



**DEEP  
UNDERSTANDING.**

**REVOLUTIONARY  
TECHNOLOGIES.**

**UNPARALLELED  
DEDICATION.**



Integrated Development  
Services - HRM

**SOFTIGEL BY PROCAPS OFFERS CUSTOMERS FULL-SERVICE**, turnkey solutions in prescription drugs, OTC products, and dietary supplements thanks to our softgel development and manufacturing expertise.

LEARN HOW SOFTIGEL BY PROCAPS' SCIENTIFIC AND TECHNICAL EXPERTISE **CAN DELIVER INNOVATIVE PRODUCTS** TO MEET THE REQUIREMENTS OF OUR PATIENTS, CUSTOMERS AND STAKEHOLDERS.



**+40 years**



**US-FDA approved for Drug and nutritional products**



**Innovative products**



**Our Softgel Technologies facilities:**

- US-FDA and European GMP approved in Latin America
- Extensive formulation development and manufacturing solutions
- Flexible Manufacturing
- Product Formulation
- Technology Transfer expertise
- Much More

## **OUR EXPERIENCE DEVELOPING HUNDREDS OF SOFTGEL PRODUCTS**

is supported by a comprehensive selection of **advanced softgel technologies** and the ability to develop, manufacture and supply them efficiently.



# TECHNICAL & BUSINESS SOLUTIONS AT YOUR SERVICE

## Development Process:

- Formulation of simple or highly complex products
- Encapsulated in softgel dosage forms or other delivery systems
- High or low potent APIs
- Differentiated OTC products and nutritional supplements
- Traditional and unique delivery systems



Project Management / PDS



Supported by a robust quality system



All of our products are designed under a **Quality by Design** approach.

# PRODUCT DEVELOPMENT

Our Team has more than 30 years experience developing products for different markets, and more than 15 years experience developing products for USA, Canada and Europe.

# PRODUCT DEVELOPMENT SERVICES

We cover a wide range of services along the full lifecycle of a softgel and other drug delivery forms, from early development to large scale commercial supply.



# ACTIVITIES IN THE PHASES OF PRODUCT DEVELOPMENT

## Pre-clinical

- Pre-formulation
- Formulation development
- Analytical Method Feasibility and/or development
- Cleaning method development
- Non-GMP batches
- Trial stability studies

## Phases III

- Manufacture of registration batches
- Stability studies package
- CMC documentation package preparation
- NDA/ANDA preparation and submission
- Scale-up preparation and manufacture
- Process validation



## Phases I & II

- Formulation development
- Analytical Method validation
- Cleaning method validation
- Manufacture of Experimental batches
- Manufacture of clinical batches
- Stability studies

## Commercial Phase IV

- Manufacture of commercial batches
- Package and labeling
- Analysis of commercial batches
- Stability on-going studies
- Quality and Compliance support
- Regulatory intelligence
- Tech Transfer
- Reformulation
- Line extension
- Postmarketing surveillance
- Marketing support



## SUPPORT AND VALUE DURING ALL STAGES



Our Team works closely with our customers to understand expectations and develop a **regulatory strategy** that guarantees the **best quality, timely submissions**, and faster, positive registration outcomes.



We also count with experience preparing **submissions in eCTD Format**, and provide support during the application phase and beyond, including annual reports and other post approval submissions.



**We have proven expertise in technology transfers**, product launches, product development and manufacturing technologies, helping our customers overcome formulation challenges.

With an unparalleled dedication to our customers projects and a deep understanding of their needs and concerns, we are transforming the industry, **helping our customers grow** in their current markets and extend the life cycle of their products through innovative and alternative **solutions**.

High Regulated  
Markets

+15 years  
developing products.

