Sneak Peek

Process Scale-up, Validation & Technology Transfer

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ONLINE
TRAINING

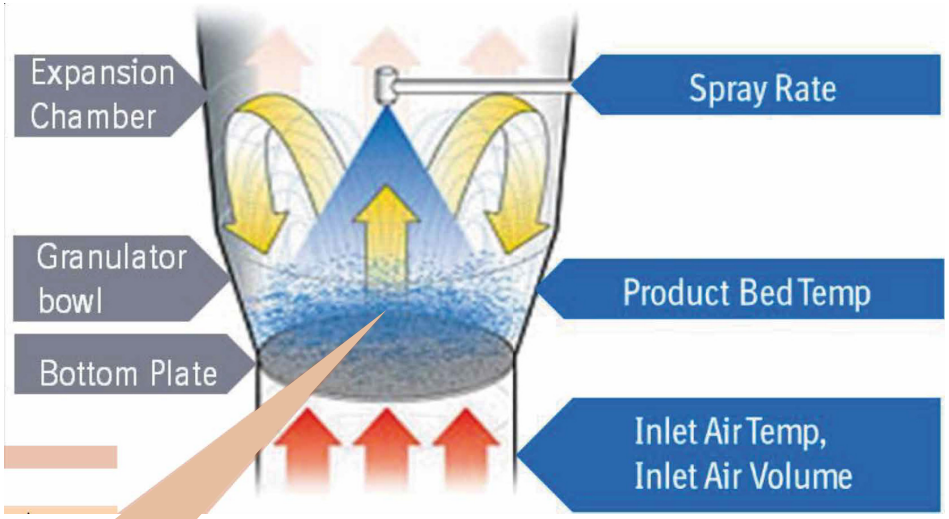
SYMMETRIC

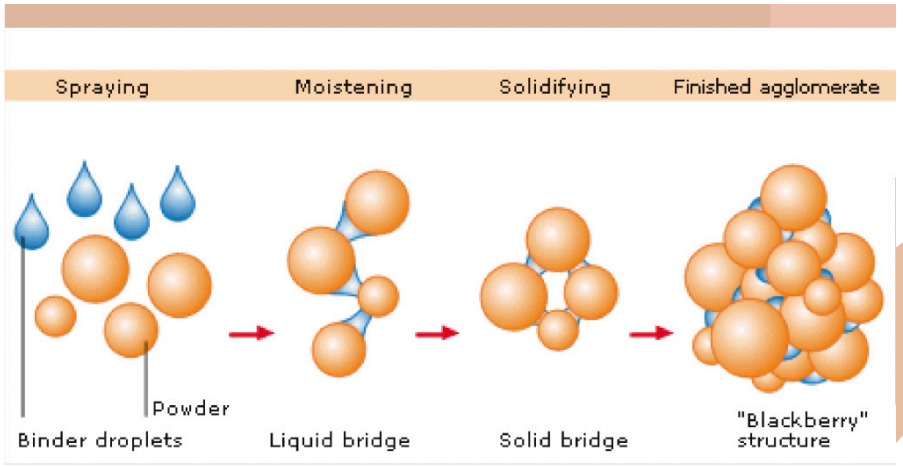
Fluid Bed Granulation (Top Spray)

01

Background

- Wet granulation inside a fluidized bed
- Particle growth (granulation) and drying occur in the same process step





- Product bed is the “heart” of the process

Fluid Bed Granulation

02

Objectives

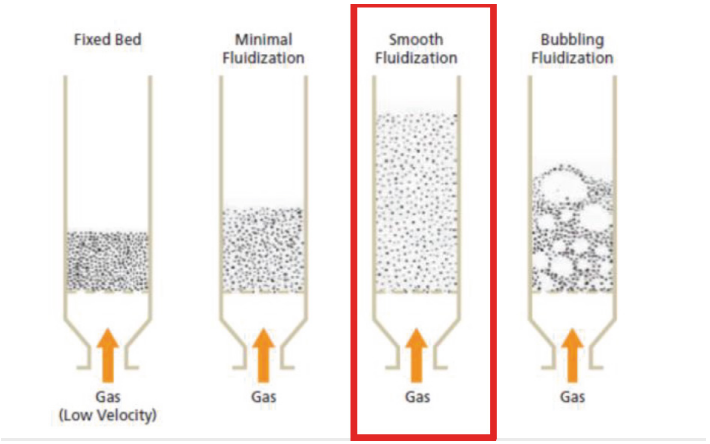
- **Identification of a simple model for scale up application of FBG**
- Evaluation of prevalent models for scale up of Fluid Bed Granulation based on Thermodynamics (heat and mass balance)

➡ **Constant product temperature as surrogate**

Practical Realisation
Step by step guidance for lean Scale up

1. **Batch size** (optimum 30% **– 80%)**

- Bulk density of the product should be known
- Batch size (X) direct proportional to bowl volume (V)



