2017 PDA Europe
10th Workshop on Monoclonal Antibodies

Manufacturing & Analytics Considerations for Antibodies and Related Products – A Decade of Progress

CALL FOR PAPERS & POSTERS

26-27 September 2017
Sofitel Berlin Kurfürstendamm
Berlin | Germany

Register by 30 July 2017 and SAVE!
This year, PDA Europe celebrates the 10th Anniversary of the Workshop on Monoclonal Antibodies in Berlin, Germany, 26-27 September.

The Program Planning Committee will select presentations that highlight some of the achievements reached in manufacturing of monoclonal antibodies and related products over the past ten years.

Aside from presentations, there will be various case studies and panel discussions regarding upstream and downstream process development, control strategy design, antibody related products and technological innovations.

This year, in addition to being the 10th Anniversary, the Workshop will be part of the PDA Exchange meeting format, together with the Particles in Injectables conference. This meeting format combines two meetings in the same place, allowing the audience to swap between the two meetings and attend different sessions with just one meeting ticket.

So register for one, get access to two & attend those topics of interest to you in either meeting!

We look forward to welcoming you to Berlin for a chance to meet old colleagues and friends, and to make some new ones!

Call for Papers and Posters
Topics/Areas of interest will include but are not limited to the following

1. UPSTREAM PROCESS DEVELOPMENT
   - Cell Banking
   - New Cell Lines
   - Cryo-Preservation
   - New Substrates
   - Clonality
   - Risk Assessment, Classification of Input and Output Parameters
   - Use of Platform Knowledge
   - Post Approval Changes
   - Glycosylation and Charge Variants
   - Raw Materials

2. DOWNSTREAM PROCESS DEVELOPMENT
   - Alternatives to Protein A
   - Filtration
   - Chromatography and Membrane Technology
   - Virus Removal
   - Scale-Down Models
   - Use of Platform Knowledge
   - Risk Assessment, Classification of Input and Output Parameters
   - QbD Approaches in Life Cycle Management
   - Continuous Manufacturing

3. REGULATORY DEVELOPMENTS, RECENT TRENDS
   - EU GMP Annex 2 Implementation Challenges
   - IVD Regulation in EU
   - Global Harmonization of Regulatory Requirements
   - Post Approval Life-Cycle Management
   - CMC Implications for Fast-tracked Products
   - Continuous Process Validation as an Alternative Approach to Process Validation
   - Product-specific EP Monographs for mAbs

4. NEW ANTIBODY FORMATS INCLUDING ANTIBODY-DRUG CONJUGATES & BISPECIFICS
   - Design and Synthesis of Antibody Derivatives
   - Starting Materials
   - Expression Systems
   - Challenges in Purification
   - Requirements Regarding Process Control, e.g. Impurities, Metabolites, etc.
   - Comparability

5. TECHNOLOGICAL INNOVATIONS
   - Single-Use System
   - Process Analytical Technology (PAT), MS, NGS
   - Multi-Attribute Methods
   - Continuous Manufacturing
   - Other Technological Advances?
   - Drug Development Tools
   - Fill/Finish
INFORMATION

The Conference will be held at the elegant Sofitel Berlin Kurfürstendamm, situated in the heart of Berlin City West.

VENUE
Sofitel Berlin Kurfürstendamm
Augsburger Strasse 41 | 10789 Berlin | Germany
Tel: +49 30 800 999 0
sofitel-berlin-kurfuerstendamm.com

6. STATISTICAL METHODS
• Specification, Definition of Acceptance Criteria/Ranges
• Statistical Methods and Approaches
• Case Studies Biosimilars

7. CONTROL STRATEGY
• Process Monitoring, Realtime Multivariate Statistical Monitoring (RT-MSPM)
• Process Capability Analysis
• Host Cell Proteins
• Analytics
• Raw Materials
• Real-time Release Testing
• Validation Requirements
• Life-Cycle Management
• Adventitious Agents
• Quality Control of mAbs
• Usage of Prior Knowledge
• PQS and QP

8. COMBINATION PRODUCTS
• Novel Concepts & Delivery Systems
• Testing Methodology
• Product / Device Considerations

9. FORMULATION
• High Concentration Products
• Dosage Forms
• Stability
• Interaction with Primary Packaging
• Excipients
• Extractables & Leachables
• Application Routes
• Subvisible Particles, Stability

pda.org/eu-Monoclonals2017
Paper abstracts and posters must be non-commercial in nature, describing new developments or work that significantly contributes to the body of knowledge relating to Monoclonal Antibodies. Case Studies are particularly desired.

All submitted abstracts will be reviewed by the Scientific Program Planning Committee for acceptance. A more detailed draft presentation will be due for committee review one month prior to the conference to ensure scientific nature of the content. Abstracts not selected for a 30 minute podium presentation may be eligible as a scientific poster during the conference. Please note that additional presenters/authors or poster presenters will be subject to a registration fee.

Please click or scan the QR Code to submit your abstract.

**Deadlines**
Abstracts of papers for presentation: **28 April 2017**
Poster abstracts: **5 September 2017**

If you have any further questions, please do not hesitate to contact programs-europe@pda.org

**TO EXHIBIT:**
Exhibition and sponsorship opportunities are available and limited.
Contact [expo-europe@pda.org](mailto:expo-europe@pda.org)