IQPC's Second European Conference

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Successfully Implementing Process Analytical Technologies

Two day conference:
20th & 21st January 2005
Pre-conference workshops:
19th January 2005
Arabella Sheraton Grand Hotel,
Frankfurt, Germany

Improving quality, process control and risk analysis from design through production

Featuring key regulatory, industrial and academic insights from:

Final FDA guidelines for PAT have now been published, but what are the next steps for Europe?

Discover the strategies and best practices for the implementation of Process Analytical Technologies:

- Hear the latest on European regulatory guidance and feedback on submissions referring to PAT
- Discover the recent advances in process analytical techniques and their impact on process control
- Improve process understanding to ensure successful PAT implementation
- Achieve quality 'right first time' and work towards real-time release
- Learn lessons on PAT implementations from cross industry experiences

Interactive pre-conference workshops: 19th January 2005

A: Developing process improvement strategies through PAT applications
B: Improving manufacturing performance and developing manufacturing excellence by using PAT
C: How Geometric Process Control delivers PAT

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PRE-CONFERENCE WORKSHOPS: **WEDNESDAY 19TH JANUARY 2005**

09:00 – 12:00 Workshop A

Developing process improvement strategies through PAT applications

The first part of this interactive workshop focuses upon the context within which PAT applications are set, and the tools and techniques that deliver bottom line benefit from PAT applications. It will address measurement technique selection, data processing, mining and visualisation, integration into control strategies and delivery of flexible processes. The application of inferential and model based process control will be reviewed. The opportunities arising within and across unit operation stages will be explored with tools and techniques for identifying key process behaviours and developing process improvement strategies. The context for the discussion is process consistency and repeatability as a foundation for improved operability and asset flexibility.

The focus of the second part of the session will be on the implementation of FT-NIR technology for different PAT applications such as raw material identification, tablet content uniformity, dryer monitoring and reaction monitoring. Practical examples will be used to support interactive discussions. During this session, the benefits and limitations of NIR technology will be addressed and illustrated and the critical factors that govern the success of a PAT project will be reviewed, in particular: project justification, typical schedule, model development, equipment qualification, documentation and software compliance.

Key topics of workshop discussion will include:

- Drivers for PAT
- Near-infrared spectroscopy
- Other measurement methods
- Process control
- Chemometrics
- Instrument validation
- Sample interfaces and practical issues

Ian Clegg, Measurement Science Leader, ABB
Ian holds a first degree in Chemistry and a PhD in applied measurement science. He has nearly 20 years of experience in the implementation of applied measurement science to process control problems in pharmaceuticals and associated industries. He has several recent publications on PAT and is a full member of the ASTM committee E55 on process analytical technology.

Frédéric Despagne, FTIR Application Specialist, ABB
Frédéric holds a PhD in chemometrics from the free University of Brussels (1999) and has been involved in a number of implementations of near-infrared process analysers for the refining, chemical, semi-conductor and pharmaceutical industries. He also acts as European Technical Sales Support and Solution Manager for Dryer Monitoring applications.

12:15 – 15:15 Workshop B (includes working lunch)

Improving manufacturing performance and developing manufacturing excellence by using PAT

The increased emphasis on cost reduction and improving production efficiency needs real-time process information. Product safety methodologies result in an increased need to track product quality throughout the manufacturing process. The recent FDA's PAT initiative goes a step further than just the tracking of product quality.

Process monitoring alone is not sufficient to ensure safety - the quality system has to be built in to the manufacturing process, meaning that both monitoring and adequate process control are required to ensure that the product that is produced is safe. How this can be achieved is not obvious, but this session will describe how to build a PAT-system like this as a potential solution.

The interactive workshop will explain the critical issues concerning manufacturing performance and will explore a different way to use PAT to ensure patient safety; a science-based approach to process optimisation and real-time product release.

