

Expertise

PROXIMITY,

Integrated development,
Superior Technologies



across Rx, OTC
& Specialized nutraceuticals





Integrated Services in **Development,**
Scale up, Commercial Manufacturing and **Packaging**

I SOFGEN PHARMACEUTICALS I

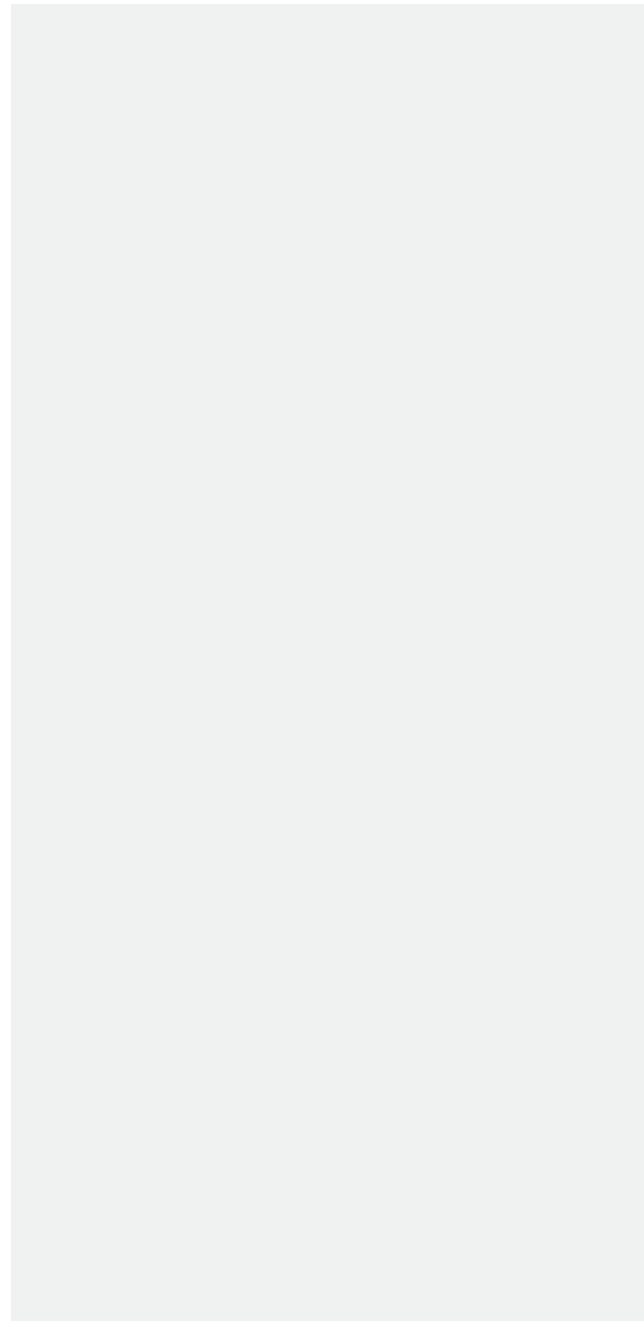
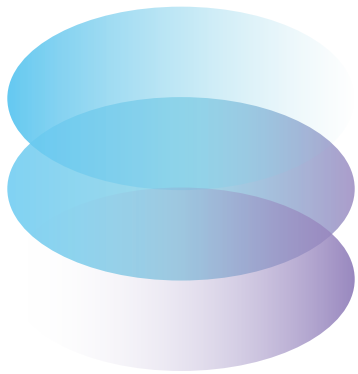




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Procaps Group (NASDAQ: PROC)

Is a developer and manufacturer of **pharmaceutical** and **nutraceutical solutions, medicines**, and **hospital supplies** that reaches more than 50 countries in all five continents.

Procaps has a direct presence in 13 countries in America and more than 4,500 collaborators working under a sustainable model. Procaps **develops**, manufactures, and markets **over-the-counter ("OTC") pharmaceutical products, prescription pharmaceutical drugs ("Rx"), nutritional supplements** and **high-potency clinical solutions**



Procaps Group Business is structured to enable market focus and innovation



Manufacturing & Product Development services

Sofgen USA & OTHER HRM
Softi Gel LATAM, MENA, SEA
SOFTCAPS BRASIL, MERCOSUR, SOUTH AFRICA
funXtrition Nutraaceutical Gummies GLOBAL



Patient/Consumer Centered solutions

FARMA PROCAPS
CLINICAL ESPECIALIDADES
VitalCare
DIABETRICS 361° EN FUNCIÓN DE LA VIDA

Global Footprint

10 extensive state-of-the-art manufacturing facilities and laboratories across America.

