



The Parenteral Drug Association presents...

2011 PDA Europe Pharmaceutical Freeze Drying Technology

Risk Management &
Approaches for
Practical Challenges

25-28 October 2011
Hotel Icaria Barcelona
Barcelona, Spain



CONFERENCE, EXHIBITION 25-26 October | WORKSHOP 27 October | TRAINING COURSE 27-28 October

<https://europe.pda.org/FreezeDrying2011>

Freeze Drying is one of the most popular routes for stability enhancement of pharmaceutical products. This conference will provide a forum to present and discuss new developments in freeze drying process understanding and control. Additionally, participants get updated about the expectations of regulators.

As a result of ICH Q9, risk based approaches are receiving a greater focus. The understanding and management of risk will be a key topic. This involves various areas like the risk for the operators when handling potent substances, redundancies for key equipment components and optimized maintenance programs in order to mitigate the risk of equipment failure. The above will be examined from an investment and a quality assurance perspective.

This conference is an excellent opportunity to learn more about the latest developments in freeze drying and to discuss these with the experts. We have provided time in the program for networking with the speakers and for discussion of your specific challenges. As in past years, the meeting will feature an exhibition where attendees can learn about the latest in freeze drying hardware and process control systems.

A training course on the development of a freeze drying process and a workshop on the application of risk-based principles to freeze drying processes follows the conference.

We welcome you in Barcelona and we look forward to an interesting meeting.

Harald Stahl,
Co-Chair of Conference, GEA Pharma Systems

Enric Jo,
Co-Chair of Conference, Reig Jofré Group

Scientific Planning Committee

Enric Jo, *Reig Jofré Group, Co-Chair*

Harald Stahl, *GEA Pharma Systems, Co-Chair*

Georg Frinke, *OPTIMA Pharma*

Laura Noguera, *Reig Jofré Group*

Yves Mayeresse, *GlaxoSmithKline Biologicals*

Borke Van Belle, *Janssen Supply Chain, Unit of Cilag AG*

Georg Roessling, *PDA Europe*

Who Should Attend

Specialty Areas

API Development & Production | Pharmaceutical Development and Production | Process Engineering | Process Development | QC & QA | Container Development

Departments

Development | Quality Assurance | Manufacturing | Engineering

Job Function

Development | Quality | Manufacturing | Engineering | Business Development

Venue

Hotel Icaria Barcelona

Avinguda Icària, 195

08005 Barcelona

Spain

Tel: +34 93 221 82 00

Fax: +34 93 221 24 58

Website: www.hotelicariabarcelona.com

Special rates

Double room for single use € 110*

Double room: € 120*

* Rates per room and night

Buffet breakfast and VAT included.

Room Reservations

PDA has secured a limited number of rooms at a special group rate until **23 September 2011**. Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.

Reservation via booking form only

<https://europe.pda.org/FreezeDrying2011>

Contacts

For additional conference information, please contact:

PDA Europe gGmbH

Adalbertstr. 9

16548 Glienicke/ Berlin, Germany

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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 and services become a valuable tool or resource for our attendees.

For exhibition information, please contact:

Ailyn Kandora

Event & Program Manager PDA Europe

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Email: kandora@pda.org

Conference Agenda

Tuesday, 25 October 2011

9:00	Welcome	Harald Stahl, <i>Co-Chair of Conference, GEA Pharma Systems</i> Enric Jo, <i>Co-Chair of Conference, Reig Jofré Group</i>
Session 1: Regulatory Aspects		Moderator: Georg Roesling
9:15	Regulatory Insights: Concerns and Expectations	Manuel Ibarra, <i>AEMPS (Spanish Health Authority)</i>
9:45	Inspection Program for Freeze-Dried Biologicals	Roland Guinet, <i>Former AFSSAPS Inspector, RGmp Compliance</i>
10:15	Coffee Break & Exhibition	
Session 2: New Technologies		Moderator: Yves Mayeresse
10:45	The Final Quality Approach for Freeze-Dried Products	Gerhard Schramm, <i>Wilco</i>
11:15	Energy Efficient Freeze Drying	Jens Philipp, <i>GEA Lyophil</i>
11:45	Technology for the Bulk Generation of Lyophilized Microspheres	Bernhard Luy, <i>MERIDION Technologies</i>
12:15	Lyophilization, Monitoring and Process Scale-up	Miha Andrejašič, <i>LEK Pharmaceuticals</i>
12:45	Q & A, Discussion	
13:00	Lunch & Exhibition	
Session 3: ICH Q9, Risk Management		Moderator: Harald Stahl
14:00	Risk Management for Lyophilization Processes	Yves Mayeresse, <i>GlaxoSmithKline Biologicals</i>
14:30	Media Fill Strategies	Borke Van Belle, <i>Janssen Supply Chain</i>
15:00	Cold Leaks in Lyophilizers: How to Detect them, and How to Mitigate the Risk	Oliver Rüttsch, <i>Janssen Supply Chain</i>
15:30	Q & A, Discussion	
15:45	Coffee Break & Exhibition	
Session 4: Container Closure		Moderator: Borke van Belle
16:15	Raised Stoppers in Freeze-Dried Vials	Derek Duncan, <i>Lighthouse Instruments</i>
16:45	Glass Container/Elastomer: How to Ensure Container Closure Integrity	Renaud Janssen, <i>Helvoet Pharma</i>
17:15	Elastomeric Components and Innovative Plastic Caps for Container Closure Systems for Lyophilization Applications	Sascha Karhöfer, <i>West Pharmaceutical Services</i>
17:45	Q & A, Discussion	
18:00	End of Conference Day 1 Networking Event	

