PDA
Parenteral Drug Association

The Parenteral Drug Association presents:

PDA Europe Conference, Exhibition

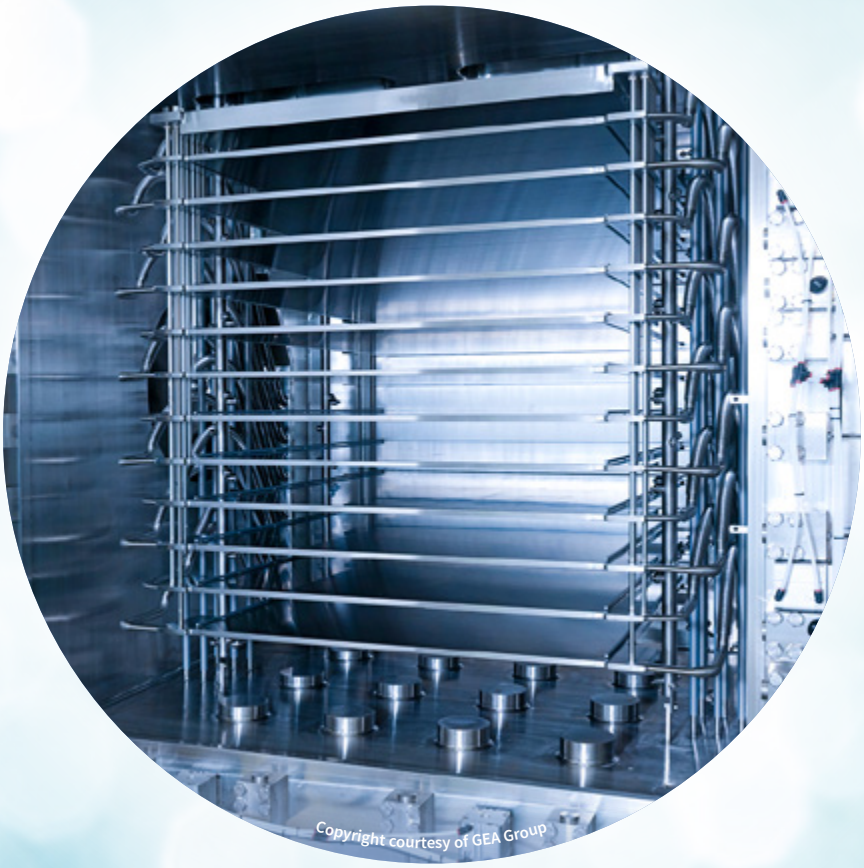
Pharmaceutical Freeze Drying Technology

21 September
Application of a Risk-based Approach to Freeze Drying Processes

21–22 September
Development of a Freeze Drying Process

21–22 September
Einfache und Prozessorientierte Qualifizierung

COURSE IN GERMAN



Register by 23 July 2017 and SAVE!

19–20 September 2017

Lindner Hotel City Plaza
Cologne | Germany

pda.org/eu-FreezeDrying2017

LETTER FROM THE CHAIR

Dear Colleagues,

on behalf of PDA Europe and the Scientific Program Planning Committee, I am delighted to invite you to attend the **2017 PDA Freeze Drying conference.** It has now been over ten years that the PDA Freeze Drying conference exists, and this year, we return to the very historical city of Cologne.

Since its inception, the aim of the conference has been to foster science- based discussion between experts in the particular area of lyophilization.

In the past, some people believed that pharmaceutical freeze drying may just be a fashionable trend, soon replaced by liquid formulation that is fully stable over years. Looking at the current market, however, freeze dried products are well established and continue to grow in quantity. The reason is linked to the fact that freeze drying is a wonderful technology and a perfect way to easily stabilize complex molecules while reducing development time.

As such, we have witnessed a constant evolution of the industrial equipment involved, as well as in process understanding and formulation design, allowing to improve stability of new products.

Each year at this conference, we are proud to be at the forefront presenting examples of this evolutionary process, inviting quality speakers from industry and academia to share their knowledge.

This year, the conference focus will be on the following subjects :

- New Developments in Nucleation, Lyocycle Design & Formulation
- New Technologies such as Wireless Temperature Monitoring
- New Facility Design
- Product Control
- Scale-up & Transfer
- Filling & Materials

The agenda provides a lot of opportunity for discussion with your peers, and to visit industry service providers during the breaks. PDA provides lunches and a networking reception to facilitate exchange, making time for you to meet colleagues and friends - old and new.

