

EuPAT

5

Fifth pan-European QbD & PAT Science Conference

Final Programme – March 2012

Continuous Innovation in Process Analytics & Control

May 9-10 • 2012 • NH Hotel Ghent Belfort • Ghent • Belgium

Invitation to Join EuPAT 5

The topic of EuPAT 5 – Continuous Innovation in Process Analytics & Control – underlines the importance of bringing innovation into pharmaceutical manufacturing based on QbD and PAT sciences. Building quality into drug products should commence during the early phases of research and development and sustain during the product and process life cycle. Consideration and implementation of the quality requirements for new medicines should facilitate effective process development and robust large-scale manufacture. Advanced process analytics should therefore play a crucial role in design, analysis, and control of manufacturing processes based on timely in-process measurements for integrated system approaches, innovative developments and cutting edge scientific advances.

This is to invite you to submit abstracts and attend the fifth pan-European Science Conference on QbD and PAT Sciences, building on the successes of the EuPAT conference series that started in 2006. **EuPAT 5 will be held on May 9-10, 2012, in Ghent, Belgium, and organised back-to-back to a training day on “continuous pharmaceutical manufacturing of solid dosage forms”, to be held on May 8, 2012, at the Faculty of Pharmaceutical Sciences from the University of Ghent.** The attendees of EuPAT 5 are welcome to register to the pre-conference day and vice versa.

Topics of EuPAT 5

- Continuous pharmaceutical processing
- PAT in bio-active pharmaceutical processing
- Advanced process sensors for control
- Process modeling for in-depth understanding and control
- Material characterization and understanding at molecular level in (bio)process environment

Podium and Poster Presentations

In addition to the podium lectures from recognized leaders in the field, researchers will be given the opportunity to present the latest advancements in QbD & PAT sciences. Based on the submitted abstracts a number of authors are invited to present their research orally.

Wednesday, May 9, 2012 (8.00 – 18.00)	
8.00-8.30	Registration
8.30-8.45	Opening
	Invited Lectures
8.45-9.20	Modeling of Pharmaceutical Processes in the Context of Continuous Manufacturing <i>Prof. Dr. Johannes Khinast, Technical University of Graz, Austria</i>
9.20-9.55	Process Tomography for Imaging of Pharmaceutical Manufacturing <i>Prof. Dr. Wuqiang Yang, University of Manchester, United Kingdom</i>
	Oral Presentations
9.55-10.15	NIR Multipoint Spectroscopy and Chemical Imaging as PAT and Research Tools in the Optimization and Analysis of Continuous Pharmaceutical Manufacturing Process <i>Maunu Toivainen, VTT, Finland</i>
10.15-10.35	Application of In-line Particle Size Measurements for Advanced Process Control of Roller Compaction Processing <i>Lubomir Gradinarsky, AstraZeneca, Sweden</i>
10.35-11.05	Break & Posters
11.05-11.25	Real-time Monitoring of Granulator Torque to Identify the Steady State Phase of a Continuous Wet Granulation Process: Observation of an Unexpectedly Long Start-up Phase <i>Gunnar Haeffler, AstraZeneca, Sweden</i>
11.25-11.45	In-Depth Analysis of Multiple Logged Process Parameters during a Continuous Granulation and Drying Process <i>Jurgen Vercruyse, Ghent University, Belgium</i>
11.45-12.05	Real-time Tablet Formation Monitoring with Ultrasound Measurements in Eccentric Single Station Tablet Press <i>Jari T.T. Leskinen, University of Eastern Finland, Finland</i>
12.05-13.00	Lunch & Free Poster Session
13.00-13.45	Interactive Poster Presentations
	Parallel Session I
	1. Printing as a Flexible Tool for Manufacturing of New Products for Diagnostics and Drug Delivery Systems <i>Maria Smolander, VTT, Finland</i>
	2. How to Create a PAT Data Management Platform to Support Continuous Production? <i>Kjell François, Siemens, Belgium</i>
	3. Comparison of Granulation Methods: Preparation of Paracetamol Granules by Fluidized Bed, High Shear and Continuous Wet Granulations <i>Maiju Järvinen, University of Eastern Finland, Finland</i>
	4. Validation of Powder Mixing Process using Capacity Index <i>M. Llabrés, Universidad de la Laguna, Spain</i>
	5. Continuous Production of Solid Biodrug Formulations by Electrospinning <i>I. Wagner, Budapest University of Technology and Economics, Hungary</i>

