules are not suitable for encapsulating hygroscopic and moisture-sensitive products and are chemically unstable under certain conditions.

In addition to meeting patients' dietary and cultural needs, **HPMC capsules have emerged in the market as the most viable alternative** because of their vegetal origin, chemical inactivity, absence of crosslinking, low moisture content and excellent microbiological qualities.



Pharmaceutical  
Grade



100% Vegetal Origin  
Qualicaps® innovation



TiO<sub>2</sub>-free  
option available



Gelatin Equivalent  
Dissolution Profile



Chemically Inert



Minimal Brittleness



# Partnering with Qualicaps®





# Qualicaps<sup>®</sup>, more than just a supplier

Qualicaps<sup>®</sup> differentiates itself by accompanying a customer's chosen capsule product with the best comprehensive service. **Our approach is to provide customers with the capsule they need and a knowledgeable and skilled team of experts to ensure its performance on all levels**, either start-to-finish development or focused support at any critical stage of the drug product's life cycle.

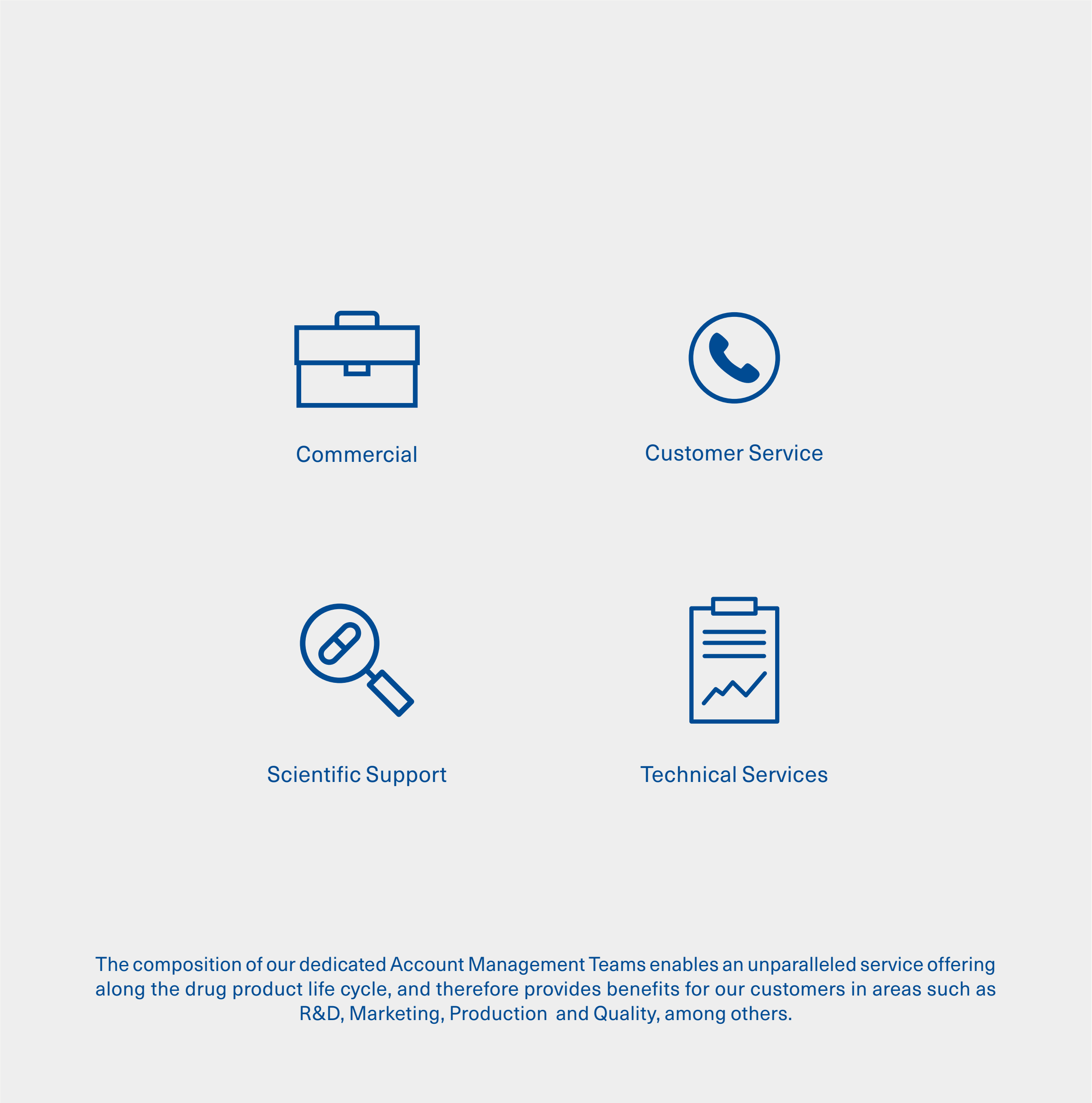
The Qualicaps<sup>®</sup> team combines an experienced manufacturing backbone, quality assurance authorities, knowledgeable commercial representatives, scientific experts, and technical production engineers, all of whom work towards the success of our customers.