Wednesday, 26 October 2011

Session 5: Case Studies		Moderators: Enric Jo, Georg Frinke
9:00	Case Study – Isolator Project for Freeze-Dried Biopharmaceuticals	Hans Hörmann, <i>Boehringer Ingelheim</i>
9:30	Occupational Health Aspects in Freeze Drying of Oncological Drugs	Walter Spieler, <i>F.Hoffmann-La Roche</i>
10:00	Implementation of QbD to Develop the Lyophilization Cycle for an Antiviral Product	Enric Jo, <i>Reig Jofré Group</i>
10:30	Coffee Break & Exhibition	
11:00	Technical and Regulatory Experiences with VHP-sterilized Freeze Dryers	Bogdan Oghina, <i>Sidan Pharma</i>
11:30	Transfer & Scale Up for a Freeze Dried Product in a CMO	Nerea García, <i>Reig Jofré Group</i>
12:00	Long Term Storage of Red Blood Cells by Freeze-Drying	Isobel Cook, <i>Biopharma Technology Limited</i>
12:30	Q & A, Discussion	
13:00	Lunch & Exhibition	
	Site Visit at Reig Jofré	
14:00	Departure	
17:00	End of Conference	

Development of a Freeze Drying Process – From Formulation to a Robust Process –

Course Agenda

This two-day course gives an advanced introduction of freeze drying. It covers the whole range of aspects which are needed to develop a freeze drying cycle and to produce a product in a pharmaceutical environment. The participants will also learn about the physico-chemical background, the measurement of relevant properties and parameter setting for the cycle, container closure issues, hands-on analytics of freeze dried products, technical aspects of freeze dryers and process environment including regulatory aspects.

Thursday, 27 October 2011

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|--------------|---|--------------|--|
| 9:00 | Welcome & Introduction <ul style="list-style-type: none">- Overview of drying technologies- Overview of the freeze drying process | 13:30 | What Are the Relevant Parameters for the Freeze Drying Cycle? <ul style="list-style-type: none">- Testing methods- What information can you get?- Critical assessment of the data |
| 10:00 | Theoretical Background of Freeze Drying <ul style="list-style-type: none">- Physical and chemical principles- Thermodynamic aspects of sublimation and desorption | 15:30 | Coffee Break |
| 11:00 | Coffee Break | 16:00 | Development of a Freeze Drying Cycle <ul style="list-style-type: none">- What are the correct parameter for the cycle- Primary, secondary drying- TWO EXAMPLES (HANDS-ON) |
| 11:30 | Theoretical Background of Freeze Drying (continued) | 17:30 | Close of Day 1 |
| 12:30 | Lunch | | |

Friday, 28 October 2011

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|--------------|---|--------------|--|
| 8:30 | Repetition of Theory / Previous Day Questions | 13:00 | Qualification, Validation and Cleaning of Freeze Dryers <ul style="list-style-type: none">- Temperature mapping- Documentation aspects |
| 9:00 | How to Run the Cycle in a Freeze Dryer <ul style="list-style-type: none">- General concept of freeze dryer- In-process-controls | 14:00 | Regulatory Issues |
| 10:30 | Coffee Break | 14:30 | Q & A, Discussion |
| 11:00 | What Can Go Wrong? (HANDS-ON) <ul style="list-style-type: none">- How do samples look like if wrong parameters are taken- Container closure system- Freeze dryer (seals, measurement etc.) | 15:00 | Coffee Break |
| 12:00 | Lunch | 15:30 | The Freeze Drying Process from Filling to Capping |
| | | 17:00 | Close of the Training |

Faculty:

Georg Frinke, Optima Group Pharma GmbH, Germany

Georg holds an Engineer's degree from UAS, Cologne, Germany. He is currently process technology manager in the Optima Group Pharma GmbH (formerly Klee). From 2005 to 2008 he worked with GEA Lyophil GmbH (formerly Steris) as a R&D Engineer. 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.