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	Parallel session II
	1. A New Trend for NIR Spectroscopy: In-situ Monitoring of Dissolution Tests <i>Raquel Figueiredo</i> , Universidade do Porto, Portugal
	2. Powder Handling in Pharmaceutical Processes – Innovation or Perpetuation? <i>R.J. Farnish</i> , University of Greenwich, UK
	3. Comparison between Multipoint NIR Spectroscopy and DEM Simulations via a Water Spray Process <i>R. Hohl</i> , Research Center Pharmaceutical Engineering GmbH, Austria
	4. PAT Based Control for a New Manufacturing Drug Substance Process <i>Cédric Schaefer</i> , UCB Pharma, Belgium
	5. Application of Model Uncertainty Analysis on the Modelling of the Drying Behaviour of Single Pharmaceutical Granules <i>Séverine Mortier</i> , Ghent University, Belgium
	Invited Lectures
13.45-14.20	Making continuous processing a reality: Tales from an early adopter <i>Dr. Marcel de Matas</i> , AstraZeneca, Macclesfield, United Kingdom
14.20-14.55	PAT based advanced control of continuous manufacturing of solid dosage form <i>Dr. Steve Hammond</i> , Pfizer, New Jersey, USA
	Oral Presentations
14.55-15.15	Ultrasound and NIR Monitoring of a Pharmaceutical Hot-Melt Extrusion Process <i>Lien Saerens</i> , Ghent University, Belgium
15.15-15.50	Break & Posters
15.50-16.10	Continuous Technology of Nanopharmaceuticals Controlled with Micro-Raman Spectrometry <i>Gyorgy Marosi</i> , Budapest University of Technology and Economics, Hungary
16.10-16.30	Continuous Pharmaceutical Manufacturing with Hot Melt Extrusion <i>Daniel Markl</i> , Research Center Pharmaceutical Engineering GmbH, Austria
16.30-18.00	Industrial Session

Industrial session

Conference day 1 will end with a discussion session on ‘Bridging the Gap between Industry and Academia for Stimulating QbD and PAT Underpinning Scientific Research’. The session will start with two 15 minute presentations, one given by an industrial QbD and PAT scientist (Dr. A. Gerich, MSD, The Netherlands) and one given by an academic QbD and PAT scientist (Prof. J. Rantanen, University of Copenhagen, Den-

mark), in which both speakers will give their vision on the session topic. Both presentations will form a starting point for interactive discussion with the audience, which will be chaired by Prof. S. Folestad (Chalmers University and Astra Zeneca, Göteborg and Mölndal, Sweden) and Dr. Philippe Cappuyns (J&J and ISPE Belgium, Beerse, Belgium).

