

Informa Life Sciences' Inaugural

Process Validation: New Developments for Pharmaceutical Processes and Integrating Product Lifecycle

Practical industry advice and interpretation of current updates to process validation requirements with examples for implementation

22 - 23 November 2011 | Andel's Hotel | Berlin | Germany

EXPERT SPEAKER PANEL INCLUDES:

- **Florentine Nieuwmeijer**, *Scientist, Pharmaceutical Development Department, Astellas Pharma Europe BV*, The Netherlands
- **Alain Poncin**, *Head of Manufacturing, ProtAffin Biotechnologies AG*, Austria
- **Robert McCombie**, *Senior Development Scientist, UCB*, UK
- **Tom Cochrane**, *Head of Security Operations and Process Development, Napp Pharmaceuticals*, UK
- **Jan Gunnar Gustafsson**, *Vice President Process Development and Manufacturing, BAU Therapeutics AB*, Sweden
- **Keith Bader**, *Director of Technical and Quality Services, Hyde Engineering + Consulting*, USA
- **Alice Redmond**, *Commissioning and Qualification Technical Director, PM Group*, Ireland
- **Ron Kenett**, *Chairman and CEO, KPA*, Israel and *Research Professor, University of Turin*, Italy
- **Brian Andreasen**, *Specialist, GMP and Compliance, NNE Pharmaplan*, Denmark
- **Shirley Coleman**, *Technical Director, Industrial Statistics Research Unit, School of Maths and Stats, Newcastle University*, UK

10 REASONS WHY YOU CANNOT AFFORD TO MISS PROCESS VALIDATION 2011:

1. **15 process validation experts** to learn from and share experiences with
2. **Hear key industry perspectives** from pharmaceutical and biotechnology companies including **Pfizer, Novartis, Astellas, UCB, ProtAffin, Napp Pharmaceuticals** and take away key lessons on process validation to your organisation
3. **10+ hours networking** with peers and industry experts including formal and unstructured sessions
4. Gain key insights into the **new paradigm for process validation** and practical implications for your business and development processes
5. Learn how to plan your **design of experiment studies** to provide meaningful process knowledge
6. Take-away practical advice on implementing **continuous process verification**
7. **Exclusive interactive session: Applied statistics for non-statisticians** giving you critical insight and hands-on experience on how to analyse, interpret and present your data
8. Explore techniques to **validate down-scale models as representative of at-scale process**
9. Understand the translation of the **new process validation guideline to cleaning processes**
10. Discuss **statistical process control and its importance in CPV**

PLUS... DON'T MISS DISCUSSION OF THESE HOT TOPICS:

Pre-conference Workshop W: Monday 21 November 2011

Applying Quality by Design (QbD) Principles into the New Process Validation Paradigm

Led by: **Ron Kenett**, *Chairman and CEO, KPA*, Israel and *Research Professor, University of Turin*, Italy

Evening Seminar S: Tuesday 22 November 2011

Implementation of Process Analytical Technology (PAT) and Successes in Real-Time-Release (RTR)

Led by: **Michael Hahn**, *Quality by Design Specialist, GMP & Compliance, NNE Pharmaplan*, Denmark

Christian Zachariassen, *Senior Process Data Analyst, NNE Pharmaplan*, Denmark



Pre-conference Workshop W: Monday 21 November 2011

Applying Quality by Design (QbD) Principles into the New Process Validation Paradigm

Led by: **Ron Kenett**, *Chairman and CEO, KPA, Israel and Research Professor, University of Turin, Italy*

Registration is at 13:30 for a 14:00 start. The workshop will finish no later than 20:00. Workshop documents, refreshments and an evening meal will be provided.

With a strong focus on the lifecycle concept in the new process validation guideline, a shift in paradigm is elicited, focusing on integrating quality from the outset of product development, manufacturing and continuous monitoring to the end of the product.

This workshop is specifically designed to provide practical insight into how QbD can be applied to process validation to fulfil the lifecycle concept, and gain key development advantages.

Through practical examples and case studies, topics to explore will include:

- The FDA guidance on Process Validation
- The three stages: Process design, process qualification and continued process verification
- Integrating quality into the development and process validation lifecycle
- Understanding how QbD, statistical methods and process validation are integrated
- Identifying how QbD can impact your project

INCLUDES
NETWORKING
DINNER!

Afternoon start | Less time out of office | Save on accommodation costs

Conference Day 1: Tuesday 22 November 2011

08.30 Registration

09.00 Opening remarks from the Chair

Alice Redmond, *Commissioning and Qualification Technical Director, PM Group, Ireland and Regular Contributor to ISPE and PDA Forums*

Interpreting and Implementing the New Process Validation Paradigm

09.10 **KEYNOTE: Critical development insights into Process Validation: General Principles and Practices**

- Understanding the key drivers and rationale behind *Process Validation: General Principles and Practices*
- Agency expectations for the implementation of the new guideline
- Regulatory interpretation and expectations for continued process verification
- Evaluating the impact of the new guideline on submissions and inspections, including pre-inspection approval
- Understanding the role and integration of related ICH activities (inc QbD, PAT) into the new guideline

