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White Paper # 2

Achieving Continuous Manufacturing for Final Dosage Formation: Challenges and How to Meet Them

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Paper Outline/Sections

1. Introduction to Continuous Manufacturing Final Dosage Form
2. How the Vision of Continuous Manufacturing will Change Final Dosage Form Operations
 - 2.1 Heterogeneous versus Homogeneous Processing
3. Challenges and Barriers
 - 3.1 Business and Organizational Challenges
 - 3.2 Challenges Facing Manufacturing & Development
 - 3.3 Overview of Technical Challenges
 - 3.4 Key Choices and Design Constraints
4. Technologies for Continuous Final Dosage Formation
 - 4.1 Overview
 - 4.2 Upstream-Downstream Interface

Paper Outline/Sections

4. Technologies for Continuous Final Dosage Formation

4.3 Powder Handling

4.4 Emergent Continuous Processes for Homogeneous

4.5 Excipients and Formulation

4.6 Transitional Continuous Technologies

4.7 Technical Approach to Development of Continuous Equipment

4.8 Systems Engineering, Characterization, and Control for Final Dosage Form

5. What the Industry Should Do and Timing Including Resource Allocation

Key Issues

■ Vision

- Integrated, full process understanding and control
- Seamless Scale-up
- Small, modular equipment with high turndown & rapid changeover
- 24/7, 50 weeks/yr operation

■ Homogenous vs. Heterogeneous Processing

- Homogeneous – uniform within a given length scale
- Heterogeneous – non-uniform

■ True Continuous avoids the “Rube-Goldberg problem”

■ New approach to excipients

- Formulation and Process Development go hand in hand
- Why not think of new excipients

Emergent Technologies-- examples

- Spray drying
- Electroprocessing
- Casting
- Injection molding
- Printing
- Continuous coating
- Ultrasound Compaction

Challenges and Decision Points

- When to make the necessary investments?
- Dedicated vs. Platform?
- Different approaches for Primary vs. Secondary markets?
- Small-scale equipment for early studies?
- Approaches to start-up and shut-down?
- How to approach regulatory authorities outside of Europe and the U.S.
- Investing in manufacturing research?
 - E.g. University-Industry partnerships for new technologies and Platforms

Sample Questions/Points for Discussion

- How can we maximize the benefits of continuous for final dosage formation?
- What technologies are most promising?
- How do we address the challenges?

Discussion