I look forward to welcoming you to an informative and enjoyable conference later this summer!

Yves Mayeresse, *GlaxoSmithKline Vaccines*
Conference Chair

SCIENTIFIC PROGRAM PLANNING COMMITTEE

1 Yves Mayeresse, *GSK, Conference Chair*

2 Jörg Lümkemann, *F. Hoffmann - La Roche*

3 Harald Stahl, *GEA Pharma*

4 Ingo Presser, *Boehringer Ingelheim*

5 Raf De Dier, *Janssen J&J*

6 Sascha Pfeiffer, *Lyo Engineering*

7 Julian Gitter, *Ludwig-Maximilians-Universität München*

8 Falk Klar, *PDA Europe*

SCHEDULE AT A GLANCE

19 September	**9:00 – 18:30**	**Pharmaceutical Freeze Drying Technology**	**Conference, Exhibition**
19 September	**19:00 – 21:30**	**Networking Event**	
20 September	**9:00 – 16:30**	**Pharmaceutical Freeze Drying Technology**	**Conference, Exhibition**
21 September	**9:00 – 17:00**	**Application of a Risk-based Approach to Freeze Drying Processes**	**Training Course**
21 September **22 September**	**9:00 – 18:30** **8:30 – 17:00**	**Development of a Freeze Drying Process**	**Training Course**
21 September **22 September**	**9:00 – 17:45** **9:00 – 18:00**	**Einfache und Prozessorientierte Qualifizierung - Course in German**	**Training Course**

For latest information, please visit: **pda.org/eu-FreezeDrying2017**

Tuesday, 19 September 2017

9:00	**Welcome & Introduction**	Falk Klar, *PDA Europe*
	IG Meeting Report, Outlook 2018	Yves Mayeresse, *GSK*
Opening Plenary		*Moderator:* **Yves Mayeresse,** *GSK*
9:20	**Freeze Drying in the Food Industry: A Best-Practice Example for Pharma**	Søren Holm Rasmussen, *GEA Process Engineering*
9:50	**Being Prepared for Regulatory Review and Inspection of Lyophilized Products**	Robert Darius, *Sanofi*
10:20	**Quality by re-Design of a Legacy Product: Strategy, Execution and Regulatory Experience**	Sasha Nicolic, *Reig Jofre*
10:50	**Q & A, Discussion**	
11:00	**Coffee Break, Poster Session & Exhibition**	
Session 1:	**New Technologies & Developments**	*Moderator:* **Ingo Presser,** *Boehringer Ingelheim*
11:30	**Continuous Lyophilization of Unit Doses**	Thomas de Beer, *Ghent University*
12:00	**Continuous Freeze Drying**	Jos Corver, *RheaVita*
12:30	**Impact of Controlled Nucleation on Quality and Stability of Lyophilized Biologics**	Thomas Bosch, *Coriolis Pharma Research*
13:00	**Controlled Nucleation & Stability Data**	Jake Luoma, *Roche / Genentech*
13:30	**Q & A, Discussion**	
14:00	**Lunch Break, Poster Session & Exhibition**	
Session 2:	**Product Control**	*Moderator:* **Raf de Dier,** *Janssen J&J*
15:00	**Case Study: Innovative Technology of a New FD Filling Line**	Wolfgang Lau, *Roche Diagnostics*
15:30	**Complexity of Wireless Product Temperature Measurement under Isolator Conditions**	Franz Bosshammer, *NNE*
16:00	**Process Analytics across the Manufacturing Process for Lyophilized Product**	Mark Smith, *Pfizer Global Supply*
16:30	**Optoelectronic Product Inspection prior to Freeze Drying**	Tobias Werk, *F. Hoffmann - La Roche*

17:00	**Q & A, Discussion**
17:30	**End of Day & Networking Dinner**

THE PARENTERAL DRUG ASSOCIATION IS PROUD TO INVITE YOU TO A VERY SPECIAL

Networking Dinner

19 September 2017 | 19:00 – 21:30

JOIN US FOR A FABULOUS EVENING IN THE TRADITIONAL "BREWERY PÄFFGEN"

We will meet at the lobby at 19:00.
This location is within 10 minutes´ walking distance from the conference hotel.
Dress Code: Casual

