

## Practical Solutions for

# Filing Variations 2007

Achieve current compliance and get ready for impending revisions

30th–31st October 2007, Hotel Okura, Amsterdam

### Expert speaker faculty:

- Marlies Kubbinga, *Chemical Pharmaceutical Assessor, NATIONAL INSTITUTE OF PUBLIC HEALTH AND THE ENVIRONMENT, The Netherlands*
- Adam Aparicio, *Head Global Regulatory Operations, MERCK SERONO*
- Monica Unger-Bady, *Consultant, Former Head of Variation Management and Compliance, SCHERING AG*
- Gudrun Busch, *Head Product Licensing, CSL BEHRING AG*
- Elke Piller, *Senior Manager, European Regulatory Affairs, Innovative R&D, TEVA PHARMA*
- Matthew Neal, *Director, Global Regulatory Affairs & Safety, AMGEN*
- Borislav Borrisov, *Consultant, PRESCRIPTIA*
- Claire Griffiths, *Consultant, PAREXEL Consulting*
- Liesbeth Versteeg, *Submissions Supervisor Regulatory Affairs, GENZYME EUROPE*
- Anne-Marie Georges, *Consultant, AMQUID PHARMA*

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Pharma Company Insight

### Key topics:

- Get up to date with the latest EU Variations Guidelines proposals
- Clarify variations filing requirements for Decentralised Procedure
- Examine the intricacies of variations for biologics
- Accurately define the variation type for accelerated filing
- Hear crucial case studies from industry colleagues
- Gain a thorough understanding of the global future of variations filing
- Understand the impact of transition to electronic documentation and the eCTD on variations filing

### INCLUDING

Fully incorporated afternoon breakout session:

Planning, documentation and lifecycle management for variations

Led by Borislav Borrisov, *Consultant, PRESCRIPTIA*

To Register Please Tel: +44(0) 20 7017 7481

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# Practical solutions for Filing Variations 2

DAY ONE: Tuesday 30th October 2007

09.10 Registration and coffee

09.45 **Opening remarks from Chair**

**Monica Unger-Bady**, *Independent Consultant (Former Head of Variation Management and Compliance)*,  
**SCHERING AG**

10.00 **Achieving regulatory compliance: how Product Quality Review influences companies**

- Overviewing the revised EU guidelines for GMP
- Enabling a stronger alignment between product supply and regulatory affairs
- Defining regulatory compliance
- Overcoming hurdles to compliance for a global product portfolio

**Monica Unger-Bady**, *Independent Consultant (Former Head of Variation Management and Compliance)*,  
**SCHERING AG**

10.45 Morning coffee

Overcoming current obstacles to compliant variations submission

11.15 **Outlining processes for filing variations under national/decentralised procedures (DCP)**

- Deciding when a national submission is suitable
- Clarifying the common grey areas in variation classification
- Dealing with either electronic or paper submissions or both
- Ensuring you classify your variation correctly
- Outlining some of the common deficiencies of variation documentation
- Discussing the filing of variations under Mutual Recognition Procedure (MRP)

**Marlies Kubbinga**, *Chemical Pharmaceutical Assessor*,  
**NATIONAL INSTITUTE OF PUBLIC HEALTH AND THE ENVIRONMENT, The Netherlands**

12.00 **Filing of variations under Mutual Recognition Procedure (MRP): the industry perspective**

- Managing variation for MRP submissions across all of Europe
- Classifying variations correctly for expeditious MRP compliance
- Filing variations electronically or paper or both
- Choosing between MRP and DCP

**Elke Piller**, *Senior Manager, European Regulatory Affairs, Innovative R&D*, **TEVA PHARMA**

12.45 Lunch

14.00 **Completing a variation application properly for full compliance under national/decentralised procedures (DCP)**

- Accurately and correctly categorizing the variation
- Overviewing the guidance documents available
- Preparing documentation for variation filing
- Intricacies of variations for biologics

**Guðrun Busch**, *Head Product Licensing*,  
**CSL BEHRING AG**

CASE STUDY

Improving the Variations Regulations system in Europe and globally

14.45 **Assessing the impact on industry of the new European variations proposals**

- Discussing what company groups handling variations will now need to consider
- Outlining the timescale: when will industry need to act?
- Highlighting what industry would like to see in new regulations
- Providing a simplification of regulations in an environment of increased technical complexity