➡ **Formula : $X_2 = X_1 V_2 / V_1$**

2. **Fluidizing velocity**

- Keep air velocity at distribution plate constant to ensure similar fluidization across scales
- Air volume (AV) is scaled up using cross sectional area (A) of the bowl bottom

➡ **Formula : $AV_2 = AV_1 A_1 / A_2$**

Top 10 Challenges to QbD Adoption

McKinsey & Co. Survey commissioned by FDA, 2010

1. Internal misalignment
2. Lack of belief in business case
3. Lack of technology to execute
4. Alignment with third parties

} Company Driven

5. Inconsistency of treatment of QbD across agencies
6. Lack of tangible guidance for industry
7. Regulators not prepared to handle QbD applications
8. Lack of clear, consistent regulatory benefits
9 Misalignment of international regulatory agencies
10. A need for less formal interaction with FDA

} Regulatory Agency Driven

Registration

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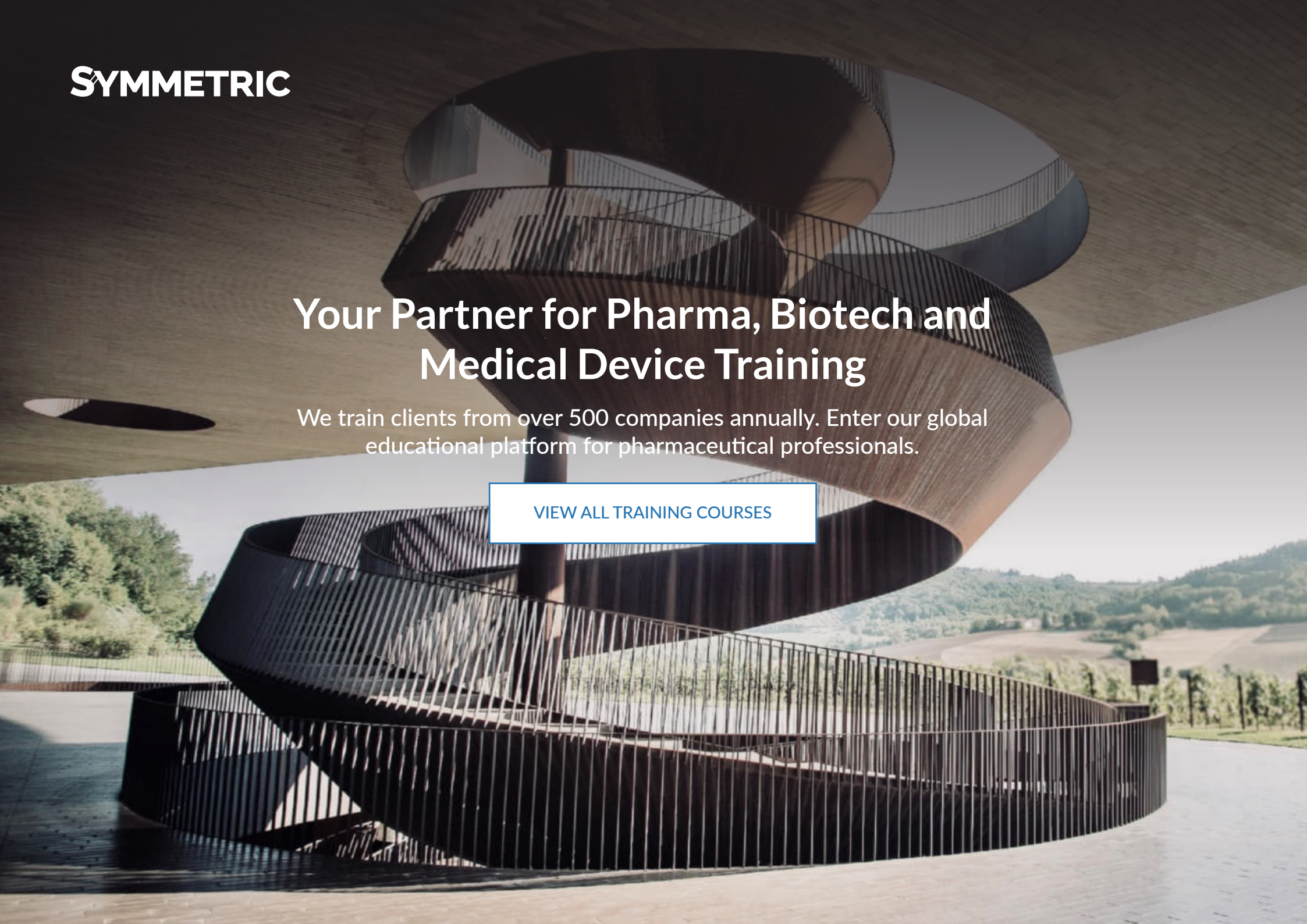
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