## **Qualicaps**

CAPSULE CORE COMPETENCY



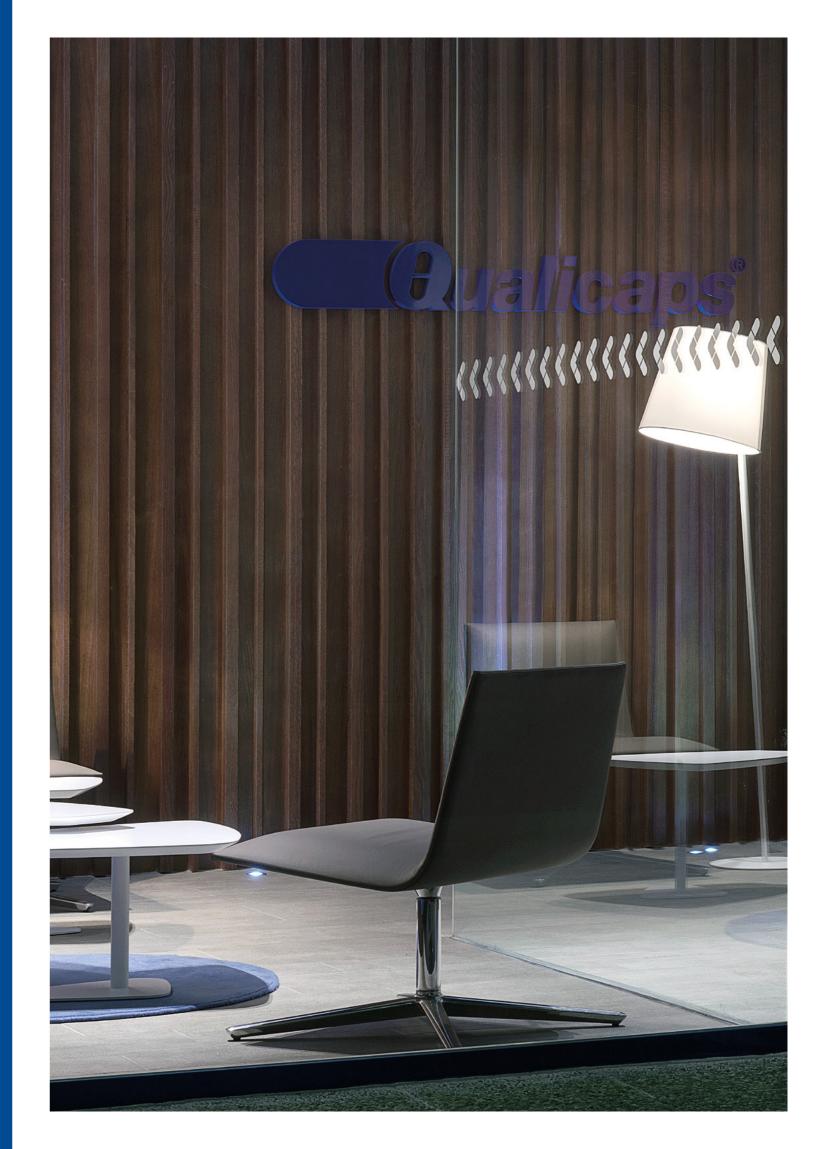
# About Qualicaps

At Qualicaps®, we do our part to contribute to health on a worldwide scale through the manufacture and supply of two-piece capsules and related equipment, offering a portfolio of:

- Pharmaceutical-grade capsules
- Capsules for Consumer Healthcare
- Pharmaceutical Processing Equipment

Qualicaps® is a wholly-owned subsidiary of Mitsubishi Chemical Holdings Corporation (MCHC) through its Life Science Institute, Inc. (LSII), which unites the Group's healthcare businesses. MCHC is a Japanese chemical, industrial and healthcare company that aims to achieve a KAITEKI society, based on the philosophy "Good Chemistry for Tomorrow". The Life Science Institute has the mission of offering the most advanced and high-quality solutions to contribute widely to people's health, through all stakeholders, in an inspiring manner.

Qualicaps® originated in 1897 within Eli Lilly & Co. as a capsule manufacturing plant in the company's headquarters in Indianapolis, USA. Our century-long heritage within the pharmaceutical industry dictates a profound understanding of the needs of our customers, for whom we have focused on delivering at high-quality standards since the very beginning.



# Qualicaps and KAITEKI Culture

KAITEKI is the foundation of the Qualicaps® corporate culture and is at the core of our strategy, our management style, and our enterprise-wide responsibility. This concept, unique to Mitsubishi Chemical Holdings Corporation companies, and the way Qualicaps® integrates it into our day-to-day business differentiates us in the healthcare world, where our customers rely on ethical business partners.

KAITEKI essentially means a sustainable condition that promotes wellbeing for individuals, society, and the Earth, transcending time and generations. Qualicaps® integrates KAITEKI into the business as a value philosophy based on the management of three strategic pillars: economy, technology, and sustainability.

Achieving KAITEKI is realized by contributing to the resolution of social and environmental issues through our products and services, and as such drives innovation.



