

# The next generation pharma skills you will need in view of continuous manufacturing

Exclusive 3-day training  
by leading academic, industry and regulatory experts

11-13 SEPTEMBER, 2018  
BINZEN, GERMANY

Demo's and case studies each day

"Entire picture covered: (flow sheet) modelling, PAT, control, regulatory"  
Feedback fully booked event 2017

LIMITED TO 50 SEATS

REGISTER HERE  
(early bird)

## Day 1

Introduction to continuous manufacturing platforms and material characterisation

## Day 2

Modelling and simulation towards design space definition

## Day 3

PAT for process monitoring and control of continuous manufacturing processes



Venue:

**TTC** TECHNOLOGY TRAINING CENTER

Organised by:



Prof. Thomas De Beer



Prof. Ingmar Nopens



www.AM-TEAM.com/training



Great to see theory practically implemented during the DEMO sessions.  
 Good combination of presentations and demonstrations.

Participant feedback 2017

Demo at training event 2017, Belgium

## Tuesday, Sep 11<sup>th</sup>

### Introduction to continuous manufacturing platforms and material characterisation

**12.30-13.00** Registration and lunch buffet

**13.00-13.20** Welcome and introduction

**13.20-14.50** Importance of raw material and formulation blend characterisation (raw materials and blends)

- Relevant raw material and blend properties and their characterisation techniques
- Material property data bases: overview, predictive use, maintenance and challenges
- Material variability
- Impact of material properties on the behaviour, performance and residence time of screw feeding systems in a continuous manufacturing platform

**14.50-15.20** Coffee break

**15.20-16.00** **Case study:** design space determination of a continuous tablet manufacturing process via wet granulation through empirical process models

**16.00-16.45** Empirical versus mechanistic modelling of continuous drug product manufacturing processes. Fundamentals - their complementarity - importance of proper data collection

**16.45-17.30** Material data base **DEMO** + Q&A

**17.30-17.45** Take home messages of the day

**19.00** Dinner

## Speakers

- Prof. Thomas De Beer (Ghent University)
- Prof. Ingmar Nopens (Ghent University)
- Ir. Jan Verelst (Siemens)
- Dr. David Slade (PSE)
- Victoria Pauli (Novartis)
- Dr. Anna Novikova (Glatt)
- Scientists from Fette Compacting
- Regulatory experts

## Demo's include:

- Continuous process lines in action
- Impact of material properties on CM unit operations
- Flow sheet modelling of continuous manufacturing
- Mechanistic modelling of twin-screw granulation, drying and milling

## Organisers



## Venue

TTC - Technology Training Center,  
 Meitner Ring 1, 79589 Binzen, Germany



[www.AM-TEAM.com/training](http://www.AM-TEAM.com/training)

## Wednesday, Sep 12<sup>th</sup>

### Modelling and simulation towards design space definition

**8.00-8.30** Transfer from hotel to TTC + coffee

**8.30-8.45** Introduction to Day 2

**8.45-9.15** Current status on feeding and blending modelling

**9.15-14.00** Modelling of CM unit operations

**9.15-9.45** Twin-screw granulation: collection of high quality data for model development, calibration and validation

**9.45-10.30A** holistic systems view of drug product manufacture and in-vitro/in-vivo performance - Flow sheet modelling - Generic model + **DEMO**

**10.30-11.00** Coffee break

**11.00-12.00** Twin screw granulation: model development, calibration and validation + **DEMO**

**12.00-13.00** Lunch break

**13.00-14.00**Data collection and modelling of drying and milling in a continuous manufacturing platform + **DEMO**

**14.00-14.45** Optimal experimental design (OED) - OED vs Design of Experiments (DoE) - OED for efficient model

calibration and process optimisation for new formulations - Uncertainty analysis as essential step in the establishment of the model-based Design Space determination for continuous manufacturing processes

**14.45-15.35** Coffee break and transfer to innovation center

**15.35-17.00** **LIVE DEMOS** with continuous process lines including feeding, blending, wet granulation, fluid bed drying, dry milling

**17.00-17.20** Take home messages of the day

**19.00** Wine tasting and dinner

## Thursday, Sep 13<sup>th</sup>

### PAT for monitoring and control of continuous manufacturing processes

**8.00-8.30** Transfer from hotel to TTC + coffee

**8.30-8.45** Introduction to Day 3

**8.45-9.15** 3D modelling of liquid mixing for pharma applications

**9.15-9.45** PAT for monitoring and control of continuous manufacturing processes for drug products - SPC - traceability - F-test

**9.45-10.30** Experiences and perspectives from industry (Novartis, Glatt, Fette Compacting)

**10.30-11.00** Coffee break

**11.00-12.00**Advanced process control of CM processes for drug products

**12.00-13.00** Lunch

## Register here

### Rates (EUR, excl. VAT)

Industry	1,700	1,500
Government/academia	1,200	1,000
Student	1,000	800

LIMITED TO 50 SEATS

Early bird rate ends July 30<sup>th</sup>

Normal rate

[AM-TEAM.com/training](http://AM-TEAM.com/training)  
[training@AM-TEAM.com](mailto:training@AM-TEAM.com)

## Sponsoring and exhibition

Ample exhibition space in the direct vicinity of the lectures is foreseen. Breaks will be organised in the exhibition hall.

Application and info: [training@AM-TEAM.com](mailto:training@AM-TEAM.com)