Presentation and discussion topics will include:

- PAT - more then just monitoring?
- Measuring what and how? Examples on new PAT concepts for various processes (from API synthesis to packaging)
- Advanced process control and real-time product release

Ingrid Maes, Consultant Advanced Technologies, Siemens
Ingrid is responsible for Advanced Technologies, including PAT, within the Siemens Headquarter competence centre Pharma, located in Antwerp. She obtained a Masters degree in Chemical Engineering, and in Biotechnology & Medicinal Chemistry, from the University of Brussels. She has worked for 15 years in Process Analytics and Chemometry as Marketing & Sales Manager, and has developed new application fields for Process Analytics and control in many industrial branches. She lectures at the University of Ghent and is author of many presentations at international conferences. She is also involved in various PAT related organisations, such as the ASTM E55 committee.

15:30 – 18:30 Workshop C

How Geometric Process Control delivers PAT

PAT requires continuous monitoring of quality and this in turn requires a model able to predict product qualities that can be measured in real-time from the values of real-time process measurements. The answer turns out to be n-dimensional geometry and not statistics or chemometrics.

This interactive workshop will introduce and explain GPC and how it can deliver PAT. Geometric models are easy to create using historical process and quality data and visual analysis methods. They do not require any mathematical training to build or maintain because geometry makes these models 'equationless'. They are similarly easy for the process operator to use because:

- They use only the original process and quality variables that are already familiar
- The standard multi-variable display shows the currently usable ranges of all variables that will allow the operator to achieve the quality objectives – information never available before
- The display gives advice to correct the process to ensure the quality specifications are met

A continuous record of quality achievement is available both as charts and as a numeric file. Real-time release is a reasonable short-term objective.

This interactive workshop will include real examples including some from other application areas such as improvement of the 6-Sigma methodology.

Robin Brooks, Curvaceous Software
Robin worked for many years with a major computer manufacturer on diverse computer applications for process plants and became convinced that engineers and scientists needed substantially better mathematical methods to use large volumes of data. He founded PPCL in 1994 as a Management Consultancy for large application projects in Oil Refining, and Curvaceous Software in 1998 as a technology company to turn n-dimensional geometry into effective everyday tools. This has so far led to several patent applications, with the first already awarded, and the wholly new 'equationless' modelling that is taking the process industries from Food and Pharmaceuticals to Chemicals and Oil Refining by storm.

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DAY ONE: **THURSDAY 20TH JANUARY 2005**

08:30 Registration and coffee

09:00 Chair's welcome and introduction

Frank Cottee
Director of Analytical Sciences
GlaxoSmithKline and Chair, CPACT

09:15 **A historical view of Process Analytical Technology and its implications for the future**

This session will reflect on the development of PAT as a concept in the early 1980s up until the present day, and will explore the possible future of PAT and the opportunities it offers through new sampling and measurement technologies.

- A historical discussion about the development of the concept of PAT
- Brief description of applications of PAT in other industries
- Discussion of the lessons learnt from implementing PAT from other industries
- A look towards the technologies of the future for PAT

Brian Marquardt
Senior Research Scientist,
CPAC, University of Washington

10:00 **Implementing PAT in the European Union: the regulatory viewpoint**

This session will explore the latest developments from the EMEA PAT group on their review of the current regulatory infrastructure. It will provide an insight into the expectations of European regulators and will discuss the next steps for the industry.

- Assessing how to structure a regulatory submission referring to the use of PAT: the necessary details and data
- Reviewing the hopes and aspirations that the regulatory authorities have for the industry
- Harmonising the regulatory approach across Europe

Keith Pugh
Chair of EMEA PAT Team
MHRA

10:45 Coffee

11:15 **PAT as a process and its application to full-scale manufacture in a solid dosage facility**

In this presentation a full explanation of PAT as a process will be defined using a 'PAT ROUTE MAP' from both a product development and manufacturing perspective. Concepts such as Quality by Design and Risk Assessment, Process Understanding, Process Capability and Risk Mitigation will be discussed. An operational example of how to implement such a system will be presented based on a solid dosage facility in AstraZeneca, which will be the subject of a PAT submission during 2005 Q1.

