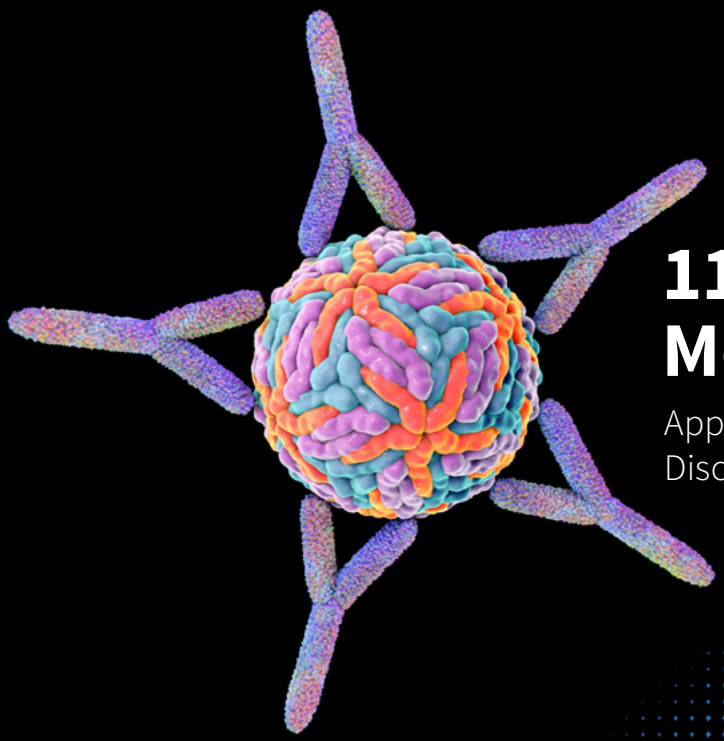
PDA Europe Conference, Exhibition, Education

The Parenteral Drug Association presents:

PDA Exchange Series

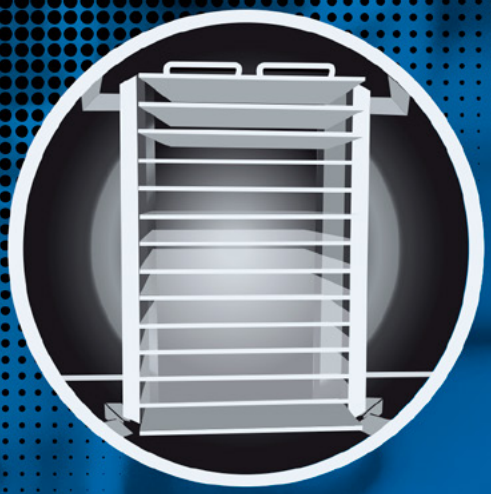
Meet, Exchange and Connect with Professionals
from related Fields and Expand your Knowledge!

TWO
CONFERENCES IN ONE TICKET!



11th Workshop on Monoclonal Antibodies

Applications of Prior Knowledge to Monoclonal Antibody Discovery, Development and Commercialization



Pharmaceutical Freeze Drying Technology

Freeze Drying of the Future

27-28 November 2018

Hotel Meliá Sevilla

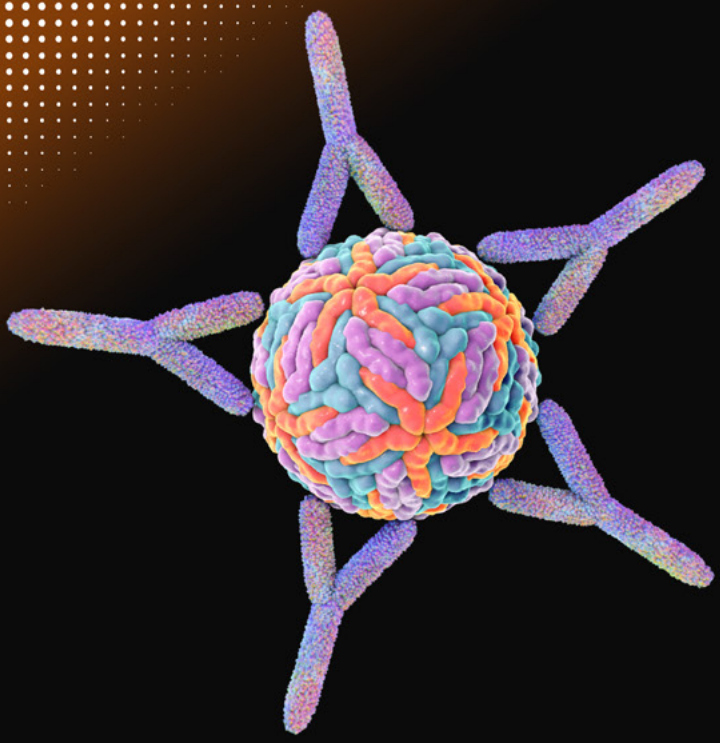
Seville | Spain


Welcome
to the beautiful city
of Seville!
EXPOSICION IBERO AMERICANA

SCHEDULE AT A GLANCE

27 November 28 November	**11th Workshop on Monoclonal Antibodies**	**Conference, Exhibition**
27 November 28 November	**Pharmaceutical Freeze Drying Technology**	**Conference, Exhibition**
27 November	**Networking Dinner**	
29 November	**Application of a Risk-Based Approach to Freeze-Drying Processes**	**Training Course**
29 November 30 November	**Development of a Freeze-Drying Process**	**Training Course**
29 November 30 November	**CMC Regulatory Compliance for Biopharmaceuticals**	**Training Course**
29 November 30 November	**Extractables & Leachables**	**Training Course**

Welcome to the **11th Workshop on Monoclonal Antibodies**



Dear Colleagues,

We warmly invite you to come join the **PDA Europe 11th Workshop on Monoclonal Antibodies, 27-28 November** in **Seville, Spain.**

Three decades after the licensure of the first monoclonal antibody, interest remains strong in this product class.

An estimated 300 compounds are currently in various stages of clinical development for treatment of cancers, inflammatory and autoimmune diseases and other disorders. The intense focus on monoclonal antibodies has in turn driven significant developments in the chemistry, manufacturing and control aspects associated with commercial production. The PDA Workshop offers an overview on all these developments, inviting speakers from the manufacturing side as well as regulatory experts.

The workshop has been taking place annually since 2007, and it stands out as a highly interactive event with presentations, case studies and panel discussions.

This year, the workshop will once again be part of the **PDA Europe Exchange Series** Format. This means it happens **in parallel to the Pharmaceutical Freeze Drying Conference** held in the same location, offering you the chance to participate in two meetings when you register for either one!