Wednesday, May 10, 2012 (8.30 – 16.45)	
8.30-8.45	Opening
	Invited Lectures
8.45-9.20	How to Optimize Biopharmaceutical Production Processes in a Small Pilot Scale Approach <i>Prof. Dr. Reiner Luttmann</i> , Hamburg University of Applied Sciences, Germany
9.20-9.55	PAT Tools for Fermentation Processes <i>Prof. Dr. Krist Germaey</i> , Technical University of Denmark, Denmark
	Oral Presentations
9.55-10.15	Is Ultrasonic Resonator Technology an Alternative to Raman spectroscopy for Drug Quantification in Complex Lipid-Based Formulations? <i>Cordura Stillhart</i> , University of Applied Sciences Northwestern Switzerland, Switzerland
10.15-10.35	Near-Infrared Spectroscopy for In-line Monitoring of Protein Unfolding and its Interactions with Lyoprotectants during Freeze-Drying <i>Sigrid Pieters</i> , Free University of Brussels, Belgium
10.35-11.05	Break & Posters
11.05-11.25	Freeze Drying Formulation and Process Design using Raman Spectrometer Equipped Micro Scale Freeze Drying Stage <i>Ari Kauppinen</i> , University of Eastern Finland, Finland
11.25-11.45	PAT and Smart Chemometrics in Rapid Prototyping and Scale-up <i>Ornella Preisner</i> , Newcastle University, UK
11.45-12.05	Freeze-Drying in Well-Plates as Formulation Development Tool <i>Holger Grohganz</i> , University of Copenhagen, Denmark
12.05-13.00	Lunch & Posters
13.00-13.45	Interactive Poster Presentations
	Parallel Session I
	1. Main and Interactions of Individual Principal Components Regression (MIPCR) as a Robust Method in Modelling of Moisture Content in Freeze-Dried Mannitol Containing Products <i>Wai Lam Yip</i> , University of Oslo, Norway
	2. Diffusing Wave Spectroscopy for Contact-Free Rheological Analysis of Self-Emulsifying Drug Delivery Systems <i>Andreas Niederquell</i> , University of Applied Sciences Northwestern Switzerland, Switzerland
	3. Physical Stability of the Calcium Salt of Atorvastatin in the Presence of Acidic Excipients <i>Niels Peter Aae Christensen</i> , University of Copenhagen, Denmark
	4. Evaluation of Lyophilized Viral Vaccine Formulations Using NIR Spectroscopy <i>Laurent Hansen</i> , Ghent University, Belgium
	5. On-line Ultrasound Microstructure Characterisation of Pharmaceutical Materials <i>Richard J. Tweedie</i> , Industrial Tomography Systems plc, UK

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	<p>Parallel session II</p> <ol style="list-style-type: none"> 1. Definition of a Successful Control Strategy for API-CQAs by Using the Quality by Design Principle <i>Zadeo Cimarosti</i>, Aptuit, Italy 2. Eyecon™ Particle Imager in Granule Size Measurements: A case study with Cellets® <i>Tuomas Ervasti</i>, University of Eastern Finland, Finland 3. Optimisation of Alfuzosin Tablet Formulations by Using Genetic Algorithm Program <i>B. Mesut</i>, Istanbul University, Turkey 4. Real-Time Raman Spectroscopy for Crystallization Processes <i>Hajnalka Pataki</i>, Budapest University of Technology and Economics, Hungary 5. Comparative Study to Evaluate the Performance of DMA vs. DSC and the Rheometer to Study the Thermal-Mechanical and Rheological Properties of Polymer Coating Film <i>Abraham M. Abraham</i>, University of Bradford, UK
	Invited Lectures
13.45-14.20	Modeling Tools for Process Understanding of Biopharmaceutical Problems <i>Prof. Dr. Anna de Juan Capdevila</i> , University of Barcelona, Spain
14.20-14.55	PAT Based Control for a Biopharmaceutical Production Process <i>Dr. Paul Jeffers</i> , Pfizer, Ireland
	Oral Presentations
14.55-15.15	Improvements in Moisture Monitoring by a Novel Dual Frequency Microwave Resonance Technology Sensor <i>Benjamin Kollar</i> , Heinrich-Heine-Universität, Germany
15.15-15.50	Break & Posters
15.50-16.10	Development of a Fluid Bed Granulation Control Strategy using Real-Time Process and Product Measurements <i>Anneleen Burggraeve</i> , Ghent University, Belgium
16.10-16.30	Novel Microwave Technology Platform for Process Tomography in Monitoring and Control of Pharmaceutical Processes <i>Livia Cerullo</i> , Chalmers University of Technology, Sweden
16.30-16.45	Closing Remarks

Pre-conference Workshop on Continuous Processing for Tablet Manufacturing

The pre-conference workshop will provide training on how to establish and optimize continuous processes from a scientific perspective. The morning session (at Ghent University) will theoretically approach the following topics:

- Overview and general introduction into continuous manufacturing of formulated products
- PAT based monitoring and control of continuous manufacturing processes

- How to establish and optimize continuous process trains from a scientific perspective
- The afternoon session will be a hands-on training, organised at GEA Pharma Systems (Antwerp) - Collette™, in which the morning session topics will be considered from a practical point of view.