Alice Redmond, *Commissioning and Qualification Technical Director, PM Group, Ireland and Regular Contributor to ISPE and PDA Forums*

09.55 **PANEL DISCUSSION: Conducting a regulatory submission under the new process validation guideline**

- Key changes required for your business/development processes to comply with the new guideline
- Understanding the critical differences in submission requirements under the new process validation guideline

10.30 Morning coffee break

Process Design: Defining Commercial Process on Knowledge Gained through Development and Scale-Up

11.00 **Design of experiment (DOE) studies: Practical guide to designing experiments to determine process parameters, variability and required controls**

- Incorporating key elements from *ICH Q10 Pharmaceutical Quality System* into experimental design
- Planning DOE studies to provide meaningful process knowledge
- Identifying the critical factors that could influence your process
- Effectively using DOE studies to define your design space
- Communicating your design space to the authority and regulatory acceptance and feedback
- Establishment of effective documentation methods for internal use

Alain Poncin, *Head of Manufacturing, ProtAffin Biotechnologies AG, Austria*

11.35 **Incorporating QbD from early phase development onwards: A prerequisite for further process and product development**

- Guidance for industry: *PAT - A Framework for Innovative Pharmaceutical Development, Manufacturing and Quality Assurance*
- Developing methods to focus on process development, process understanding and control
- Case study: Practical guidance on the application of PAT
- Reviewing ICH guidelines *Q8, Q9, Q10*

Florentine Nieuwmeyer, *Scientist, Pharmaceutical Development Department, Astellas Pharma Europe BV, The Netherlands*

12.10 Lunch and networking

13.30 **Implementing a risk-based approach to process development, technology transfer and validation**

- Reviewing *ICH Q9 Quality Risk Management, ICH Q11 Development and Manufacture of Drug Substances* and integration with *Process Validation: General Principles and Practices*
- Evaluating the tools best suited to risk analysis for each stage of development such as Right First Time (RFT), Failure Modes and Effects Analysis (FMEA), Failure Modes Effects and Criticality Analysis (FMECA)
- Practical application of risk assessments including:
 - When in the development cycle to apply risk analysis
 - Which risk assessment for which purpose
 - Developing mitigation plans for high risk items
- Linking requirements for process validation documentation with *ICH Q11* practices

Representative from Chemical Research and Development, Pfizer, UK (visit www.informa-ls.com/proval for speaker update)

14.05 **Developing efficient models to relate small-scale to large-scale data**

- Evaluating the pros and cons using models to simulate the commercial process
 - Implementing techniques to ensure that your small-scale model is sufficiently robust
 - Understanding measures which validate whether down-scale models are representative of at-scale process
 - Common areas of failure and how these can be avoided
 - Key success factors in using representative small-scale models
- Robert McCombie**, *Senior Development Scientist, UCB, UK*

14.40 **Successfully implementing process validation for technology transfer**

- Evaluating the types of technology transfer and related processes
 - Assessing the extent of process validation required for technology transfer
 - Determining the studies to perform
 - Analysing the results and determining an action plan
- Jan Gunnar Gustafsson**, *Vice President Process Development and Manufacturing, BAAU Therapeutics AB, Sweden and Sven Petré*, *Consultant, Bio Consulting BO AB, Sweden*

15.15 Afternoon tea break

Cleaning Validation in the New Paradigm

15.45 **Translating the new process validation paradigm to cleaning processes**

- Optimising selection of cleaning agent based on process residue characteristics
 - Determining directional cleaning process design space information
 - Identifying worst case residues relative to the cleaning process
 - Outlining an initial set of cleaning process parameters for full-scale cycle development
 - Formulating a scientific basis for an overall cleaning program strategy
- Keith Bader**, *Director of Technical and Quality Services, Hyde Engineering + Consulting, USA*

Multivariate Quality Control

16.20 **Multivariate quality control: Leveraging the experience of the electronics industry to pharma CMC**

- Displaying multivariate data
- The role of multivariate data in QbD
- Process and quality control with multivariate data
- Advanced methods for analysing multivariate data: Principal Components, Bayesian Networks, PLS

Ron Kenett, *Chairman and CEO, KPA, Israel and Research Professor, University of Turin, Italy*

16.55 Discussion of issues arising from the day and closing remarks from the Chair

17.15 End of Day 1

Media Partner:

PharmaVOICE

Two valuable days out of the office to gain first-hand insight on interpretation and implementation of process validation and network with key industry leaders

Evening Seminar S: Tuesday 22 November 2011

Implementation of Process Analytical Technology (PAT) and Successes in Real-Time-Release (RTR)

Led by: **Michael Hahn**, *Quality by Design Specialist, GMP & Compliance, NNE Pharmaplan, Denmark* and **Christian Zachariassen**, *Senior Process Data Analyst, NNE Pharmaplan, Denmark*

Registration is at 17.45 for an 18.00 start. The seminar will finish no later than 21.00. Seminar documents and an evening networking dinner will be provided

The emergence of Real-Time-Release (RTR) is a new paradigm in the pharmaceutical industry, assuring a system that when the last manufacturing step is passed all the final release criteria are addressed. RTR offers a number of benefits, including high level of process understanding and control and real time monitoring to assure quality of the finished product. Implementation of RTR requires the successful application of process analytical technology.