Bob Chisholm
International Technology Manager
AstraZeneca

12:00 **Quality by design in pharmaceutical development**

There is a drive to ensure product quality by designing quality into the processes at an early stage. The new ICH Q8 draft guideline on pharmaceutical development opens the door for describing as an option the process knowledge. It gives the industry the opportunity to use modern process control technology to mitigate the risk and in return to get regulatory relief for continuous improvement and real-time release. This case study will explore the possibilities and limitations of how quality by design can be put in a dossier for a novel product or in a post-approval submission. It will describe from a global perspective:

- What to put in the pharmaceutical development report
- What is mandatory and what is optional
- How to get to the desired state of real-time release and continuous improvement
- What regulatory relief can be expected

Fritz Erni
Head of Technology Liaison
Global Quality Operations, Novartis

12:45 Networking lunch

14:00 **PAT within chemical development and production: the implementation and the successes**

Reaction monitoring is widespread within the chemical industry, but not often used in the pharmaceutical industry. The progress of synthetic reactions is generally determined by taking samples that are analysed remotely in a laboratory. Here, the advantages of on-line reaction monitoring in chemical development and production are explained by three examples. During the discussion, special attention will be paid to some difficulties and problems faced during implementation. The specific examples include:

- Using MIR to analyse reactions with unstable intermediates and developing the right reaction conditions in order to increase yield
- Evaluating the advantages of NIR and MIR for a specific reaction and developing one technique for use in production
- Understanding and predicting problems in scale-up, such as the need for system re-calibration

Koen De Smet
Scientist, Chemical Development
Johnson & Johnson PRD

14:45 **Applying PAT within R&D to streamline development and technology transfer**

Increasingly, PAT is being applied to R&D processes, where huge returns will be seen in the long term. This session will explore the role of PAT in R&D, and how the knowledge gained here can be transferred to scale-up and to manufacturing.

- Identifying the crucial steps and the control of critical parameters
- Establishing new routes of interaction in product development projects
- Recognising the importance of technology transfer and maintenance of PAT tools

Nils-Erik Andersson
PAT Team Manager
AstraZeneca Sweden

15:30 Coffee

16:00 **Learning lessons from cross industry PAT experiences**

The food industry faces many challenges that are also recognised in the pharmaceutical industry, such as raw material variation, sampling and process monitoring and control. This session will give a unique insight into the approach adopted in the food sector and applications concerning the following topics will be presented:

- Handling raw material variation
- Batch process monitoring
- Pre-processing of instrumental data
- Making models robust
- Including prior knowledge in modelling

Frank Westad
Research Scientist
Norwegian Food Research Institute

16:45 **Advances in process analysis techniques and their relevance to PAT**

Advances are being made all the time in process analytical techniques, with most of the developments of interest to those tasked with implementation of PAT. This talk will review recent advances with emphasis on developments in on-line and in-line Raman spectrometry, mass spectrometry for liquid processes, and mid-infrared spectrometry. Trends towards the miniaturisation of instrumentation will also be considered.

- Learn how advances in probes and sampling devices have extended applications of the above techniques
- Understand the relative advantages of different process analysis techniques
- Consider the developments in instrumentation necessary to meet future requirements in process monitoring and control

David Littlejohn
Professor
University of Strathclyde, CPACT

17:15 **Discussion session: Effective strategies to realise the benefits of PAT**

Many different approaches are being taken when adopting PAT and this discussion will allow participants to benchmark their strategies against those of their peers. Discussion topics will include:

- Should you view PAT as a toolkit or an integrated process component?
- Where should you begin and how can you prioritise projects?
- Integrating the approach between R&D and manufacturing

17:45 Chair's summary and close of day one

DAY TWO: **FRIDAY 21ST JANUARY 2005**

08:30 Registration and coffee

09:00 Chair's welcome

09:15 **Developing standards for the pharmaceutical application of PAT**

The ASTM E55 committee has been established to develop science-based consensus standards for 'process quality' by addressing issues related to process control, design and performance, as well as quality acceptance/assurance for the pharmaceutical manufacturing industry. This session will explore the role of the committee and will reveal the latest developments of the standards that will support the FDA guidelines for PAT implementation.