Location: Brauerei Pfäffgen | Friesenstrasse 64–66 | 50670 Cologne, Germany

Wednesday, 20 September 2017

Session 3: Scale-up & Transfer		*Moderator:* **Jörg Lümkemann,** *F. Hoffmann - La Roche*
9:00	**Lyocycle Development and PAT-based Optimization – A Case Study including Modern Lyocycle Process Performance Qualification**	Andrea Weiland, *Explicat Pharma*
9:30	**Optimization Elements, Tech Transfer & Scale-Up**	Jean-Rene Authelin, *Sanofi*
10:00	**Lyophilization-Cycle Design for Dual Chamber Cartridges and a Method for Online Process Control: The "DCC-LyoMate" Procedure**	Christoph Korpus, *Merck KGaA*
10:30	**Q & A, Discussion**	
11:00	**Coffee Break, Poster Session & Exhibition**	
Session 4: Filling & Materials		*Moderator:* **Julian Gitter,** *University of Munich*
11:30	**Evaluation of Collapse Temperature Modifiers for Freeze-Dried Protein Formulations**	Christina Häuser, *F. Hoffmann - La Roche*
12:00	**Lyophilization in SiO2 Vials**	Christopher Weikart, *SiO2 Medical*
12:30	**New 1° Packaging Materials for Freeze Drying**	Florence Buscke, *SCHOTT*
13:00	**Q&A, Discussion**	
13:30	**Lunch Break, Poster Session & Exhibition**	

Session 5: PDA Interactive: Knowledge Meets Discussion *Moderator:* **Falk Klar,** *PDA Europe*

Committee members and selected speakers will facilitate lively discussions and exchange around a choice of controversial key issues. Results will be collected and presented as a summary at the end of the day.

14:30 **Roundtable Discussions:**

- **Participants will rotate every 20min.**
- Each moderator will prepare a short summary of the discussions and present it to the audience

	DISCUSSION 1	DISCUSSION 2	DISCUSSION 3
	ANNEX 1 REVISION: CONSEQUENCES FOR FREEZE DRYING	CONTINUOUS FREEZE DRYING	CONTROL STRATEGY
14:40	GREEN GROUP	RED GROUP	BLUE GROUP
15:00	RED GROUP	BLUE GROUP	GREEN GROUP
15:20	BLUE GROUP	GREEN GROUP	RED GROUP

15:40	**Coffee Break & Exhibition**	
16:00	**Summary of Roundtables**	Committee Members and Moderators
16:30	**Closing Comments & Farewell**	Falk Klar, *PDA Europe*

