

Lonza Capsugel®

**The Right Partner for Your Next Drug
Development Project**

March 12, 2020

Presenters



Mary Ellen Johnson

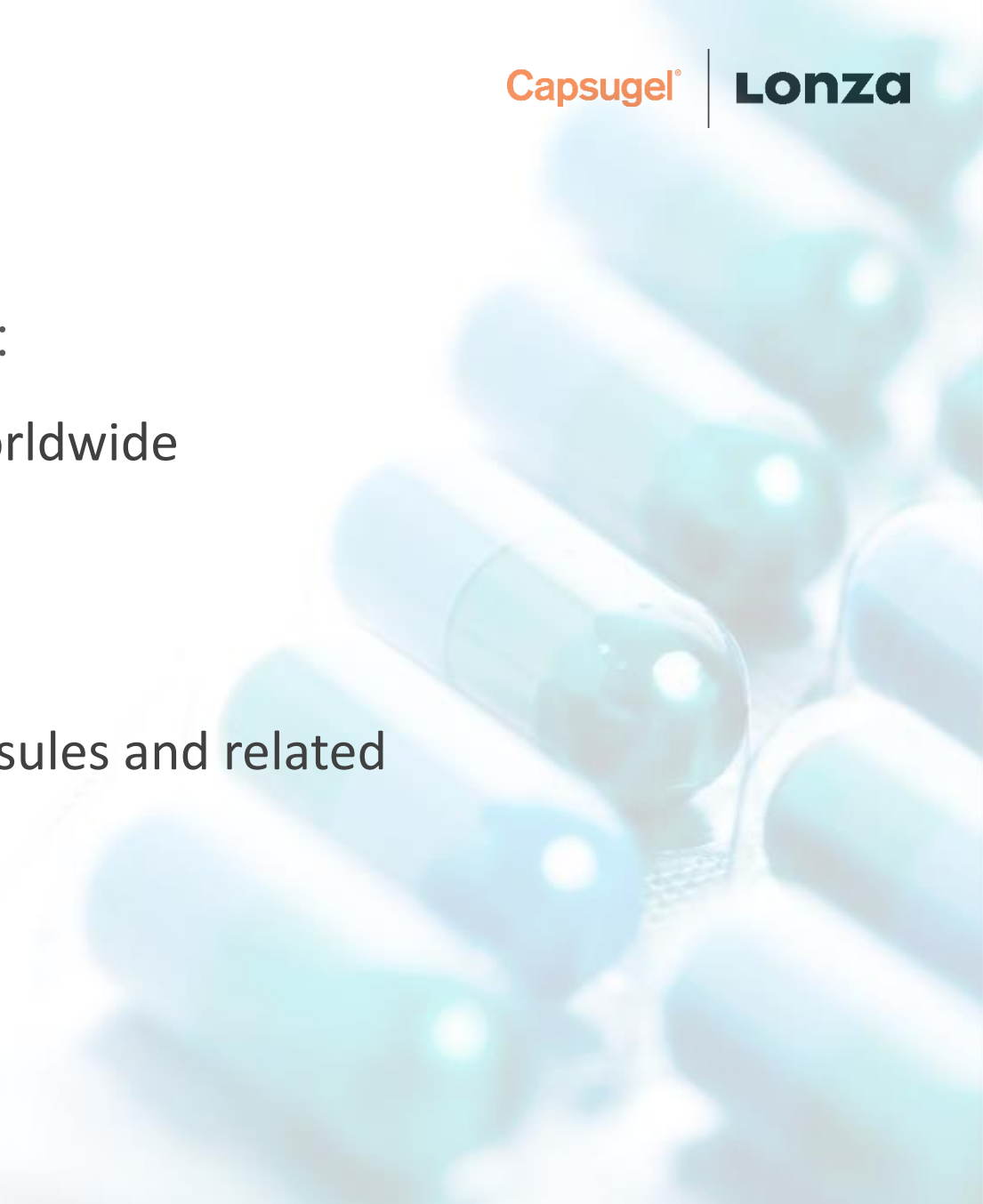


Julien Lamps

About Us

We are a global business unit within Lonza that:

- Produces over **210 billion capsule** units worldwide
- in **8** global production sites
- to serve over **2000** pharma customers
- with a **broad portfolio** of gelatin and HPMC capsules and related services
- that proudly offers **Capsugel® products**



Our Promise



High-quality excipients and formulations for the medicines of tomorrow.



