

EuPAT

6

Sixth pan-European QbD & PAT Science Conference

Second Announcement – June 2013

Tailoring QbD & PAT Sciences to Pharmaceutical Industry Needs

September 23-24 • 2013 • HF Hotel Ipanema Park • Porto • Portugal

Invitation to Join EuPAT 6

The topic of EuPAT 6 (Tailoring QbD&PAT Sciences to Pharmaceutical Industry Needs) underlines the importance of innovation by the pharmaceutical industry in the underpinning QbD & PAT sciences. Desirable product quality should be designed in during the early phases of development and be continually improved throughout a medicine's lifecycle. Quality requirements must therefore be fulfilled through effective process development, robust large-scale manufacture and application of cutting edge process analytics and advanced control systems.

The sixth pan-European Science Conference

on QbD and PAT Sciences (EUPAT 6) brings together pharmaceutical industrialists and academics to discuss recent developments in the continuous production of medicines, quality risk assessment, process knowledge management, and biopharmaceutical manufacturing. It builds on the success of the EuPAT series established in 2006. The main meeting will be held on September 23-24, 2013, in Porto, Portugal, and is organised back-to-back to a training day on "Science-based implementation of QbD and PAT concepts in the

pharmaceutical industry", to be held on September 22, 2013, at the Faculty of Pharmacy at the University of Porto. The attendees of EuPAT 6 are welcome to register for the pre-conference day and vice versa.

Session topics at EuPAT 6

- Manufacture and downstream processing of biopharmaceuticals
- Fast and flexible continuous processing
- Risk assessment and life-cycle process knowledge management
- PAT/QbD for active product ingredients and drugs manufacturing

Abstract Submission

Abstracts should be submitted electronically using the Abstract Submission form available at <http://www.eupatqbd.com> by June 28, 2013. Please indicate which EuPAT 6 session topic best suits the abstract on the electronic form. The selection of oral presentations and poster presentations will be based on the review of abstracts by the Scientific & Planning Committee. Notification of abstract acceptance will be sent before July 21, 2013.

EuPAT6 Preliminary Program

Monday, September 23, 2013 (08:00 - 22:00)

Registration (08:00 - 08:45)

Welcome and opening remarks (08:45 – 09:00)

Session I – Fast and flexible continuous processing

Invited lectures (09:00 – 10:20)

“The understanding of pharmaceutical granular flows - state-of-the-art and challenges”

Prof. Johannes Khinast, RCPE, Graz University of Technology, Graz, Austria

“Towards continuous tablet manufacturing”

Prof. Jarkko Ketolainen, University of Eastern Finland, Kuopio, Finland

Poster session, Exhibition, Networking & Coffee break (10:20 – 10:50)

Oral presentations (10:50 – 12:30)

Lunch (12:30 – 13:30)

Oral poster presentations (13:30 – 14:00)

Session II – Risk assessment and life-cycle process knowledge management

Invited lectures (14:00 – 15:20)

“New frontiers in medicines development and manufacturing science: from quality by design to continuous manufacturing in nanomedicines”

Prof. Rogério Gaspar, University of Lisbon, Lisbon, Portugal

“Risk assessment in supporting the implementation of a PAT technology in a manufacturing process – issues for consideration”

Dr. Kevin O'Donnell, Irish Medicine Board, Dublin, Ireland

Poster session, Exhibition, Networking & Coffee break (15:20 – 15:50)

Oral presentations (15:50 – 17:30)

Industrial session: “Challenges and priorities for the pharmaceutical industry in PAT & QbD implementation” (17:30 – 18:30)

Cocktail & dinner at Hotel HF Ipanema Park (19:30 – 22:00)

Podium and Poster Presentations

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

Tuesday, September 24, 2013 (08:45 - 16:45)

Opening remarks (08:45 – 09:00)

Session III – Manufacturing and downstream processing of biopharmaceuticals

Invited lectures (09:00 – 10:20)

“Innovative data-based strategies for biologics process development and manufacturing”

Prof. José Menezes, Technical University of Lisbon, Lisbon, Portugal

“Proteins in tablets”

Dr. Kaisa Naelapää, Novo Nordisk, Bagsvaerd, Denmark

Poster session, Exhibition, Networking & Coffee break (10:20 – 10:50)

Oral presentations (10:50 – 12:30)

Lunch (12:30 – 13:30)

Session IV – PAT/QbD for active product ingredients and drug product manufacturing

Invited lectures (14:00 – 15:20)

“Printing technologies in fabrication of tailored and personalised drug delivery systems”

Prof. Niklas Sandler, Åbo Akademi, Turku, Finland

“The production of solid pharmaceutical dosage forms using 3D printing”

Prof. Clive Roberts, The University of Nottingham, Nottingham, UK

Oral presentations (14:50 – 16:30)

Closing remarks (16:30 – 16:45)

Industrial Session

Conference day one will end with a discussion session on ‘**Challenges and priorities for the pharmaceutical industry in PAT & QbD implementation**’. The session will start with two sort introductions presentations, one given by an industrial QbD and PAT scientist and one given by an academic QbD and PAT scientist 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).

Pre-conference Course

A Complete PAT & QbD Primer/Refresher September 22, 2013

The pre-conference course entitled “A Complete PAT & QbD Primer/Refresher” will provide an integrated perspective of the current trends of PAT&QbD making a link between basic science and industrial applications.