REGULATORY ASPECTS

SCALE UP AND TRANSFERS

MANUFACTURING

PRODUCT CONTROL

NEW TECHNOLOGIES & DEVELOPMENTS

FREEZE DRYING PRODUCTS

DEVICES & APPLICATION SYSTEMS

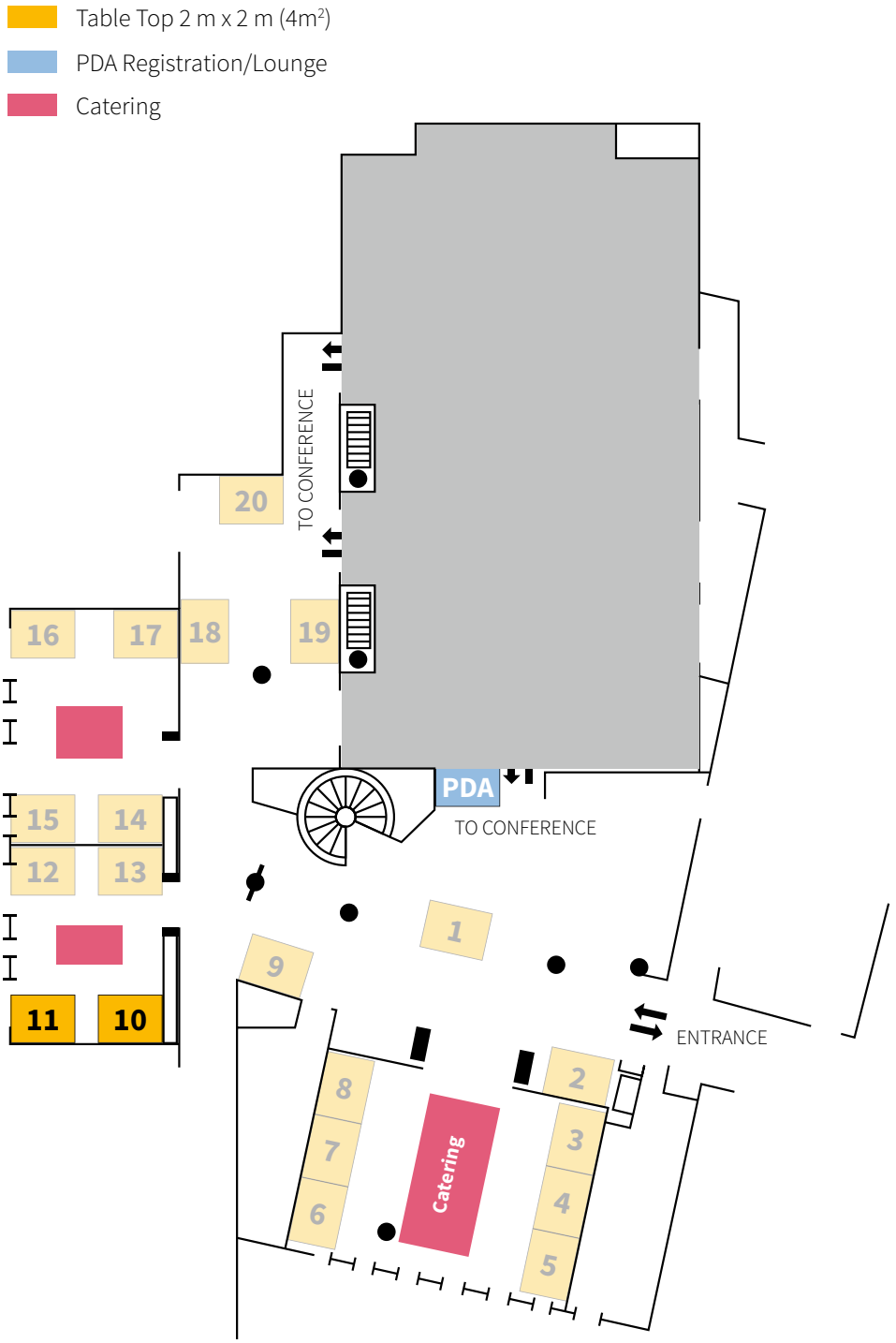
QUALIFICATION / VALIDATION / MAINTENANCE

CASE STUDIES

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 **expo-europe@pda.org**

Exhibitor	Table Top
Lighthouse	1
Martin Christ	2
Wilco	3
Steriline	4
Seidenader	5
Teclen	6
Telstar	7
Biopharma	8
Ellab	9
Pfeiffer-Vacuum	12
Hof Sonderanlagen	13
Tempris	14
OPTIMA	15
MA Services	16
Sio2Med	17
Lives International	18
SCHOTT	19
Kaye	20



ONLY TWO TABLE TOPS AVAILABLE!

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.

Facts that Make a Difference

- 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

21 September 2017
Application of a Risk-based Approach to Freeze Drying Processes
One-Day Training Course

21 – 22 September 2017
Development of a Freeze Drying Process
Two-Day Training Course

21 – 22 September 2017
Einfache und Prozessorientierte Qualifizierung – Course in German
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.

27 Jul 2017

Thursday, 21 September 2017 — 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

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, 21 September 2017 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, 22 September 2017 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