Regulatory, compliance & technical expertise and assistance



Tailor-made formulations to meet all new market needs



A globally integrated supply chain



A global quality organization



Broad suite of offerings across formulation development, clinical trials and commercial manufacturing



Unique combination of science, engineering, formulation and capsule expertise to optimize the bioavailability, targeted delivery and overall performance of customers' products.

Capsugel

LONZA



We Are Everywhere You Need Us To Be

A Truly Global Footprint

Capsugel® | **LONZA**



Manufacturing sites ○

Corporate R&D ○

Sales & Business Development ○

Focus on Patient Centricity



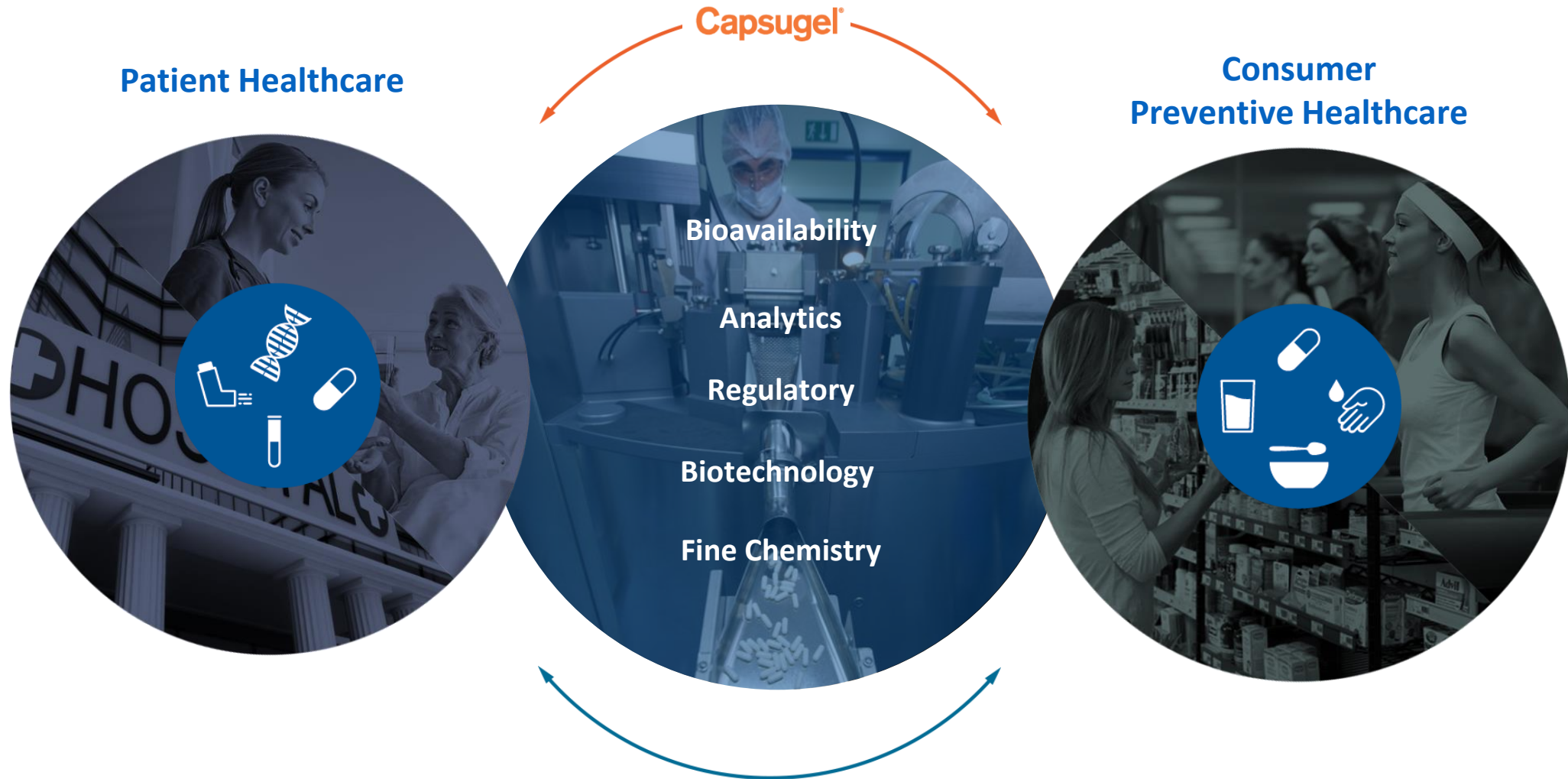
Attention to medication compliance and advancements in digital technologies add to the ever-changing healthcare landscape. We are meeting today's and tomorrow's patients' needs through:

- ✓ **An integrated approach to products and services along the entire value chain of design, development and manufacturing for biologics and for small molecules**
- ✓ **Cutting-edge delivery solutions and dosage forms**
- ✓ **A wide spectrum of drug substance and drug formulation services**
- ✓ **New technology platforms for patient compliance and drug efficacy monitoring**

Lonza Capsugel® - At the Intersection of Patient Health

Capsugel®

Lonza



Capsule Product Portfolio



The Capsule Advantage



Growing number of new entities cannot be tableted



Fewer excipients are required in capsules



Combo products are under investigation

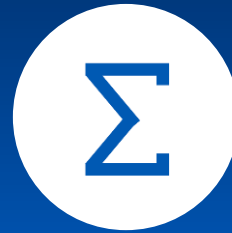
Capsugel Pharmaceutical Portfolio

Solutions to Bring Products to Market Faster

With a diverse portfolio including HPMC, liquid-filled hard capsules, or specialized capsules for clinical applications, we are a global leader in capsule development and manufacturing, bringing unmatched products and technical support to our worldwide customer base.



**Quality &
Compliance**



**Six Sigma
Principles**






**Capsugel®
product portfolio**

Early Stage to Commercial Solutions



Addressing Customers' Needs for...

	Product Performance	Delivery Solutions	Consumer Experience
Hard Capsules 	Hard gelatin HPMC Encapsulation	Modified release Protection for acid-sensitive ingredients	Easy to swallow Halal, Kosher certified Vegetarian/ Vegan
End to End Solutions 	Inhalation Fast absorption	Multi-function for combo products	Enrobing gelcaps Liquid filled
Technology & Solutions 	Enhanced bioavailability Product stability- shelf life Sealing & Anti-counterfeiting	Multi-particulates	Reflux reduction Taste masking Odor masking

Capsugel® Pharmaceutical Product Suite



CONI-SNAP® HARD GELATIN CAPSULES

The reliable and outstanding performance of Coni-Snap® hard gelatin capsules has made them a product of choice for biopharmaceutical companies since their unique locking closure was introduced. Designed and engineered to perform, they are a reliable and widely used capsule.



CONI-SNAP® SPRINKLE CAPSULES

Designed to be easily opened by patients and caregivers, these capsules are ideal for pediatric and geriatric populations. Available in gelatin and HPMC.



VCAPS® PLUS CAPSULES

An immediate-release HPMC capsule, without gelling agents. Vcaps® Plus capsules offer excellent dissolution profile with pH-independent performance, standard or low-moisture content, great machinability and visual quality.