Registration

Register online on the EUFEPS Online (www.eufeps.org – Current Meetings) by using the registration link. Or fill out and send the below registration form. When using the form, information on payment procedures and deadlines will be provided as soon as possible. The registration is complete when payment is received.

To register to the training day on ‘continuous pharmaceutical manufacturing of solid dosage forms’ (May 8, 2012, at the Faculty of Pharmaceutical Sciences from the University of Ghent), also register online (see above), or use the registration form below. For more information on the pre-conference workshop, see the information on the University website: <http://www.ugent.be/fw/en/research/pharmaceutical-analysis/pat>

The Early bird registration fee is available until March 15, 2012. As of March 16, 2012 the Late registration fee will apply. Notification of cancellation must be made in writing to Congress.

Additional Information

For more information and registration, see the EuPAT 5 Website, e.g. through EUFEPS Online (www.eufeps.org – Current Meetings), or contact:

EUFEPS Meetings and Events
Veddesta Business Center
SE-175 72 Jarfalla, Sweden
Email conferences@eufeps.org

<http://www.ugent.be/fw/en/research/pharmaceutical-analysis/pat>

Accommodation

For accommodation, special rate rooms have been blocked at the NH Hotel Ghent Belfort, Hoogpoort 63, B-9000 Gent, Belgium (Tel +32 9 2683613; Fax +32 9 2336400). To make use of the reduced room rate, please use the accommodation registration form below, the hotel list also being available online. Other accommodations also have special rates for conference participants. For reservation at one of these hotels, clearly mention the conference (EuPAT 5) and the conference organisation (Ghent University).

EU PAT 5 Programme Committee

Jukka Rantanen, University of Copenhagen, Denmark (QbD and PAT Sciences Network Chair)
*Wim Oostr*a, MSD, Oss, The Netherlands (QbD and PAT Sciences Network Vice-Chair)
Marcel de Matas, Astra Zeneca, Macclesfield, United Kingdom (QbD and PAT Sciences Network Secretary)
Buket Aksu, Santa Farma, Istanbul, Turkey
Joao Almeida Lopes, University of Porto, Portugal
Philippe Cappuyns, J&J and ISPE Belgium, Beerse, Belgium
Thomas De Beer, University of Ghent, Belgium



On Ghent and the EuPAT 5 Venue

Ghent is a historic and very lively city in Belgium with a large cultural line-up, an active harbour and business life, innumerable sport facilities and an internationally renowned university (www.ugent.be/en/). Ghent is stimulating and idiosyncratic, but above all authentic. Unique culture and services of excellent quality make the city an appealing place to live. Against the unique historic setting of Ghent, there is a vibrant city where easy accessibility is a key trump – no tailbacks and just 45 minutes from Brussels Airport. The NH Hotel Ghent Belfort attracts both business and leisure travellers, located right in the centre of Ghent, next to the historic city hall building. There are numerous cosy restaurants in the neighbourhood of the hotel (<http://www.nh-hotels.com/nh/en/hotels/belgium/ghent/nh-gent-belfort.html>).

Important Dates

Abstract Submission Deadline	February 15, 2012
Early-Bird Registration Deadline	March 15, 2012

Staffan Folestad, Chalmers University and Astra Zeneca, Göteborg and Mölndal, Sweden
Jarkko Ketolainen, University of Eastern Finland, Kuopio, Finland
Hans H. Lindèn, EUFEPS Executive Director, Stockholm, Sweden
Guido Pareijn, Siemens AG and ISPE Belgium, Antwerp, Belgium
Kris Schoeters, GEA Pharma Systems, Wommelgem, Belgium
Tom Van Den Kerkhof, J&J, Beerse, Belgium
Marco Weimer, Sanofi-Aventis, Frankfurt, Germany



Founded in 1991, the mission of EUFEPS is to advance excellence in the pharmaceutical sciences and innovative drug research, and to represent the interests of scientists engaged in drug research and development, drug regulation and drug policymaking. Currently, EUFEPS links 24 Member Societies in 24 European countries. It has, in addition, around 600 individual members (<http://www.eufeps.org>).



