

Qualicaps



Qualicaps Co., Ltd

321-5, Ikezawacho, Yamatokoriyama, Nara Prefecture Tel: 0743-57-8920 Fax: 0743-56-5113

QUALICAPS, CO., LTD.

321-5 lkezawacho Yamatokoriyama Nara, 639-1032 Japan Tel: +81 743 57 8920 Fax: +81 743 56 5113 www.qualicaps.co.jp

QUALICAPS EUROPE, S.A.U.Avenida Monte Valdelatas, 4

28108 Alcobendas Spain Tel: +34 91 663 08 00 Fax: +34 91 663 08 30 e-mail: contact@qualicaps.es

QUALICAPS, INC.

6505 Franz Warner Parkway Whitsett, NC 27377-9215 USA Tel: +1 336 449 3900 Fax: +1 336 449 3333 e-mail: info@qualicaps.com

Genix Indústria Farmacêutica Ltda.

V.P. 1E, Quadra 3 Módulos 1 e 2 – DAIA Anápolis – Goiás – Brasil Brasil CEP: 75132-040 Tel: +55 62 4014 9000 e-mail: Sales@genix.ind.br

Mission

Qualicaps Delivers Satisfaction to Partners, People, and the Planet through Creativity



Our 3 visions

A World that Brims
with
Innovative Qualicaps Products





A Global Company from Nara, Committed to National Treasure-Class Technology





Smiling Employees Who Boast "Our Company is Awesome"





Quality & Innovation

Reliable Quality and Innovative Value Creation.

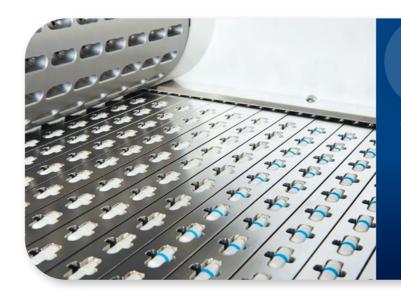
As we are in the business of life and health, it is only natural for us to pursue "quality" in our products.

However, our concept of "quality" does not only refer to our products.

We consider "quality" to be integral to everything we do as a company, including development and manufacturing, our global network, and above all, the efforts and attitude of each and every employee.

With quality as our focus, we aim to be a company that continues to create new value with social significance.





01

Expertise in Capsules and Pharmaceutical Equipment

Our hard capsules are manufactured with the reliable technology we have cultivated since our founding. Our pharmaceutical equipment supports integrated production lines for capsules and tablets, and provides comprehensive solutions for the design of the entire production line and GMP compliance.

As experts in capsule and pharmaceutical equipment, we will continue to pursue and provide high quality products.

02

Global Network

The Qualicaps Group has manufacturing and sales sites in Japan, Europe, North America, and South America, which ensures a reliable global network that can cover each other in case of emergencies, while monitoring the safety of people around the world from a global perspective.





03

Quality and Development Capability

In response to demands for higher quality, we are constantly promoting improvements in quality and service that accurately meet customer needs throughout the process from receiving raw materials to production, process control, and product shipment. In addition, we are actively engaged in the research, development, and manufacture of capsules with future functionality, as well as pharmaceutical equipment that leverages our expertise in the manufacture of solid dosage forms.

GMP

Commitment to Environmental Preservation and Quality.

Aiming to be an Environment and People-Friendly Company

Qualicaps is located almost in the center of the Nara basin, home to many cultural assets and historical sites, including Horyuji Temple, the first place in Japan to be registered as a World Heritage Site.

We are deeply aware that our company is also a member of society. Qualicaps should be a company that is kind to the environment and people by developing business activities that are conscious of the conservation of the natural environment, the prevention of pollution, and the safety of people. To that end, we have formulated a "Qualicaps Environmental Policy" and promote continuous improvement activities in an environmental management system in accordance with our mission and with the participation of all our employees.

Quality First

In order to supply high quality products that satisfy our users, we are committed to Quality First in all processes from development, manufacturing, quality assurance, shipping, and transportation, and have established the "Qualicaps Quality Policy" to promote continuous improvement activities under a quality management system in which all employees participate.



Focus on GMP Quality Control Leads to Improved Quality.