We look forward to welcoming you to beautiful Seville later this Fall for a chance to meet, exchange and connect with old colleagues and new ones!

Sincerely,

The Co-Chairs

Michael de Felippis, *PhD.,*
Eli Lilly, Workshop Chair

Martijn van de Plas, *PhD.,*
Medicines Evaluation Board, Workshop Chair

Tuesday, 27 November 2018

9:00	**Welcome: Opening Remarks & Introductions**	Falk Klar, *PDA Europe* Martijn van der Plas, *Medicines Evaluation Board* Michael De Felippis, *Eli Lilly*
9:15	**Keynote: Regulatory Perspective on Prior Knowledge**	**Martijn van der Plas,** *Medicines Evaluation Board*
Session 1	**Regulatory Updates**	

The regulatory landscape is continuously evolving, and several long-term developments can be discerned (ICH Q12; Reflection paper on comparability and statistics). Importantly, the 2017 EMA workshop on Prior Knowledge has triggered new regulatory thinking in this field. This session will present and summarize some of the important current conversations.

9:45	**Microbial Control Strategies in the Manufacturing of Monoclonal Antibodies: Lessons Learned and Moving Forward**	Patricia Hughes, *US FDA*
	Quality Assurance & Quality Control	AEMPS, *Speaker invited*
10:45	**Coffee Break, Poster Session & Exhibition**	
11:15	**The European Pharmacopoeia Approach to Monoclonal Antibodies**	Emmanuelle Charton, *EDQM*
	Industry Perspective on Product Specific Monographs	Amgen, *Speaker invited*
	Panel Discussion with Regulatory Representatives	
13:00	**Lunch Break, Poster Session & Exhibition**	
Session 2	**Bioassays – Trends, Development and Expectations**	*Moderator:* **Mihaela Buda,** *EDQM*

Monoclonal antibodies are structurally complex, and may have several functional domains within a single molecule. Their biological activities are characterised by a specific binding characteristic to a ligand, and may be dependent on immune effector function such as antibody dependent cellular cytotoxicity (ADCC), complement-dependent cytotoxicity (CDC), Fc gamma receptor binding activity, and neonatal Fc receptor (FcRn) binding activity. Assessment of biological activity using various cell-based and binding assays is an essential component of product characterisation and quality control, as well as of the biosimilar comparability exercise. In turn, these bioassays must be reliable and standardised, relevant to reflect the product's mode of action, and sensitive to evaluate impact of process-related heterogeneity on critical product quality attributes and detect structural differences between closely related molecules. This session will include presentations describing bioassay case studies and highlighting perspectives and best practices across the scientific community. These case studies will cover aspects related to bioassay validation expectations, choice of reference standards and control of assay performance, as well as to the use of bioassays to understand the impact of post-translational modifications, and characterise the structure-activity relationship. Current initiatives to develop a common cell-based assay for the determination of potency of different TNF-alpha antagonists will be outlined.

14:00	**Regulatory Perspective on Bioassays**	Mihaela Buda, *EDQM*
	International Standards for Bioassay Calibration	*NIBSC Speaker*
	Stability Indication of Bioassays	*UCB Speaker*
15:30	**Coffee Break, Poster Session & Exhibition**	

Session 3	**Drug Products, Formulation and Delivery**	*Moderator:* **Susanne Joerg,** *LONZA*

Over the last decades, challenges and requirements for biologics drug products did evolve significantly. Whereas on the one side, an increasing number of bio-therapeutics that differ from the traditional monoclonal antibody format made their way into clinical studies and onto the market, on the other hand biosimilars have become important to make treatment for severe diseases more affordable. The drug product design of a Biosimilar – involving various components such as formulation, container closure system, drug product process design and control strategy - is of utmost importance, as it directly relates to patient efficacy, safety and product quality and comparability to the reference originator product. In addition, many new drug products are nowadays developed as products using drug delivery technologies, such as pens, autoinjectors or subcutaneous infusion pumps. Development of these combination products need to consider product compatibility and quality, device functionality as well as regulatory requirements. Another frequent challenge during early drug product development is the requirement for low clinical dosing strategies to enable the regulatory requirements with regards to initial clinical doses for healthy volunteers according to the MABEL approach. Particular dosing strategies need to be put in place and analytical methods need to be established to prove that the product can be delivered to the patient in the right quality and quantity.

16:00	**Challenges of Low Dose Administration (MABEL Dosing Approaches)**	LONZA, *Speaker invited*
	QbD Elements for DP Formulation	Roche, *Speaker invited*
	Advancements in Drug Product Delivery Technologies	Ypsomed, *Speaker invited*
18:00	**End of Conference Day 1**	
18:30	**Networking Dinner**	

Wednesday, 28 November 2018

9:00	**Welcome**	Martijn van der Plas, *Medicines Evaluation Board* Michael De Felippis, *Eli Lilly*

Session 4	**Control Strategy Development Using Prior Knowledge**	*Moderator:* **Michael De Felippis,** *Eli Lilly*

Control strategies for monoclonal antibodies have evolved with the experience gained over decades of development, commercialization and regulation of this therapeutic class. The ability to produce a variety of monoclonal antibodies based on a shared molecular architecture but with different specificities has resulted in significant product understanding related to a given manufacturer's product portfolio. Likewise, the implementation of platform manufacturing processes has enabled manufacturers to acquire extensive process knowledge. All of this accumulated prior knowledge is foundational for the life-cycle management of existing products and applicable to the control strategies for future products. This session explores the application of prior knowledge for developing the control strategies of monoclonal antibody products.

9:10	**How to Use '-Omics' Technologies in MAbs Manufacturing**	*University College Dublin, Speaker invited*
	Use of Prior Knowledge in Establishing Control Strategies	Amgen, *Speaker invited*
	QRM Application to Biopharma Operations in the Q12 Era	4Tune Engineering, *Speaker invited*
	Leveraging the Learnings of 10 Years of Developing Control Strategies Post ICH Q8 Part II	Roche, *Speaker invited*

	Application of Prior Knowledge to Drug Substance Process Development	Eli Lilly, *Speaker invited*
11:15	**Coffee Break, Poster Session & Exhibition**	
Session 5	**Post-Approval Life Cycle Management**	*Moderator:* **Juan Gimenez,** *Genentech / Roche*

In this session, different aspects of the life-cycle management of licensed products will be discussed, including key features of emerging guidelines for managing post-approval changes such as ICH Q12 and the WHO document on procedures and data requirements for changes to approved biotherapeutic products. Considerations around interpretation of the guidelines for product comparability after manufacturing changes with respect to quality, safety, and efficacy will be presented. This session will also cover examples of how manufacturers manage life-cycle of licensed products, such as Control System updates, by which cumulative manufacturing experience, product knowledge, and advances in analytical methods are used to bring commercial product controls up to newer standards and current expectations from Health Authorities.

