

ConsiGma™

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

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GRANULATION & AGGLOMERATION SEMINAR 25TH OF OCTOBER 2016



Why Continuous Processing ?



U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

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

Why is the FDA so supportive of continuous manufacturing?

Dr. Janet Woodcock
Head of FDA CDER
Center for Drug Evaluation Research



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



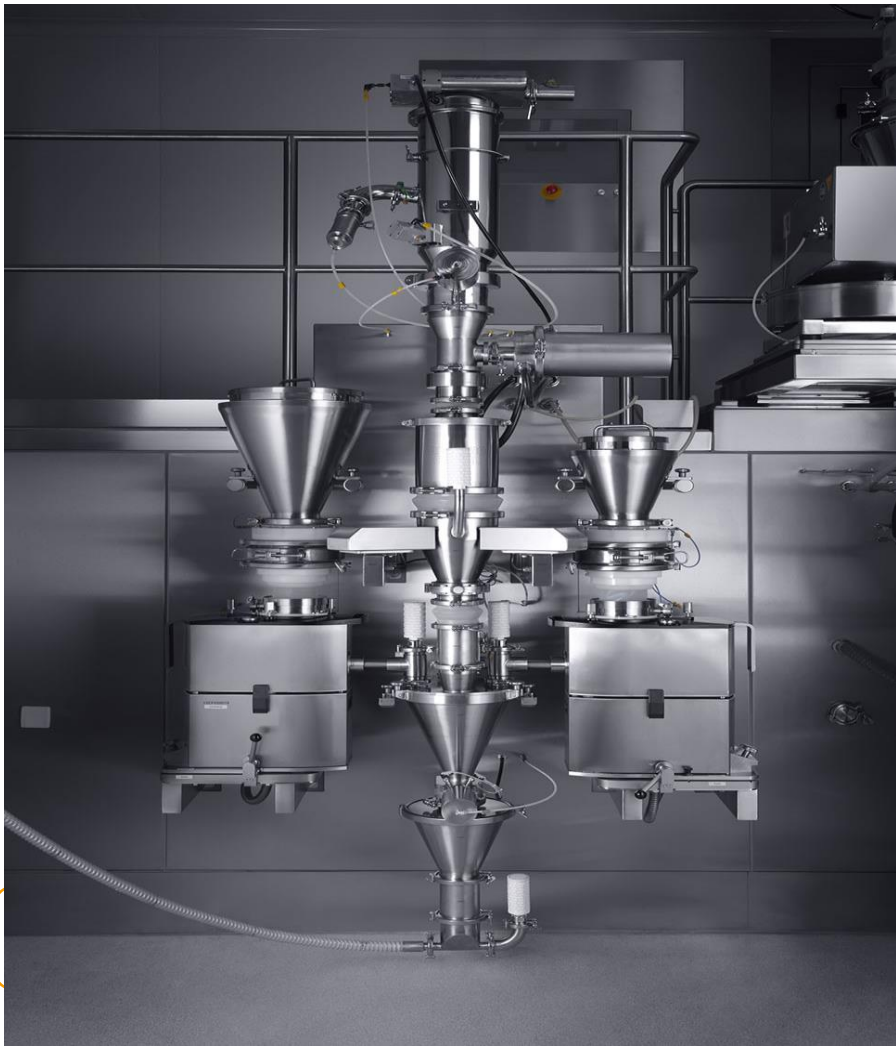
ConsiGma™ CDBU

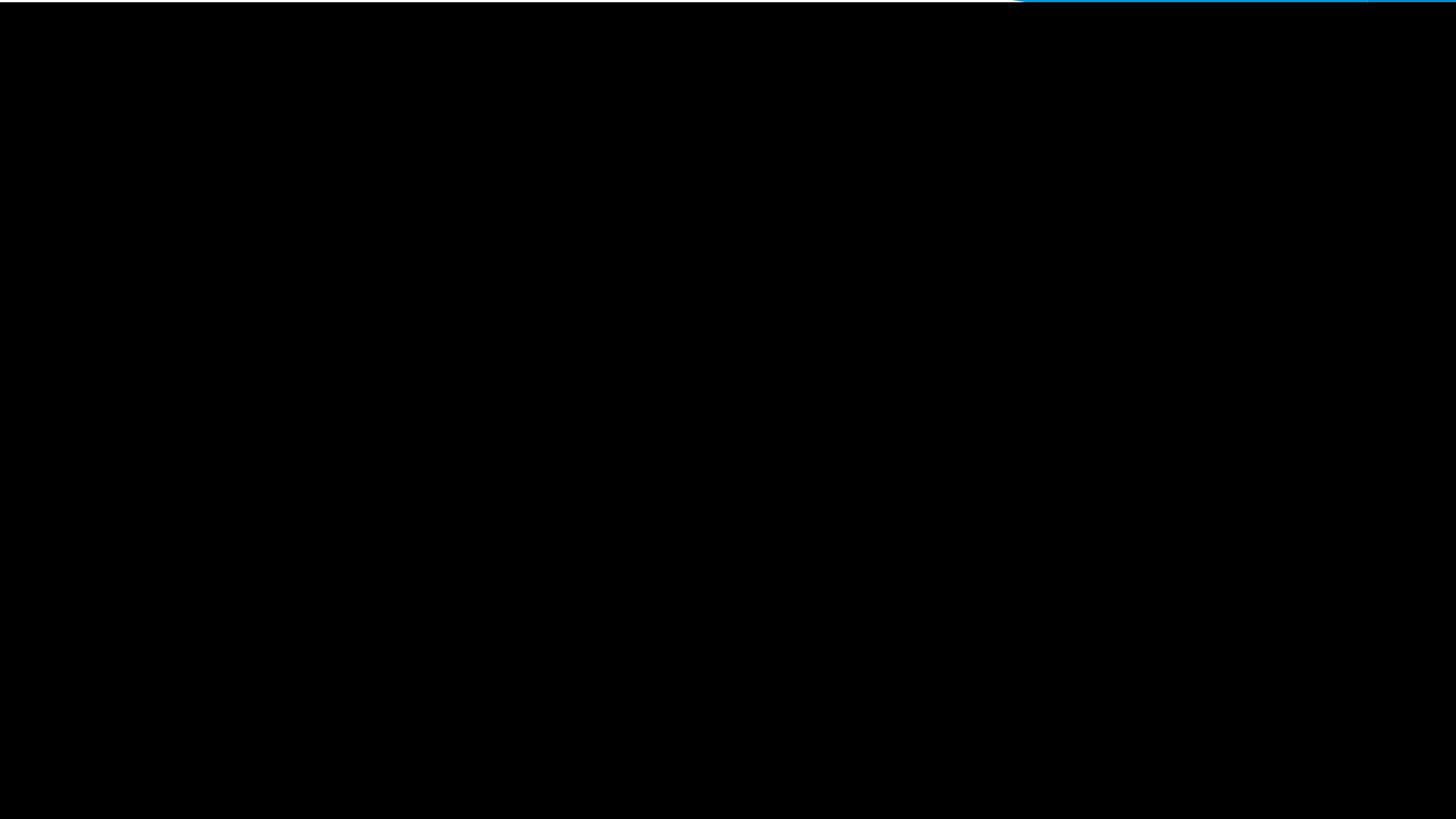
2nd step Ext. Phase Blending

1st step Dry Blending