ICH Q9: Application of a Risk-based Approach to Freeze Drying Processes

Thursday, 27 October 2011

Moderator: Yves Mayeresse

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
 - Dependant / Independant parameters
 - CQA : critical quality attributes
 - FMEA approach
 - Examples

10:30 Coffee Break

11:00 Practical part

- Team rule's 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

14:00 Practical part

- Part II con't : Process
 - Independant 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 con't : ancillary function
 - CIP
 - Part V : aseptic level

16:30 Conclusions

- Q&A
- Feed-back about the approach

17:00 End of the Course

agenda subject to change without notice

Workshop description:

This one day workshop will introduce the concept of risk management described in the ICH Q9 and will apply the it to the freeze-drying process. The first part will review the guidelines, the freeze-drying process and the tools available to score the risks. In the second part the session will be fully interactive. The participants will express their view in term of detectability, occurrence and control of the various risk linked to the freeze-drying process. The process will be sub divided in different chapter: product, process, critical quality attributes ancillary function of the equipment and aseptic level. The day will be closed by answering the different questions remaining and by an a review of the usefulness of the approach.

The training will provide to the participant:

- A practical approach to risk management
- A deeper understanding of the freeze-drying process
- Learning from peers during the practical part
- A methodology to perform risk management

Workshop Leader:

Yves Mayeresse, GSK Biologicals , Belgium





Yves Mayeresse is senior freeze drying manager by GlaxoSmithKline Biologicals. He has more than fifteen years of experience in the pharmaceutical sector and has worked for different companies. He has managed activities such as parenterals production, set-up of new freeze drying facilities, transfer of new and life cycle products inside the group, design of freeze drying cycle and development of new stabilizers for freeze-dried products. Now he's leading the Center of Excellence for filling and freeze drying inside the Manufacturing Strategy. He is engineer in biochemistry, he's member of pharmaceuticals association and writer of article dealing with freeze drying science.