Superior development and manufacturing expertise, distribution and vertical integration capabilities.



+140,000 Million
Capsules Manufactured

+10 Dosage Forms

Fully integrated products
Development service(PDS)
With commercial supply



We are an integrated CDMO that offers end-to-end solutions, from development throughout delivery, in innovative Softgel technologies for pharma and healthcare companies interested in launching novel products within North America and other Highly regulated markets.

OUR PURPOSE

To **Provide** an **unparalleled experience** with reliable development **manufacturing services** and niche proprietary products, innovation in technologies, contributing to health and well-being of consumers and patients in key markets.



WELCOME TO OUR Center for Pharmaceutical Excellence (CPhE)

At our CPhE we have the capability of delivering our **pharmaceutical products to our strategic partners** and ensuring the continuous quality of their most valued asset, their brands.

Bringing Pharmaceutical Excellence to the USA market.

Through our innovative technologies for oral delivery systems plus our vast knowledge in Softgel technologies, we offer the **highest degree of flexibility**, on-time deliveries, with exceptional production and **superior quality**.

At our CPhE we have proven expertise in:

- Research in advanced delivery technologies
- ⚙️ End-to-end solutions for new softgel technologies/Fast track development.
- 🏭 Specialized in complex oral modalities and differentiated manufacturing technologies
- 🔗 Pre-clinical and Clinical development for new molecular entities.
- Specialized and dedicated facilities for handling **hormonal substances**.



WHY Sofgen Pharmaceuticals?

Multisite working in synergy to offer additional value to customers.

Specialized in **high-value products** and high-growth segments.

Strong and proven **capabilities** to **develop** winning products under strict **cGMP environment**.

Strong technology platforms and **intellectual property** position.

Long-standing strategic partnerships and **business alliances** with key branded **pharma, nutritional and generic** organizations.

Client-centered experience model based on **flexibility, connectivity, trust** and **empathy**.

Leaders in the development & manufacturing of Pharmaceutical solutions in HRM markets for 20+ years.

DRIVEN BY OUR 3 C's






Capability

- 4 segregated Softgel Encapsulation Lines
- Preclinical, clinical trial, experimental and commercial manufacture of softgels
- Softgel Encapsulation machines that can produce between **3,000 to 500,000 capsules per hour**, offering volume flexibility to our customers.
- Analytical and formulation development laboratories
- Dedicated **Hormonal Suite**.



Compliance

- Quality Control Systems to support **cGMP** manufacturing (Rx and Nutritional) 
- Impeccable history with recent **FDA inspection** 
- US fish and Wildlife license to import and export fish oils. 
- An experienced, professional, **cGMP** trained development, manufacturing, quality and logistics staff 

Florida Food Hemp Establishment Permit, allowing for dietary supplements including CBD products



Convenience

- Strategically located: **Closer to our HQ, our suppliers, and most importantly our clients.**
- With several International ports and airports within **85 miles of the facility to receive and export goods.**

Advanced Softgel Technologies

for RX, OTC & Specialized Nutraceuticals

The **softgel capsule** has been on the market since the 19th century, evolving to the present day. Because of this, consumers feel familiar with the technology, trusting in its efficiency, robust quality control and convenience.

SoftGels

Applications

Nutritional: Supplements, vitamins, concentrates and other natural products



Pharmaceutical: Products for any type of indication (OTC and Rx)



Cosmeceuticals: Cosmetic products that have medicinal properties



Characteristics

- Enhanced bioavailability of active ingredients
- Attractive physical appearance
- Greater Stability
- Extended Shelf Life
- Masks Unpleasant odors and flavors
- Consumer preferred dosage form (easier to swallow than traditional dosage forms)










Unigel™, a first-to-market Technology, ideal for companies who want their consumers to have simplicity and effectiveness backed by technology and expertise when taking their meds and supplements.