Although hard capsules for pharmaceuticals are not subject to GMP regulations for soft capsules, we manufacture them in a pharmaceutical GMP-compliant plant that meets the strictest standards for controlling microorganisms and preventing contamination. In the health food sector, we have obtained GMP certification from the Japan Institute for Health Food Standards (JIHFS) in compliance with the health food GMP guidelines of the Ministry of Health, Labor and Welfare.

As a company in the life-related industry sector, we are always highly conscious of quality and promote manufacturing and quality control in accordance with GMP guidelines to provide products that our customers can use with confidence.



Sales & Marketing

Collaboration on Capsules and Equipment to Accurately Identify Customer Needs.

Our hard capsules are manufactured with the reliable technology we have cultivated since our founding, and with pharmaceutical-related equipment that utilizes this know-how. We believe that our strength lies in our ability to support our customers' product manufacturing through this collaboration.

Through customer feedback and market research, we accurately identify their needs and collaborate with their R&D and manufacturing divisions to develop next-generation capsules and equipment for our users.

In addition, our sales staff provide appropriate information and our CTS (Customer Technical Service) department has built a support system for product development and manufacturing to provide services that are closely aligned with our customers.



Demonstration Room at Head Office

We conduct filling tests and other demonstrations in response to customer requests.

Exhibitions in Japan

We exhibit at Interphex Japan and other health food trade shows to access key opportunities for negotiations with customers.



The Field is Becoming Global. Making Advances in High-profile Overseas Markets.

As globalization advances in the pharmaceutical and health food sectors, globally-oriented companies are opening offices around the world.

With our business base in Nara, we at Qualicaps have primarily focused on domestic customers, but in order to promptly respond to inquiries from our customers across the globe, we work with our group companies in Europe and the United States to deliver our world-leading products, technologies, and services.



Overseas Exhibitions

Our group members participate in international exhibitions held in the United States and Europe.

*Capsule Production Process

Advanced Technology and Reliable Quality.





Acceptance tests ensure that raw materials such as gelatin, HPMC, and coloring agents conform to specifications.



02 Weighing and Dissolving Raw Materials

Weighed raw materials are added to the dissolution tank and dissolved in purified water.



03 Gel Preparation

Dyes and other additives are added to the gelatin or HPMC gel to adjust the color, concentration, and viscosity as required.



Capsule Molding 1 Gel is added to the capsule manufacturing

Gel is added to the capsule manufacturing machine, and the gel is evenly adhered to the molding pins and dried.



05 Capsule Molding 2

The capsules are withdrawn from the molding pins, cut to the correct dimensions, and caps and bodies are temporarily joined.



06 100% Visual Inspection

All capsules are visually inspected by automatic inspection equipment immediately after molding.



607 Imprinting

Capsule printers allow us to print to our customers' specifications.



08 Inspection and Counting

Capsules are inspected and counted using dedicated inspection equipment.



09

Packaging

Capsules are packed in labeled containers for shipping.



10

Shipping Tests

Sampled capsules are tested according to specified methods to assure the quality of



Shipping - Delivery

Products that have passed the shipping test are delivered safely and hygienically to customers.





Rigorous Inspection and Testing

Qualicaps conducts the following rigorous tests and inspections to deliver safe, reliable, and high-quality products: "raw material acceptance tests," "100% visual inspection," "inspection and counting," and "shipping tests."



Service System for Post-delivery Peace of Mind

Qualicaps has extensive experience and achievements in capsules, including the manufacturing of capsules, and the manufacturing of capsule filling equpment and other pharmaceutical equipment.

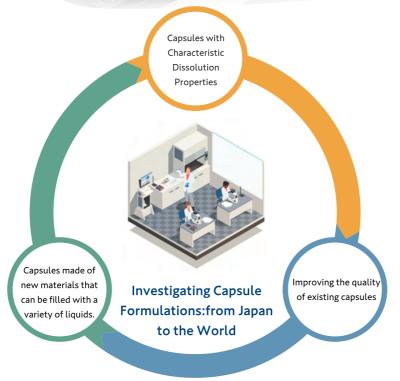
Our experienced staff will respond positively to customer requests and inquiries on both capsules and equipment.

*Capsule research and development

Delivering Capsules from Nara to the World.

In accordance with the needs of our customers, our R&D Department is working to improve the quality of our existing capsules and to develop functional capsules for the next generation.