11:30	**ICH Q12 – An Industry Perspective**	Novartis, *Speaker invited*
	Control System Updates	Genentech / Roche, *Speaker invited*
12:30	**Lunch Break, Poster Session & Exhibition**	
Closing Plenary:	**Biosimilar Variations & Biosimilar Product Development**	*Moderator:* **Steffen Gross,** *Paul-Ehrlich-Institut*

Despite the fact that biosimilars are developed based on the information for the reference product developing and manufacturing as well as finally the approval of biosimilars remains challenging. A stepwise approach is based on a comprehensive structural and functional comparability assessment of the biosimilar to the reference product. Demonstrating a high level of analytical similarity is the first step. All structural elements and modifications of a protein should be evaluated with full capability of detecting differences. Based on observed characteristics of the reference product, a quality target product profile is defined for a biosimilar. The definition of similarity ranges and the acceptance of certain quality differences are a major challenge during evaluation of MAA. It should be noted that after initial approval the biosimilar products will have their own life cycle. Biosimilar manufacturers may need to make changes or alter their own manufacturing processes for enhancement of product quality and yield, or increased efficiency and improved reliability of the manufacturing process. As it is currently not foreseen to re-demonstrate biosimilarity to the reference material or even among different biosimilars it will be a major future task for industry as well as for regulatory agencies to maintain continuity of product quality and/or biosimilarity. The session should help exploring how this goal might be achieved.

13:00	**European Medicines Agency**	*Speaker invited*
	Sandoz	*Speaker invited*
15:00	**Coffee Break, Poster Session & Exhibition**	
	Coherus BioScience	*Speaker invited*
	Closing Panel Discussion - Hot Topics	
16:30	**Closing Remarks and Farewell**	Martijn van der Plas, *Medicines Evaluation Board* Michael De Felippis, *Eli Lilly* Falk Klar, *PDA Europe*

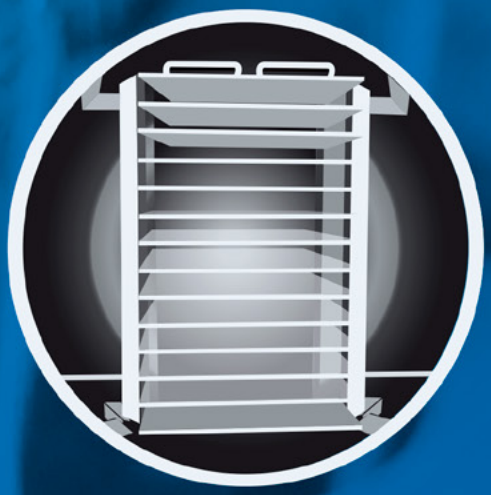
The Parenteral Drug Association is proud to invite you to a very special Networking Dinner.

Tuesday, 27 November 2018

18:30h – Meeting Point: Hotel Lobby
Joint Walking Tour and Sightseeing in Seville
19:30h – Dinner, Ristorante „La Raza“, Avda. Isabel the Catholic 2, 41013 Seville
21:00h – Walking Tour back to Conference Hotel

Join us for a fabulous evening in a traditional Spanish Restaurant. Restaurant La Raza: In the park of Maria Luisa, opposite the Casino Exhibition and Teatro Lope de Vega, surrounded by extensive vegetation and several outdoor terraces, is a privileged place in the city that has become a benchmark for an evening out in Seville.

Welcome to **Pharmaceutical Freeze Drying Technology**



Dear Colleague,

We warmly invite you to come join the 2018 conference on **Pharmaceutical Freeze Drying Technology, 27-28 November in Seville, Spain.**

During the last ten years, freeze-drying of biopharmaceuticals has become a routine procedure, yet the freeze-drying process remains complex. This meeting provides updates of various technical and regulatory aspects regarding lyophilization.

Speakers from the pharmaceutical industry, manufacturers and regulatory agencies regularly share their knowledge and give insights into this process, deepening the understanding of the underlying physicochemical principles as well as explaining freeze-drying techniques and the efforts to implement them on a big scale. All attendees learn about current and novel concepts of freeze-drying and get to connect and exchange ideas with experts in the field.

This year, the workshop will be part of the **PDA Europe Exchange Series** Format. This means it happens in parallel to the **11th Workshop on Monoclonal Antibodies** held in the same location, offering you the chance to participate in two meetings when you register for either one!

The friendly yet professional atmosphere of PDA's meetings provides abundant room for questions and answers, networking and exchange.

Come meet with highly qualified and diverse professionals at this must-attend conference on lyophilization in beautiful Seville in November!

Sincerely,

The Co-Chairs

Yves Mayeresse,
GSK Vaccines, Chair

Sascha Pfeiffer,
Lyo Engineering, Co-Chair

24 Jul 2018

Tuesday, 27 November 2018

9:00	**Welcome & Introduction**	Kerstin Wilken, *PDA Europe* Yves Mayeresse, *GSK, Chair* Sascha Pfeiffer, *Lyo Engineering, Co-Chair*
	OPENING PLENARY	
Session 1	**Advancements in Process and Product Development**	*Moderator:* **Yves Mayeresse,** *GSK*
9:15	**The European F-Gas Regulation and the Consequences for Pharmaceutical Freeze-Drying**	*GEA*
9:45	**Freeze Dryer Refrigeration System**	*OPTIMA Pharma*
10:15	**Coffee Break, Poster Session & Exhibition**	
10:45	**Freeze Drying of Live Vaccine**	*GSK Vaccines*
11:15	**Freeze-Drying of a New Class of Medicines: Live Biotherapeutics**	*4DPharma*
11:45	**Tert-Butyl Alcohol as an Excipient in Freeze-Drying of a Monoclonal Antibody**	*University of Munich*
12:15	**Q&A, Discussion**	
12:45	**Lunch Break, Poster Session & Exhibition**	
Session 2	**Equipment Characterization**	*Moderator:* **Thomas Beutler,** *GEA*
13:45	**Opportunities of Using Mass Spectrometer Technology in Lyophilization**	*Pfeiffer Vacuum*
14:15	**Lyophilizer Characterization: Determination of Equipment Heat and Mass Transfer Properties to Support Scale-up and Technical Transfer of Lyophilized Biopharmaceuticals**	*Sanofi*
14:45	**Use of Water Sublimation Test for Freeze-Dryer Cycle Adjustment to Avoid Meltback of a Low Cake Weight Lyo Product**	*Universal Farma*
15:15	**Q&A, Discussion**	
15:30	**Coffee Break, Poster Session & Exhibition**	
Session 3	**Determination of Critical Product Quality Attributes**	*Moderator:* **Julian Gitter,** *University of Munich*
16:00	**Fast NIR Sensor for Online Moisture Control**	*GEA*