- Facilitating the implementation of the PAT framework through participation with industry, academia and the FDA
- Exploring the current status of the PAT standards
- Discussing the future role of PAT and standards from ASTM E55

Line Lundsberg-Nielsen
Senior Consultant
Lundsberg Consulting

10:00 **Leveraging process information to advance pharmaceutical manufacture**

This presentation will demonstrate some of the key requirements for efficiently obtaining product data (process and testing) via a data warehouse. The data obtained can be analysed in order to learn about the capabilities of the product and its process. This information can then be used to assess product cost and manufacturing risk. The information can be further utilised for controlling inventory levels within a manufacturing facility, thereby minimising stock on hand to levels commensurate with manufacturing risk. Furthermore, manufacturing and testing efficiency can be evaluated in order to improve process manufacturability as well as testing efficiency. Finally, from such systems, objective metrics can be developed for monitoring product performance.

Jean-Marie Geoffroy
Manager, Manufacturing Sciences
Abbott Laboratories

10:45 Coffee

11:15 **Improving manufacturing performance with PAT: Using PAT applications for process control**

New online analytical technologies like online-spectroscopy or online-chromatography have been established in manufacturing over the last decade. Combined with advanced process control techniques they result in an innovative process control strategy, which has enormous potential for improving processes in manufacturing.

- Access to relevant process information by using online analytical technologies
- New technology for automated pH measurements in pharmaceutical productions
- Spectrobay - an example for a modern online spectroscopy system
- Monitoring continuous chromatography with online analytical technologies
- Experiences with PAT applications for process control

Hans Tups
Head of Process Analyser Technology Life Sciences
Bayer Technology

12:00 **Panel session: Exploring the latest process analytical technologies**

This session will discuss some of the leading techniques that are being applied within the pharmaceutical industry to aid process understanding and gain efficiencies in production. Various technologies will be presented and you will then have the opportunity to compare and discuss their use, equipping you to better select the most appropriate technologies for your PAT projects.

Volker Frost, International Sales Support NIR
Büchi Labortechnik GmbH
Ingrid Maes, Senior Consultant Advanced Technology
Siemens AG
Vinod Mehta, Product Manager, Spectral Sensors Group,
Carl Zeiss Ltd

12:45 Networking lunch

14:00 **How useful are acoustic methods in process analysis?**

Acoustic methods are attracting increasing interest in all areas of process analysis, mainly because they are relatively low-cost and can be used non-invasively. This talk will examine the nature of broadband acoustic emission signals, how they are detected and their usefulness for real-time process monitoring.

- Learn about the information that can be obtained from acoustic monitoring of batch reactions and powder blending
- Consider the signal processing challenges
- Look forward to future developments

David Littlejohn
Professor
University of Strathclyde, CPACT

14:30 **Risk mitigation in the tabletting process using FT-NIR PAT tools**

Reliable tablet manufacturing presents a challenge for many pharmaceutical firms. Manufacturing risk presents itself throughout the process from the raw materials through formulation and into the tabletting itself. This session examines a risk assessment / risk mitigation approach to the use of FT-NIR for PAT applications within the tabletting manufacturing process.

- Understanding risk within the context of a manufacturing process
- Deciding on the critical measurement and control points in a process
- Risk mitigation strategies

Examples will be drawn from the application of FT-NIR spectroscopy to control:

- Raw material inspection and qualification
- Controlling the dispensary
- Formulation analysis and control
- Tablet analysis

Brian Davies
Director of Process Analytical Technology
Thermo Electron Corporation

15:15 Coffee

15:45 **Rapid Microbiological Methods**

This session will give an evaluation of the development of rapid microbiological methods to a 'near' real-time evaluation of samples. It will introduce the advancements in microbiology to provide efficiencies in process control and product quality.