# Capsule core competency

As a business, what we think, envision, create, is born from the capsule.



### **GLOBAL PRESENCE**

With 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. These customers have recognized our value in terms of product and service quality, collaboration in the scientific, technical and service aspects of the capsule delivery form, and flexibility to fulfill special customer needs. 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.

### LOOKING FORWARD TO THE FUTURE OF HEALTHCARE INNOVATION

## "We are pioneers, we are innovators"

Qualicaps® is responsible for several milestones in the history of hard capsule development within the pharmaceutical industry. We are a leader in being the first to design and implement features in two-piece hard capsules that are now so widely accepted and trusted, that they have since become industry standards:

- in incorporating a self-locking structure to capsules
- n applying the **Rotoprint™** imprinting techniques
- in creating a preservative-free formula in gelatin capsules
- in bringing to the pharmaceutical market a capsule of vegetal origin
- in producing a gelatin capsule for use in dry powder inhalers, then subsequently a hypromellose capsule with superior functional properties specific to inhalation
- in developing and marketing a cellulose capsule
  with an extremely low moisture content specifically
  dedicated to hygroscopic and moisture-sensitive
  pharmaceutical drugs

By way of our rich history, knowledge, capabilities, global presence, and our KAITEKI values, we are leading the way for the next-generation capsule.

Continuously collaborating with customers to meet current needs and address emerging expectations

### **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

### DELIVERING QUALITY GIVES PEACE OF MIND

Producing capsules for pharmaceutical and wellbeing purposes is about quality of life, and life itself. Qualicaps® takes pride 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

Local health authoriti
/ FDA certified

ISO 9001-1400

Manufactured in a cGMP compliant facility

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



# Partnering with Qualicaps

### PROVIDING A DEDICATED SERVICE BEYOND THE CAPSULE

Qualicaps® 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.

The Qualicaps® 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.

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.

The composition of our dedicated Account Teams enables an unparalleled service offering along the drug product life cycle, and therefore provides benefits for our customers in areas such as R&D, Marketing, Production and Quality, among others.

These AMT are multi-functional in nature, comprised of a member from each of our specialized areas of expertise:



Commercia



Customer Servic



Scientific Busines

Development



Technical Service



Regulatory Assistance

With more than 10 languages spoken, these different but complementary profiles come together to form account-focused teams with the objective of addressing specific customer needs.



# Qualicaps today

Our vision is to be the #1 preferred capsule partner to the pharmaceutical industry through high standards of quality, functionality and performance.

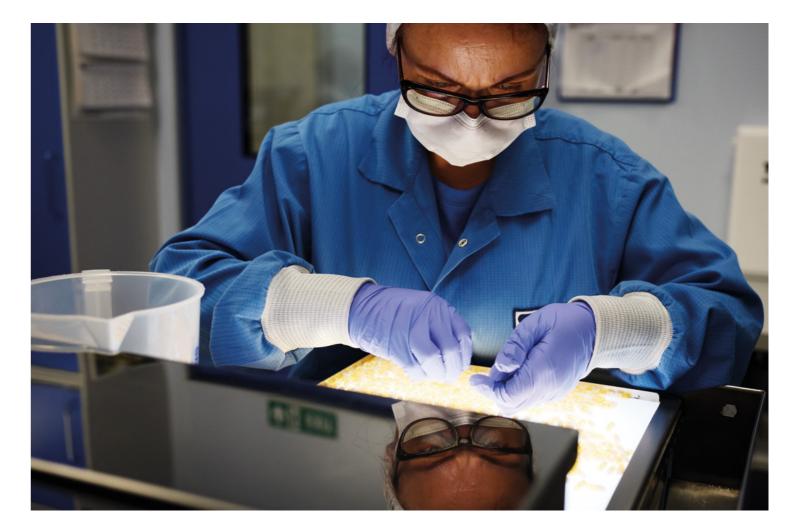
Our mission is to successfully achieve our vision through:



These four pillars of Qualicaps® drive us towards enduring, lasting value creation for all of our stakeholders, from our employees and customers, to the medical community, patients, and even society as a whole.







# Qualicaps product portfolio

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 auto-administer, 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

Qualicaps® manufactures capsules for a wide range of formulation types ranging from dry powders and pellets to pastes and liquids. We produce high-quality pharmaceutical-grade capsules, and offer them in a wide range of sizes, colors and printing options for your product to stand out in the market.

### **QUALICAPS® CONSUMER HEALTH CAPSULES PORTFOLIO**

Qualicaps® capsules for consumer health are engineered from the environment, carved from its elements, to represent the best of 'nature+science' in shaping the state of wellbeing.

As one of the principal suppliers to the pharmaceutical industry, Qualicaps® has applied its knowledge and customer approach in developing a high-quality product portfolio of capsules directed to the neutraceutical sector. More information can be found at www.qualicaps.com.