VCAPS® ENTERIC CAPSULES

Capsule technology that simplifies enteric drug delivery implementation. It offers an enteric-release profile to the upper gastro-intestinal tract that meets the disintegration requirements for delayed-release capsules from the European, US and Japanese Pharmacopoeia. The pharmaceutical grades of cellulosic derivatives used in Vcaps® Enteric capsules have extensive market precedence for use in providing enteric protection.



COLORISTA® CAPSULES

An optimized tool for formulation development enabling compatibility studies before deciding on the final color for the commercial drug products. Available in gelatin and HPMC.

Capsugel® Pharmaceutical Product Suite



CAPSUGEL® ZEPHYR™

DRY-POWDER INHALATION CAPSULES

Custom inner surface properties, customized moisture levels and more stringent microbial limits all designed to optimize inhalant end-product performance. Available in gelatin, gelatin-PEG, Capsugel® Vcaps® and Capsugel® Vcaps® Plus.



DBCAPS® CAPSULES

DBCaps® capsules were developed with a tamper-evident design to specifically address the clinical trial challenges of testing without bias. The wider diameter of opaque DBcaps® allows containment and blinding of large-diameter or uniquely-shaped tablets or other comparator products, while their shorter length makes them easier to swallow.



PCCAPS® CAPSULES

PCcaps® provide a simple way for pre-clinical oral administration of pharmaceutical actives and formulations to rodents. These small gelatin capsules have been designed for performing pre-clinical trials such as pharmacokinetic, pharmacodynamic and animal safety studies.



PRESS-FIT®/XPRESS-FIT® GELCAPS

Press-Fit® and Xpress-Fit® Gelcaps utilize a Capsugel® technology that is difficult to mimic and enables brands to create a new product look without having to reformulate their product. Flexible gelcaps are stretched around a caplet of specified shape and dimension using a patented cold-shrink process.



LICAPS® LIQUID-FILLED HARD CAPSULES

Licaps® two-piece capsules are an advanced dosage form for liquid, semi-solid, paste and multi-particulate applications. This unique and elegant dosage form has a proven track record for addressing complex formulation challenges and improving/re-positioning existing formulations. Available in gelatin and HPMC.



VCAPS® GEN C CAPSULES

Vcaps® Gen C is a high-quality capsules based on a carrageenan gelling agent formulation. It offers a good dissolution profile with no discernible lag time, great machinability and visual quality.

What is Capsugel[®] Vcaps[®] Plus?



**Immediate release HPMC capsule
without gelling agents**



**Wide storage range with less chance
of brittleness and breakage**



**Solid functionality and
performance**



**Broad cultural and religious
acceptance**

Capsugel[®]

LONZA



What is Capsugel® Vcaps® Plus?

YES

- ✓ Gelatin-like Dissolution
- ✓ Low Moisture Sensitivity
- ✓ Immediate Release



NO

- ✗ Gelling Agents
- ✗ Animal Origin
- ✗ Cross-linking

Capsugel® Zephyr™

*Dry-Powder Inhalation
Capsule Portfolio*

Flexibility



Performance



Dosage



Range



Capsugel® Zephyr™ DPI Portfolio



Vcaps® DPI

The superior HPMC performer with very low powder retention



Vcaps® Plus DPI

The glossy and transparent HPMC capsule with consistent performance



Coni-Snap® Gelatin DPI

The cost-effective solution for less-challenging formulations



Coni-Snap® Gelatin-PEG DPI

The more robust gelatin-based solution



We Are More Than
Just Capsules...

Supporting You, Every Step of the Way Beyond the Capsule™ ...