# Providing a dedicated service beyond the capsule

As an integral part of our approach as a truly customer-centric organization, we have defined **specific Account Management Teams (AMT) to better serve our customers** in achieving their capsule-related business metrics at both an individual site and global level on a continual basis.

These Account Management Teams, continuously supported by the breadth of the Qualicaps® Company (including Operations, Quality Assurance & Quality Control, and Regulatory Assistance), are **multifunctional in nature and comprised of a member from each of our specialized areas of expertise that will strive to address any specific needs.**







## Our state-of-the-art Customization Center

Besides a dedicated capsules R&D center in Japan allowing for the development of potentially new types of capsules' compositions, **Qualicaps® operates a dedicated capsules customization center** in its Alcobendas (Madrid), Spain facility.

Our capsules 'customization center allows to **develop tailor-made capsules solutions for our customers**, together with offering scientific formulation support for both existing and new customer's encapsulated products.



# Qualicaps® portfolio





# Our capsules

**Solid oral dosage forms** (tablets and capsules, both hard and soft) are the most popular delivery option among patients, doctors and pharmaceutical companies. They are “**patient-friendly**”: readily portable, convenient to autoadminister, easy to swallow, stable and precise in delivering the active ingredient.

Hard two-piece capsules also offer additional advantages over tablets, mainly:

- **Less complex formulations**, using less excipients
- Possibility of **combining drug products**
- More **appropriate for hygroscopic active ingredients**
- Option of using two colors (for the capsule cap and body) for **product marketing**
- **More efficient product manufacturing process** (reduced amount of steps), reducing validation and analytical costs
- **Absence of compression forces** in product manufacturing

















# A solution for each of your needs

We are a reliable company that takes pride in producing each capsule with the aim of offering specific and optimal solutions for drug delivery and overall health and well-being challenges.

\* Now available in TiO<sub>2</sub>-free option

Pharmaceutical Applications		
HPMC CAPSULES		
ORAL	 Quali-V® (*)	 Quali-V® Extra Dry
INHALED	 Quali-V®·I Inhalation	 Quali-V®·I Extra Dry
BOVINE BONE GELATIN CAPSULES		
ORAL	 Quali-G™ (*)	 Quali-G™ Liquid
	 Quali-G™ PEG	 Quali-G™ PEG Extra Dry
INHALED	 Quali-G™·I Inhalation	 Quali-G™·I Extra Dry
Consumer Healthcare Applications		
HPMC CAPSULES		
ORAL	 Nutra V™	 Nutra V™ Slow



# Pharmaceutical Applications



# Hard two-piece HPMC capsules, the trend in market preference



## The first vegetal capsule in the pharmaceutical market

Beyond their **equivalence to gelatin in dissolution time**, Quali-V<sup>®</sup> HPMC capsules present advantages for hygroscopic drugs due to their **reduced moisture content (4-6%)** and **physical stability** when filled with hygroscopic materials or exposed to low humidity conditions.

They are also **chemically inert** (no cross-linking reactions), enabling their **use for new drug developments** in solid oral dosage forms.

NEW



Now available the 100% TiO<sub>2</sub>-free plant-based capsule specifically formulated for pharmaceutical applications



## The cellulose capsule solution when an extremely low moisture content is required

Quali-V<sup>®</sup> Extra Dry, with a guaranteed **extremely low moisture content (2.0-3.5%)**.

Maintain their **physical stability** and show minimal brittleness when exposed to ambient conditions with low humidity.

Specifically designed **for use in administering moisture-sensitive or hygroscopic pharmaceutical drugs**.



