

# 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 OCTOBER, 2017  
GHENT, BELGIUM

Multiple demo's  
and hands-on

Exhibitors

PLATINUM

**SIEMENS** **Glatt**

SILVER

**ELSCOLAB**

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REGULATORY SPEAKERS



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## 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

Demo's and case studies each day

Organised by:



**GHENT**  
**UNIVERSITY**



Prof. Thomas De Beer

Laboratory of Pharmaceutical Technology

Prof. Chris Vervaet

**BIOMATH**

Prof. Ingmar Nopens



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

## Wednesday, Oct 11<sup>th</sup>

### Introduction to continuous manufacturing platforms and material characterisation

**8.30-9.00am** Registration and coffee

**9.00-9.30am** Welcome and introduction

**9.30-10.30am** Importance of raw material and formulation blend characterisation (raw materials and blends) - Jens Dondt (UGent)

- Relevant raw material and blend properties and their characterisation techniques
- Material property data bases: overview, predictive use and challenges
- Excipient variability **case** - Prof. Thomas De Beer

**10.30-11.00am** Coffee break

**11.00am-12.00pm** Impact of material properties on the behaviour, performance and residence time of screw feeding systems in a continuous manufacturing platform - Dr. Valérie Vanhoorne (UGent)

**12.00am-1.00pm** Lunch break

**1.00-2.00pm** Status quo continuous manufacturing according to GEA - Joel Aerts and Jake Deighton (GEA)

**2.00-2.45pm** **Case study:** design space determination of a continuous tablet manufacturing process via wet granulation through empirical process models - Prof. Thomas De Beer (UGent)

**2.45-3.15pm** Coffee break

**3.15-4.30pm** Empirical versus mechanistic modelling of continuous drug product manufacturing processes. Fundamentals - their complementarity - importance of proper data collection - Prof. Ingmar Nopens (UGent)

**4.30-5.00pm** Take home message of the day

**7.00pm** Social event and dinner

## Speakers

- Ir. Jan Verelst (Siemens)
- Dr. Sean Bermingham (PSE)
- Dr. Dolores Hernán (European Medicines Agency)
- Prof. Thomas De Beer (Ghent University)
- Prof. Chris Vervaet (Ghent University)
- Prof. Ingmar Nopens (Ghent University)
- Joel Aerts & Jake Deighton (GEA)
- Multiple scientists with hands-on expertise

## Demo's and hands-on include:

- Impact of material properties on CM unit operations
- PAT for process monitoring & control (ConsiGma25)
- Population balance modelling of twin-screw granulation

## Organisers



Laboratory of Pharmaceutical Technology  
Prof. Chris Vervaet



## Venue

13th century building 'Het Pand', Ghent, Belgium



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## Thursday, Oct 12<sup>th</sup>

### Modelling and simulation towards design space definition

**8.30-9.00am** Registration and coffee

**9.00-9.15am** Introduction to Day 2 - Prof. Thomas De Beer (UGent)

**9.15-9.45am** Current status on feeding & blending modelling - Prof. Thomas De Beer (UGent)

**9.45am-3.45pm** Modelling of CM unit operations

**9.45-10.15am** Twin-screw granulation: collection of high quality data for model development, calibration and validation - Maxim Verstraeten (UGent)

**10.15-10.45am** Coffee break

**10.45-11.45am** Twin screw granulation: model development, calibration and validation - Prof. Ingmar Nopens & Daan Van Hauwermeiren (UGent)

**11.45am-12.45pm** Lunch break

**12.45-1.45pm** Data collection and modelling of drying and milling in a continuous manufacturing platform - Prof. Ingmar Nopens & Michaël Ghijss (UGent)

**1.45-2.30pm** Tablet process modelling and control - Wouter Grymonpré (UGent)

**2.30-3.00pm** Coffee break

**3.00-4.00pm** A holistic systems view of drug product manufacture and in-vitro/in-vivo performance - Flow sheet modelling - Dr. Sean Bermingham (PSE)

**4.00-4.45pm** 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 - Prof. Ingmar Nopens (UGent)

**4.45-5.15pm** Take home message of the day

## Friday, Oct 13<sup>th</sup>

PAT for monitoring and control of continuous manufacturing processes

**8.00-8.30am** Transport to other demo location

**8.30-8.45am** Registration and coffee

**8.45-9.00am** Introduction to Day 3 - Prof. Thomas De Beer (UGent)

**9.00-9.30am** PAT for monitoring and control of continuous manufacturing processes for drug products - SPC - traceability - F-test - Prof. Thomas De Beer (UGent)

**9.45-10.30am** Importance of data management systems for continuous manufacturing processes - Jan Verelst (Siemens)

**10.30-11.00am** Coffee break

**11.00am-12.00pm** Continuous manufacturing: EMA experience and regulatory considerations - Dolores Hernan (EMA)

**12.00-1.00pm** Lunch break

**1.00-2.00pm** Advanced process control of continuous processes for drug products - Niels Nicolaï (UGent)

**2.00-4.00pm** Parallel demos

- PAT for process monitoring & control of continuous twin screw granulation

- Implementation of in-line PAT tools on a rotary tablet press: API quantification, RTD and punch monitoring (CDAAS)

**4.00-4.30pm** Advanced modelling for industry - AM-TEAM

**4.30-4.45pm** Event wrap-up

## Exhibitors

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**SIEMENS**



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