Sunday, September 22, 2013 (08:30-13:30)

Local: Main Hall, ICBAS/Faculty of Pharmacy, University of Porto

Part I (08:30-10:30)

Prof. José Cardoso Menezes, Technical University of Lisbon, Lisbon, Portugal

- QbD: Focus on Product
- PAT Goals and Tools
- Process Systems Engineering Background

Networking and Coffee break (10:30 – 11:00)

Part II (11:00-13:00)

Dr. Pedro Felizardo, 4Tune Engineering Ltd

- Working with Real-World Data
- Whole Process Analysis Historic Batch Analysis
- Life-Cycle Analysis Early-Stage Development

Conference Fees

Fee		Excluding VAT	21% VAT included
Industry	Early Member	€480	€581
	Early Standard	€560	€678
	Late Member	€520	€629
	Late Standard	€680	€823
Academy/ Regulatory	Early Member	€280	€339
	Early Standard	€360	€436
	Late Member	€320	€387
	Late Standard	€400	€484
Student	Early	€160	€194
	Late	€240	€290

Pre-Conference Fees

Fee		Excluding VAT	21% VAT included
Industry	Member	€135	€163
	Standard	€150	€182
Academy/ Regulatory	Member	€100	€121
	Standard	€115	€139
Student	Member	€50	€61
	Standard	€50	€61

Registration

Register online by using the registration link on the conference website www.eupatqbd.org. The registration is complete when payment is received. To register to the training day on ‘A Complete PAT & QbD Primer/Refresher’ (September 22, 2013, at the Faculty of Pharmacy from the University of Porto, also register online (see above). For more information on the pre-conference workshop, see the information on the conference website www.eupatqbd.org. The Early bird registration fee is available until July 28, 2013. As of July 29, 2012 the Late registration fee will apply. Cancellation of registration will be accepted until August 30, 2013, up to which dates the total amount will be refunded less a handling fee of 50 EUR. For cancellations made after above given dates no refunds can be made.

Additional Information on EuPAT 6

is available on the EuPAT 6 conference website at www.eupatqbd.org or through the EUFEPS website (<http://www.eufeps.org/PATnetwork.html>), or contact:

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Accommodation

For accommodation, special rate rooms have been blocked at the Hotel Ipanema Park, Rua De Serralves, 124, 4150-702 Porto (Tel +351 225322100; Fax +351 22 610 28 09). To make use of the reduced room rate, please access the hotel reservation system through the conference website at <http://www.eupatqbd.org> or directly using the link <https://www.hfhotels.com/gb/?b2b>. For an additional list of nearby hotels please access the conference website <http://www.eupatqbd.org>.

Important Dates

Abstract Submission Deadline	July 22, 2013
Communication of Accepted Abstracts	July 31, 2013
Early-bird Registration	Aug 9, 2013
EuPAT6 Pre-conference Courses	September 22, 2013
EuPAT6 Conference	September 23-24, 2013

On Porto and the EuPAT 6 Venue

Porto is the second-largest city in Portugal and one of the major urban areas in Southern Europe with a 1.7 million population in the Metropolitan area. Located along the Douro river estuary in northern Portugal, Porto is one of the oldest European centres, and registered as a World Heritage Site by UNESCO in 1996. On the region outskirts two other World Heritage Sites can be discovered: the famous Port wine region (Alto Douro Wine Region) and the city of Guimarães the birth-place of the Portuguese nationality. The warm and friendly Porto people, richness of its monumental and artistic patrimony, the Port Wine cellars, the many spots dedicated to leisure and culture are only some of the reasons that invite you to visit Porto. You can get to Porto by plane from almost anywhere in the world, either directly or by means of other connections (Porto airport is also the hub for low-cost air companies in Portugal). Porto is easily accessible through its award winning airport located only 15 Km away from the city centre and served by a fast and excellent metro line service (20 min travel only). The HF Hotel Ipanema Park is a five-star hotel conveniently located between the Porto historic and business centres. Hotel offers excellent accommodations with room for all participants being a guarantee of a pleasant stay.

EuPAT 6 Programme Committee

João Almeida Lopes, U. Porto, Portugal (Chairman)
Jukka Rantanen, U. Copenhagen, Denmark (QbD and PAT Sciences Network Chair)
Marcel de Matas, Astra Zeneca, United Kingdom (QbD and PAT Sciences Network Secretary)
Hans Linden, EUFEPS Central Office, Sweden
Per Öhmgren, EUFEPS Central Office, Sweden
José Costa Lima, U. Porto, Portugal
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Jarkko Ketolainen, U. Eastern Finland, Finland
Thomas De Beer, U. Ghent, Belgium
Staffan Folestad, Chalmers University and AstraZeneca, Sweden
Wim Oostra, MSD, The Netherlands
Rui Cerdeira, BIAL, Portugal
Buket Aksu, Santa Farma, Turkey
Marcela Segundo, U. Porto, Portugal
Mafalda Sarraça, U. Porto, Portugal (Conference Secretary)



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 inter-disciplinary scientific discussion that bridges between the various fields underpinning QbD and PAT. The focus of the Series 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. EuPAT 6 is at Facebook and LinkedIn.

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 QbD 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).

Co-sponsors:



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