Added value capsule solution

# Hard two-piece inhalation-grade capsules

Inhalation-grade capsules also available in 100% bovine premium gelatin option (Quali-G™-I and Quali-G™-I Extra Dry)

Qualicaps® inhalation-grade portfolio is the first range of capsules with properties specific to inhalation introduced in the pharmaceutical marketplace.



The first HPMC capsule with properties specific to inhalation introduced in the pharmaceutical marketplace

Specifically designed for moisture-sensitive formulations. The grades of hypromellose used have been **optimized for puncturing**.

A controlled lubricated internal shell surface, enables **superior powder emptying, delivery, and aerosolization**.

These characteristics, along with **strict microbiological process** controls, allow for the use of Quali-V®-I in an inhalation device with constant (reproducible) performance.



The HPMC capsule with extremely low moisture content for use in DPIs

Same properties as Quali-V®-I capsules with a **very low moisture content (2.0-3.5%)** making them **ideal for hygroscopic and very moisture-sensitive inhalation formulations**.

Quali-V®-I Extra Dry capsules are produced with a **special drying process and unique equipment developed by Qualicaps® Europe**, with funding awarded by the European Union through the Centre for the Development of Industrial Technology (CDTI).



Added value capsule solution



# Hard two-piece gelatin capsules, the market standard dosage form



## The first preservative-free formula in gelatin capsules

With a very predictable dissolving drug profile, **Quali-G™ capsules** can be used at all stages in the development process, and finally to product launch and commercialization, as they do not undergo any changes in physical and chemical performance when empty throughout their shelf life.

Now available the 100% TiO<sub>2</sub>-free gelatin capsule specifically formulated for pharmaceutical applications



## The definitive solution for encapsulation of liquid formulations of varying viscosities

Specifically designed to contain and permanently seal low/very low viscosity liquid products, until now difficult to handle with existing capsules on the market.



Added value capsule solution

# Hard two-piece gelatin capsules, the market standard dosage form



## The adaptation of the standard gelatin capsule with higher robustness

With the same disintegration and dissolution properties than the standard Quali-G™ capsules, Quali-G™ PEG capsules have demonstrated **better performance in terms of brittleness** (the addition of PEG gives more elasticity to the capsule).



## The capsule that needs extra robustness specifically designed for products that have moisture-sensitive and hygroscopic properties

The dissolution profile of Quali-G™ PEG Extra Dry is identical to standard Quali-G™ capsules. Additionally, when compared to standard gelatin capsules, the **mechanical strength** of Quali-G™ PEG Extra Dry capsules **is properly preserved in low-moisture condition.**



Added value capsule solution





# Consumer Healthcare Applications

# Hard two-piece vegetal capsules, specifically designed to meet the ever-increasing demands of health-conscious consumers



## The vegetal capsule that meets dietary, functional and lifestyle preferences

With a **low moisture content and excellent dissolution profile**, this Clean label vegetal-origin capsule provides a superior and high-performance solution that makes these capsules ideal for a broad range of nutraceutical and nutritional applications.

**Nutra'V meets the increasing clean-label demands** of health-conscious consumers, as well as the specific dietary needs of **vegetarians and vegans**.



All our capsules are available in a Titanium Dioxide free (TiO<sub>2</sub>-free) option.



## The vegetal coated-free capsule that incorporates inherent delayed-release functionality

Nutra'V Slow capsules are **specifically designed to target moisture-sensitive and acid-labile ingredients by slowing down capsule rupture and release of contents**.

Offering additional protection of ingredients from stomach acidity, this **coated-free capsule** facilitates product benefits thanks to a more appropriate delivery, while reducing the risk of unpleasant odors, aftertaste and reflux.



