Date

PPAR, Seattle

International Perspectives

Dr Jan Gustafsson

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PAT – EMEA (1)

- EMEA Reflection paper: Chemical, Pharmaceutical and Biological information to be included in dossiers when Process Analytical Technology (PAT) is employed.
  - Introduction
    - Provide preliminary recommendations on how PAT related information should be presented in applications
    - Flexible regulatory approach
    - Avoid unnecessary barriers to improved product quality
    - To assist companies already planning to file PAT-based submissions
    - Expert report should include PAT critique (pos. & neg. aspects)
    - Recommend early discussion with appropriate regulatory authority
  - Quality Risk Management
    - QRM sections should be provided at the beginning of each part of the dossier
    - A tabulated summary should be provided of the conclusions reached with headings such as parameter studied, consequence of failure, the level of risk and any mitigation measures
    - Raw data: some raw data is necessary to support the conclusions reached
  - Recommendations for particular sections of the dossier

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PAT – EMEA (2)

- Mock P2 Submission for *exemplain* tablets – EFPIA PAT topic Group
  - Final publication draft "Quality by Design enabled by Quality Risk Management and Process Analytical Technology (PAT)
    - Benefit from ICH Q8, ICH Q9, and PAT principles and strategies because they foster Quality by Design approaches
    - Promote discussion
    - Facilitating the scientific dialogue between industry and regulators
    - Exemplifying application of "Quality Risk Management" principles, ICH Q9
    - Demonstrating how application of "Quality by Design", ICH Q8, principles can be used to establish "Process understanding" and "Design space"
    - Illustrating PAT-based manufacturing and process control strategies that enable "Continuous Quality Verification" and ultimately "Real-Time release"
  - Power Point presentation "PAT and Quality by Design exemplified in a Mock P" submission for *exemplain* tablets (80 slides)
  - Draft discussion paper: "Mock P" for "Exemplain" Hydrochloride

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PAT – EMEA (3)

- Workshop: Quality by Design in pharmaceutical development and manufacture – Stockholm 2006-03-28 – Christina Graffner
- Joint FIP/EMEA/EFPIA workshop on Design Space, London (Docklands) May 8 and 9, 2006

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ISPE PAT

- PAT-COP
  - Two meetings in 2006 + one at Annual meeting
- PAT SIGs
  - ISPE Nordic PAT-SIG
    - Two meetings/seminars in 2006
  - ISPE UK PAT-SIG
    - Two meetings/seminars in 2006
  - ISPE DACh PAT-SIG
    - Two meetings/seminars in 2006

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ISPE PAT

- ISPE conferences/seminars in Europe
  - 2 days PAT seminar at the conference in Vienna 09/2006
  - 2 days PAT seminar at the conference in Paris 04/2007
  - 2 days Design Space seminar at the conference in Paris 04/2007

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EuPAT

Scientific Progress Underpinning
Process Analytical Technology (PAT)

November 21-22 • 2006 • Swedish Exhibition Centre • Gothenburg • Sweden

Organisers:
EUFEPS (European Federation of Pharmaceutical Sciences
ISPE Nordic (International Society for Pharmaceutical Engineering

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PRELIMINARY PROGRAMME

Day 1 – Tuesday, November 21, 2006

Opening Address
Prof. Staffan Folestad, AstraZeneca, Sweden

How PAT is changing the boundaries in chemical engineering sciences
Prof. Peter York, Bradford University, United Kingdom

Investing in the future – European industries need for progress in science underpinning PA
Dr Gert Moelgaard, NNE, Denmark

PAT and downstream bioprocessing
Dr Günter Jagschies, GE Healthcare, Sweden

Optimisation of chemical processing through PAT
Prof. Kevin Roberts, Leeds University, United Kingdom

Towards intelligent simulation tools through mechanistic modelling of process
Prof. Jonathan Seville, University of Birmingham, United Kingdom

Online imaging of tablets by means of a Pushbroom Imager
Dr Rudolf W. Kessler, Reutlingen University, Reutlingen, Germany

Poster Session & Short Communications

Process Tomography – process monitoring in 3 dimensions
Prof. H. McCann, University of Manchester, United Kingdom

The European perspective on bioprocesses and PAT
Prof. Carl-Fredrik Mandenius, University of Linköping, Sweden

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PRELIMINARY PROGRAMME (cont´d)

Day 2 – Wednesday, November 22, 2006
Multivariate informatics for process understanding and advanced control
Prof. Rasmus Bro, The Royal Veterinary & Agricultural University, Denmark

Poster Session & Short Communications

Online PAT monitoring and control of bioprocesses
Dr Andreas Lübbert, Halle Wittenberg University, Germany

Optical 100% inspection of capsules on a filling machine MG
Dr Peter Stoeckel, Boehringer-Ingelheim, Ingelheim, Germany

Interpretation of data-driven models
Prof. Johan Trygg, Umeå University, Umeå, Sweden

On-line PAT monitoring of physical processes
Prof. Jukka Rantanen, Danish university of Pharmaceutical Sciences, Denmark

Summary of highlights, invitation to EuPAT2, and closing remarks
Prof. Staffan Folestad, AstraZeneca, Sweden

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ASTM E55 standards summary (1)

E55.01 - PAT System Management

WK5930	Risk Assessment
WK5935	Process understanding
WK9192	Continuous processing
WK9645	Process capability
TBD	Sampling

E55.02 PAT System implementation & practice

WK4185	Effusivity
WK4694	Measurement system
WK5015	PH Process Design
WK5931	PAT data management
WK6275	Raw materials critical attributes
WK9182	Quality of PAT systems
WK9191	Multivariate Analysis

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ASTM E55 standards summary (1)

E55.03 - General Pharmaceutical Standards

WK9944	Dissolution
WK9864	Qualification
WK 9935	CQV
WK11898	On line TOC validation