- Identifying the technologies involved
- Illustrating the applications and benefits
- Ascertaining how it fits into the PAT philosophy

Robert Johnson
Senior Director, Global Quality
PLIVA

16:30 **Food PAT: Comparing spectroscopy and chemometrics in different application fields**

In 2006 a new master program entitled Food PAT (FPAT) starts at KVL. A main contribution in this program will be to educate and train students in novel PAT tools. The Spectroscopy and Chemometrics Group has more than ten years experience in applying PAT in food and pharmaceutical industries. In this session both case studies will be presented based on the course material for the new FPAT program and other research developments. The similarities and differences between food technology and other application fields like the (petro)chemical or pharmaceutical industry will be highlighted from a data-analytical point of view.

- In-process spectroscopy in combination with multivariate calibration
- Multivariate statistical process monitoring and control
- Chemometric multi-way, multivariate data analysis

Frans van den Berg
Associate Professor, The Royal Veterinary and Agricultural University (KVL) - Denmark

17:15 Chair's summary and close of conference

What is holding you back from achieving these goals?

- ✔ Decreasing production cycle times
- ✔ Increasing product yields
- ✔ Reducing waste materials
- ✔ Preventing rejects and reprocessing
- ✔ Improving efficiency and managing variability

These gains in quality, safety and efficiency can be realised through the implementation of Process Analytical Technologies. But have the costs and challenges of implementation, alongside regulatory uncertainty, made you hesitant to adopt this new approach?

"The Agency is encouraging manufacturers to use the PAT framework to develop and implement effective and efficient innovative approaches in pharmaceutical development, manufacturing and quality assurance."

The recent FDA final guidelines are opening the door to PAT implementation, and many companies are already beginning to reap the rewards. However, there are a host of scientific and technical issues that must be addressed in order to develop an effective PAT strategy. That's why this major European forum is bringing together leading organisations, such as **AstraZeneca, Abbott Laboratories, Novartis** and **Johnson & Johnson,** to share the practical details behind their successful implementations.

IQPC's second **Process Analytical Technologies** conference will again showcase the very latest developments in **process understanding and control**. By exploring in detail the regulatory, strategic and technical aspects of PAT in both R&D and Production, this comprehensive event will help you to establish a risk-based approach that will ensure regulatory compliance and a quick and efficient release.

Leading thinkers from industry and academia will highlight best practices for the analysis, design and control of pharmaceutical processes using PAT, which can dramatically improve your efficiency and product quality. These valuable insights will give you a greater understanding of the implications and applications of PAT, moving you one step closer to **'right first time' quality and real-time release.**

Key conference highlights include:

- Hear the latest European regulatory guidance from the **EMEA PAT Team** and their feedback on how to structure a **submission referring to the use of PAT**
- Explore the recent advances in the tools and techniques for PAT and understand how to **select the best technologies for your PAT projects**
- Understand the technical details of implementation and the benefits that can be realised from PAT through **practical case studies from AstraZeneca Sweden** and **Johnson & Johnson**
- Apply PAT to advance pharmaceutical manufacture by sharing the successes from **Abbott Laboratories** and **AstraZeneca**
- Mitigate risk and ensure product quality by hearing **Novartis** highlight their approach to **quality by design** and the latest on the ICH Q8 guidelines
- Examine the latest developments from the **ASTM E55 committee** and the **future standards to support the FDA guidelines**
- Identify the lessons and potential pitfalls with **cross industry experiences** from the food sector

The PAT initiative is having a dramatic impact on the pharmaceutical industry. Take this opportunity to benchmark your PAT strategy against your peers and make sure you don't get left behind!

What delegates have said about Pharma IQ's previous events:

"It didn't meet my expectations – it exceeded them. Great job!"
Velimir Simicevic, Eli Lilly SA

"Great platform for networking and exchange of best practices and experience"
Joerg Neumann, Chiron Vaccines

"Very impressed. Great content, great networking."
John Evans, Polarspeed

"Excellent, very informative. This was exactly what I needed. Excellent content."
Carol Butcher, NAPP

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