ConsiGma™

A platform for Continuous Solid Dosage manufacturing enabling Quality by Design and Lean Manufacturing

O. GOLDSTEIN

GRANULATION & AGGLOMERATION SEMINAR 25TH OF OCTOBER 2016
Why Continuous Processing?

Pharmaceutical Manufacturing: The Path Ahead..

“Right now, manufacturing experts from the 1950s would easily recognize the pharmaceutical manufacturing processes of today. It is predicted that manufacturing will change in the next 25 years as current manufacturing practices are abandoned in favor of cleaner, flexible, more efficient continuous manufacturing.”

Dr. Janet Woodcock, AAPS Annual meeting, October 2011
ConsiGma™ milestones

- 2005 Start development of the ConsiGma™ wet granulation concept
- 2006 First working prototype
- 2007 First commercial project with customer
- 2008 Formal launch of ConsiGma™ ‘powder-to-granule’ at Interpack
ConsiGma™ milestones

- 2009 Formal launch of ConsiGma™ ‘powder-to-tablet’ at Achema
- 2010 Realization of new Process Development Centre
- 2011 Launch of ConsiGma™ 1 for R&D applications at Interpack
ConsiGma™ milestones

- 2012 First prototype of ConsiGma™ for direct compression (CDC) at Achema
- 2013 First prototype and commercial project of the ConsiGma™ coater
- 2014 Official launch of the ConsiGma™ coater and CDC at Interpack
ConsiGma™

Our product range & How does it work?
GEA’s ConsiGma R&D and manufacturing platform

ConsiGma™ Product Portfolio

Continuous Granulation & Tableting Lines (ConsiGma™ 25, 50, 100)

- Tablet Coating
- Compression
- Dry Milling / Ext. Phase Blending
- FB Drying
- Wet Granulation
- Dry Blending
- Dispensing Feeding
- Roller Compaction
- Melt Granulation

ConsiGma™ 1

- FB Drying
- Wet Granulation
- Dispensing Feeding

Continuous Direct Compression (ConsiGma™-DC 50)

- Tablet Coating
- Compression
- 2nd step Ext. Phase Blending
- 1st step Dry Blending
- Dispensing Feeding
- 2nd step Ext. Phase Blending
- 1st step Dry Blending
- Dispensing Feeding

APC Pharma
Wet granulation and tableting lines
ConsiGma™: how does it work?
Working principle of a Intermeshing Twin Screw System
Wet granule formation in the TSG is based on understanding the fundamentals of the twin screw granulation process.

**Powder Flow Through Twin Screw Granulator**

A) Dry powder mixing in zone 1,
B) over and under wetting of powder in zone 2 depending upon the barrel position,
C) Breaking of saturated agglomerated and mixing with remaining dry powders in zone 3 to create primary granules,
D) low shear forces exerted in zone 4 gives liquid limited time to pull particles together due to capillary forces,
E) secondary agglomeration of primary granules in zone 5,
F) breakage of oversized clusters in zone 7.
ConsiGma™ Coater
ConsiGma™ Coater
ConsiGma™ Coater: How does it work?
ConsiGma™ Tablet Coater working Principle
ConsiGma™ Tablet Coater working Principle
R&D – No Scale-up
ConsiGma-1 GMP granulator with integrated FB dryer

- Loss-in-weight powder feeder
- Fluid bed dryer w/ blow back filter bags and HVAC system
- Temperature control system w/ compressor chiller for TS granulator
- 21 CFR Part 11 compliant HMI & PLC control system incl. UPS
- Mass-flow controlled liquid dosing system
- Modular Twin Screw granulation system w/ split barrel and torque measurement

Stand alone & mobile unit!
ConsiGma™: Efficient R&D: No scale-up
ConsiGma™ Business cases

- Batch Production vs Continuous Production Product X
- Vertex, Boston US Business Case; streamline and accelerate drug development
- Pfizer G-CON GEA Portable Compact Miniaturized Manufacturing; POD Concept
ConsiGma-25: Pfizer Groton – USA PCMM
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ConsiGma-25: Pfizer Groton – USA PCMM
Today more than 50 ConsiGma™ References
ConsiGma 25: PDC Testcenter