Founded in 1980, ISPE has worldwide headquarters in Tampa, Florida; an Asia Pacific office in Singapore; a European office in Brussels, Belgium; and Affiliates and Chapters in numerous countries around the world (<http://www.ispe.org>).



Founded in 1817 as a Latin-speaking State University by William I, King of the Netherlands, Ghent University is a relatively young university. After its independence in 1830, the Belgian

State was in charge of the administration of Ghent University; French was the new official academic language. In 1930 Ghent University became the first Dutch-speaking university in Belgium. The Decree of 1991 assigned great autonomy to the university. Over the years eminent scientists such as Joseph Plateau (physicist, considered as a pioneer in the development of motion pictures), Leo Baekeland (inventor of Bakelite) and Corneel Heymans (Nobel Prize winner in Medicine) studied and worked at Ghent University.

With a view to cooperation in research and scientific service, numerous research groups, centres and institutes have been founded over the years. Several of them are renowned worldwide, in various scientific disciplines such as biotechnology, aquaculture, microelectronics, history,...

Today, after decades of uninterrupted growth, Ghent University is one of the leading institutions of higher education and research in the Low Countries. Ghent University is an open, committed and pluralistic university with a broad international perspective. Located in Flanders, the Dutch-speaking part of Belgium and the cultural and economical heart of Europe, Ghent University is an active partner in national and international educational, scientific and industrial cooperation.

Because it plays a leading role in the academic and scientific world, Ghent University attaches great interest to a transparent organization structure, a dynamic human resources policy, an active environmental policy, its support to spin-offs and other new initiatives,...

On the EuPAT Series

The EuPAT Conference Series is a unique forum for scientists and engineers, encouraging and promoting progress in science behind QbD and PAT, and strengthening the interdisciplinary scientific discussion that bridges between the various fields underpinning QbD and PAT. The focus of it is on scientific progress underpinning Innovative Manufacturing Control and Quality by Design. New findings and results from scientific research and technology development are discussed in the four areas that constitute the cornerstones of sessions of the EuPAT Conferences; Process Informatics; Process Modelling and Understanding; Advanced Process Sensors; and PAT Based Control and Process Integration.

On the EUFEPS QbD and PAT Sciences Network

Powering Science Based Process Understanding and Quality-by-Design for Medicines, the Network is there to focus on Process Analytical Technology and underpinning sciences, create and maintain a unique and effective forum to encourage and improve collaboration, actively contribute to education and training, and to promote innovation in relevant sciences - all to power science based process understanding and Quality-by-Design for medicines. All scientists involved in QbD and PAT sciences are more than welcome to become a member of the EUFEPS QbD and PAT Sciences Network (www.eufeps.org - Network and Networking).

EuPAT 5 sponsors



EuPAT 5 Registration Form

Please, register using the link on the Eufeps Online (www.eufeps.org – Current Meetings), or fill out the below form and send.

Early registration deadline will be March 15, 2012.

- I register for EuPAT 5 (May 9-10, 2012) I register for EuPAT 5 + the pre-conference workshop
- I register for the pre-conference workshop (May 8, 2012)
- I submit an abstract for EuPAT 5

Title _____

Organisation _____

First Name _____

Family Name _____

Address _____

Postal address _____

Country _____

Tel _____

Email _____

EuPAT 5			
	Fee	Excl. VAT	21% VAT added
Industry	Early Member	€ 600	€ 726
	Early Standard	€ 650	€ 787
	Late Member	€ 700	€ 847
	Late Standard	€ 850	€ 1 029
Academy/ Regulatory	Early Member	€ 350	€ 424
	Early Standard	€ 400	€ 484
	Late Member	€ 450	€ 545
	Late Standard	€ 500	€ 605
Student	Early	€ 200	€ 242
	Late	€ 300	€ 363