### CUMULATIVE CORPORATE EXPERIENCE



**+50**  
products launched  
per year



**Devoted**  
teams for client/market



**+600**  
products developed  
in softgels



**+100**  
formulation scientists  
including PhDs, MSCs  
and technicians

*\*Data as of January 2019*

## MANUFACTURING EQUIPMENT

### Pilot Facility plant for:

- Soft gelatin capsules
- Tablets
- Liquid dosage forms
- Creams
- Hot melt extrusion applications
- Lyophilization applications
- Among other applications



**Pilot encapsulation machine**



**Drying system**



**Hot melt extruder**

## ANALYTICAL EQUIPMENT AVAILABLE FOR R&D INCLUDE:

### ANALYTICAL EQUIPMENT available for R&D include:

+20 HPLC/UHPLC with several such as: GPC; RI, Fluorescence; DAD,GC, FTIR

### All USP Dissolution apparatus

- All climatic zones
- Photostability studies
- Refrigerators
- Freezers for Freeze and thaw studies



**+20 Liquid Chromatography Systems** dedicated to Analytical R&D



**UV Photodiode array detector** Fluorescence



**All USP** dissolution apparatus



**Stability and photostability chambers** for all climatic zones

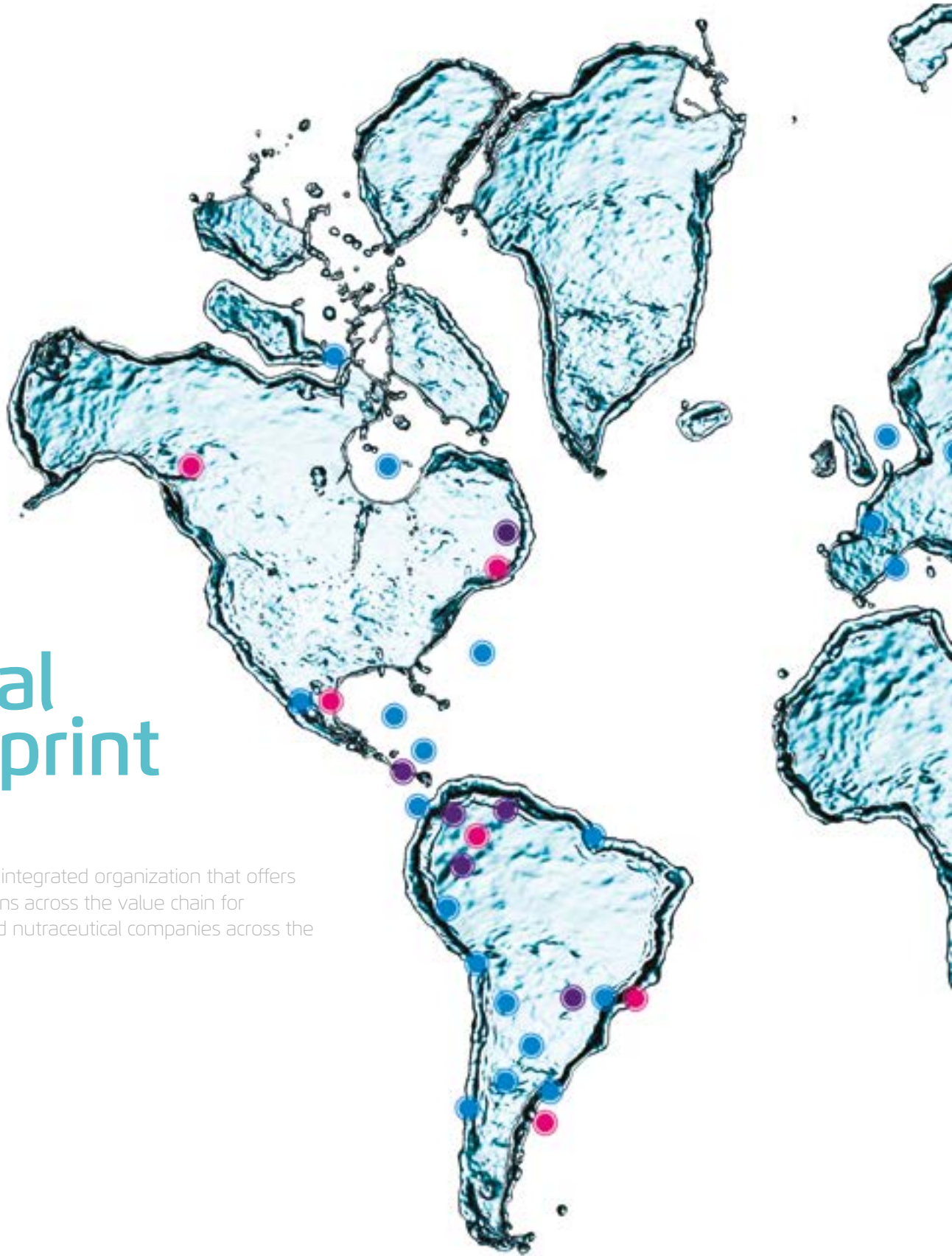
**+13 Billion**  
*Softgels Annually*

**+8** *Softgel advanced technologies*

**+7** *Manufacturing Sites supporting customers around the globe*

# Global Footprint

We are a vertically integrated organization that offers end-to-end solutions across the value chain for pharmaceutical and nutraceutical companies across the globe







- Manufacturing facilities
- Partners around the world
- Commercial offices

# SOFTIGEL BY PROCAPS CAPABILITIES



Manufacturing expertise for **oral and sterile dosage forms**.



**Proven Quality System by:** US-FDA, MHRA, TGA, Health Canada: among others.



**Leading marketer:** of advanced delivery systems, with +8 proprietary softgel technologies.



**High-potency:** Softgel development and manufacturing.



**Technology Transfers:** deep project management, technical, and operational expertise to support any transfer requirements at all phases.



**Product Launches:** with +600 products developed in softgels and +50 launched annually worldwide.



**Environmental Health and Safety:** deep expertise handling all types of compounds from development to commercial supply, using a toxicologic classification system for high potent, hormonal and controlled compounds; among others.



Dedicated Hormone Facility.



