Conference Agenda

Day One, Wednesday 11th November 2009

09:30 Registration and refreshments

10:00 Opening address from the chair

Lawrence Rhodes
DES Analytical & Micro Lab Manager
Abbott Vascular

10:10 Increasing the efficiency of stability testing studies
• Maximising efficiency of sample preparation
• Automating dissolution testing
• Optimising data management

Nicola Hulme
Principal Scientist, AR&D
Bristol-Myers Squibb

10:50 Outsourcing stability studies - achieving successful relationships and outcomes
• Exploring your particular needs and matching them to a vendor's capabilities
• Understanding the vendor's value proposition
• Defining the relationship between client and vendor
• The importance of the contract as a project management tool
• Avoiding the pitfalls

Rob Aitchison
Associate Research Fellow
Pfizer

11:30 Morning refreshments

11:50 Facing the challenges of therapeutic protein aggregation
• Mechanisms and pharmaceutical relevance of protein aggregation
• Analytical methods to tackle protein aggregates
• Hands-on experiences demonstrating pros and cons of different methods

Dr Sabine Boeckle
Group Head Analytical R&D and QC Biotech Products
F. Hoffmann-La Roche

12:30 Forced degradation studies of API's and drug products
Using forced degradation studies to validate stability indicating methods
Choosing the optimum conditions for conducting a study
Comparing long term stability data with forced degradation studies

Dr Simon Hicks
Team Manager, European Degradation Chemistry and Genotoxin Analysis, Analytical Sciences
GlaxoSmithKline

13:10 Networking lunch

14:30 Assessing the stability of amorphous or semi-amorphous materials
• Defining of physical stability
• Methods for determining changes in the physical properties of amorphous materials with low limits of detection
• Relaxation upon storage
• Crystallisation upon storage
• Implications for chemical stability
• Recommendations: selecting the most appropriate analytical tools

Dr Paul G Royall
Department of Pharmaceutics
King's College London

15:10 Ongoing stability testing - Requirements, economical solutions and potential pitfalls
• Basic GMP requirements and their impacts on your laboratory work
• Finding your economical approach - opportunities and pitfalls
• (Statistical) data evaluation and possible pitfalls
• Steps beyond analytical testing
• Teamwork inside and outside your company

Dr Sven Oliver Kruse
CEO
Diapharm

15:50 Afternoon refreshments

16:10 The strategic use of outsourced stability services – from Arrhenius to patient
• Stability outsourcing – The background and the benefits
• Stability outsourcing – The client / provider relationship
• Stability testing – An outsourcing perspective

Tony Engel
Head of Analytical Services
Penn Pharma

16:50 Practical examples of stability testing and primary packaging
• Stability sample storage management
• The choice of appropriate primary packaging
• Early indicators of instability
• Stability indicating methods

Linda Forsyth
Technical Specialist (Pharma)
RSSL Pharma

Jacinta George
Commercial Director
RSSL Pharma

17:30 Closing remarks from the chair

17:40 Networking drinks
Take your discussions further and build new relationships in a relaxed and informal setting

Day two, Thursday 12th November 2009

09:30 Registration and refreshments

10:00 Opening address from the chair

Lawrence Rhodes
DES Analytical & Micro Lab Manager
Abbott Vascular

10:10 Increasing probability of success by application of ICH Q8-10 principles in early phase of development
• ICH Q8 to Q10 applicability to early phase of development
• Streamlined drug product development towards PK and FHD trials
• Stability strategy along that path
• Positive impact on costs and timelines
• Benefits for later development stages

Dr Stefan Adam
Director, Analytical Development and Quality Control
LifeCycle Pharma

10:50 Case Study: Stability testing of Dexanabinol Concentrate for Infusion
A new investigational parenteral drug, Dexanabinol Concentrate for Infusion, has been a subject of a systematic study aimed at:
• developing a stability-indicating method
• stress testing of the Dexanabinol drug substance and product
• testing the photostability according to ICH guide
• stability testing at long-term and accelerated conditions of both the concentrate and constituted solution
• stability testing at extreme conditions
• *in-use* stability testing
• determination of shelf life

Dr Raphael Bar
Pharmaceutical Consultant, BR Consulting
President, Israel Chapter, Parenteral Drug Association (PDA)

11:40 Morning refreshments

12:00 Stress testing of APIs and drug products
• Planning and performing stress test of API-s and drug products
• Stress test conditions during development
• Using stress test results for formal stability testing

Maja Tabak-Slošic
Stability & Audit Manager
PLIVA

12:40 Using calculations to predict shelf-life and release limits

Dr Simona Bohanec
Head of Formulations Stability
Lek Pharmaceuticals*

13:20 Networking lunch

14:20 Estimating shelf life and post-licensure stability studies
• Stability and product life cycle
• Approaches to setting lot release and shelf life specifications
• Post-licensure stability studies: goals and approaches

Dr William M. Egan
Vice President
PharmaNet Consulting

15:00 Presentation to be announced

Dr. Thomas Dries
Honeywell - Specialty Films
Healthcare Market Manager Europe

15:40 Afternoon refreshments

16.00 Overcoming key challenges in stability testing for generics
• Understanding guidelines and regulatory requirements for generic products
• Stability testing programme for generic products;
• Strategies to keep costs low
• Specific issues on filing generics worldwide and/or different regions
• Bracketing and matrixing as a possible tool for filing generic products
• Comparison of the generic product to the innovator, prove the similarity in stability through analytical testing

Jan Jiskra
Project Leader Analytical Project Management,
Synthon

16.40 Chair's closing remarks

16:50 End of conference

-Pricing-

-Standard Rate for 2 day Conference-
£1299 + VAT:£194.85 = Total:£1493.85

Academic & Health Care Organisations Rate for 2 day conference-
£899 + VAT:£104.85 = Total:£1033.85
- If you would like to send more than 1 person then take advantage of the 3 for 2 offer. Send 3 people but only pay for 2.

- How to book -

Booking is simple! All you need to register is contact Bijal.
You can either call me on TEL:**+44(0)2075499946**
or email:**bijal.patel@vgpharma.com**

Please feel free to contact me should you have any questions, I look forward to hearing from you.

Kind Regards,
Bijal Patel