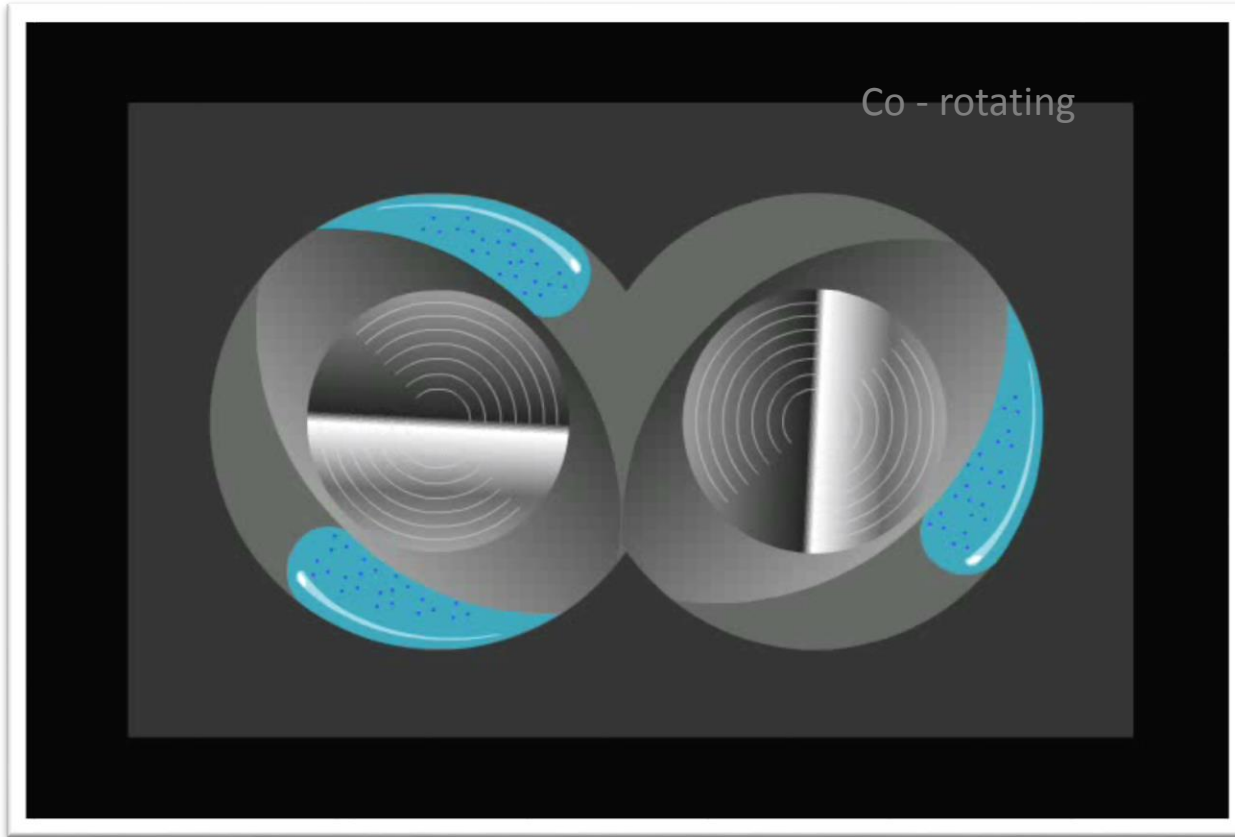
Dispensing Feeding

Wet granulation and tableting lines





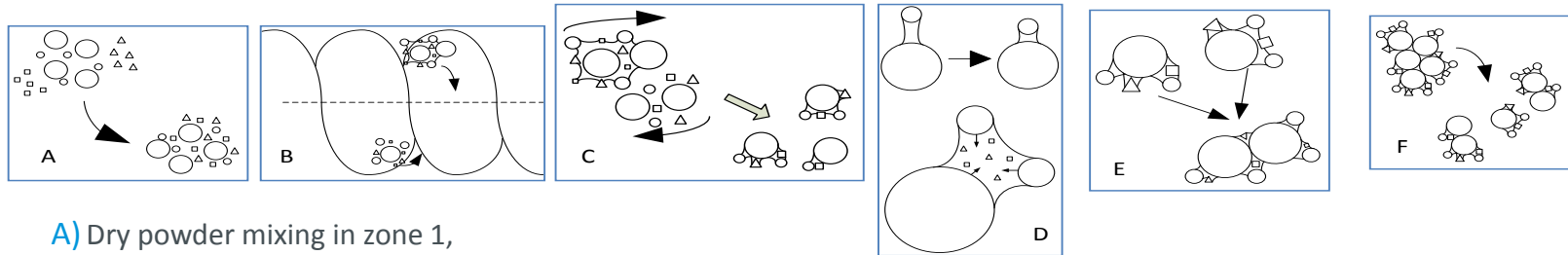
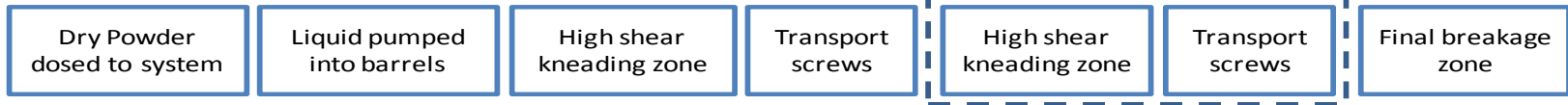
Working principle of a Intermeshing Twin Screw System



PSD optimization in Twin Screw Granulation Process

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.