### CAPSULE COLORS

**GN**utra'V

**GN**utra'V

**EN**utra'G

Qualicaps® capsules are available in a wide range of colors for product customization. The standard warehouse-available offer consists of the following options:







Green





Clear

### CAPSULE SIZES

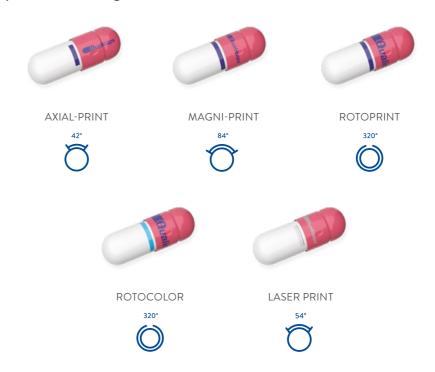
Qualicaps® capsules are available in all the main sizes:



<sup>\*</sup>Standard warehouse-available offer

### CAPSULE PRINTING

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

Qualicaps<sup>®</sup> uses only edible printing inks available in the following colors:



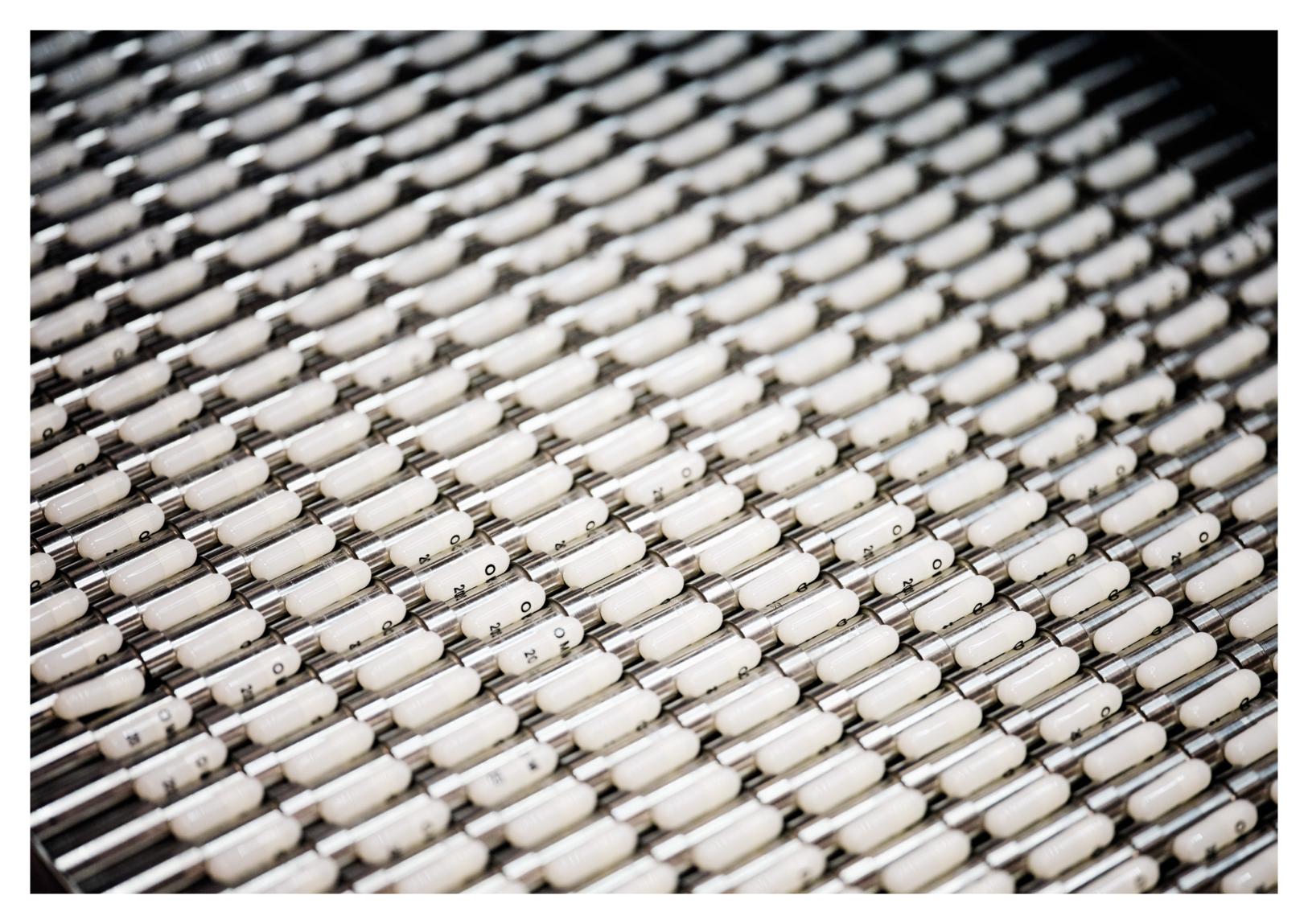
Qualicaps® also offers TiO<sub>2</sub>-free capsules upon request.



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Note: Residual solvents in the ink applied to a capsule comply with limits in

the ICH Q3C Guideline for Residual Solvents.



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