**Pilot Plant:** created for pilot batches, trials, and other small-scale preparations, for analytical, stability and packaging purposes.



**Packaging Capabilities:** from package development to full commercial scale packaging, with modern state-of-the-art equipment bringing value and flexibility for our customers supply chains.



**Package design:** we offer a comprehensive range of packaging engineering services.



**Smart Logistics:** we have the ability to support our clients' needs for shipping, temperature cycling, or package integrity studies.



**Serialization:** capability and equipment for serialized packaging solutions.



**Novel Technologies:** extensive experience in the development and manufacture of softgel fixed dose combinations, increasing patient compliance, improving safety and offering a superior consumer experience.



**Regulatory Support:** for successful product registration in the expected markets and to support all the post approval activities (Annual product review; FARs, PAS, CBE, etc)



**Vertically integrated CDMO:** we strive for efficiency by designing and producing our very own equipment, molds, customized blister and printer tooling, built at our in-house engineering division called Dismec, much faster than any other CDMO and at a lower cost.



**Capsule printing capabilities:** either traditional or in-line.



**Project management** capabilities.



Strategic/global sourcing.

## Thinking B2C Acting B2B:

Generating ideas and creating solutions based on Customer knowledge



# INNOVATIVE SOFTGEL TECHNOLOGIES FOR EVERY CONSUMER NEED

DISCOVER SOME OF OUR **MAIN TECHNOLOGIES**

## **Versagel™**

Soft capsules  
free from animal  
derivatives.

## **Gummygels™**

Easy nutrition with  
unique formulations  
in nutritional gummies.

## **Chewgels™**

Solid chewable softgels with great flavor  
and a variety of formulations.

## **G-tabs**

Gelatin coated tablets that  
mask unpleasant flavors.

## **Unigel™**

Oral dosage form that allows  
capsules, tablets or hard capsules,  
inside a single soft gelatin capsule.

[WWW.SOFTIGEL.COM](http://WWW.SOFTIGEL.COM)



[www.softigel.com](http://www.softigel.com)

Follow us!