Einfache und Prozessorientierte Qualifizierung

Kursbeschreibung

Das Design und die Funktionsweise einer Pharmaanlage beeinflussen maßgeblich die Qualität der mit ihr hergestellten Produkte. Deshalb müssen Ausrüstungsgegenstände qualifiziert werden. Die Qualifizierung ist die dokumentierte Beweisführung, dass die Anlagen und Geräte geeignet sind, festgelegte Qualitätsanforderungen – allgemeine GMP-Anforderungen sowie individuelle Produkt- und Prozessbedürfnisse – zu erfüllen. In der Praxis ist die Qualifizierung jedoch oftmals ein langwieriger und komplexer Prozess. Dutzende von Dokumente werden erstellt, deren Nutzen und Zusammenhänge häufig unklar sind. Technisches Personal müht sich um die Aufnahme von Datenkolonnen, deren Aussagekraft oft limitiert ist. Teure Geräte kommen wegen der langen Qualifizierungsphase erst verzögert zum Einsatz. Nach Abschluss der Qualifizierung sind zwar viele Ordner befüllt, aber es verbleibt oftmals eine Unsicherheit, ob das Gerät beim Einsatz wirklich die Anforderungen erfüllen wird. Das muss und soll so nicht sein. Ziel dieses Trainingskurses ist die Vermittlung der wesentlichen Kernelemente für eine erfolgreiche und gleichzeitig effiziente Qualifizierung. Der Schlüssel dazu ist das Verständnis des untrennbaren Zusammenhangs von Produkten, Prozessen und Ausrüstungsgegenständen. Die bei der Qualifizierung empfohlene Herangehensweise wird an wichtigen, qualitätskritischen Geräten beispielhaft vorgestellt. In zahlreichen und intensiven Workshops wird die Methodik schrittweise entwickelt. Abschließend erarbeiten die Teilnehmer ihre eigene „Guideline“, die sie in die Lage versetzt, die erlernten Grundprinzipien auf beliebige Geräte anzuwenden.

Zielgruppe:

- Qualifizierungsingenieure
- Techniker
- Technologen
- Geräte-Bediener
- Supervisor (Bereich Technik)
- Meister (Bereich Technik)

Zielsetzung:

Die Teilnehmer

- Lernen, aus den konkreten Produkt-Prozessanforderungen die zu qualifizierenden Parameter zu identifizieren und daraus das erforderliche Maß an Gerätequalifizierung abzuleiten.
- Haben verinnerlicht, dass Nutzung und Qualifizierung eines Geräts untrennbar miteinander verbunden sind und sind in der Lage, die Wertebereiche zu identifizieren, innerhalb derer das Gerät zu qualifizieren sind.
- Haben verstanden, dass eine richtige Qualifizierung nicht darin besteht, so viele Daten wie möglich aufzunehmen.
- Haben den grundlegenden Inhalt und Sinn von Regelwerken und Normen verstanden.
- Sind in der Lage, die Qualifizierungsdokumentation so zu gestalten, dass die Dokumentation angemessen, vollständig, nachvollziehbar und gleichzeitig effizient ist.
- Können technische Dokumente zur Inbetriebnahme sinnvoll mit formalen Qualifizierungsdokumenten verknüpfen und dadurch die Effizienz der Qualifizierung erhöhen.
- Sind in der Lage, die erlernte Vorgehensweise auf beliebige Geräte anzuwenden und diese effizient und richtig zu qualifizieren.

Normen Schüpferling, *Site Quality Specialist, Bayer AG*

Nach dem Studium der Biopharmazeutischen Technologie an der Fachhochschule Gießen-Friedberg. war Dipl.-Ing. (FH) Normen Schüpferling bei der gempex GmbH in Mannheim in unterschiedlichen Positionen, zuletzt in der Funktion als Senior Consultant und Projektleiter, tätig. Im Mittelpunkt standen hierbei Projekte zur Qualifizierung von Ausrüstungsgegenständen und entsprechenden Prozessumgebungen, die Validierung von Prozessen, die Erstellung von GMP-Konzepten sowie GMP-spezifische Beratungsleistungen, schwerpunktmäßig im Bereich der Sterilproduktion bzw. der aseptischen und biotechnologischen Herstellung von Arzneimitteln und ATMPs. Mit insgesamt mehr als 12 Jahren Erfahrung im GMP Umfeld ist Herr Schüpferling aktuell bei der Bayer AG in Leverkusen beschäftigt, wo er im Bereich der Qualitätssicherung unter anderem für die Entwicklung und Optimierung des Qualifizierungskonzeptes verantwortlich ist.

Donnerstag, 21. September 2017 — 9:00 – 17:45

9:00 **Begrüßung und Einführung**
- Vorstellung der Teilnehmer
- Erfassen von Fragen und Erwartungen

9:30 **Grundlegende Probleme der Qualifizierung, Kick-off**
- Warum werden bei der Gerätequalifizierung häufig die falschen Parameter gemessen?
- Warum dauert Gerätequalifizierung häufig so lange?
- Warum ist man sich häufig nach erfolgter Qualifizierung trotzdem nicht sicher, ob das Gerät adäquat funktioniert?
- Warum ergeben sich bei Audits häufig so viele Beobachtungen zur Gerätequalifizierung?
- Warum muss das Gerät so häufig zur Reparatur außer Betrieb genommen werden?

