KEY CONCERNS OF R&D DEPARTMENTS

- Gastro-irritative compound
- Acid-sensitive compound
- API prone to cross-linking
- Oxygen-sensitive
- Bioavailability
- Need for enteric delivery
- Low solubility
- Water-sensitive API or hygroscopic formulation
- Highly potent / Low dose
- Speed to clinic

PRODUCTS THAT ADDRESS THOSE R&D CONCERNS

**PCcaps®**
Very small hard gelatin and Vcaps® Enteric capsules that are ideal for oral delivery of the neat active in pre-clinical animal studies. They have been designed for performing pre-clinical trials such as animal safety and pharmacokinetic studies.

**Colorista®**
Single R&D solution for pharmaceutical formulation development. It allows the ability to progress with compatibility and stability testing before deciding on a color for the commercial drug product. Capsugel® Colorista® capsules are the perfect tool for pharmaceutical customers who are looking for flexible and time-efficient development of new products or generics. Available in hard gelatin Coni-Snap® and in Vcaps® Plus.

**DBcaps®**
Two-piece hard gelatin or Vcaps® Plus capsules, developed with a tamper-evident design to specifically address the challenges of double-blind clinical trials.

**Vcaps® Plus**
An immediate-release capsule for pharmaceutical products in HPMC only, 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**
Capsule technology that simplifies enteric drug delivery implementation. It offers an enteric-release profile to the upper GI tract that meets the disintegration requirements for delayed-release capsules from the European, US and Japanese Pharmacopoeia.

* Colorista® is a trademark of Lonza or its affiliates registered in US and/or EU.
**DEDICATED SOLUTIONS THAT MAKE A DIFFERENCE**

**THE DRUG PRODUCT DEVELOPMENT PROCESS**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Duration</th>
<th>Description</th>
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<tr>
<td>DISCOVERY</td>
<td>5-7 years</td>
<td>Discovery and initial research</td>
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<tr>
<td>PRE-CLINICAL</td>
<td>5-7 years</td>
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<tr>
<td>PHASE 1</td>
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<td>PHASE 3</td>
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<td>APPROVAL</td>
<td>1-2 years</td>
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</tbody>
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**DISCOVERY**

- **PCCAPS®**
  - Hard Gelatin
  - VCAPS® Enteric

**PRE-CLINICAL**

- **VCAPS® Plus**
  - Hard Gelatin

**FORMULATION & DOSAGE FORM DEVELOPMENT**

- **DBCAPS®**
  - Hard Gelatin
  - VCAPS® Plus

**COLORISTA®**

- **Hard Gelatin Coni-Snap®**
  - VCAPS® Plus

**CMC DEVELOPMENT**

- CMC development occurs incrementally

**R&D/Pilot scale production**

**Industrial scale production**

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Clinical supply for small batches with the standard Capsugel® capsule portfolio:

- R&D bottle: the right-sized sample packaging for lab trials.
- CapsuleCaddy™: the big R&D solution in a small package: the perfect size for clinical trial batches, R&D projects or small manufacturing runs.

Capsule customization capabilities to reduce time in the development process:

- Build your own capsule tool: allows for quick color selection and branding based on market segment and region to accelerate the formal color development and get an immediate ready-to-use visual image of your capsule.
- Pre-formulated colors and pre-developed print rolls: allow fast responses for tight development timelines.

Support for Quality By Design (QBD) approach:

- Identification of critical capsule parameters (size, polymer, water content, ...) to address the equation between process design, process performance & product performance.
- Supply of specific samples to support design space investigation.

Customer portal www.mycapsugel.com:

- Regular updates and technical information → Contact us to get access.
R&D EQUIPMENT
LONZA ENGINE™

Equipment range and applications:
- Manual fillers for lab bench filling
- Xcelolab®/Xcelodore® for Micro-dosing & Powder-in-Capsule (PIC) evaluations, containment option available
- Semi-automated capsule filling machine Ultra III™ for DBcaps® capsules and small batches manufacturing
- Capsule filling and sealing (CFS) machine for liquid formulations, lab scale to clinical
- Micronization and containment equipment (MC20, MC44, MC50, MC100) – Lab and Pilot lines

SUPPORT FOR YOUR R&D PROJECTS
OUR TEAMS

COMMERCIAL TEAM
Business Development and Sales representatives

R&D
Research & Development teams from our Centers of Excellence

QUALITY ASSURANCE TEAM
Regulatory Affairs department, Color Labs and Technical Service Engineers
For further information about the products:
Visit: www.capsugel.com
EMEA: solutions.emea@lonza.com / +33 389 205 725
AMER: solutions@lonza.com / 800 845 6973
Or contact your Lonza representative