

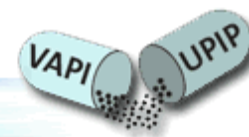
# Risk Based Decision Making

A 1-day interactive Training organized by  
VAPI-UIIP  
in collaboration with **David Begg Associates**

Tuesday 24 November 2009

Hotel Abbey-'t Wit Paard

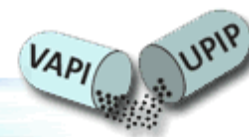
Grimbergen, BE



# About this course

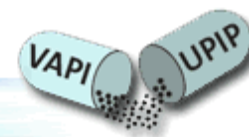
In March 2008 Annex 20 on 'Quality Risk Management' came into operation. It is the expectation of regulators that in a more and more complex growing pharmaceutical industry an effective quality system is implemented. This should be based on scientifically sound **Risk Management**.

This course will help you to further develop your Risk Based approach or give you an indispensable help to start implementing a Risk Based approach.



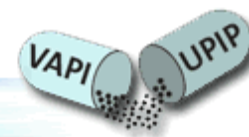
# What You Will Learn

- How to implement Annex 20 and integrate into the Quality System through a structured approach.
- How to apply risk assessments to deviations.
- How to use risk analysis during change control.
- How to use risk based approaches to:
  - Ensure compliance with applicable legislation
  - Oversight of the quality system and its operation
  - Complex and more global supply chain
- Regulatory issues. How to deal with them and what is the risk.
- QP 'discretion' and how to use it.



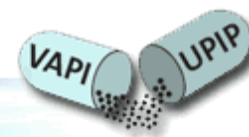
# Who should attend

- This course is aimed at managers and personnel in production, quality, regulatory and technical/supportive departments.
  - Production: how to decide on issues during production: critical or not?
  - Quality: release decisions, risk-based approach in non-conformities and deviations
  - Regulatory: Is the submitted information correct, not too strict?
  - Technical/supportive: validated state always under control?
- This course helps companies who already have a Risk Based approach to refine and improve.
- This course is an aid to companies who want to implement a Risk Based approach.



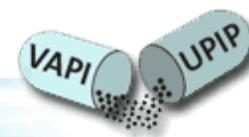
# Course Outline - 1

- Risk Based Approach to Decision Making
  - How we intuitively make decisions...and why these are usually wrong
  - The difference between good and bad decision making
  - How to reduce uncertainty in the decision making process
  - How to design a decision making process that will enable you to make the right decision most of the time



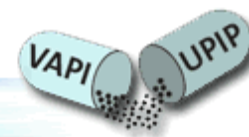
# Course Outline - 2

- Other Decision Making Tools and Techniques
  - 6 Hats Thinking
  - 'Peeling the Onion'
  - Force Field Analysis
  - SWOT Analysis
  - Facts: Assumptions: Don't Knows
- Case Studies
  - Groupwork where theory is put into practice, with a lot of interaction between participants and tutor.



# Tutor: Martin Lush

- Microbiologist by training, Martin has over 24 years experience in medical and pharmaceutical microbiology.
- During his time with AstraZeneca, Martin gained practical experience in the design, validation, operation and management of both sterile and non-sterile manufacturing plants and he has specialist knowledge of aseptic manufacture, lyophilisation, pharmaceutical water systems and all aspects of contamination control.
- Since joining David Begg Associates in 1995, Martin has provided expert assistance in many areas of GMP compliance. He also has a keen interest in helping companies to drive out unnecessary complexity to improve efficiency as well as regulatory compliance.
- Like all the Partners in David Begg Associates, Martin is eligible to act as a Qualified Person and is an honorary lecturer in Pharmaceutical Sciences at the University of Strathclyde.



## Booking Information:

## Risk Based decision Making

Tuesday 24 November 2009

Hotal Abbey- 't Wit Paard, Grimbergen, BE

- First delegate attending and VAPI-UIIP member 600€ (incl VAT)
- Additional delegate and colleague of a participating VAPI-UIIP member 600€ (incl VAT)
- Delegate and not a VAPI-UIIP member 800€ (incl VAT)

Includes: tuition, course notes, attendance certificate, sandwichlunch and refreshments.

Excludes: hotel accomodation and dinner.

Course begins at 08h30 and finishes at 17h00.





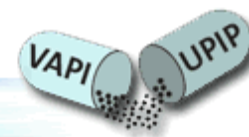
Booking Form: Risk Based Decision Making  
Tuesday 24 November 2009  
Hotal Abbey- 't Wit Paard, Grimbergen, BE

Mr/Mrs/Miss/Ms/DR		First Name		Surname	
Job Title		Company			
Full Street Adress					
			Post Code		
Delegate Tel No		Delegate Fax No		Delegate Email	
Accomodation: I require accomodation (please tick box)			yes	No	
			Date		
Authorised signature					

VAPI-UIPI – Nievelveldweg 1 • B-9310 Aalst

Tel: +32 (0)2 309 06 19 • Fax: +32 (0)2 270 25 77 • e-mail: [upip-vapi@telenet.be](mailto:upip-vapi@telenet.be) • [www.vapi-upip.be](http://www.vapi-upip.be) • [www.upip-vapi.be](http://www.upip-vapi.be)

KBC: 407-0074751-50 • IBAN: BE86 4070 0747 5150 • SWIFT: KREDBEBB



# The Venue

't Wit Paard, Grimbergen

Kerkeblokstraat 5  
1850 Grimbergen

Tel. 32 (0)2 270 08 88

Fax. 32 (0) 270 81 88

[info@hotelabbey.be](mailto:info@hotelabbey.be)