

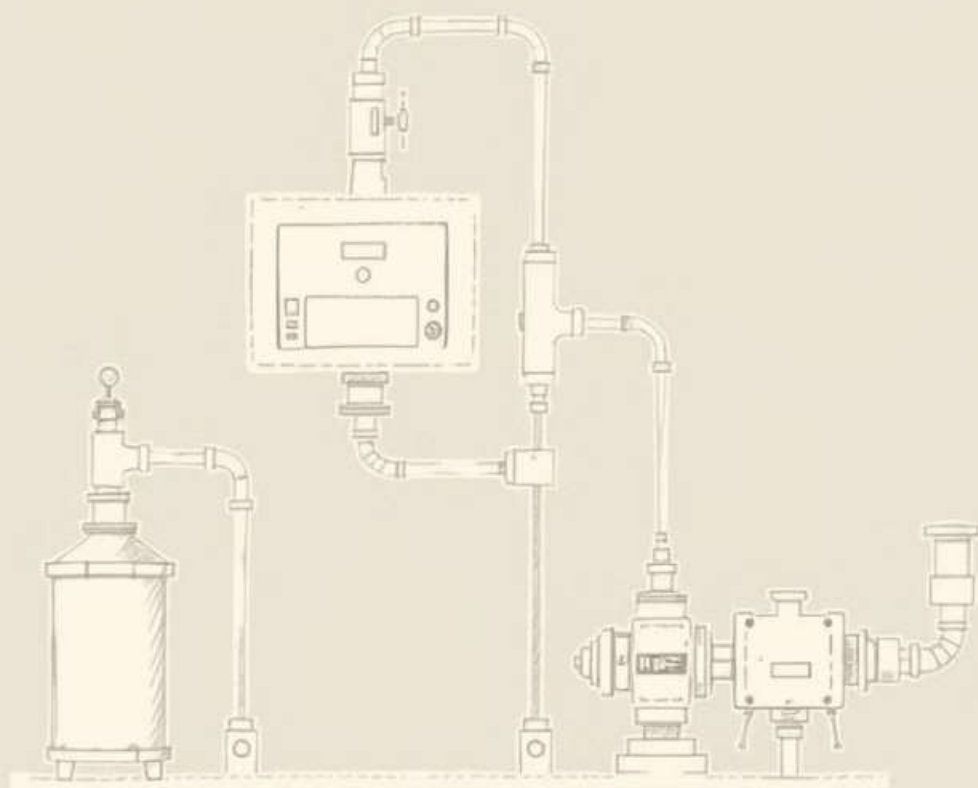
Pilot Plant Scale-Up Techniques for Solids and Semi-Solids

This presentation explores essential techniques for scaling up production of solid and semi-solid materials from laboratory to commercial scale. We will cover critical considerations from raw materials to advanced process monitoring.

R by Rathish Ramankutty

PILOT PLANT

Introduction to Pilot Plant Scale-Up



1

Bridging Production Gaps

Pilot plants connect lab-scale development to full commercial output.

2

Validate Processes

They confirm process feasibility and efficiency.

3

Identify Issues

Scale-dependent challenges are revealed here.

4

Broad Scope

Applicable to powders, granules, pastes, and creams.



Raw Material Considerations

Source Variability

Changes in suppliers affect particle size and shape.

Consistent Suppliers

Reliable supply chains are crucial for quality.

Pre-processing

Milling or sieving controls material specifications.

Batch-to-Batch Effects

Variations can impact blending uniformity significantly.

Equipment Selection and Design



Blenders

Choose from ribbon, V-blenders, or paddle mixers.



Granulators

High-shear and fluid bed granulators are common.



Dryers

Options include tray, fluid bed, and spray dryers.



Scale Differences

High-shear granulation scales uniquely with impeller speed.



Mixing and Blending

5%

RSD Target

Blend uniformity should target an RSD less than 5%.

Residence Time

Distribution impacts the overall blend uniformity.

Shear Rate

Excessive shear can degrade sensitive particles.

Scale-Up Rules

Maintain constant tip speed or power per unit volume.

Drying Processes

Heat Transfer

Surface area to volume ratio changes significantly with scale.

Airflow Management

Fluid bed drying requires precise airflow control for efficiency.



Mass Transfer

Diffusion limitations become pronounced at larger scales.

Temperature Control

Critical to prevent overheating and maintain consistency.

Granulation Techniques

1

Wet Granulation

Focuses on binder distribution and liquid-to-solid ratio.

2

Dry Granulation

Involves techniques like roller compaction and slugging.