16:30	**Statistical Confidence in the Process: Insights Gained using Non-Destructive Moisture Determination Methods**	*LIGHTHOUSE Instruments*
17:00	**Methods to Predict Fogging in Lyophilized Drug Products**	*LONZA*
17:30	**Panel Discussion, Q&A**	
18:30	**Networking Event**	

Wednesday, 28 November 2018

Session 4	**QbD Considerations**	*Moderator:* **Raf De Dier,** *Janssen J&J*
9:00	**Lyophilization Validation - Thermal Mapping**	*Kaye*
	Another View of Freeze Dryer Design Space	*OPTIMA Pharma*
	Recent Experiences with Continued Process Verification of a Lyocycle - Implementation of Product Temperature as Control	*Explicat Pharma*
	Q&A, Discussion	
10:30	**Coffee Break, Poster Session & Exhibition**	
Session 5	**New Technologies & Container Systems**	*Moderator:* **Jörg Lümkemann,** *Roche*
11:00	**Optimization of Freeze Drying Nanocapsules by Using Experimental Design**	*University of Lyon*
	Novel Approach to Drug Delivery: Spray Freeze-Dried Particles	*University of Bonn*
	Freeze Drying in Novel Container Platforms	*Hoffmann-La Roche*
	Q&A, Discussion	
13:00	**Lunch Break, Poster Session & Exhibition**	

Session 6	**Predictive Models in Freeze Drying**	*Moderator:* **Yves Mayeresse,** *GSK* **Sascha Pfeiffer,** *Lyo Engineering*
14:00	**Process Modelling in Combination with Experimental Model Parameter Determination**	*Technical University Clausthal*
	Process Parameter Determination by Through Vial Impedance Spectroscopy: A Prediction of Ice Interface Temperatures and Single-vial Heat Transfer Coefficients	*De Montfort University*
15:00	**Coffee Break, Poster Session & Exhibition**	
15:30	**Industry Best Practice / Future Prospects**	*Speaker invited*
	Closing Panel Discussion - Hot Topics • Revision of Annex 1 • Steam Sterilization for FDs • Media Simulation Duration	
16:30	**End of Conference & Farewell**	

“No me ha dejado”

SEVILLE

“NO8DO” is the official motto of Seville. It is popularly believed to be a rebus signifying the Spanish “No me ha dejado”, meaning “It [Seville] has not abandoned me”. The eight in the middle represents a madeja or skein of wool. Legend states that the title was given by King Alfonso X, who was resident in the city’s Alcázar and supported by the citizens when his son, later Sancho IV of Castille, tried to usurp the throne from him. The emblem is present on the municipal flag and features on city property such as manhole covers, and Christopher Columbus’s tomb in the Cathedral.

Source: Wikipedia

NO8DO

FLOOR PLAN

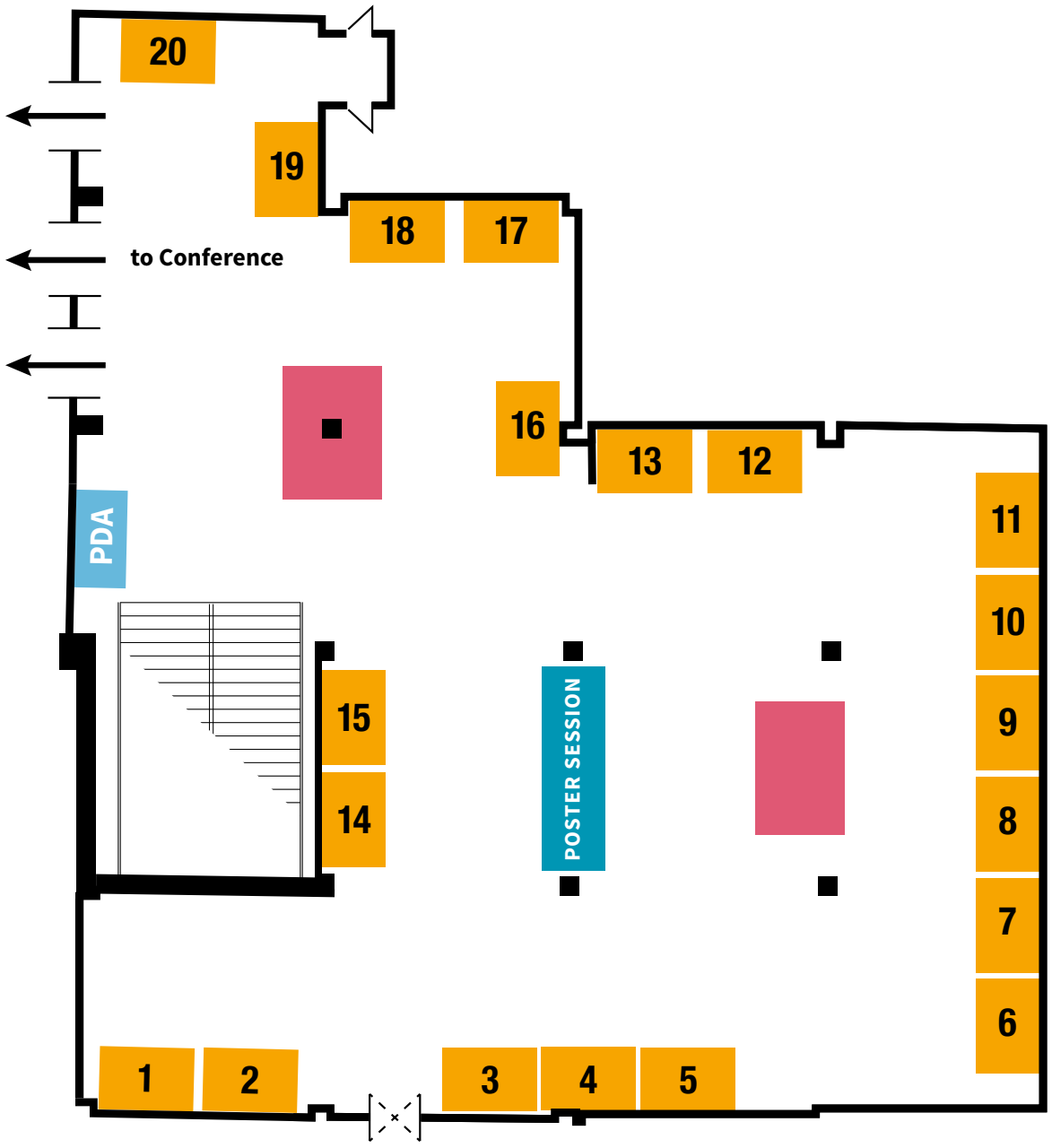


Table Top 2 m x 3 m (6 m²)