Unigel™ provides different configurations for fixed-dose combinations. It allows multiple ingredients that are chemically incompatible to coexist in one softgel.

unigel™

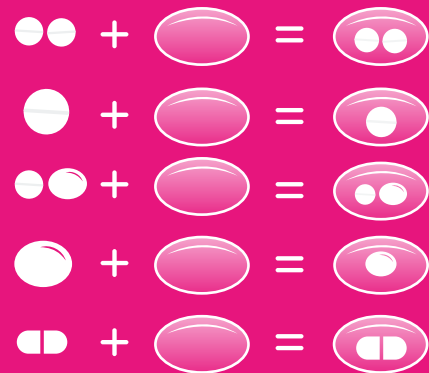
Benefits by Procaps

-  Clear look inside the capsule, Physically Appealing
-  Different Release Profiles available
-  Combines Multiple Purpose Ingredients in one form
-  Diversifies Portfolio Enables Brand Differentiation
-  Impossible to counterfeit
-  Exact Dosage Form
-  Different Gelatin formulations, Suitable for Vegetarians and/or vegan diets

One of the different advantages of Unigel™ is that it allows you to include different formats within a Softgel

- One or two tablets
- One or two softgel
- One softgel and one tablet
- Hard capsule with Granules

INSIDE A UNIGEL™ CAPSULE:



| Chewgels™

Discover our **Chewable Softgel** Platform: **Chewgels™**, chewable soft capsules as a solution and line extension to existing or new products. With new ingredients, **special shapes** and **flavors**, we can offer our customers a range of formulations for different **therapeutic lines**.

Advantages

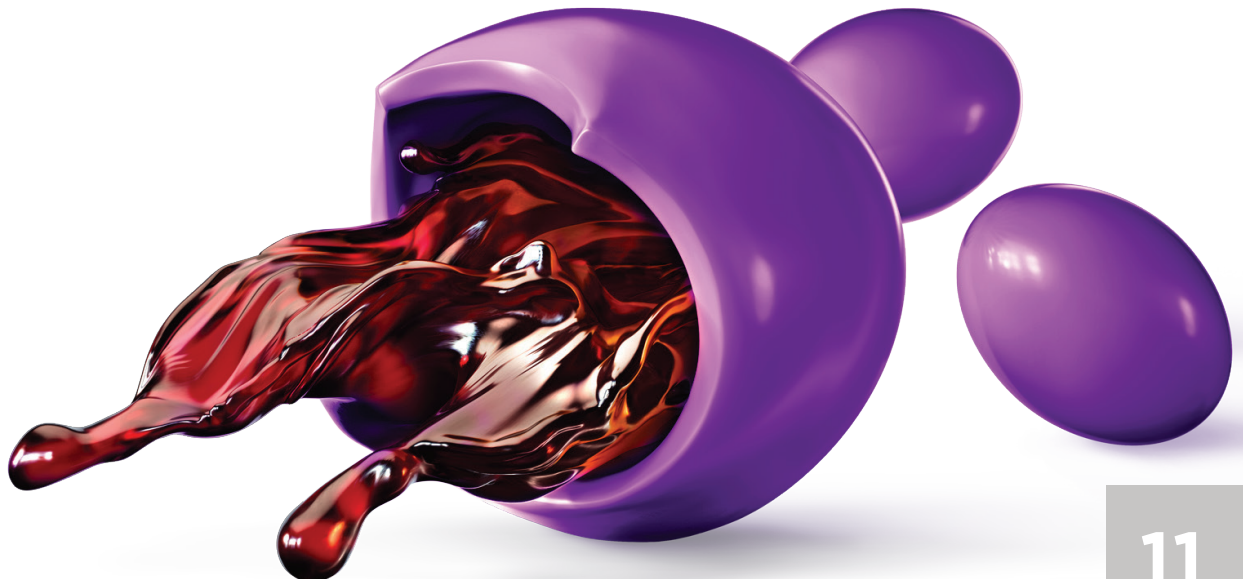
- No sugar-added
- Shell solubility and stability assurance
- Portable exact dose form: the fill content may contain solutions, suspensions, pastes and emulsions.
- Non sticky softgel due to its drying process.
- Lipid coating of the API for special taste masking applications.

Chew gels

Consumer Benefits

- ✓ No water needed: Taken easily on the run without water or food.
- Easy to swallow: Suitable for children or senior adults who often reject traditional dosage forms.
- Fast effect: Immediate release and absorption in the mouth and stomach.

Great taste & Experience: Once a Chewgel enters the mouth and is chewed, a burst effect of the sweet, creamy and tasty liquid inside kicks in. This explosion of flavor is accompanied by the activation of the ingredients.



