



## Building on particle engineering expertise to optimize pulmonary drug delivery and bring advanced inhalation therapeutics to market

The lung provides an attractive drug absorption target for both local and systemic disease states and is increasingly utilized for the delivery of both small molecules and biotherapeutics. Dry powder inhalers (DPIs) are often a preferred drug delivery platform due to their inherent formulation flexibility and patient convenience.

Our core particle engineering expertise is complemented with extensive formulation and process development, specialized CMC/analytical, and encapsulation capabilities to provide integrated DPI product development from concept through the clinic and commercialization.

## We provide unparalleled expertise in spray dry processing and jet milling for optimized particle engineering

Particle engineering is crucial to successful respiratory product design. At Capsugel, we have more than 20 years' experience in advanced top-down and bottoms-up particle engineering techniques specific to inhalation applications, with specialized, proprietary equipment in place for all stages of product development.

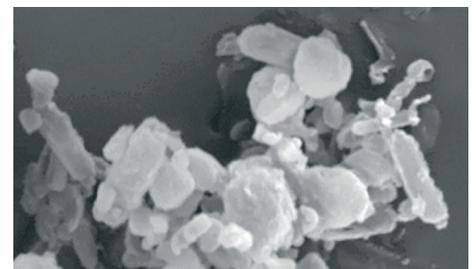
Spray dry processing is finding increasing use in DPI applications due to its efficiency and flexibility vs. traditional milling and lactose blend approaches. Capsugel has unique capabilities in spray drying with a range of engineered inhalable product concepts developed to fit specific compound properties and target product profiles.

## We provide extensive formulation and process development based on a rich legacy

Having formulated more than a thousand compounds, our scientists have encountered a myriad of API characteristics and delivery challenges. This has enabled Capsugel to optimize its formulation selection methodologies based on modeling, and optimize our process development and scale-up approaches. A comprehensive analytical platform with specialized CMC expertise is in place to support all aspects of inhalable product development.

## Our full service offering includes state-of-the-art encapsulation for capsule-based DPI systems

Customized DPI capsules and encapsulation are additional Capsugel core competencies, with dedicated equipment in place for efficient, phase-appropriate capsule filling.



CRYSTALLINE API IN AMORPHOUS MATRIX

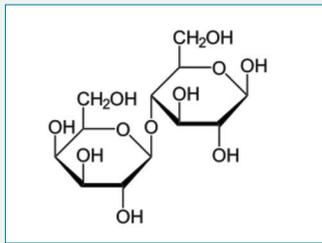


XCELODOSE® 600S FOR CLINICAL PHASE ENCAPSULATION

## Complete Inhalation Platform

### Inhalation Product Development

Capsugel offers a full range of services, from POC and formulation identification to powder manufacture for clinical studies, cGMP manufacturing and capsule filling optimized for inhalation drug development.



#### MATERIALS

Precedented and GRAS  
Materials science



#### PRODUCT CHARACTERIZATION

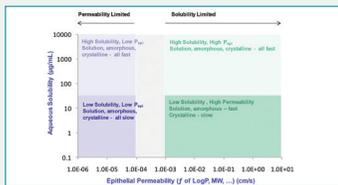
Performance  
Stability  
Release



#### ENCAPSULATION

Xcelodose® 600S  
Harro Modu-C MS with 100k CPH

#### ACTIVE PRODUCT CONCEPT



### TARGET PRODUCT PROFILE

#### FORMULATION/ PROCESS GUIDANCE

Compound physical properties  
Biomodel guidance for formulation impact on PK/PD



#### PARTICLE ENGINEERING

300mg to >1kg scale  
Development + cGMP



#### CAPSULE-BASED DPI DEVICE

Specialized capsules  
FTO device

#### ROBUST FORMULATION & PROCESS FOR CLINICAL TRIALS

### Specialized Dry Powder Inhaler capsules designed to meet the unique challenge of pulmonary delivery

By combining polymer science, engineering and formulation know-how, we are creating breakthroughs in capsules and encapsulation technologies that are changing the functional role of capsules in medical research, drug formulation and drug delivery. This unique capability has been utilized to develop specialized DPI capsules to optimize drug delivery to the lung.

Capsugel's DPI capsules are customized to your specific application, achieving optimal and consistent performance by adjusting key design parameters including the capsule size and design, polymer/ gelling agents, moisture content, lubricant levels and weight tolerances.



**Capsugel**

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Pharma & Biotech

Learn how Lonza's integrated inhalation product development and manufacturing can be tailored to meet your exact needs

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