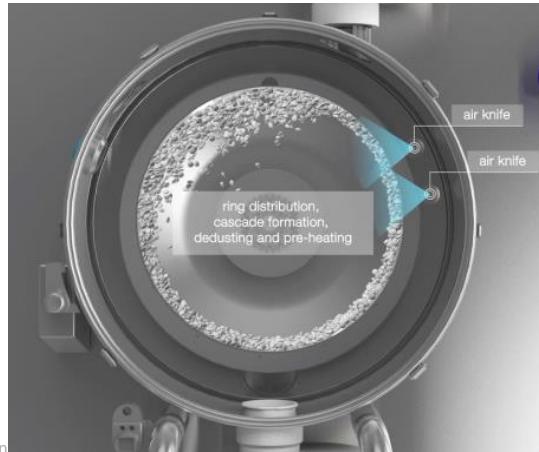
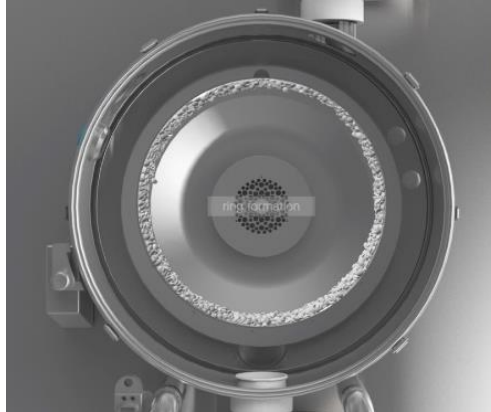
ConsiGma™ Coater



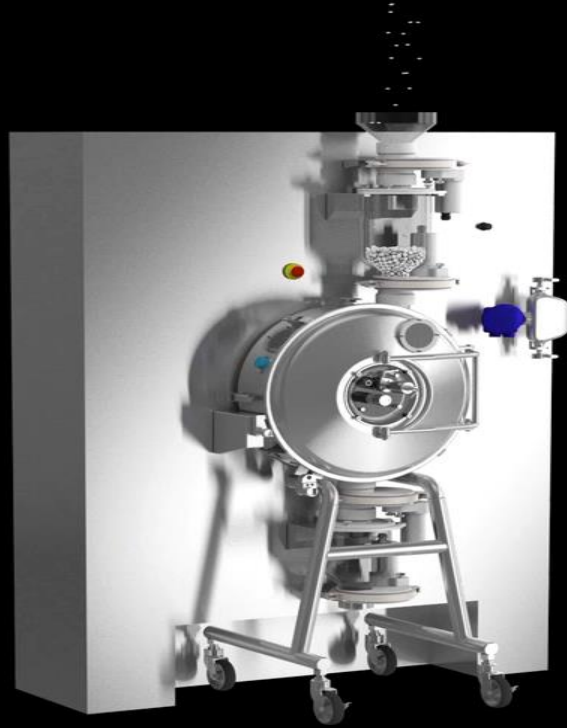
ConsiGma™ Coater



ConsiGma™ Coater: How does it work?