Versagel™ |



Meet our vegetarian softgel technology, **Versagel™**, a versatile option for the encapsulation of high viscous, semisolid or high pH fill contents

Versa
gel™



Advantages

- More stable than proteins at extreme pH values and moderate ionic strengths.
- Ability to encapsulate high temperature fills.
- Ability to develop Modify Release Options
- No Crosslinking over time
- They solve complex formulation challenges.
- Non-GMO, Gluten Free, Vegetarian.
- Vegan Certifiable

Consumer Benefits

Suited for Consumers with dietary and religious or cultural restrictions.

Ideal for consumers seeking products to fit their healthy lifestyles

Offers the same benefits as a **Softgel Capsule:**

- Easy to Swallow
- Odor and Taste Free.
- Consumer's Preferred Dosage Form.

Options available in a variety of: Colors, Shapes, Sizes and Clarity.

| Twistgels

A soft gelatin capsule with twist-off cap that allows access to a measured dose for topical and/or oral applications.



Twistgels

Advantages

- Better Dosage Accuracy
- Eliminates contamination by repeat use
- Improves Compliance
- Improved Stability

Consumer Benefits

- ➔ Portable, on-the-go
- ➔ Easy to twist – Ideal for geriatric, Pediatric and Veterinary use
- Custom shapes, sizes and colors
- ⊘ No water Needed



As the leading manufacturer of softgel-related technologies, Softigel offers unparalleled custom capsule services. Design your very own Stripegels!

Stripegels

Advantages

- Physically Appealing
- Completely Customizable
- Brand Identification
- New Customer Experience

Consumers are willing to pay top dollar for customization to extend their product lines and increase sales*

Source: Personalization Trend Enters the Vitamin Market. 2020. English. Laura Industry Manager Machecha. Kline & Company



| Reducedgels

With Reducedgels, consumers receive **full strength and power in a smaller size softgel.**

ReducedGels

Advantages

- Enables **higher API concentrations** in smaller capsules
- A **solutions** for complex API formulation
- Capable of **delivering** single and combination API formulations
- Tamper-evident

Consumer Benefits

- Ideal for **seniors** and **children**
- Available in **variety** of colors, shapes, sizes, and clarity
- Suitable for **Vegetarians**



The softgel vaginal ovule or insert, Vaogels, was designed with mucoadhesive properties to facilitate retention of the product in the vagina and availability of the active ingredient in a site-specific manner.

Vaogels



Advantages

- ▶ Conical Shape for easy application
- Softgel Hydrophilic outer layer
- ↑ Improves treatment efficiency
- ↑ Greater dissolution/ Faster disintegration
- 🎯 Exact Dosage
- 💡 Lipophilic Exipients for better vaginal adherence and efficacy.
- ♥ Gentle and non-irritating
- ⚖ Stable Until Inserted

Sofgen[®] offers Complete formulation & R&D SERVICES

At **Sofgen Pharmaceuticals** we work with **efficiency**, **quality** and **flexibility** to develop and unleash the power of your ideas. With an in-depth knowledge on development services, our experts are driven by **science** and **technology** that can solve any formulation challenges along the way.

OUR SERVICES INCLUDE

- Development of novel patentable formulations
- Solubility Screening
- Fill formulation development (Solution, suspension, self emulsifying drug delivery systems, lipid-based drug delivery systems and controlled release)
- Gel formulation development
- Gel/Fill compatibility study
- Small-scale encapsulation for early development and final formulation selection following **Quality by Design (QBD) cGMP clinical supplies** manufacturing and Packaging

MANUFACTURING FACILITY FACTS



Strategically Located:
US-based with an excellent **South Florida Location.**



86,000 Sq ft Facility: 20+ manufacturing rooms including **4 segregated soft gelatin capsule encapsulation.**



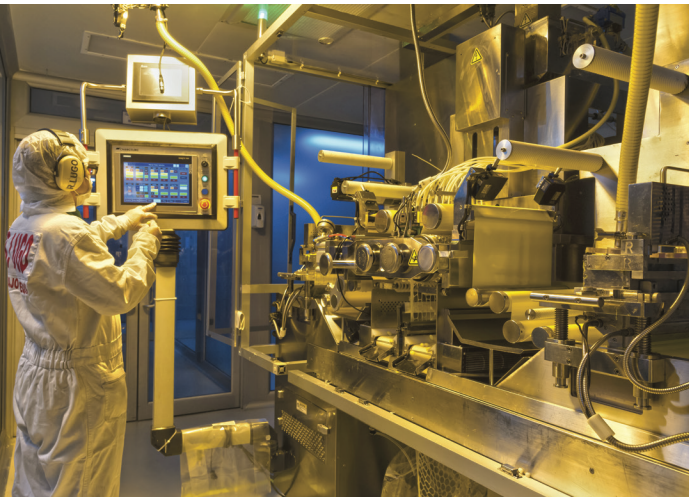
Capacity of **1.8 billion Capsules** per annum.



