www.informa-ls.com/proval

With new FDA guidance in January 2011 and upcoming changes to European guidelines - Make sure your processes are aligned with product lifecycle requirements to avoid costly regulatory warning letters

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 Nieuwmeyer,** *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,* **BAAU 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

Don't miss this first-time event addressing key elements and changes to process validation for pharmaceutical and biopharmaceutical companies

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 Petrén, *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

Due to unforeseen circumstances, the programme may change and Informa reserves the right to alter the venue and/or speakers

PROMOTIONAL OPPORTUNITIES

Use Informa Life Sciences' Inaugural **Process Validation** conference to raise your corporate profile and demonstrate your products and services to our targeted, multidisciplinary audience. By joining us in sponsoring and exhibiting at this event, you will be able to:

- Meet new clients with an **exhibition stand** in the main networking area
- Launch new products and ensure market presence with a **speaking slot**
- Raise your profile and shape your corporate image with **logo placement**
- Develop new client relationships and affirm existing ones with your **presence at the event**

We are able to tailor a sponsorship solution to your needs and to find out more, please contact:

Chamatkar Sandhu, Tel: +44 (0)207 017 7278, Email: chamatkar.sandhu@informa.com

informa
life sciences

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

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

www.informa-ls.com/proval

Conference code:	**CQ5165C**
Pre-conf workshop code:	**CQ5165W**
Evening seminar code:	**CQ5165S**

LS/MB/CS/SN/MP/DH

5 Easy ways to Register

+44 (0)20 7017 7481

+44 (0)20 7017 7823

registrations@informa-ls.com

www.informa-ls.com/proval

The Bookings Department
Informa UK Ltd
PO Box 406
Byfleet
KT14 6WL

Group Bookings: To take advantage of group bookings please contact Simon Lau on +44 (0) 207 017 7165 or email simon.lau@informa.com

Your VIP number is on the address label. If there is no label, please quote

Are we mailing you correctly? To update your contact details on our database please email **integrity@informa.com**
Tel: +44 (0) 207 017 7077
or Fax +44 (0) 207 017 7828

Scan with smartphone QR reader App

Select Package	Code	Book before Friday 2nd September 2011	Save	Book between Friday 2nd September 2011 & Friday 21st October 2011	Save	Book after Friday 21st October 2011	Save
☐ FULL Pass: Conference + Pre-Conference Workshop + Evening Seminar	CQ5165CWS	☐ £2497 + VAT @ 19% = £2971.43	£300	☐ £2597 + VAT @ 19% = £3090.43	£200	☐ £2697 + VAT @ 19% = £3209.43	£100
☐ 2 Day Pass: Conference + Pre-Conference Workshop	CQ5165CW	☐ £2098 + VAT @ 19% = £2496.62	£200	☐ £2198 + VAT @ 19% = £2615.62	£100	☐ £2298 + VAT @ 19% = £2734.62	
☐ 2 Day Pass: Conference + Evening Seminar	CQ5165CS	☐ £1898 + VAT @ 19% = £2258.62	£200	☐ £1998 + VAT @ 19% = £2377.62	£100	☐ £2098 + VAT @ 19% = £2496.62	
☐ 2 Day Pass: Conference only	CQ5165C	☐ £1399 + VAT @ 19% = £1664.81	£200	☐ £1499 + VAT @ 19% = £1783.81	£100	☐ £1599 + VAT @ 19% = £1902.81	

The VAT rate is subject to change and may differ from the advertised rate. The amount you are charged will be determined when your invoice is raised

DELEGATE DETAILS – Please photocopy form for multiple bookings!

(Mr/Mrs/Ms/Miss/Dr) Family Name

Forename

E-mail

Tel Fax

Job Title

Any special requirements? .....

To assist us with future correspondence, please supply the following details:

Head of Department:

E-mail

Tel Fax

Booking Contact:

E-mail

Tel Fax

Name of Company

Department

Address

City

Postcode Country

Tel Fax

Nature of Company Business

No. of employees on your site: 1) 0-49 ☐ 2) 50-249 ☐ 3) 250-499 ☐ 4) 500-999 5) 1000+ ☐

PAYMENT INFORMATION

☐ Please invoice

☐ Credit Card. Please debit my: ☐ VISA ☐ MasterCard ☐ Diners ☐ American Express

Card No: ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

CVV No: (this is the 3 digit code on the back of your credit card) ☐☐☐

CVV No Amex: (this is the 4 digit code on the front of your credit card) ☐☐☐☐

Expiry Date: .....

Signature: .....

Credit card billing address:

.....

.....

.....

Contact Number for Card Holder:

.....

Please note that cards will be debited within 7 days of your registration on to the conference

☐ Yes I agree to the terms and conditions as stated on this form.

Delegates who do not pay with their booking are requested to provide a copy of bank transfer / credit card / cheque details to help payment allocation. Staff at the event will request a credit card guarantee for delegates without proof of payment.

Venue Details:
Andel's Hotel Berlin, Landsberger Allee 106, D-10369 Berlin, Germany
Tel.: +49 30 453 053 0 • Fax: +49 30 453 053 2099
E-Mail: info@andelsberlin.com • Web: www.andelsberlin.com/en/home/

Reduced Rate Hotel Accommodation:
The cost of accommodation is not included in the conference fee. In order to book reduced rate accommodation, please fill in the accommodation booking form available to download from the "Accommodation" section on the event website www.informa-ls.com/proval and return it directly to the hotel (fax number and email address are available on the form). Please book early to avoid disappointment.

Conference Documentation: Cannot Attend?
For those busy executives who cannot take full advantage of this event, the papers give you a useful record of the presentations made at the event. The set of speakers papers and/or slides from the conference is available after the event for £399 + 20% VAT. Contact Customer Services on tel: **+44 (0) 20 7017 7481**, fax: +44 (0) 20 7017 7823 or e-mail: registrations@informa-ls.com

Terms and Conditions

FEE: This includes all technical sessions, lunch and documentation.

CANCELLATIONS: Cancellations received in writing before and on Monday 7 November 2011 will be subject to a service charge of £99. The full conference fees remain payable after Monday 7 November 2011. Substitutions are welcome at any time. It may be necessary for reasons beyond the control of the organiser to alter the content and timing of the programme or the identity of the speakers. In the unfortunate event that an event is cancelled Informa are not liable for any costs incurred by delegates in connection with their attendance. This contract is subject to English Law.

ARE YOU REGISTERED?: You will always receive an acknowledgement of your booking. If you do not receive anything, please call us on +44 (0) 207 017 7481 to make sure we have received your booking.

ANY SPECIAL REQUIREMENTS: Please inform us if you have any special requirements by calling Customer Services. +44 (0) 20 7017 7481

DATA PROTECTION: The personal information shown on this form, and/or provided by you, will be held on a database and may be shared with other companies in the Informa Group in the UK and internationally. If you do not wish your details to be available to other companies in the Informa Group please contact the Database Manager at the above address, Tel +44 (0)20 7017 7077, Fax +44 (0)20 7017 7828 or email: integrity@informa.com. Occasionally your details may be obtained from, or made available to, external companies who wish to communicate with you offers related to your business activities. If you do not wish to receive these offers, please tick the box ☐.

INCORRECT MAILING: If you are receiving multiple mailings or you would like us to change any details or remove your name from our database, please contact the Database Manager at the above address, Tel +44 (0)20 7017 7077, Fax +44 (0)20 7017 7828 or email: integrity@informa.com - quoting the reference number printed on the mailing label.