We are always at the forefront of R&D activities through close connections with Japanese and international pharmaceutical designers and extensive joint research with government and academia. Through our global network, we gather the latest intelligence on pharmaceuticals and health foods in Asia (including Japan), the United States, and Europe, and reflect this information in the development of new capsules to meet diverse needs. In addition to providing useful information for the development of capsule products, we are also actively involved in supporting pharmaceutical development.



Research & Development

Design of Capsule Formulations with World-leading Focus.

In capsule development, we use raw materials that can be used for pharmaceuticals and foods to design capsules that dissolve at specific sites in the body and capsules that can be filled with a variety of liquids.

To meet the needs of our customers, we are also using a range of scientific approaches to improve the quality of our existing capsules in terms of solubility, mechanical properties, and other qualities.

Example of capsule dissolution behavior











Capsule quality assurance

Advanced Technology and Reliable Quality.



With the aim of "contributing to the improvement of people's health", we are constantly working to improve quality and services that accurately meet customer needs.

Reliable Quality

Our capsules for health food are GMP-certified by the Japan Institute for Health Food Standards (JIHFS). We provide high quality products by utilizing the technology we have cultivated for pharmaceutical capsules.

Regulatory Support

We manufacture and sell capsules for pharmaceuticals and health foods in compliance their individual quality standards.





Improved productivity and higher quality products for our customers

Follow-up Service

Qualicaps not only provides our customers with the best products, but also offers feedback that leads to quality improvement in accordance with requests and inquiries, thereby contributing to the development of better products.

*Equipment manufacturing

Comprehensive Solutions for Integrated Production Lines.

Qualicaps' pharmaceutical equipment is designed for integrated capsule and tablet production lines and provides comprehensive solutions for overall production line design and GMP compliance.

We have developed fully automatic capsule filling machines, band sealing machines, as well as laser, inkjet, and offset printers, which have been patented in major countries and are widely available overseas.

Qualicaps' formulation equipment has advantages such as "multi-functionality and high functionality," "ease of use," "high accuracy," and "GMP compatibility."

Even more noteworthy, we can play a turnkey role in the development and commercialization of products based on special technologies in response to customer requests.





CO2 Laser Marking Equipment

QUALIS-Lite CO2

CO2 laser marking system for soft capsules. Capable of high-precision printing tailored to capsule orientation and applicable to a variety of capsule shapes.



Fully Automatic Capsule Filling Equipment

F-150\F-100\F-80\F-40\JCF\F-5\F-Labo

Fully automatic capsule filling equipment for filling powder, granules, tablets, liquids, etc. into hard capsules.



Non-contact Marking Equipment

LIS-250D、IMS-300D、QUALIS、CIMS

Non-contact type printers. Print designs are created using CAD or image data, eliminating the need for design rolls.



Integrated Equipment for Capsule Appearance Inspection and Weight Inspection

Qwv

Capsule visual inspection and weight inspection functions integrated in a single unit.

Compact chassis for saving space.



Fully Automatic Capsule Sealing Machine

S-125、S-15

Seals the joint between the cap and body of hard capsules, contributing to product stability and tamper evidence.



Offset Printer

IS-500\IS-500D\QI-300\QI-300D

Offset printer for tablets (sugar-coated, film-coated, and irregularly shaped tablets) and soft capsules.

Features high rate of tablet supply and high speed processing.



Appearance Inspection Equipment

ACROCIA、VIM+T、CES-150、CES-100、CES-50

Equipment to inspect the appearance of tablets and capsules.



Weight Inspection Equipment CWI-60、CWI-125、CWI-150、MWI

Equipment for checking the weights of tablets and capsules.

Equipment development

The Needs of Our Users are Paramount... "Customers First" is Our Policy.



Leveraging our expertise in the production of solid dosage forms, we are actively engaged in the research, development, and production of pharmaceutical equipment. Our policy is to put the needs of our users first. We aim to customize our products as much as possible. In collaboration with our Sales Division, we closely monitor the needs of our users and are always ahead of the curve in research and development to meet those needs. Research and development from the user's perspective is Qualicaps' strength in being able to offer custom-made products.



Drawings are created and products are brushed up with 3D CAD.



We strive for higher quality development through repeated prototyping, investigation, measurement, and evaluation.

Equipment quality assurance

An Unwavering Relationship of Trust with Users is Born from Strict Quality Control.