1 packaging line: 2.5 mm bottles per month.



Fully automated Shubham **Automation Serialization and Aggregation process.**



Specialized MANUFACTURING SERVICES:

- 1. Specialized** Hormone Suite
- 2. Complete Packaging Lines** including serialization
3. Advanced **Softgel technologies**



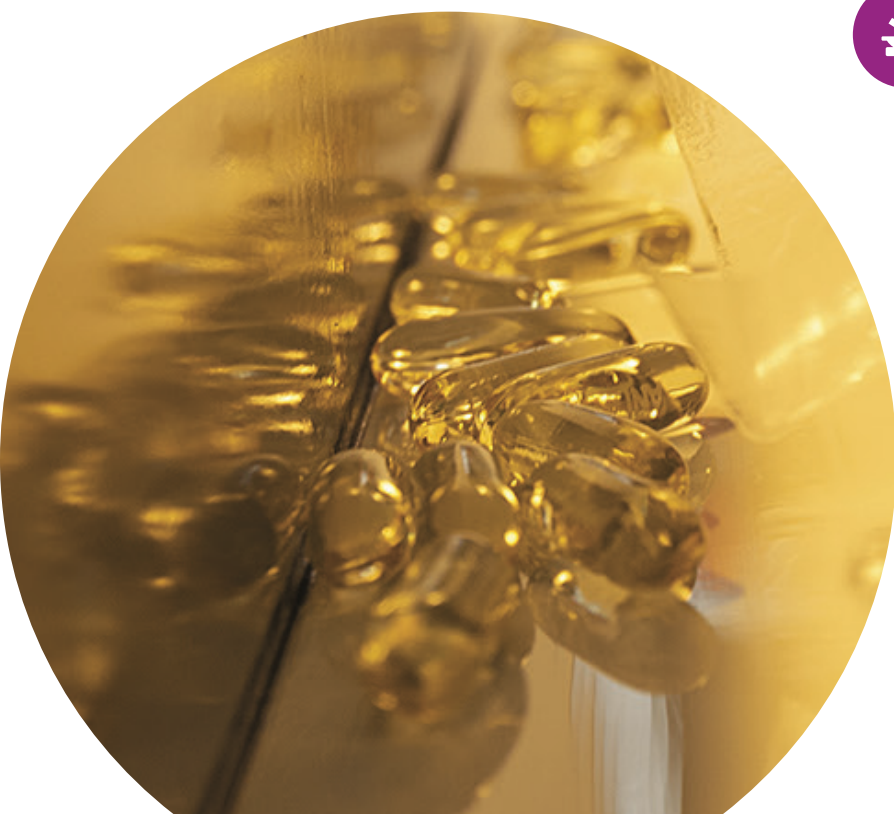
| Other Services and Capabilities

Analytical Capabilities



Analytical Testing

- **Analytical method** development, validation, and testing
- **Validation** of swab methods for cleaning verification
- **Batch/lot release testing for APIs**, raw materials and formulated drug products
- **Stability testing**
- **Compendial testing**
- **Micro testing of raw materials and finished products** and critical utilities



Analytical Testing

- **HPLC** (High Performance Liquid Chromatography)
- **LCMS**
- **Gas Chromatography**
- **Dissolution** (Apparatus I, II, III, IV)
- **UV-Vis Spectroscopy**
- **FTIR** (Fourier-Transform Infrared Spectroscopy)
- **TLC** (Thin-Layer Chromatography)
- **Karl Fischer**
- **Viscometer**



EQUIPMENT & PACKAGING CAPABILITIES

Encapsulation Equipment:

Sky 6" Encapsulation
Line (R&D Suite)

Sky 6" Encapsulation Line
(Drug Manufacturing Suite)

Sky 10" Encapsulation
Line (Suite 250)

Pharmagel 12" Encapsulation
Line (Suite 225)





For more info on our technologies and services visit:

Sofgenpharma.com





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