

# EXAMPLE PROCESS CHALLENGES IN NANOSUSPENSION FORMULATIONS AND APPLICATIONS

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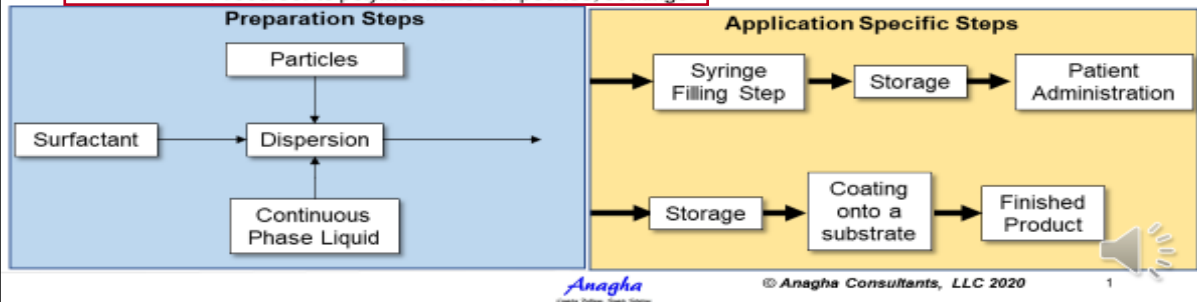
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## Introduction

### Nano Suspensions (or Nano Dispersions) Applications and Processing Flow Chart

- Pharma
  - Injectables, ophthalmics
  - Suspensions of API particles in an excipient continuous phase, stabilized by surfactants
- Specialty products
  - Inks for various niche applications
  - Precursor to polymer nanocomposites, coatings

Focus of this poster



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## Troubleshooting Challenges

### Preparation Size Reduction with High Shear Mixing

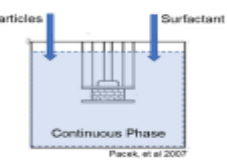


- Material Properties
  - Liquid properties
  - PSD of Particles
- Process Conditions
  - Mixing RPM
  - Volume of liquid
  - Duration of Mixing
- Equipment Characteristics
  - Mixing head geometry
  - Vessel geometry

Product Quality  
PSD of Particles  
Rheology of the suspension  
Shelf life

- Need to understand the underlying interactions for trouble shooting

- Balancing rate of particle surface generation to be balanced with the rate of surfactant coverage

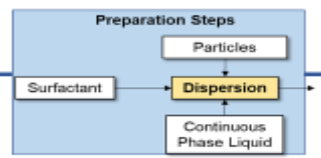


Batch mixing with rotor stator (or any high shear mixer)

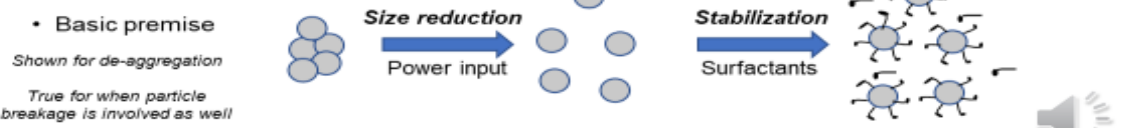
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### Nano Suspensions Preparation

- Depending on the incoming particle characteristics (3D or 2D materials) and the need, different approaches are used for dispersing differing in the level of energy input



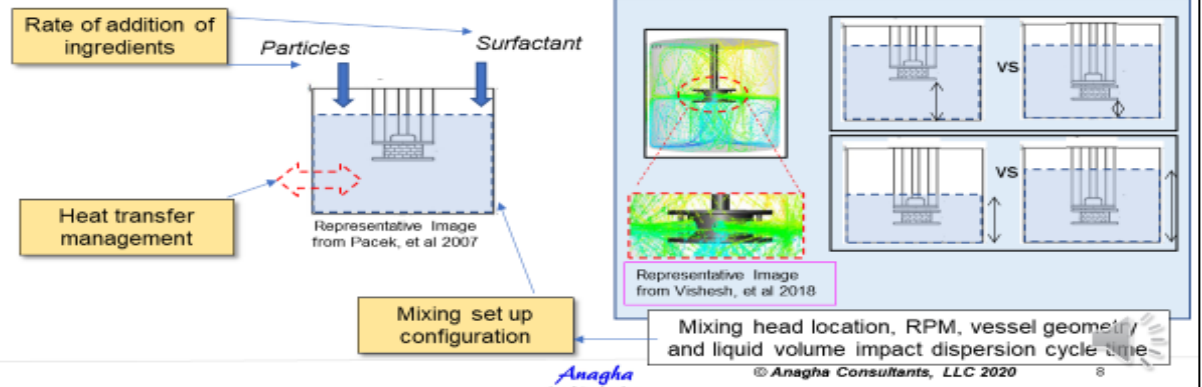
- De-aggregation of particles
  - bead milling
- Breaking of particles
  - high shear homogenization (rotor-stator type)
- Others
  - HPH/ Microfluidizer, etc



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### Troubleshooting Reproducibility Challenges Key Considerations

- Details of usage of the mixer are important, as they can influence mixing characteristics and the energy imparted to disperse the particles



Mixing head location, RPM, vessel geometry and liquid volume impact dispersion cycle time