ConsiGma™ Tablet Coater working Principle



ConsiGma™ Tablet Coater working Principle



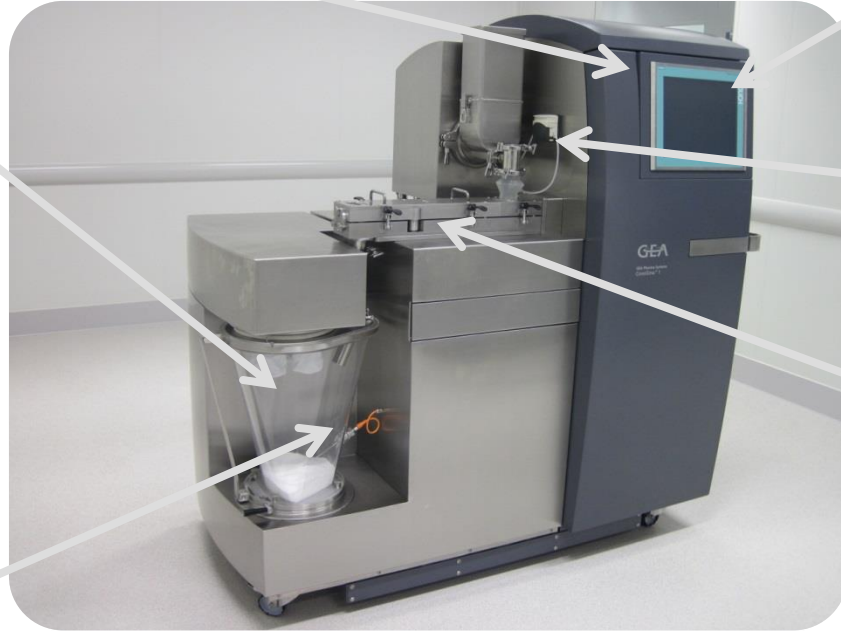
R&D – No Scale-up

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 !