10:00 **Kaffeepause**

10:30 **Vorstellung der Prinziplösung und des methodischen Herangehens**
- Zweck der Qualifizierung
- Vorstellung der Vorgehensweise
- Vom Prozess über die URS zur Qualifizierung
- Wozu dient eine Risikoanalyse
- Grundsätzlicher Aufbau von Qualifizierungsdokumenten

12:00 **Mittagspause**

13:00 **Technisches Funktionsprinzip eines Sterilisierungstunnels / Depyrogenisierungstunnels**
- Grundprinzip der Sterilisation/ Depyrogenisierung mit trockener Hitze
- Baugruppen Sterilisierungstunnel
- Welche Parameter sind wichtig für den Sterilisationserfolg?

14:00 **Workshop zur Bestimmung der grundlegenden Geräte- und Qualifizierungsanforderungen eines Sterilisierungstunnels (Gruppenarbeit)**
- Durchführung einer Risikoanalyse
- Vorstellen und Diskussion der Lösungen der einzelnen Gruppen

15:30 **Kaffeepause**

16:00 **Workshop zur Erstellung der grundlegenden Qualifizierungsdokumentation eines Sterilisierungstunnels (Gruppenarbeit)**
- Schrittweises Entwickeln der Qualifizierungsdokumente
- Vorstellen und Diskussion der Lösungen der einzelnen Gruppen

17:30 **Wiederholung der wichtigsten Lerninhalte des Tages**
- Die drei wichtigsten „take home messages“ des Tages

17:45 **Ende des ersten Tages**

Freitag, 22. September 2017	9:00 – 18:00

09:00 **Technisches Funktionsprinzip eines Autoklaven**
- Grundprinzip der Sterilisation mittels feuchter Hitze
- Baugruppen Autoklav
- Welche Parameter sind wichtig für den Sterilisationserfolg?

10:00 **Kaffeepause**

10:30 **Workshop zur Bestimmung der grundlegenden Geräte- und Qualifizierungsanforderungen eines Autoklaven (Gruppenarbeit)**
- Durchführung einer Risikoanalyse
- Vorstellen und Diskussion der Lösungen der einzelnen Gruppen

12:00 **Mittagspause**

13:00 **Workshop zur Erstellung der grundlegenden Qualifizierungsdokumentation eines Autoklaven (Gruppenarbeit)**
- Schrittweises Entwickeln der Qualifizierungsdokumente
- Vorstellen und Diskussion der Lösungen der einzelnen Gruppen

14:30 **Kaffeepause**

15:00 **Vom Engineering zu den Regularien**
- Unterschied zwischen Richtlinien und technischen Standards
- Unterscheidung von technischen/ inhaltlichen und formalen Anforderungen
- EU Annex 15

16:00 **Workshop zur Erstellung einer „eigenen“ Guideline für Qualifizierung (Gruppenarbeit)**

17:30 **Fragenrunde, Wiederholung der wichtigsten Lerninhalte**

18:00 **Ende Trainingskurs**

The Parenteral Drug Association presents:

2017 PDA Europe Conference, Exhibition

The Universe of Pre-filled Syringes & Injection Devices

Accompanying Education Program on Monday, 6 November, and on Thursday and Friday, 9-10 November

Register by 7 Oct 2017 and SAVE!

7-8 November 2017

Austria Center

Vienna | Austria

VENUE

Lindner Hotel City Plaza
Magnusstrasse 20
50672 Cologne
Germany
Tel: +49 221 20 34-700
https://www.lindner.de/

Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.

DIRECTIONS

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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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2017 PDA Europe Conference, Exhibition

Outsourcing & Contract Manufacturing

Register by 24 Sep 2017 and SAVE!