Conference Exhibition Floor Plan

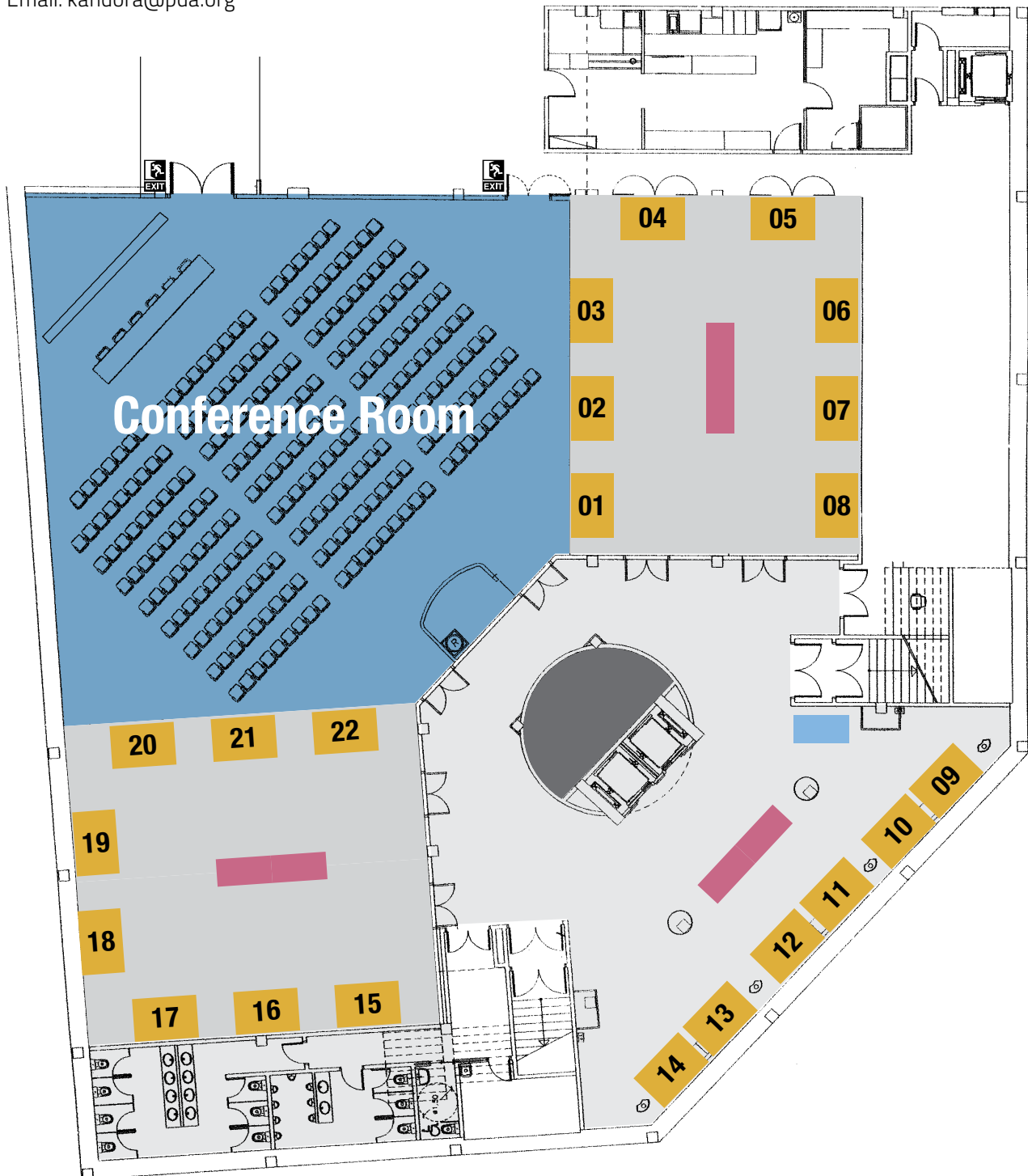
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-  Registration
-  Coffee Station
-  Desk = 180cm x 50cm
-  Table Top $\approx 6,0 \text{ m}^2$

For exhibition information, please contact:

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Event & Program Manager PDA Europe
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3 WAYS TO REGISTER

- 1** FAX: +49 33056 23 77 77
- 2** Email: petzholdt@pda.org
- 3** MAIL: PDA Europe, Adalbertstr. 9, 16548 Glienicke/Berlin, Germany

Your Contact Person is Antje Petzholdt at PDA Europe

1 Your Contact Information

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

Mr. Ms. Dr. PDA Member Nonmember

Name (Last, First, MI) *

Job Title *

Company* Department

Mailing Address

City Postal Code

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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 Event Registration

Special Group Rate for Reig Jofré colleagues only

All fees given in Euro and excluding VAT (18%)

By 15 Sep 2011

Special Rate **795**



3 Payment Options

By Credit Card American Express* MasterCard* VISA*

Total Amount (+ 18 % VAT) _____

Card Number _____ Exp. Date _____

Name _____
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*All cards are charged in Euro.

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MAKING IT EASIER FOR BOTH OF US

1 Please include your member ID number on the registration form if available/known

If uncertain about your member ID number and/or your membership status, call or email Ms. Antje Petzholdt.
+49 (0)33056 2377-10 **petzholdt@pda.org**

2 Don't send money in advance

Please wait until we send our invoice to you.
It is helpful to reference our invoice number in your bank transfer details.

3 Complete and sign the event registration form

Please note the registration and cancellation policies at the bottom of the form.

4 Purchase Orders

Registration cannot be completed by sending a Purchase Order alone. A Purchase Order is only accepted if a complete registration form is enclosed or follows very soon.

5 Please state your company's VAT ID number

This number starts with your country code
(example: PDA Europe's VAT ID number = DE254459362)

6 Please state the correct billing address on the registration form

This is particularly important if billing address and site address are different.
Contact your accounting department for correct address and company name.
There could be special requirements for accounting.

7 Confirmation of your registration

Credit card charges are confirmed immediately if successfully approved.
Bank transfers are confirmed upon receipt of full payment.

8 Refund/Credit Notes

Refunds to credit card can be done immediately.
For refund to bank accounts please provide:

- a) Name of your bank**
- b) IBAN number**
- c) Swift/ BIC code**

9 For assistance contact: Antje Petzholdt, PDA Europe

Tel: +49 (0)33056 2377-10

Email: petzholdt@pda.org

WE SEND A KIND 'THANK YOU' FOR YOUR COOPERATION!