The quality assurance of our pharmaceutical equipment is implemented under strict control. Parts are inspected to ensure that they have been machined according to design. For critical parts, dimensional measurements are recorded and material certificates are secured at the same time. We assemble the equipment using parts that have passed acceptance inspection and verify that the machine operates according to URS specifications. We then conduct factory acceptance tests in the presence of the user, and upon agreement between our two companies, determine the schedule for shipment and installation at the local factory.



Design Qualification

We verify that the hardware and software that make up the system meet the performance, functionality, and other requirements described in the specifications.



Factory Acceptance Testing

With the customer present, we verify that the performance and functions are as indicated on the relevant specification sheets, and the hardware and software that make up the system are operated under simulated usage conditions.



Site Acceptance Testing

After the system has been delivered to and installed at the customer's site, we verify that the system can reproduce its performance and functions, and offer technical support for IQ and OQ.

Company overview

Company Name

Qualicaps Co., Ltd.

Head Office

321-5, Ikezawacho, Yamatokoriyama, Nara Prefecture

Capital

1,000,000,000 JPY

Founded

April 26, 1965

Representative Director

Seiichiro Matsumura, Representative

Director and President

(Group CEO/ Head of Japan Operations)

Business Operations

Manufacture and sale of hard gelatin capsules and

HPMC capsules Manufacture and sale of pharmaceutical-related equipment such as tablet

printers and inspection machines



Head Office

321-5, Ikezawacho, Yamatokoriyama, Nara Prefecture

Main Contact

Tel: 0743-56-0651 Fax: 0743-56-6666



Imago Equipment Business Center

Tel: 0743-83-1390 Fax: 0743-83-1391



5F Keihanna Plaza Labo Bldg.

Kvoto, Japan

Tel: 0774-93-3032 Fax: 0774-93-3033



387-1 Imagocho, Yamatokoriyama,

Keihanna R&D Center

1-7, Hikaridai, Seika-cho, Soraku-gun,



Nara Prefecture





Business Center Contact



1998

capsule products" and ISO9001 for "capsule visual inspection machines."

2001

Obtained ISO14001 certification for environmental management system.

1997

Obtained ISO9002 certification for quality system related to "manufacture and marketing of Japanese Pharmacopoeia capsules." Change of company name from "Japan Elanco Co., Ltd." to "Shionogi Qualicaps Co., Ltd." Obtained ISO9001 certification for quality system standards for "the design, installation, and servicing of capsule visual inspection machines."

1996

Completed review of GMP structural facilities and equipment.

Completed construction of Nara Factory Building No. 2, equipped with a filling room for investigational new drugs, and the head office functions were relocated from Osaka to Nara Factory Building No.2.

1993

Production of health food capsules begins.

1990 1966

Hard capsule composed of hydroxypropyl methylcellulose (HPMC) was developed.

1965

Nara Factory (Building No. 1) completed at the current location in the Showa Industrial Park in Yamatokoriyama City. Approvals were obtained for the manufacturing, importation and sale, and general sale of pharmaceuticals.

Japan Elanco Company Ltd." established as a 50:50 joint venture between Shionogi & Co. and Eli Lilly & Co.



Since our establishment in 1965, we have

for pharmaceuticals and health foods, as

well as pharmaceutical equipment, with a

commitment to quality first and foremost,

and have supplied these products

developed and manufactured hard capsules

2018

Completed construction of new capsule manufacturing building (Building No. 7)

Production Division

transferred to Imago

Fauipment Business

Extended ISO9001 certification to all equipment models.

2020

Qualicaps acquired Genix Industria Farmaceutica Ltda. (Brazil)

2013

Change in stockholder from The Carlyle Group to Mitsubishi Chemical Holdings Corporation as a result

Completed construction of new capsule manufacturing building (Building No. 6).

2017

2008

2012

Qualicaps Romania S.R.L. (Romania) established.

2015

2007

2005

worldwide.

2003

Change in stockholder from Shionogi & Co., Ltd. to The Carlyle Group as a result of stock transfer. Company name changed from "Shionogi Qualicaps Co., Ltd." to "Qualicaps Co., Ltd." New capsule manufacturing building was completed (Building No. 5). Obtained JIHFS health food raw materials GMP certification for health food capsules.

Obtained ISO9001 quality system certification, integrating ISO9002 for

History