Catering

PDA Registration

Poster Session

TO EXHIBIT:

PDA meetings and conferences are a great opportunity for your company to gain on-site exposure in front of highly-qualified, upper-level professionals in the pharmaceutical and biopharmaceutical industry. Exhibition and Sponsorship Opportunities are available. A basic exhibition package for this event is priced **1.895 Euro net (table-top).** For more information please contact **gomez@pda.org**

PDA Scientific Poster Presentation

Exhibit your Work

To join our scientific poster session, please send a printable PDF file according to the following specifications:

Document size of the PDF:
85 cm x 206 cm (33,4646 x 81,1024 in) – portrait format
Slug / Bleed: 2 mm (0,0787 in)

Canvas size to work on:
85 cm x 120 cm (33,4646 x 47,2441 in) – portrait format
Slug / Bleed: 2 mm (0,0787 in)

Images: 120dpi (low) - 150dpi (high) depending on size.

All Images color Profile ISO Coated v2 (ECI)

Deadline: 12 October 2018

All posters will be printed by PDA and displayed as part of the exhibition.
Every poster presenter may collect their poster after the conference.

Poster Display is included in the regular conference registration fee. Please send your file and poster title to Nadjeschda Gomez-Stahl **gomez@pda.org**.

Training & Education Program

europe.pda.org

PDA Education offers courses that are developed and taught by experts. They are uniquely targeted to professionals involved in the development and manufacturing of quality pharmaceutical and biopharmaceutical products.

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- Up-to date training courses and workshops taught by internationally renowned experts
- Wide range of training courses with hands-on experience to drive expertise, awareness, and innovation
- Customized in-house training courses and workshops available

PDA Education Program

29 November 2018
Application of a Risk-Based Approach to Freeze-Drying Processes
One-Day Training Course

29-30 November 2018
Development of a Freeze-Drying Process
Two-Day Training Course

29-30 November 2018
CMC Regulatory Compliance for Biopharmaceuticals
Two-Day Training Course

29-30 November 2018
Extractables & Leachables
Two-Day Training Course

Application of a Risk-Based Approach to Freeze-Drying Processes

Overview

One masterpiece of current process validation approach is risk analysis. It allows defining and measuring the critical parameters of the process for which a specific level of scrutiny is necessary in order to end-up with a robust process under control. The objective of this course is to give an understanding of risk management through ICHQ9 applied to the Freeze-Drying process. The first part will review the guidelines, the Freeze-Drying process and the tools available to score the risks. The second part will be fully interactive. Participants will express their views in terms of detectability, occurrence and control of the various risks linked to the Freeze-Drying process. The session will be subdivided into different chapters: Product, Process, Critical Quality Attributes, Ancillary Function of the equipment and Aseptic Level. The different tools to perform risk analysis will be described and the main focus will be on an FMEA (Failure Mode and Effects Analysis) approach. The output of the workshop is a table consisting of the different parameters with their associated level of criticality that will be shared with the participant.

Who Should Attend:

This course is designed specifically for people having an interest in Freeze-Drying. The audience can come from the various horizons of people performing technical risk assessment, including, but not limited to: production, quality assurance, validation, engineering and development specialist.

Learning Objectives:

Upon completion of this course, you will be able to:

- Better understand the Freeze-Drying process explained through the different examples
- Master ICH Q9 approach in term of risk-based approach
- Recognize a critical parameters for a process
- Score the criticality of a parameters
- Work in team by reaching consensus around criticality levels

Yves Mayeresse, *GlaxoSmithKline Vaccines*

Yves Mayeresse is director in manufacturing technology inside MSAT by GlaxoSmithKline Vaccines. He has more than twenty years of experience in the pharmaceutical sector and has worked for different companies. Yves has managed activities such as parenteral production, set-up of new Freeze-Drying facilities, design of Freeze-Drying cycle and development of new stabilizers for freeze-dried products. Transfer of product towards different internal and external site. He has worked on the industrialization of new freeze-dried products and then in the technical life cycle management. Now, Yves is focusing on different technologies used for the primary and secondary operations. He is an engineer in biochemistry, has written articles about Freeze-Drying science and is a regular speaker for conferences on Freeze-Drying. Since 2016 he is the Leader of the PDA Interest Group Lyophilization and coordinates the group's activities in Europe.

24 Jul 2018

Thursday, 29 November 2018 — 9:00 – 17:00

9:00 **Theoretical Part**

- ***Brief review of ICH Q9***
- ***Description of Freeze-Drying Technology***
  - The equipment
  - The process
  - The product and the primary packaging items
  - The ancillary function (SIP, CIP)
  - Aseptic level (automatic loading, people presence)
- ***Tools Presentation***
  - Input / Output parameters
  - Dependent / Independent parameters
  - CQA: Critical Quality Attributes
  - FMEA approach
  - Examples

10:30 **Coffee Break**

11:00 **Practical Part**

- ***Team rule and organization***
- ***Part I: Product***
  - Independent parameters linked to formulation
  - Independent parameters linked to freeze-dryer load
- ***Part II: Process***
  - Independent parameters linked to the freeze-dryer

12:30 **Lunch Break**

14:00 **Practical Part**

- ***Part II (continued): Process***
  - Independent parameters that are measured and controlled during the cycle
  - Dependent parameters linked to the Freeze-Drying cycle
- ***Part III: Critical attributes linked to Freeze-Drying process***
- ***Part IV: Ancillary Function***
  - SIP

15:30 **Coffee Break**

15:45 **Practical Part**

- ***Part IV (continued): Ancillary Function***
  - CIP
- ***Part V: Aseptic Level***

16:30 **Conclusions**

- ***Q&A***
- ***Feedback about the approach***

17:00 **End of Training Course**

Development of a Freeze-Drying Process

Bring your own samples for discussion

Overview

This workshop will give a thorough introduction into the Physics and Thermodynamics of Freeze-Drying. This seminar comes with an additional overview about technical aspects to be considered and gives an overview about current technologies available on the market. It is created to introduce all people who are professionally linked to Freeze-Drying and might be of special interest for cycle developers (R&D), upscale & transfer specialists, project managers & engineers, process & site engineers, qualification & validation specialists. Open problem examination allows you to bring in a current problem linked to Freeze-Drying. The group will discuss and evaluate possible approaches for troubleshooting.