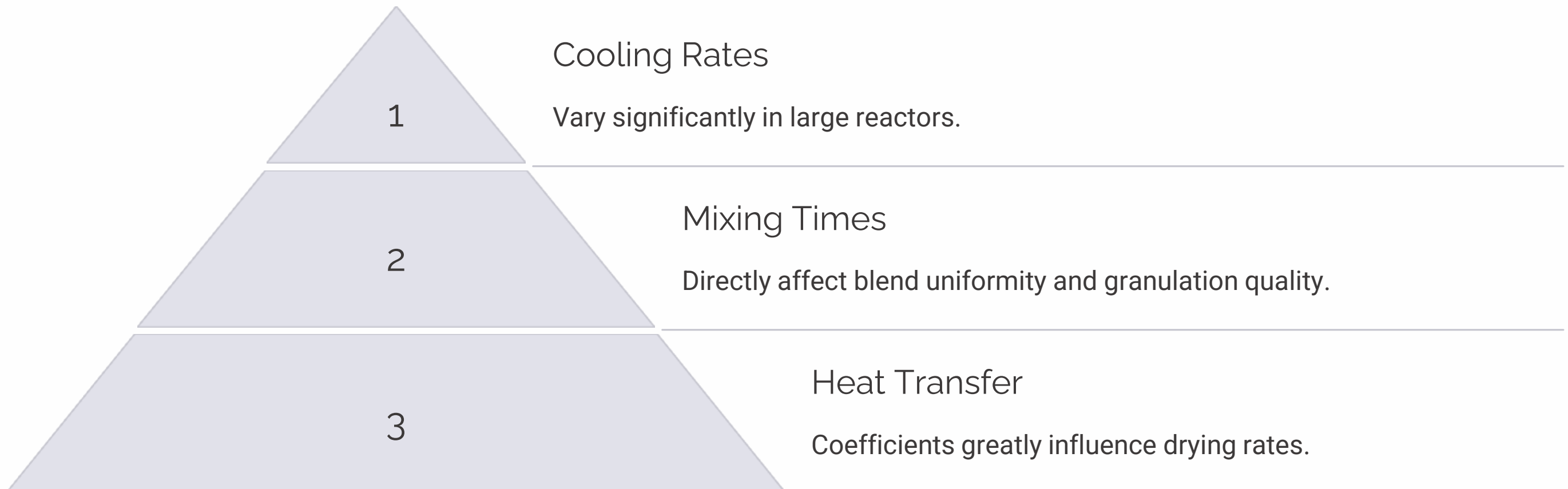
3

Endpoint Determination

Crucial for controlling final granule properties.

Key data points include granule size distribution, porosity, and density to ensure consistent product.

Scale-Dependent Parameters



These parameters are critical in predicting performance at commercial scale. Careful control prevents major deviations.



Process Analytical Technology (PAT)

Real-time Monitoring

Track particle size and moisture content continuously.

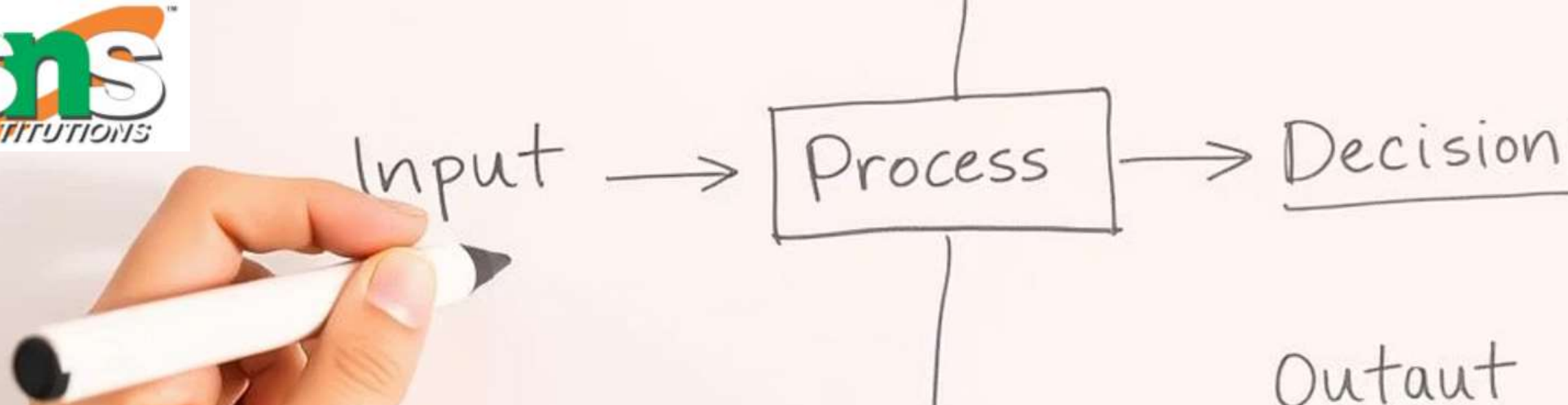
Spectroscopic Methods

NIR and Raman provide composition analysis.

Data Analysis

Statistical process control and trend monitoring are used.

PAT tools offer critical insights for real-time process adjustments and quality control, ensuring consistent output.



Conclusion and Best Practices



Lab
Characterization

Thorough small-scale
analysis is
fundamental.



Pilot Trials

Crucial for identifying
scale-dependent
issues.



PAT Insights

Real-time tools
enhance process
understanding.



Continuous
Improvement

Data from pilot plants
drives ongoing
optimization.