# Experts in the Science behind Smart Softgels





Sofgen Pharmaceuticals & Site	2
Complete formulation & R&D Capabilities	5
Advanced Softgel Technologies	6





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 pharma industry.

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

At our CPhF we offer:



Specialized development and manufacturing of softgel advanced tecnologies in Rx, OTC and specialized Nutraceuticals.



Pre-Clinical and Clinical development for new molecular entities.



Development of NCEs in Softgel technologies for specialized and complex molecules, as well as regulatory knowledge and support for **New Drug Applications** 



A state-of-the-art faciliy for handling () high potent compounds including hormonal and other complex modalities.

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# Sofgen Pharmaceuticals?

- Multi-site manufacturing working in synergy achieving supply chain efficiency.
- Strong and proven **capabilities** to **develop** winning products under strict **cGMP environment**.

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- Strong technology platforms and intellectual property position.
  - Experience in **Tech-tranfers**, emphasized in **quality assurance and time-to-market**.
  - 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.



## Sofgen Pharmaceuticals 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.

#### Inetgrated R&D Areas and Activities:

Technological and Pharmaceutical Innovation Development Activities Stability & GMP Analysis eCTD & Agency Contact

We offer complete support during the product cycle from development to post approval activities

- Analytical
   Development
   Product
   Post approv
  - Development
- Post approval Activities



## Advanced Softgel Technologies for Rx, OTC & Specialized Nutraceuticals

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

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# Softgels

### Applications

Nutritional: Supplements, vitamins	
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™∣

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





Clear look inside the capsule, Physically Appealing





Combines Multiple Purpose Ingredients in one form

Impossible to counterfeit



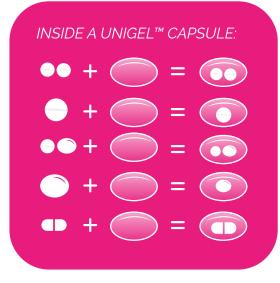


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Different Gelatin formulations, Suitable for Vegetarians and/or vegan diets

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 softgels One softgel and one tablet





#### | Chewgels™

Discover our **Chewable Softgel** Platform: **Chewgels**<sup>™</sup>, 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.

#### **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 Chewgels™ capsule 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<sup>™</sup> |



Discover our plant-based softgel technology, Versagel<sup>™</sup>, a versatile option for the encapsulation of high viscous, semisolid or high pH fill contents



#### 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.

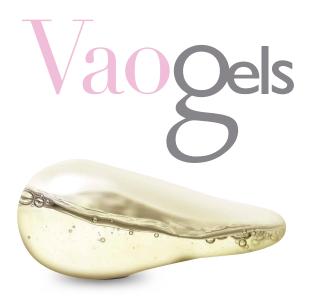
#### Options available in a variety of: Colors, Shapes, Sizes and Clarity.

#### | Twistgels

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

Advantages
Advantages
Consumer Benefits
Portable, on-the-go
Eliminates contamination by repeat use
Improves Compliance
Improved Stability
No water Needed





#### Advantages

- Conical Shape for easy application
- Softgel Hydrophilic outer layer
  - Improves treatment efficiency
- Greater dissolution/ Faster disintegration

#### Exact Dosage

Lipophilic Exipients for better v aginal adherence and efficacy.



Stable Until Inserted

Gentle and non-irritating

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*For more info on our technologies and services visit:* 

Sofgenpharma.com

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<u>www.sofgenpharma.com</u>

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