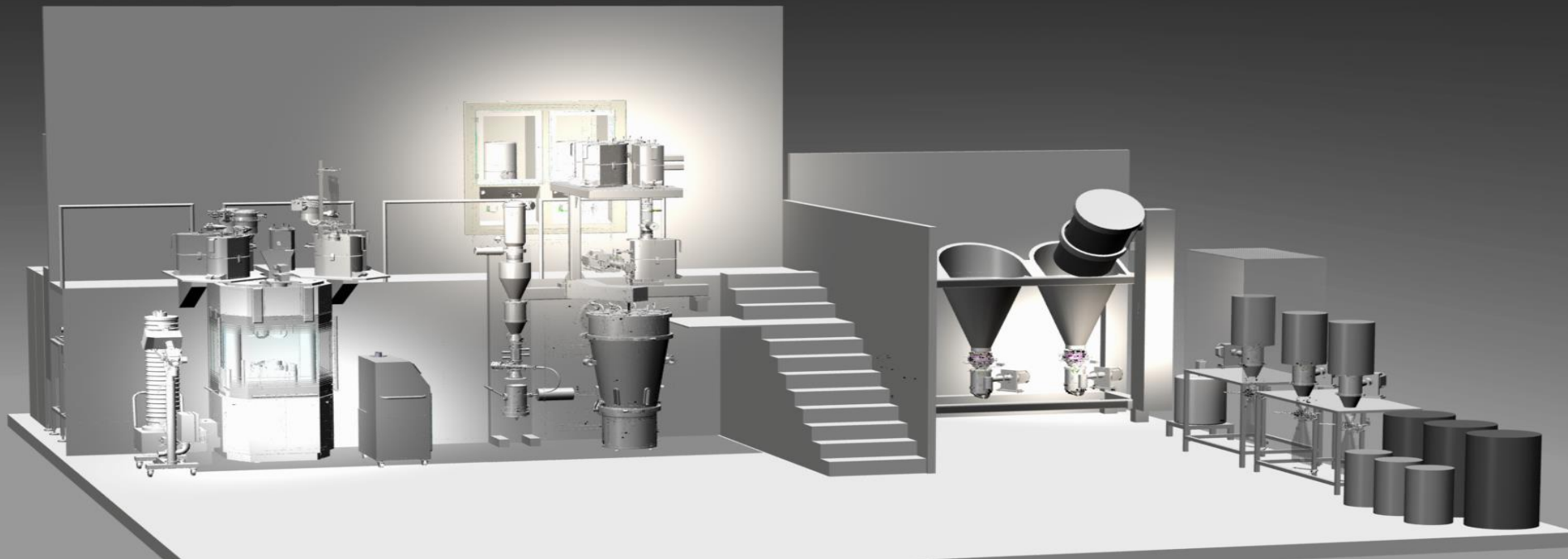
ConsiGma™: Efficient R&D : No scale-up

GEA Pharma Systems

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



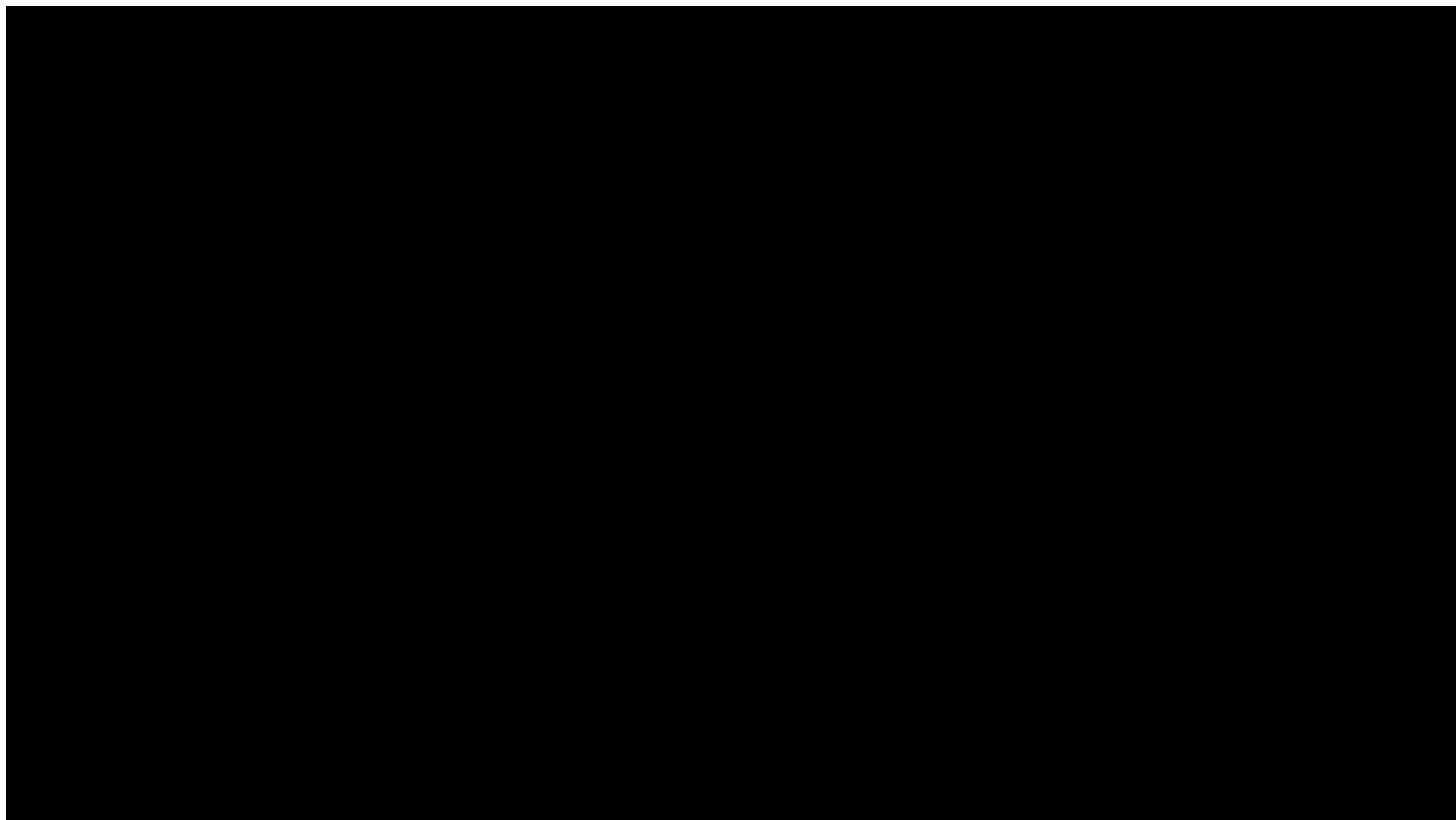
ConsiGma-25: Pfizer Groton – USA PCMM



ConsiGma-25: Pfizer Groton – USA PCMM



ConsiGma-25: Pfizer Groton – USA PCMM



Today more than 50 ConsiGma™ References



ConsiGma 25: PDC Testcenter