Added value capsule solution





# Qualicaps<sup>®</sup> tailor-made solutions

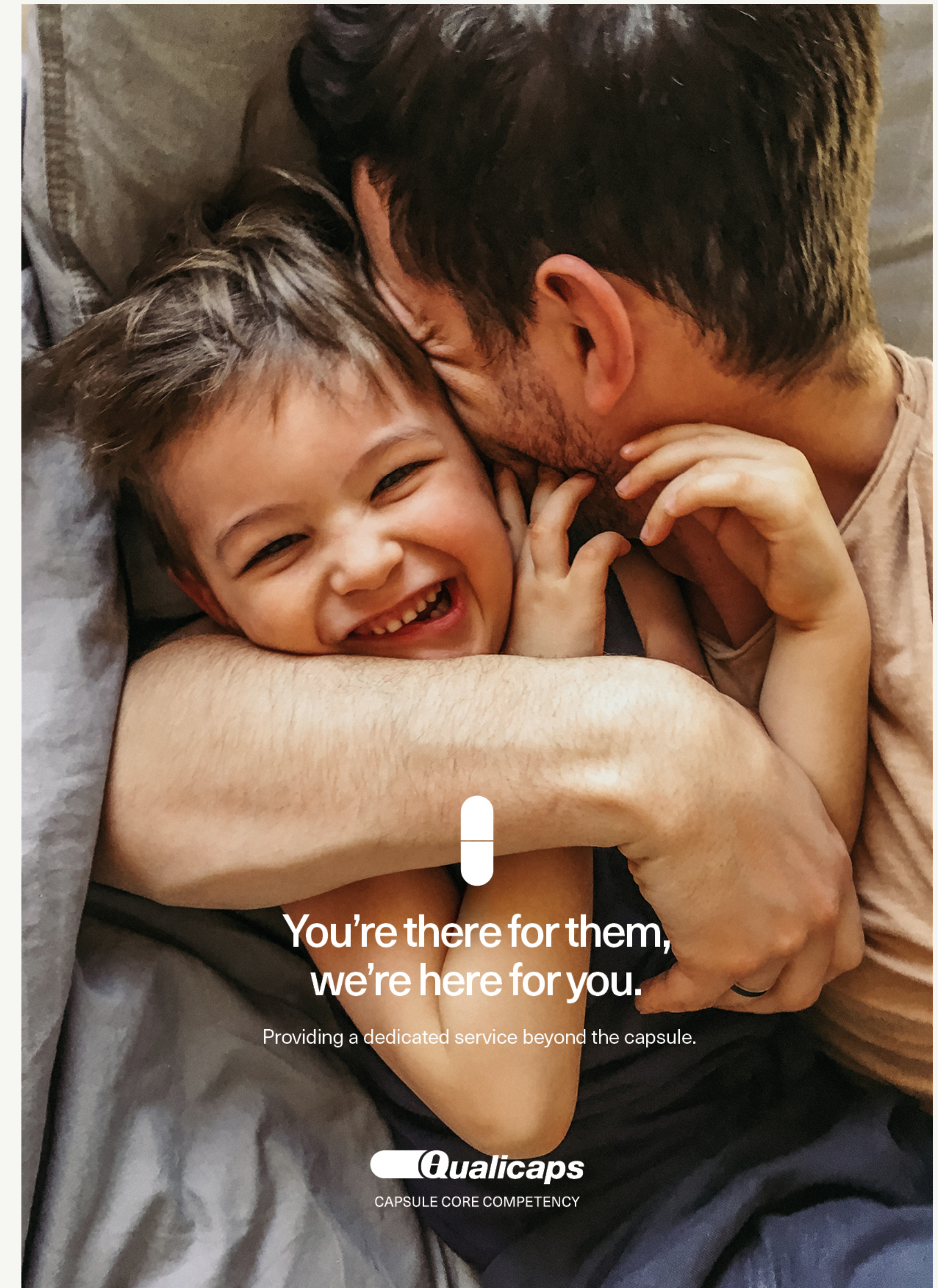


# Always striving to exceed the most challenging requirements

With a proven track record of custom capsule applications, our trained and multidisciplinary professional team is oriented to offer a solution and assist with any challenge you might encounter.

## Qualicaps® offers the possibility of developing tailor-made capsules solutions to:

- Meet **specific requirements / specifications** (weights, additional controls, etc).
- **Enhance distinctive brand images** and product differentiation (colors and print options): color-customized development service available
- **Revitalize brands** by reintroducing existing formulation in a new attractive format