Capsugel® | Lonza



A global quality organization



An integrated supply chain



Regulatory & color lab support

Incoming QC Optimization



- Enhanced rep samples
- Reduced testing support
- End-to-end testing optimization

Custom Warehousing



- Integrated VMI warehouse solution
- Strategic custom stock programs
- Enable supply chain efficiencies
- Extensive distribution network

Technical Service

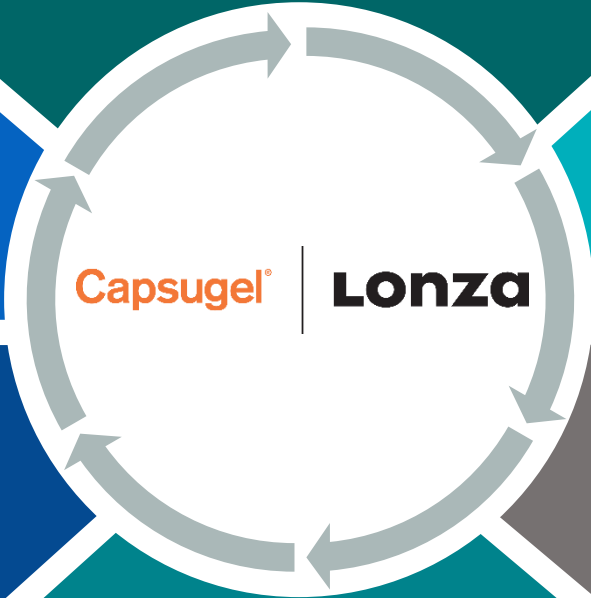


- End-to-end capsule filling support
- Manufacturing optimization
- Industry best practice knowledge base
- Engineering support
- Formulate-to-Perform expertise

Customer Service



- Streamlined B2B experience
- Vendor Managed Inventory
- Responsive lead times
- Electronic Data Interchange Capabilities



Packaging Solutions



- Fiber free packaging
- Protective packaging for improved stability
- Thermal over wrap

Product Development



- Build and strengthen customers' brands
- Design for commercial & operational success
- Regulatory and market expertise



R&D Capsule Supplies

Common R&D Challenges



Shorten
development
timing



Grow
the
pipeline



Solve
formulation
challenges

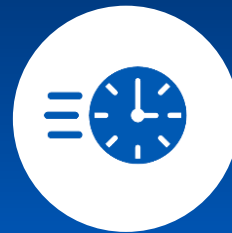


R&D Capsule Supplies

Products take a long route from discovery to final dosage form, one that can take costly steps backwards without the right products and consulting along the way. We can provide solutions for faster research and development during all stages of the R&D process. Our full technical support and assistance help ensure rapid development and timely delivery.



**Capsule
Selection**



**Fast
Turnaround**



**Pre-Developed
Print Roll**

R&D Capsule Supply Options

Capsugel® | **Lonza**



CapsuleCaddy™

Perfect size for clinical trial batches, R&D projects, or small manufacturing runs.



R&D Bottles

If you require a fast off-the-shelf solution for your R&D project, our R&D sample bottles are an excellent option.

Powder Micro-Dosing

Micro-dosing is the process of dispensing a precise amount of drug substance into a capsule (or other container, e.g. vial or bottle), for use in early phase human studies (phase I safety evaluations).



Cost effective



Simplifies testing

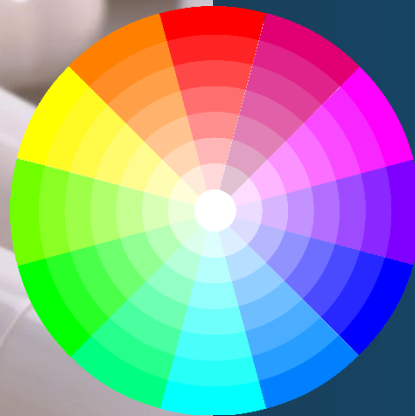


Streamlines product development



Reduces waste





Importance of Color in Product Development

Importance of Color in Drug Development



Identity

Protection

Compliance

What is Capsugel® Colorista®

All the colors you need, in one capsule



A single solution for early stage development support and compatibility testing



A great solution for stability testing



Cuts development time



Enables testing on pre-commercial products

Capsugel® | **Lonza**



160 extractable colors in gelatin
50 extractable colors in HPMC
Sizes **0-4** available

Colorista® Color Formulation Guide



Helps identify preferred colors to guide the color development process.