Who Should Attend:

This course is designed specifically for

- Cycle Developers (R&D)
- Upscale & Transfer Specialists
- Project Managers & Engineers
- Process & Site Engineers
- Qualification & Validation Specialists
- Members of Parenteral Production Teams

Learning Objectives:

Upon completion of this course participants will know the basic principles of all Freeze Drying aspects:

- Physical / Thermodynamic Theory of Nucleation, Sublimation and Desorption
- Technical & Technological Solutions to accomplish a standard process
- Based on the prior theory, several hands-on-sessions provide practical knowledge to design a Freeze-Drying process
- Basics of qualification of a freeze dryer

Georg Frinke, *Bayer Pharma*

Georg holds a degree in Engineering from UAS, Cologne, Germany. He is Process Engineer at Bayer Pharma and responsible for the technical operation of the parenteral facility. Previously, he worked as Process Engineer for Optima (Klee) and GEA Lyophil / Steris. Among others, he is specialized in the development of customized Freeze-Drying processes (particularly upscaling with PAT) and in the qualification (FAT, SAT, IQ, OQ, PQ) of pharmaceutical freeze dryers.

Thursday, 29 November 2018 9:00 – 18:30

THEORY

9:00 Introduction
- Introduction to Drying Technologies
- Overview of the Freeze Drying Process
- Properties of Water
- Properties of Heat Transfer during Lyophilization

10:00 Nucleation
- Scientific Basics
- Freezing Process
- Sensors & PAT
- Hands-on

11:00 Coffee Break

11:30 Nucleation (Cont.)
- Hands-on: Freezing of Sucrose in a Lyo with integrated thermo-resistant measurement

13:00 Lunch Break

14:00 Sublimation
- Scientific Basics
- Drying Process
- Sensors & PAT
- Hands-on

16:00 Coffee Break

16:30 Desorption
- Scientific Basics
- Residual Moisture
- Sensors & PAT
- Hands-on

Bring in your Questions:
Real problems of Freeze Drying can be presented and will be discussed as a group

18:30 End of Day 1

Friday, 30 November 2018 8:30 – 17:00

TECHNOLOGIES & PRACTICE

8:30 Repetition of Previous Day Theory & Transfer of a Freeze Drying Cycle

9:00 Hands-On: Recipe Development

11:00 Coffee Break

11:30 Module Structure of a Freeze Dryer
- Chamber & Shelf System
- Condenser & Main Valve
- Venting System / Filter Test
- Refrigeration
- Vacuum System
- CIP / SIP Systems

12:30 Lunch Break

14:00 Module Structure of a Freeze Dryer (Cont.)
- System Benchmarks
- Performance Criteria
- Installation vs. Process
- Design Criteria & Engineering Aspects

15:00 Coffee Break

15:30 Hands-on:
- Evaluation of the Lyo experiment & samples of collapsed probe

16:30 Qualification Validation Hints for the SAT

17:00 End of Training Course

CMC Regulatory Compliance for Biopharmaceuticals

Overview

Biopharmaceuticals (i.e., biological medicines sourced from genetically-engineered living systems) for treatment of human diseases have become a significant percentage of the pharmaceutical industry. And not just the recombinant DNA-derived proteins and monoclonal antibodies (both from the innovators and biosimilars); but now, an increasing awareness of the importance of gene therapy and genetically engineered cellular medicinal products.

These biopharmaceuticals are being developed by many companies whose Chemistry, Manufacturing & Control (CMC) teams have varying degrees of familiarity or experience with the regulatory requirements for these challenging products. Companies clearly understand the critical importance of their human clinical study strategy, but frequently, the development of a strategy for CMC is an afterthought. Add the frequent lack of CMC regulatory compliance experience in some companies, coupled with the complexity of the biological manufacturing processes and products, and this can be a recipe for disaster.

This course will provide insights and practical guidance for the CMC teams to develop an acceptable cost-effective, risk-based CMC regulatory compliance strategy for biopharmaceuticals (recombinant proteins, monoclonal antibodies, genetically engineered viruses and human cells) from early clinical stage development through market approval. The course emphasis will include FDA, EMA and ICH guidance.

Who Should Attend:

This course is designed specifically for those involved in or interested in the manufacture and control and CMC regulatory issues of biopharmaceuticals, including Senior Management, Directors and Managers/Supervisors, QA/QC, Regulatory Affairs, Manufacturing and Process Development personnel.

Learning Objectives:

Upon completion of this course, you will be able to:

- Explain the importance and underlying principles of an effective CMC regulatory strategy for biopharmaceuticals to move your products through clinical development into the marketplace
- Explain the importance and underlying principles for CMC regulatory compliance of biopharmaceuticals and how this leads regulatory agencies to have different CMC regulatory requirements for biotech products compared to pharmaceuticals of chemical origin.

John Geigert, *PhD, BioPharmaceutical Quality*

John Geigert is President of BioPharmaceutical Quality Solutions, which for the last 15 years has specialized in providing CMC regulatory strategy consulting for the biopharmaceutical industry. He has over 40 years of CMC industrial experience and leadership in the biopharmaceutical industry. He has held senior management positions as Vice President of Quality at both IDEC Pharmaceuticals Corporation in San Diego and Immunex Corporation in Seattle, and he was Director of Product Development at Cetus Corporation in Berkeley. At these companies, he helped lead the CMC efforts to obtain regulatory approvals for 6 biopharmaceutical products now commercially available in the U.S. and in Europe. John Geigert has served on the PDA Board of Directors, currently chairs the PDA Biopharmaceutical Advisory Board, and has served as an expert member of the USP Biotechnology Committee. He is the author of the book The Challenge of CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics 2nd Edition, and has written extensively for RAPS Focus (What Senior Management Needs to Know About CMC Regulatory Compliance for Biotech Products (Aug-Nov 2009, 4-part series)), Demystifying CMC Regulatory Strategy (Sept 2011-Mar 2012, 4-part series). John Geigert obtained his B.S. in Chemistry from Washington State University and his Ph.D. degree in Organic/Analytical Chemistry from Colorado State University.