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## Process Challenges

### Dispersion Preparation

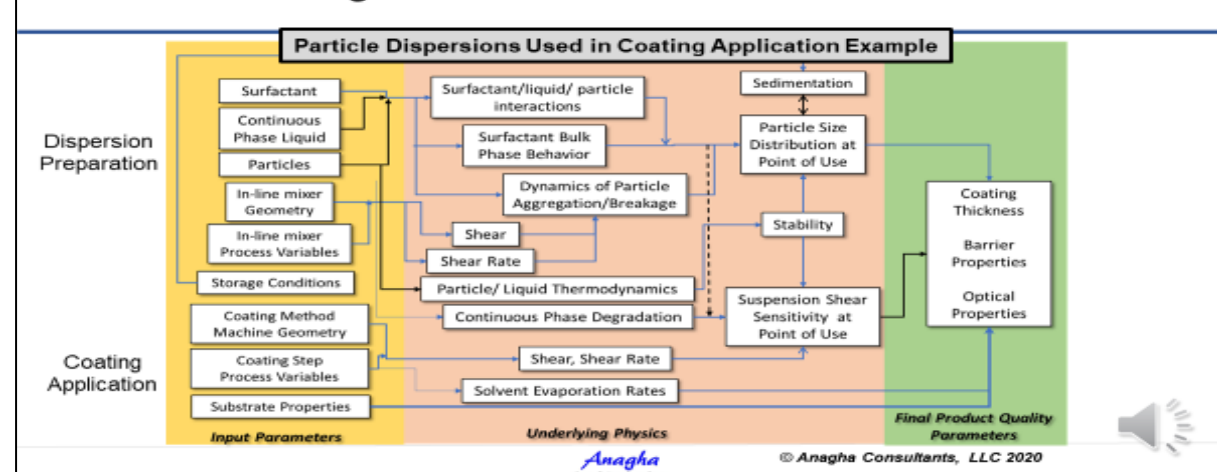
Reproducibility at lab scale  
Translating to larger scale

### End-Use Application (for ex, Coating Inks)

Product with the right quality  
Decision making on the right equipment  
Fitting the process to the existing equipment

## Focus on Vitals

### Understanding Material-Process-Performance Interactions



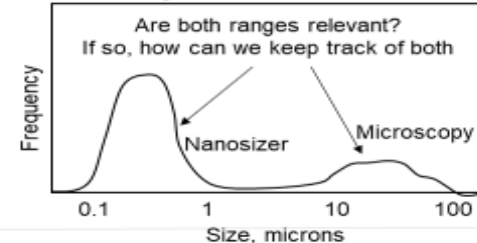
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### Troubleshooting Reproducibility Challenges Key Considerations

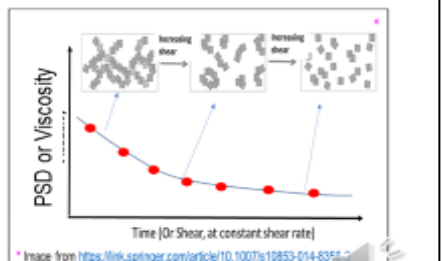
- Understand how the particles respond to the process conditions

Use of appropriate characterization techniques

For ex, particle size distribution in the relevant range of interest



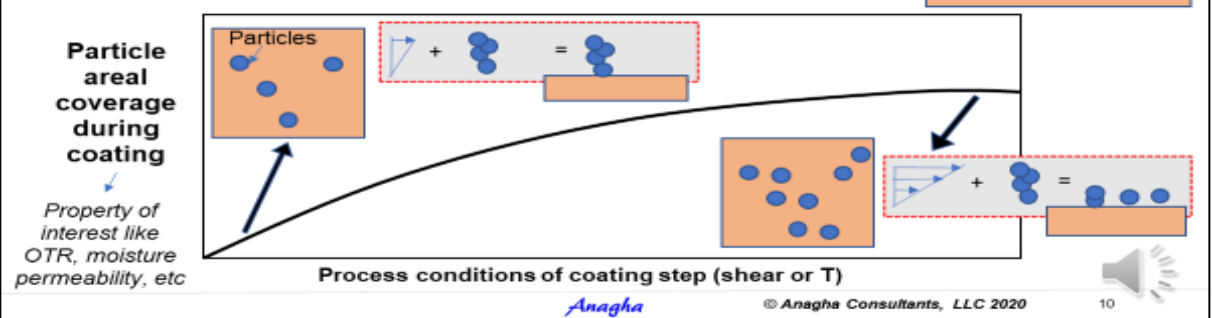
PSD ~ f(Input PSD, shear rate, total shear)



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### Troubleshooting Challenges During End-Use Applications Key Considerations

- Understanding end-use application process and underlying interactions with the suspension (specialty inks)
  - For ex, how the shear during the coating step impacts the areal coverage of particles (of a given concentration) on the coated layer
  - Selection of the coating method: roll vs. spray coating



Property of interest like OTR, moisture permeability, etc

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## Key Takeaways

Process challenges exist at both steps

Preparation of nanosuspensions

End-use application stage (for ex, coating)

How to overcome?

Attention to detail with an eye on the materials-process-performance interactions