- ➔ ① **V18.922** ② Pantone: 354C
- ③ Description: Green Op
- ④ Colorants: TiO2, B1, Y5, Y6
- ⑤ RX EU¹ RX US² RX JP

- ① Capsugel® reference
- ② Pantone reference
- ③ Color name
- ④ Colorants (see formulation key below)
- ⑤ RX EU RX US RX JP

All the colorants in this formulation are allowed.

Labeling and/or quantity restrictions – see notes below.





Lonza Engine™ Equipment Portfolio

What is the Lonza Engine™ Portfolio?

Lonza Engine™ offers state-of-the-art equipment designed to address the needs of customers throughout the entire drug development process including:



Liquid Filling
& Sealing



Automatic Capsule
Filling Machine

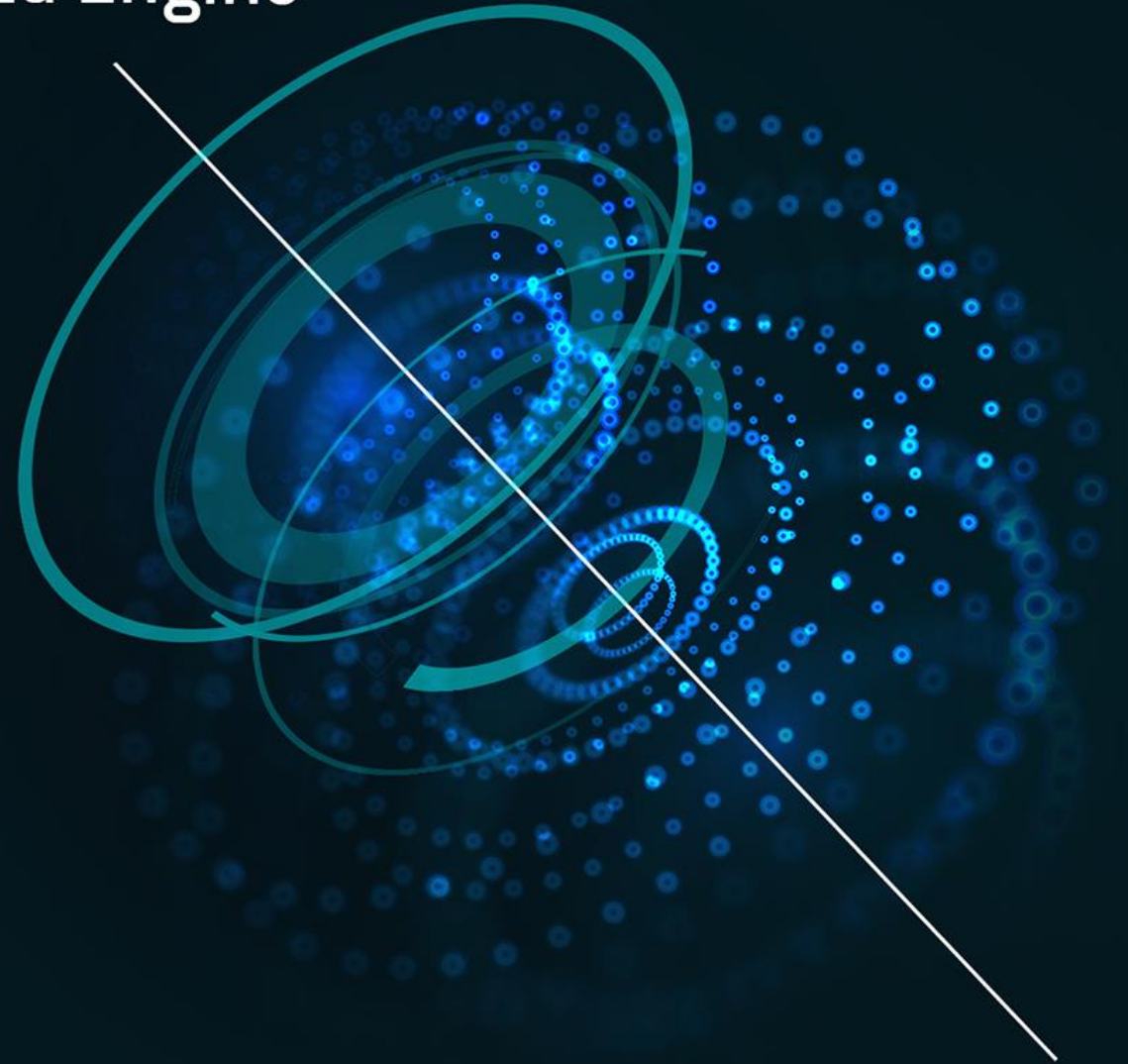


Micronization



Micro-dosing

Lonza Engine™



*Accelerate
Innovation*

In a nutshell...

What to remember about the Lonza Engine™ Portfolio

State-of-the-art Equipment

- Proven track record
- Easy to operate
- Flexible systems
- Proprietary technology

Peace of mind

- Contract services available
- Can outsource the extra needs to us in a very fast and easy way

Speed Drug Development

- Full range of equipment that enables the speeding up of drug development
- Allows you to overcome your bioavailability challenges

Outstanding technical service

- Global customer service and technical support
- Maintenance contract available



Technical Service Team

Tech Service Engineers

*Improving efficiency
and enabling growth*



Operational Excellence Guidance



Guidance Workshops



Targeted Support

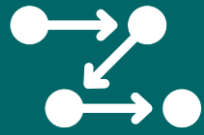


Measure Success



Formulation Support and Optimization

Formulate for success training and consultation using Quality by Design techniques



Equipment Optimization

Equipment and workflow consultation



Capsule Portfolio

The Capsugel® capsule portfolio offers a broad range of options for your development needs, with a proven record of performance

Manufacturing Efficiency

A multi-faceted approach



Industry-Leading Practices

Capsule Filling Machine (CFM) Optimization, Targeted CFM Innovations, and Performance Improvement Projects