Thursday, 29 November 2018 — 9:00 – 17:00

9:00	Welcome and Introduction
CMC Regulatory Challenges for Biopharmaceuticals are Different	
9:10	– Painting the Terminology Landscape: Biologic, specified biologic, biopharmaceutical, biosimilar, CBER, CDER, EMA, …
10:30	Coffee Break
11:00	– Understanding the CMC Differences of Biopharmaceutical Regulation between FDA and EMA – Biopharmaceuticals are not Chemical Drugs – Regulatory Compliance Consequences of the four Major CMC Differences
12:30	Lunch Break
How to Develop an Effective Corporate CMC Risk-Managed Control Strategy for Biopharmaceuticals	
13:30	– Three Major Forces that Shape the CMC Regulatory Compliance Strategy of all Biopharmaceuticals – Five Key Elements of an Effective Corporate CMC Regulatory Compliant Strategy
15:00	Coffee Break
15:30	– Impact of the Quality by Design (QbD) on Biopharmaceutical CMC Strategy – Necessity of a Clinical Phase - Appropriate CMC Regulatory Compliance Strategy
17:00	End of Day 1

Friday, 30 November 2018 — 9:00 – 17:00

Applying a CMC Risk-Managed Control Strategy to the Biopharmaceutical Manufacturing Process	
09:00	– Four Myths about Biopharmaceutical Starting Material – the Master Cell Bank – Necessity of Confirming Clonality and Genetic Stability
10:30	Coffee Break
	– Importance and Limitations of small-scale Studies for Biopharmaceuticals
	– Clinical Phase - Appropriate Control of the Biopharmaceutical Manufacturing Process
	– Formulation and Container-Closure Challenges for Biopharmaceuticals – Impact of Components on the Biopharmaceutical (e.g., protein aggregation) and Impact of the Biopharmaceutical on Components (e.g. glass delamination)
12:30	Lunch Break
Challenge of Managing Manufacturing Process Changes and Demonstrating Biologic Product Comparability – Not an Easy Task!	
13:30	– Need for Risk-based, Sequential and Clinical Phase - Appropriate Comparability Studies – Demonstrating Biologic Product Comparability – Justifying CMC Differences
15:00	Coffee Break
15:30	– "Comparability Protocol" and "Post Approval Change Management Protocol"
	– Extreme Comparability of Biosimilars: Limitations of CMC Comparison, Fingerprinting – CMC Biosimilarity Successes and Failures
17:00	End of Training Course

Extractables & Leachables

Including: Important Regulatory Updates – Case Study Section: Selection of Toxikon's most interesting Case Studies, presented over the last 10 years!

Overview

When making Parenteral Drug Products, pharmaceutical companies are faced with the need to further investigate the materials that will be in contact with the drug product, either during manufacturing, intermediate storage, storage in its final packaging, or during the delivery of the drug to the patient. While historically, the potential safety issues were the main driver in these kinds of investigations, recently, also quality issues – i.e. for biopharmaceuticals – have become an additional concern. This workshop will look at "Extractables & Leachables" from many different angles: Definitions, Regulatory, Material & Polymer Science, Analytical E/L Methodologies, Safety Assessments, Study Design for different parenteral primary packaging systems, as well as for injection devices.

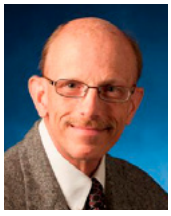
Learning Objectives

Upon completion of this workshop, you will be able to:

- Explain in detail the current regulatory requirements for container/closure qualification from an E/L perspective.
- Explain the upcoming changes in regulations, standards and recommendations from PQRI, USP and BPOG and how these changes could impact a future evaluation of a pharmaceutical C/C-system.
- Understand the materials of construction – and their composition – of container closure systems, and how they could impact the safety and quality of a parenteral drug product.
- Put together an evaluation program (review of provided documentation, analytical testing) of different types of parenteral drug product container/closure systems.
- Perform a safety/risk assessment of analytical results, obtained after completion of an E/L study.

Who Should Attend

- Pharmaceutical Packaging and Device Engineers
- Production Engineers, using SU systems
- Regulatory Affairs Officers
- Pharmaceutical R & D Managers
- Analytical Chemists, working on E/L
- Quality Assurance Officers



Dennis Jenke, *PhD, Chief Executive Scientist, Triad Scientific Solutions*

Dennis Jenke is the Chief Executive Scientist for Triad Scientific Solutions, a provider of science-based solutions to plastic/product compatibility challenges associated with packaging, manufacturing equipment and delivery devices in the pharmaceutical, cosmetic, food and related industries. He was a Distinguished Scientist at Baxter Healthcare Corporation where for more than three decades he lead a team whose primary responsibility includes the assessment of material/product compatibility, specifically with respect to establishing the suitability for use of packaging systems, manufacturing systems and administration devices for pharmaceutical products (for example, extractables/leachables and product ingredient binding). He has published extensively in the areas of analytical chemistry, environmental science and material/solution compatibility and serves as an expert reviewer for numerous pharmaceutical and analytical journals. He is the author of the book Compatibility of Pharmaceutical Solutions and Contact Materials; Safety Considerations Associated with Extractables and Leachables and a contributing author to the Leachables and Extractables Handbook. Dennis Jenke is a member of numerous industry groups whose charter is to establish best demonstrated practices in the area of material/solution compatibility.

Thursday, 29 November 2018 9:00 – 18:00

Introduction on Extractables & Leachables (E/L)

- What is the importance of a good E/L-qualification
- Historical cases of leachables, impacting the quality or the safety of a drug product
- Regulatory requirements (FDA, EMA…) for primary packaging

Understanding the Materials, Used in the Manufacture of Pharmaceutical Containers & Closures

- Types of polymers – examples in medical/pharmaceutical use
- Understanding the composition of polymers
- The issues with glass in parenteral applications

FULL Session on Updates of E/L- Regulations, Standards and Recommendations

- Pharma Packaging:
  - Preview of the final PQRI Parenteral Drug Product (DPD) & ODP Chemistry group
  - Update on the most recent developments on the USP <661> chapters
- Devices
  - Chemical characterization of devices according to ISO 10993-18: What changes are coming up?
  - Upcoming Revisions of the USP <87> and USP <88>: Where could it go to?
- (Bio)Pharmaceutical Manufacturing
  - Where is USP with the update on the USP <661.3> Plastic Manufacturing Components standard

How to Perform a Safety Evaluation – Risk Assessment on Extractables & Leachables

- Toxicology 101
- EMA Guideline on Genotoxic Impurities
- ICH M7 (DNA reactive Impurities) and its suggested staged approach
- The Threshold Concept of PQRI (OINDP and PDP/ODP)
- Examples

How to Look at Injection Devices from an E/L Perspective

- Medical device regulations versus pharma packaging
- Test selection process for devices: What to do?
- USP and ISO 10993 series for biocompatibility testing
- Case: Injection device

Piet Christiaens, *PhD, Scientific Director, Nelson Labs NV (formerly Toxikon Europe)*

Piet Christiaens received his Ph.D. from the Analytical Chemistry Department of the University of Leuven (Belgium) in 1991. From 1992 to 1997, he was Lab Manager in two Analytical Contract Laboratories. From 1997 to 2000, he worked as an independent consultant with Shell Chemical Company in Houston, Texas where he conducted research on a new hydrogenation catalyst system for Hydrogenated Triblock Co-Polymers (Kraton Polymers). Since 2001, Mr. Christiaens has been Scientific Director at Nelson Labs Europe (formerly Toxikon Europe) where he develops analytical methods and protocols for both extractables and leachables studies for the Medical and Pharmaceutical Industries. Mr. Christiaens oversees all laboratory operations at Nelson Labs Europe and supports the European business development team.