Ensure that you reap the benefits of increased yield and reduced waste by overcoming challenges and successfully implementing new ways of working with PAT and RTR!

During this interactive seminar, through discussion and case studies, gain critical insights into the PAT guideline and advice for successful implementation.

Topics of discussion will include:

- Assessing the FDA guideline PAT – A Framework for Innovative Pharmaceutical Development, Manufacturing and Quality Assurance and its integration into the new process validation paradigm
- Practical advice for integrating PAT into current processes and systems
- Comparing the benefits and costs of PAT
- Reviewing the relationship between process validation and RTR
- Successes in RTR driven by the implementation of PAT
- Regulatory acceptance and feedback to RTR

Conference Day 2: Wednesday 23 November 2011

09.00 Opening remarks from the Chair
Alice Redmond, *Commissioning and Qualification Technical Director, PM Group, Ireland and Regular Contributor to ISPE and PDA Forums*

Process Performance Qualification: Assuring Process Design for Reproducible Commercial Manufacturing

09.10 Reviewing best-practices for design and verification of equipment and facilities according to the ASTM E2500 standard

- Using ASTM E2500 and risk analysis as a basis for:
 - Identifying critical aspects and ensuring robust processes
 - Establishment of design
 - Selection and controlling of vendors and constructors
 - Test & verification activities
 - Defining responsibilities and allocating resources (SME)
- Developing an effective project plan to perform verification of processes and facility
- Common challenges/issues in verification (qualification) and how these can be overcome
- Documenting and reporting verification activities

Brian Andreasen, *Specialist, GMP and Compliance, NNE Pharmaplan, Denmark*

09.45 Translating process design to process performance qualification (PPQ)

- Determining when your process is ready to proceed to Stage 2 Process Validation: Review of pilot/clinical manufacturing data and completion of design studies
- Establishing manufacturing conditions based on DOE studies, small-scale models and commercial batches
- Applying a multidisciplinary approach to identifying and documenting the key elements for your PPQ Protocol
- Determining how many lots are needed, and how to establish this number
- Practical advice for conducting PPQ assessment and statistical analysis
- Demonstrating product quality per dose and per batch

Speaker to be confirmed (visit www.informa-ls.com/proval for speaker update)

10.20 Morning coffee break

Continued Process Verification: Ongoing Assurance of Product Control and Quality

10.50 Practical guide to interpreting and implementing continuous process verification (CPV) for old and new products



- Understanding the meaning and expectations of CPV
- Practical application of CPV including:
 - Developing a system to detect process variability
 - Understanding the type of variability in the process
 - Means of reducing variability in a process
 - Understanding process capability
 - How to get started
 - Setting the criteria to collect product and process data
 - Defining how trending and calculations should be performed
- Communicating CPV data to the authority to confirm that you have a process that is in control

Tom Cochrane, *Head of Security Operations and Process Development, Napp Pharmaceuticals, UK*

11.25 Defining the broad reach of statistical process control (SPC) and its importance in CPV

- Using SPC to show the current situation in the context of historical data and give pointers to future trends
- Reviewing the manufacturing origins of SPC and evolution for use in chemical processes and management
- Discussing SPC as a vehicle for communication and for process improvement
- Exploring SPC as a common feature within the initiatives of Six Sigma, DFSS and Lean
- The role of multivariate SPC as a mechanism for monitoring and improving complex processes
- SPC contributes to CPV by helping to monitor incoming quality and maintain process performance

Shirley Coleman, *Chartered Statistician, Royal Statistical Society and Technical Director, Industrial Statistics Research Unit, School of Maths and Stats, Newcastle University, UK*

12.00 Lunch and networking

13.15 Implementation of the QbD principles to a biopharmaceutical operation



Marianna Machin, *Senior Process Analytics Expert, Global Pharma Engineering, Novartis Pharma AG, Switzerland (awaiting final confirmation)*

13.50 PANEL DISCUSSION: Integrating ongoing process monitoring for marketed/legacy products

- Determining the additional requirements for marketed/legacy products to comply with the new FDA expectations
- Assessing the value of retrospective process validation for a previously licensed product
- Practical advice on how to conduct process validation in 'reverse order' for marketed products
- Implementing real-time-release for marketed products

14.25 Afternoon tea break

14.55 INTERACTIVE SESSION: Applied statistics for non-statisticians

Through means of case studies and hands-on examples, delegates will be provided with practical advice and a working understanding of statistical analysis, with a key focus on changes and requirements for statistical analysis with the new process validation guideline.

Topics covered will include:

- Common statistical equations and what to use in which situation
- How to analyse and interpret data obtained
- How to present the data to the regulatory authority: Identifying what and how much data to supply

Facilitated by: Tom Cochrane, *Head of Security Operations and Process Development, Napp Pharmaceuticals, UK*

16.25 Closing remarks from the Chair

16.30 End of conference

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