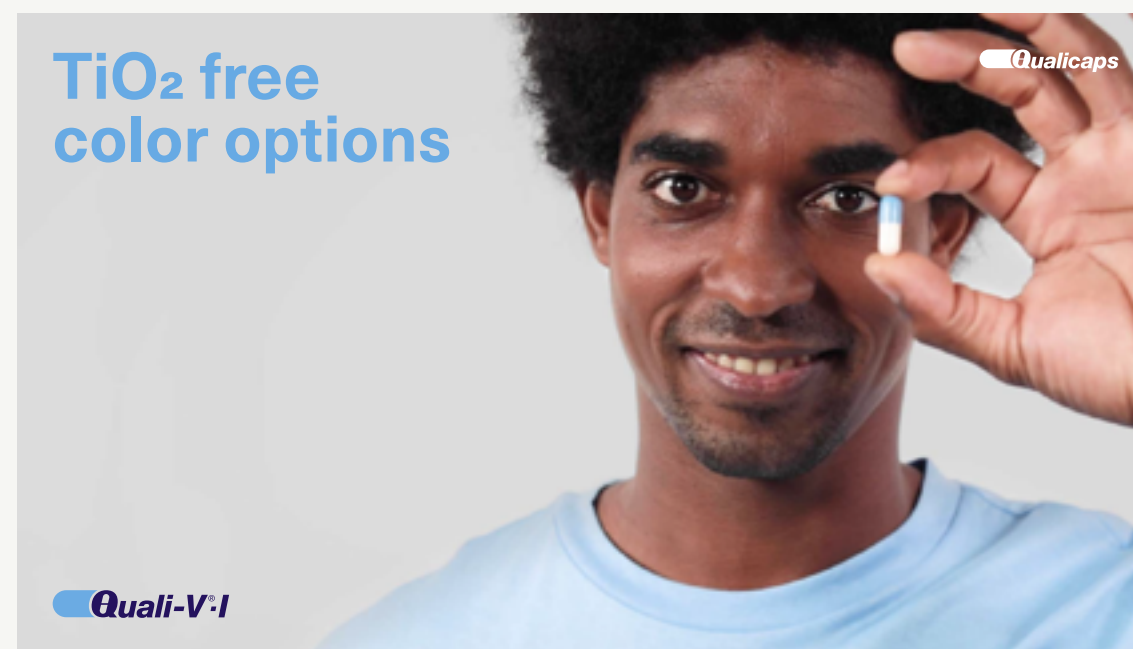


# Capsule colors

Qualicaps® capsules are available in a wide range of colors for product customization.

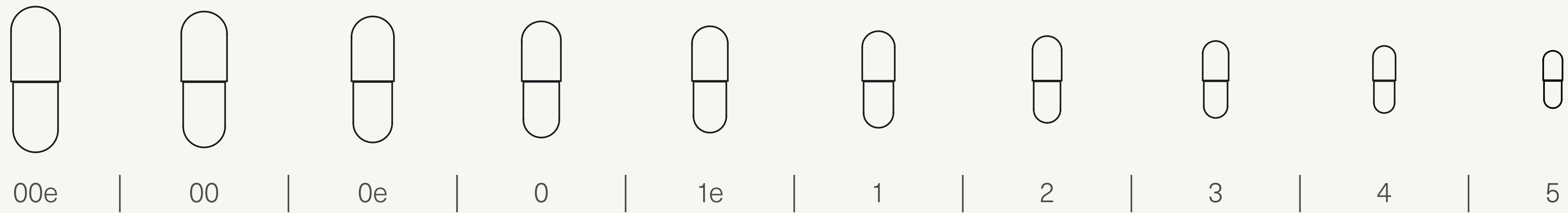
**Palletes to aid in color selection** for the marketing of products delivered in capsule form are available upon request to assist customers with the choice of colour combinations.

In addition, a **service of color-customized development** is also available (Qualicaps® manufactures capsules to customer colour specifications and can match existing formulations or colour appearances).



# Capsule sizes

Qualicaps® capsules are available in all the main sizes:







# Capsule printing


Capsule imprinting with color promotes product identity distinction and increases brand recognition, while also aiding in anti-counterfeiting measures.


Qualicaps® printing options allow for product identification by way of capsules imprinted with text such as company name, logo, product brand, ingredient information, etc.


## Capsule Print Types





AXIAL PRINT  
42°  





MAGNI PRINT  
84°  





ROTOPRINT  
300°  




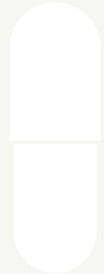
ROTOCOLOR  
300°  


## Capsule Print Inks


Qualicaps® uses only edible printing inks available in the following colors:




BLACK




WHITE




RED



BLUE



GREEN



YELLOW

Residual solvents in the ink applied to a capsule comply with limits in the ICH Q3C Guideline for Residual Solvents.



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