# PARTICLE ENGINEERING
## for High Concentration Suspensions

serán

www.seranbio.com

**There's a Science to Success™**

**There is a growing interest** across the industry in developing technologies for high dose subcutaneous delivery of protein therapeutics. Three primary approaches have emerged to overcome the technical challenges associated with high dose delivery: viscosity reducing excipients for solution formulations, high volume delivery, and high concentration suspensions.

Here at Serán, we're leveraging our expertise in particle engineering, formulation science, and drug product development to enable clients to reach doses of 500 mg-1000 mg protein using high concentration suspensions delivered subcutaneously with traditional volumes through standard devices.

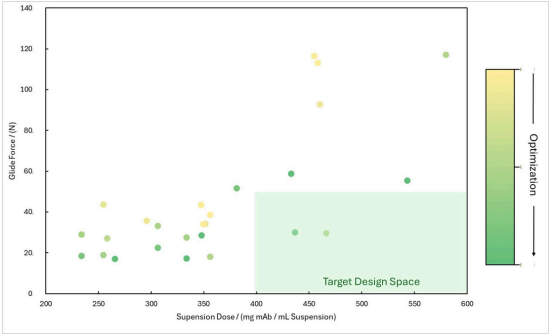
### EXAMPLE TARGET PRODUCT PROFILE

- 500 – 1000 mg dose
- 2 mL in ≤ 20 seconds
- Injectable through a 27 g ½" needle
- ≤ 50N maximum dispensing force
- Stability to support ambient storage
- Precedented excipients for parenteral administration

### SUMMARY IMPACT

- Spray drying is a precedented and scalable pharmaceutical unit operation that can be leveraged to produce solid state protein microparticles
- Particle engineering is critical to developing dosable suspensions at high concentration
- The spray drying process is optimized for protein stability and desired particle properties
- The spray dried protein formulation is optimized for maximum protein content and stability
- Suspension vehicles must be selected for compatibility with the protein, viscosity, and tolerability

### EXAMPLE TARGET DESIGN SPACE




**Bevacizumab SDP Suspension Performance in Non-Aqueous Vehicles**

*Suspensions dispensed from 1 mL BD NeoPak Syringe with 27g ½ in fixed stake needle at a rate of 1 mL / 8 seconds*

### WHY DO WE NEED THEM?

- ✓ Improved patient experience
- ✓ Reduced healthcare costs
- ✓ Expanded accessibility
- ✓ Life-cycle management
- ✓ Biosimilars (IP)

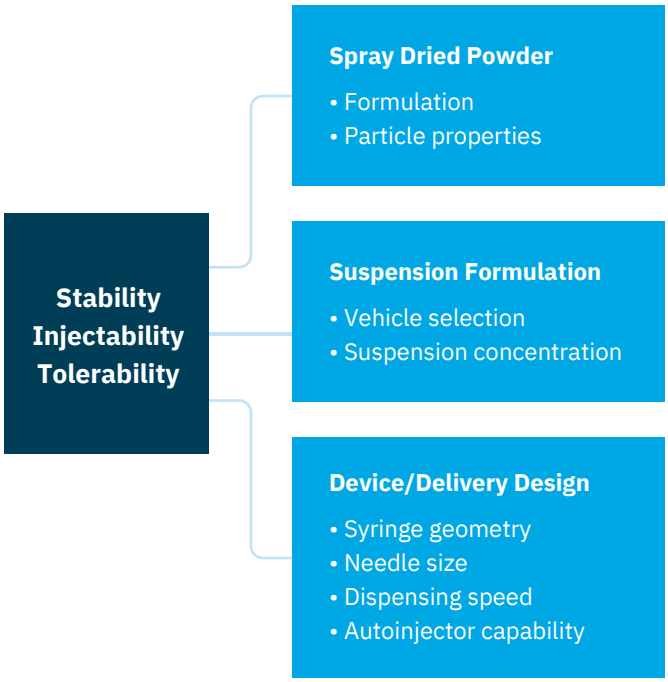
# Product Development Considerations for High Concentration Suspensions.

## SUSPENSION VEHICLE

- Vehicle optimization to minimize suspension viscosity while maintaining acceptable physical stability, colloidal stability, and protein stability
- Emphasis on pharmaceutical excipients with precedented use for parenteral administration
- Vehicles designed to target desired dissolution profile

## SPRAY DRIED POWDER

- Formulation screening to maximize protein content in the solid state while maintaining protein stability
- Particle engineering to optimize properties to minimize suspension viscosity and to support downstream processing
- Process design to achieve acceptable in-process stability, high throughput, and scalability




## STABILITY

- Achieving an acceptable stability profile is paramount in product development
- Stability considerations include physical stability of the solid-state particles, colloidal stability of the suspensions, and protein stability
- Process and formulation design are molecule specific, requiring consideration of the specific properties and stability profile for each protein, and thus a singularly defined platform approach is unrealistic
- Protein stability during processing must also be considered – excellent process engineering and spray dryer design enable in process stability for even the most sensitive molecules

**There's a Science to Success™**

## Connect & Learn More


hello@seranbio.com
1 + (541) 797-2148
www.seranbio.com
Bend, Oregon


serán

Serán is a world leader in drug development and manufacturing. Utilizing a foundation of physical and chemical science, Serán designs robust formulations and engineering solutions to some of the industry's toughest drug product problems.