Friday, 30 November 2018 9:00 – 16:30

E/L Testing for Small Volume Parenteral Applications

- Glass Syringes: the issues with tungsten, glue residues and silicone oil and glass metals leaching
- The Issue with rubbers: the plunger, the needle shield or the tip cap: different approaches needed?
- The impact of secondary packaging – option or necessity?
- Setting up extractable & leachable studies for a pre-filled Syringe or a vial system

E/L Testing for Lyophilized Drug Products

- Primary packaging for the lyophilized drug product – modus of interaction with the DP
- Impact of the "21CFR Part 4" on combination products, used in the administration of a lyo DP
- Critical aspects when designing leachable studies for lyophilized DP
- Integration of the administration procedure (e.g. IV-set, pump system) in leachables evaluation

Large Volume Parenterals

- The challenge in E/L testing for LVP's
- Primary packaging for LVP's – critical materials and components
- Secondary packaging for LVP: critical points to consider

E/L Testing for Disposable and Single-Use Systems in Bioproduction

- How to classify the risk of different single-use systems in the bioproduction process
- Understanding BPSA & BPOG recommendations, and how they can be implemented in the study design
- Performing E/L studies on filters: potential approaches

Analytical Techniques and Methodologies in E/L Research

- Discussion of the Analytical Instrumentation used
- The Analytical Chromatographic Screening Process to Discover, Identify and Quantify Organic Extractables
- The Risk of Omissions with the Screening Process
- The Risk of Inexact Identifications in the Screening Process
- The Risk of Inaccurate Quantification when Sscreening
- A Risk Mitigation Strategy when Implementing a Screening Methodology

How to Set-up Extractables & Leachables Studies

- Selecting the right conditions for extraction
- How to select the right compounds to monitor in a leachable study
- Designing a leachable study

VENUE

Meliá Sevilla
Calle Dr. Pedro de Castro 1
41004 Seville
Spain
https://goo.gl/z6qeem

Special Rates
PDA Europe has reserved a limited number of bedrooms until the 26 September 2018. Book your group rate for PDA.
Single Room 95 € per room and night
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*Rates are per room and night, including the following services and benefits free of charge: Buffet Breakfast in the restaurant, Wireless Internet Connection (WI-FI).
VAT, Taxes and Service Charge will apply.
Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.

DIRECTIONS

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TO EXHIBIT:

Exhibition and Sponsorship Opportunities are available. PDA meetings and conferences are a great opportunity for your company to gain on-site exposure in front of highly-qualified, upper-level professionals in the pharmaceutical and biopharmaceutical industry. Exhibit at PDA events and let your company's products or services become a valuable tool or resource for our attendees.

SPECIAL REQUIREMENTS

If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to registration-europe@pda.org.

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NOTE: Pop-ups must be enabled otherwise the booking platform window will not open.

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PDA Europe Conference Registration

27-28 November 2018 | Seville | Spain

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Your registration is only complete upon filling in and submitting both pages of this form.

1 Registration

EARLY BIRD DISCOUNT ☐ Book by 14 Oct 2018 to receive € 200* off the conference fee only

All fees given in Euro, excluding VAT (21 %)

27-28 November Conferences

☐ **Pharmaceutical Freeze Drying Technology**

☐ **11th Workshop on Monoclonal Antibodies**

As part of the PDA Exchange meeting format, you can attend the two meetings with just one ticket

Conferences Fee

PDA Member ☐ **1595** **Nonmember ☐ **1895** **Regulatory/Academic ☐ **800**
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☐ **Poster Presenter please mark here** (written approval required, conference fee applies)

29 November	**One-Day Training Course**	**Training Course Fee**	
Application of a Risk-Based Approach to Freeze-Drying Processes		All Participants	☐ **845**
29-30 November	**Two-Day Training Course**	**Training Course Fee**	
Development of a Freeze Drying Process		All Participants	☐ **1495**
29-30 November	**Two-Day Training Course**	**Training Course Fee**	
CMC Regulatory Compliance for Biopharmaceuticals		All Participants	☐ **1495**
29-30 November	**Two-Day Training Course**	**Training Course Fee**	
Extractables and Leachables		All Participants	☐ **1495**

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- ☐ My contact information (name, company, job title, city, state, country) being printed on the attendee list distributed at the event.
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- ☐ PDA sending me promotional information via email.
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The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be given. The fee does not include the hotel accommodation. PDA Europe has secured a limited number of rooms at a special group rate.

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PDA Europe Conference Registration

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27-28 November 2018 | Seville | Spain

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1. **ONLINE: pda.org/EU/MABS2018**
2. **FAX: +49 30 4365508-66**
3. **EMAIL: registration-europe@pda.org**

1 Your Contact Information

If this form is an update to a previously submitted form, please check here. ☐

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(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

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2 Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

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2018 PDA EUROPE EVENTS

15-16 October	Pharmaceutical Microbiology	* Berlin, Germany
23-24 October	Visual Inspection Forum	* Berlin, Germany
6-7 November	Outsourcing & Supply Chain - A 360° View	* Seville, Spain
22 November	Project Management in the Pharmaceutical Industry – Challenges & Possibilities	* Berlin, Germany
27-28 November	Pharmaceutical Freeze Drying Technology	* Seville, Spain
27-28 November	11th Workshop on Monoclonal Antibodies	* Seville, Spain

2019 PDA EUROPE EVENTS

19-20 March	Parenteral Packaging	* Venice, Italy

Subject to change | For latest info: **europe.pda.org** | Shortlist 24 Jul 2018

*** Events with additional Education Program. More information – europe.pda.org**

PDA® Parenteral Drug Association

Connecting People, Science and Regulation®

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