Guidance Workshops

How-to training focused on set-up, operation, and troubleshooting in the manufacturing environment



Technical Support

Fast and responsive, both on-site and on-call

Contact us to request your complimentary capsule samples

FILLING CAPACITIES
Inside you can find an overview of the filling capacities for every capsule size. Based on your specific product fill requirements, you can choose the capsule size that suits your needs.
For more information visit www.capsugel.com or contact your local Lonza representative

Made better. By science.™

Size	000	001	002	003	004	005
Capacity (mg)	120	100	80	60	45	30
Capacity (g)	120	100	80	60	45	30

CAPSULE SIZES

Information:
01.2007.25
lonza.com@lonza.com
your Lonza representative

Capsugel LONZA
Pharma & Biotech

Made better. By science.™

The Capsugel® Capsule Sizes Sample box provides visual samples of capsule sizes 000-5.

Capsugel® Capsule Portfolio

Empty capsules

- Controlled Release
- Immediate Release
- Controlled Release
- Immediate Release

Capsugel® OTC Portfolio

Empty capsules

- Controlled Release
- Immediate Release
- Controlled Release
- Immediate Release

Made better. By science.™

Capsugel® Portfolio sample cards provide visual samples of the capsules in our portfolio.

Capsugel® Vcaps® Plus capsules

The gold standard in HPMC capsules

Immediate release capsule
HPMC capsule with no gelling agents
Perfect for hygroscopic APIs
Non-animal, vegan friendly, cultural and religious acceptance

OPEN here to get samples.
CLOSE again to keep them safe.

Made better. By science.™

Individual Capsugel® product sample cards are also available.

Want to know more?

Visit our website to learn more about the individual Capsugel® product lines and the solutions they offer to each stage of the development process.

Contact us to be put in touch with a regional representative to discuss which solution is right for your product.

www.capsugel.com

Made better. By science.™

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