Pre-conference day			
	Fee	Excl. VAT	21% VAT added
Industry	Early Member	€ 250	€ 303
	Early Standard	€ 300	€ 363
	Late Member	€ 350	€ 424
	Late Standard	€ 400	€ 484
Academy/ Regulatory	Early Member	€ 150	€ 182
	Early Standard	€ 200	€ 242
	Late Member	€ 250	€ 303
	Late Standard	€ 300	€ 363
Student	Early	€ 50	€ 61
	Late	€ 100	€ 121

- I will attend the Welcome Reception, on May 9, 2012

Fill out and send this Registration Form to: Ghent University, Claudine Rawoens, Faculty of Pharmaceutical Sciences, Harelbekestraat 72, B-9000 Gent or send an email indicating participation, to: Claudine Rawoens, Claudine.Rawoens@UGent.be
Fax +32 9 2228236

EuPAT 5 Accomodation Form

Please book your hotel by email or fax before March 15, 2012

Personal information

First Name
Family Name
Phone
Email
Passport

Booking information (*)

Type of room	<input type="checkbox"/> Standard	€ 130,00 + € 2,50 city tax per night
	<input type="checkbox"/> Superior	€ 145,00 + € 2,50 city tax per night
Breakfast and VAT included	<input type="checkbox"/> Deluxe	€ 160,00 + € 2,50 city tax per night
	<input type="checkbox"/> Single	<input type="checkbox"/> Double = € 10,00 + € 2,50 city tax per night for 2nd person

Occupation
Check-in date
Check-out date

Method of Payment ()**

Credit card type
Expiry date
Credit card number

(*) Roombookings prior and directly after the booking can be made at the seminar rate, upon availability
 (**) Roombooking can only be guaranteed by credit card number (with expiration date). This credit card number will not be used for payment issues before arrival of the guest, except in case of no show (a guaranteed reservation which has not been cancelled in time). The following cancellation conditions apply:

- cancellation not later than the 30th day before arrival: 0%
- cancellation from the 29th to the 15th day before arrival: 50% of the guaranteed booking
- cancellation from the 14th to the 8th day before arrival: 75% of the guaranteed booking
- cancellation less than 8 days before arrival: 100% of the guaranteed booking

Fill out and send this Registration Form to:
 Hotel NH Gent Belfort, Hoogpoort 63. 9000 Ghent, Belgium
 Tel +32 9 2683613 Fax +32 9 2336400
 Email k.vandenberghe@nh-hotels.com

Hotel List

- Ghent Marriott Hotel
Korenlei 10
B-9000 Ghent
Tel +32 9 26977 22
Fax +32 9 2339394
Standard quality room (excl. breakfast): € 150,00 per night
Breakfast: € 23,00
Website www.marriottghent.com
- Novotel Gent Centrum hotel
Goudenleeuwplein 5
B-9000 Ghent
Tel +32 9 2242230
Fax +32 9 2659716
Websites www.novotel.com
www.accorhotels.com
- Ibis Gent Centrum Kathedraal hotel
Limburgstraat 2
B-9000 Ghent
Tel +32 9 2330000
Fax +32 9 2331000
Website www.accorhotels.com
- Ibis Gent Centrum Opera hotel
Nederkouter 24-26
B-9000 Ghent
Tel +32 9 2250707
Fax +32 9 2335907
Website www.accorhotels.com
- Ghent River Hotel
Waaistraat 5
B-9000 Ghent
Tel +32 9 2661010
Fax +32 9 2661015
Standard quality room: € 124,00 per night
Website www.ghent-river-hotel.be/
- Monasterium PoortAckere
Oude Houtlei 56
B-9000 Ghent
Tel +32 9 2692210 or +32 9 2692262
Fax +32 9 2692230
Website www.monasterium.be
- Youth Hostel De Draecke
Sint-Widostraat 11
B-9000 Ghent
Tel +32 9 2337050
Fax +32 9 2338001
Website www.jeugdherbergen.be/gent.htm