

# 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

Register here

2  
SEATS  
LEFT

They have  
delegates

UCB, Fette Compacting, GSK, Arlenda, European Medicines Agency, US Pharmacopeial Convention, Federal Agency for Medicines and Health Products, Siemens, Bayer, Baxter, GEA, PSE, AstraZeneca, Johnson and Johnson, Galapagos, LEO Pharma, Pharmavize, PwC, MW Group, Bosch, Elscolab, Glatt, L. B. Bohle Maschinen + Verfahren GmbH, Ashland Industries, NNE, University College Cork, Ghent University, Free University of Brussels, University of Leuven, University of Limerick

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EUROPEAN MEDICINES AGENCY  
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## 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 Vervaeet



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** Presentation GEA (title to be confirmed)

- 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

## 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 Ghijis (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

## Speakers

-Ir. Jan Verelst (Siemens)

-Dr. Sean Bermingham (PSE)

-Dr. Dolores Hernán (European Medicines Agency)

-Prof. Thomas De Beer (Ghent University)

-Prof. Chris Vervaeet (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

## 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 Nicolai (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

## Organisers



Laboratory of Pharmaceutical Technology  
Prof. Chris Vervaeet



## Venue

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



## Register here

Rates (EUR, excl. VAT)

Industry	1,900
Government/academia	1,200
Student	1,000

LIMITED  
TO 50  
SEATS  
Nearly  
fully  
booked

## Exhibitors

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