21-22 November 2017

Roomers Design Hotel

Munich | Germany

pda.org/EU-Outsourcing2017

Pharmaceutical Freeze Drying Technology

Registration Form
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19–20 September 2017| Cologne | Germany

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

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

1 Registration

EARLY BIRD DISCOUNT ☐ Book by 23 July 2017 to receive € 150* off the conference fee only

All fees given in Euro, excluding VAT (7 %)

19-20 September	Conference only	Conference Fee	
Pharmaceutical Freeze Drying Technology		PDA Member	☐ **1495**
		**Nonmember	☐ **1795**
	*** Early Bird 670 €**	**Regulatory/Academic	☐ **750**

☐ **Poster Presenter please mark here** (written approval required, conference fee applies)

21 September	One-Day Training Course	Training Course Fee	
Application of a Risk-Based Approach to Freeze Drying Processes		All Participants	☐ **845**

21–22 September	Two-Day Training Course	Training Course Fee	
Development of a Freeze Drying Process		All Participants	☐ **1495**

21–22 September	Two-Day Workshop	Workshop Fee	
Einfache und Prozessorientierte Qualifizierung	COURSE IN GERMAN	All Participants	☐ **1495**

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.

****Registration fee includes a one-year PDA membership** if no further special discount is granted. If you do not wish to join PDA and receive the benefits of membership, please check here (same rate applies). ☐

Group Registration Discount Register 5 colleagues for the conference at the same time and receive the **5th registration free.** For more information on group discounts please contact Antje Petzholdt at petzholdt@pda.org. Other discounts cannot be applied.

Join PDA and receive the Membership Rate Today!
Please go to:
www.pda.org/membership

☐ Discount for Exhibiting Companies

Please mark here if your company is an exhibitor to this event and you will receive the conference ticket at the **special price of 995 Euro per ticket.** No further discounts are applicable with this option (as PDA Membership Discount or Group Ticket discount).

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3 WAYS TO REGISTER

1. **ONLINE: pda.org/eu-FreezeDrying2017**
2. **FAX: +49 30 436 55 08-66**
3. **EMAIL: registration-europe@pda.org**

1 Your Contact Information

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

☐ Mr. ☐ Ms. ☐ Dr. ☐ Nonmember ☐ **I want to become a PDA Member.** Please send me a subsription form

☐ PDA Member ID Number

Name (Last, First, MI) *

Job Title *

Company* Department

Mailing Address

City Postal Code

Country Email *

Business Phone Fax

☐ Substituting for

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

* This information will be published in the conference attendee list. Should you not wish us to publish these details, please contact us.

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).

3 Payment Options

☐ **By Bank Transfer**

Beneficiary: PDA Europe gGmbH
IBAN: DE73 1007 0024 0922 8735 00
BIC (SWIFT-Code): DEUTDEDBBER
Bank Address:
Deutsche Bank, Welfenallee 3–7,
D-13465 Berlin, Germany

☐ **By Credit Card**

☐ American Express ☐ MasterCard ☐ VISA

For your credit card information safety: Please send your details by fax only.

☐ **Purchase Order**

Purchase Order Number

Billing Address: ☐ Same as contact information address above.
If not, please send your billing address to: petzholdt@pda.org

Your Company VAT I.D.:

This number starts by your country code with two characters
(example: PDA Europe's country code starts with: DE | followed by the number)

PDA Europe VAT I.D.: DE254459362

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

Date Mandatory Signature

CONFIRMATION: Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** A letter of confirmation will be sent to you within one week once payment has been received. You must have this written confirmation to be considered enrolled for this PDA event. PDA Europe reserves the right to deny access to anyone unable to provide written confirmation that all dues have been fully settled. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 2 weeks prior to the start of the event. After this two-weeks period, there will be a charge of € 100 per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **19 August 2017,** you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Europe works PCI-Compliant. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at **info-europe@pda.org or fax to +49 30 4365508-66. DOCUMENTATION:** With your signature you give complete picture usage right to PDA and allow to film your exhibition space and intervention in the event, including the recording of your presentation for video purposes (with your slides, voice and image). This right extends also to the use of the resulting images in film documentation for webinars and similar items produced by PDA.

2017 PDA EUROPE CONFERENCES

26 – 27 September	Particles in Injectables	* Berlin, Germany
26 – 27 September	10th Workshop on Monoclonal Antibodies	* Berlin, Germany
10 – 11 October	Pharmaceutical Cold & Supply Chain Logistics	* Prague, Czech Republic
7– 8 November	The Universe of Pre-filled Syringes and Injection Devices	* Vienna, Austria
21 – 22 November	Outsourcing & Contract Manufacturing	* Munich, Germany

Subject to change | For latest info: pda.org/pda-europe | Shortlist 27 Jul 2017

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

General Information
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PDA® Parenteral Drug Association

Connecting People, Science and Regulation ®

www.pda.org/pda-europe