**Anne-Marie Georges**, *Consultant*, **AMQUID PHARMA**

15.30 Afternoon tea

16.00 **Applying risk assessment to reduce the regulatory burden of change notification**

- Outlining why notifiable changes involve a high regulatory burden
- Clarifying the level of variation that needs to be filed
- Defining the range of filing that needs to be made for a particular variation
- Streamlining the variations process for efficient resource use

**Claire Griffiths**, *Consultant*, **PAREXEL Consulting**

16.45 Closing remarks from Chair

17.00 End of Day One

“Very well organised, good opportunities for networking and exchange of experiences”  
Regulatory Affairs Manager, Schering AG

“Diverse and Quality Speaker Panel”  
Regulatory Associate, Merck

To Register

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- 09.00 **Opening remarks from Chair**  
**Monica Unger-Bady**, *Independent Consultant*  
(Former Head of Variation Management and Compliance,  
**SCHERING AG**)
- 09.15 **Outlining the regulatory relationship between variations and product lifecycle**  
• Discussing the lifecycle consequences of filing variations  
• Examining the requirements for renewals and extensions  
• Investigating the impact of electronic submissions regulations on lifecycle management  
• Preserving the product lifecycle with effective variations submissions  
**Borislav Borrisov**, *Consultant*, **PRESCRIPTIA**
- 10.00 **Major variations: time to switch from paper to eCTD**  
• Working with variations in an eCTD environment  
• Assessing the status of eCTD implementation across Europe  
• Discussing the eCTD variation review process  
• Identifying the key elements of the eCTD specification  
• Providing practical tools for compliant eCTD submission of variations  
**Adam Aparicio**, *Head Global Regulatory Operations*,  
**MERCK SERONO**
- 10.45 Morning coffee
- 11.15 **Transition of eCTD from US filing to EU, Canada, Australia and Japan**  
• The Amgen experience of working with changes in an eCTD environment  
• Overcoming the obstacles to global eCTD filing  
• Identifying the key elements of the eCTD specification  
• Providing practical tools for compliant global eCTD change submissions  
**Matthew Neal**, *Director, Global Regulatory Affairs & Safety*,  
**AMGEN**
- CASE STUDY**
- 12.00 **Providing practical guidance on efficiently filing variations: the Genzyme experience**  
• Accurately defining the variation type  
• Examining the procedures in place for filing each variation type  
• Understanding the specifics of making documentation changes  
**Liesbeth Versteeg**, *Submissions Supervisor Regulatory Affairs*,  
**GENZYME EUROPE**
- CASE STUDY**
- 12.45 Lunch

- 14.00 **Practical Breakout session: Planning, documentation and lifecycle management for variations**  
The whole afternoon has been put aside for a practical breakout session to provide you with interactive experience of variation planning and documentation and how this impacts on product lifecycle. Delegates will be split into two groups where you will gain a hands-on look at how to prepare documentation for Type I and Type II variations and how to incorporate realistic timelines into your variations planning. You will then reassemble to examine your findings.

Led by **Borislav Borrisov**, *Consultant*, **PRESCRIPTIA**

### Case Study 1: Preparing documentation for a Type II variations for a biotechnology product

- Clarifying the parameters of a Type II classification
- Identifying the dossier requirements for different types of variations
- Shelf-life
- Test procedures
- Manufacturing changes
- Avoiding the common pitfalls

### Case study 2: Preparing documentation for a Type I Variation for a solid form product

- Clarifying the parameters of a Type I classification
- Understanding the impact on the dossier of the data required for complex changes
- Changes to synthetic products
- Deciding on the supporting documentation

- 16.30 **Closing remarks and end of Conference**

### Promotional Opportunities

Do you provide outsourced services to regulatory affairs and GMP groups in pharma and biotech companies? This event offers you the ideal opportunity to meet key decision makers from these organisations and to demonstrate your solutions to managing crucial compliant submissions processes.

The meeting will assemble directors and heads of regulatory affairs, product supply, CMC and documentation management and you can be there to meet them and provide your answers to their most pressing questions regarding regulatory and manufacturing compliance.

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**Kirianne Hanlon**, *Sales Director*,  
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