



The Parenteral Drug Association presents...

2011 PDA Europe Modern Biopharmaceutical Manufacturing

Current Best Practice

6-7 December 2011
ENSTBB
Bordeaux, France

Register by
10 Oct 2011
and SAVE!

CONFERENCE 6-7 Dec | TOUR OF ENSTBB 7 Dec | EXHIBITION 6-7 Dec | TRAINING COURSES 8 Dec

<https://europe.pda.org/BioPharma2011>

PDA Chapter France and PDA Europe welcomes you to:

2011 Biopharmaceutical Manufacturing Conference

Practical Approaches for the challenges in development and manufacturing of biopharmaceutical and biotechnological derived products in the current GMP environment will be discussed. The conference will start with a keynote presentation describing the contributions of basic science to product development and commercialization of new and innovative pharmaceuticals.

The agenda is based on four key topics:

Quality and New Regulations

- ICH Q11 and impact on biopharmaceuticals
- Industry perspective on the ICH regulations

Single-Use-Technologies and Integration in the Manufacturing Process

- Extractables & leachables in process and storage containers
- Testing strategies
- Case studies

Process Development and Validation – Starting with QbD

- The application of QbD and its practical quality
- Design of experiments, critical quality attributes, critical process parameters, risk analysis, PAT
- Comparability & Tools to identify the link between critical quality attributes and biological activities
- Risk based approach and regulatory compliance

Process Development and Validation – Continuous Verification

- From process validation to continuous verification
- Examples for process steps: Antibody purification, cleaning validation
- Economic aspects considering lean approaches

Therefore, the practical aspects and best practices for testing strategies of Extractables and Leachables and the specifics of handling single-use-systems are most important. QbD as well as new technical and regulatory approaches for the development of robust processes for biopharmaceutical products is our conference goal. International experts share their experiences and knowledge about best practices. There will be plenty of time for questions and discussions making this a very interactive meeting.

We will be pleased to meet you in Bordeaux at ENSTBB, a leading biotechnology school in France.

The Program Committee

Scientific Planning Committee

Christophe Grimm, *Co-Chair, Sartorius Stedim Biotech*

Thierry Ziegler, *Co-Chair, Sanofi*

Véronique Davoust, *Pfizer*

Philippe Gomez, *President PDA French Chapter, Sartorius Stedim Biotech*

Brigitte Lindet, *Professor ENSTBB*

Jean-Louis Saubion, *University CHU Bordeaux*

Anne Rigoulot, *Sanofi Pasteur*

Ailyn Kandora, *PDA Europe*

Georg Roessling, *PDA Europe*

Who Should Attend

Managers, supervisors, operators, scientists and responsible persons involved in development, production or registration of biopharmaceuticals including:

- QP
- QA/QC
- Microbiology
- Pharmaceutical Development
- Manufacturing
- Engineering
- Validation
- Auditing
- In-Process Control and Monitoring
- CMC Documentation
- Regulatory Affairs

Venue

ENSTBB-IPB

l'Ecole Nationale Supérieure de Technologie des Biomolécules de Bordeaux

146 rue Léo Saignat

33 076 Bordeaux Cedex

France

+33 (0)557 571 044

+33 (0)557 571 711

enstbb@ipb.fr

www.enstbb.ipb.fr

Hotel Suggestions

Hôtel des 4 Soeurs

6 Cours du 30 Juillet, 33000 Bordeaux, France

+33 (0) 5 57 81 19 20 hotel-bordeaux-centre.com

Best Western Grand Hôtel Français

12 Rue du Temple, 33000 Bordeaux, France

+33 (0)5 56 48 10 35 grand-hotel-francais.com

Hotel Ibis Bordeaux Meriadeck

35 Cours du Maréchal Juin 33000 Bordeaux

+33 (0)5 56 90 74 00

www.ibishotels.com

<http://www.accorhotels.com/fr/hotel-0950-ibis-bordeaux-centre-meriadeck/index.shtml>

Hotel Mercure Bordeaux Centre

5 Rue Robert Lateulade 33000 Bordeaux

+33 (0)5 56 56 43 55

www.mercure.com

<http://www.mercure.com/fr/hotel-1281-mercure-bordeaux-centre/index.shtml>

Hôtel De France

7 Rue Franklin, 33000 Bordeaux, France

+33 (0)5 56 48 24 11 hotel-france-bordeaux.fr

Contacts

For additional conference information, please contact:

PDA Europe gGmbH

Adalbertstr. 9

16548 Glienicke/Berlin, Germany

Tel: +49 (0) 33056 - 23 77 10

Fax: +49 (0) 33056 - 23 77 77

info-europe@pda.org

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.

For exhibition information, please contact:

Ailyn Kandora

Program and Event Manager PDA Europe

Tel: + 49 (0) 33056 - 23 77 19

Email: kandora@pda.org



Tuesday, 6 December 2011

9:00	Welcome & Overview	Philippe Gomez, <i>President PDA Chapter France</i>
Keynote: From Academia to Industry		
9:15	From Genomic Platform to Bio Industry	Dominique Rollin, <i>Directeur Scientifique Centre Génomique Fonctionnelle Bordeaux (CGFB)</i>
Session 1: Quality and Regulatory Update		<i>Chair: Véronique Davoust</i>
10:00	ICH Q11: Impact on Biopharmaceuticals	Pierrette Zorzi, <i>Former Head of Biological Evaluation of AFSSAPS</i>
10:30	Update on QbD and other recent developments at the Agency and on Bio regulations.	Carla Martino, <i>EMA</i>
11:00	Industry Perspective on Partnership with Authorities and the Status of the Paradigm Change (Quality by Design)	Georges France, <i>Pfizer</i>
11:30	Questions, Answers and Discussions	
11:45	Coffee Break & Exhibition	
12:15	Revision of GMP Annex 16: "Certification & Batch Release" – The Role of the Qualified Person	Regulatory Speaker, <i>invited</i>
12:45	Round Table with all Speakers	
13:15	Lunch & Exhibition	
Session 2: Extractables and Leachables		<i>Chair: Anne Rigoulot</i>
14:00	Single-Use-Systems: Implementation and Supplier Qualification	Steven Brown, <i>Vivalis</i>
14:30	Clarifying the E & L Compatibility, Extractables and Leachables Strategies to Apply and Case Study	Isabelle Uettwiller, <i>Sartorius Stedim Biotech</i>
15:00	Questions, Answers and Discussions	
15:15	Coffee Break & Exhibition	
15:45	Compatibilities, Extractable & Leachables Strategies, SFSTP Commission	Natacha Sehnal, <i>SFSTP/Sanofi</i>
16:15	System Approach Applied to Elastomeric Components – Syringe Manufacturer Perspective	Nicolas Eon, <i>BD Medical Pharmaceutical Systems</i>
16:45	Case Study: Autoclavable PE-Bag, a E & L Study	Hiroo Nakano, <i>HOSOKAWA YOKO</i>
17:15	Extractable and Leachable Studies for Stoppers and Elastomers: How to Set-up the Right Testing Strategy?	Piet Christiaens, <i>Toxikon</i>
17:45	Round Table with all Speakers, Questions, Answers and Discussion pertaining to Case Studies: - Extractables & Leachables Strategies of Complete Single-Use-Systems - Strategies for Single-Use-Systems & Devices - Strategies Regarding Primary Packaging - Regulatory Aspects & Qualification & Validation	<i>Chair: Steven Brown, Vivalis</i>
18:30	End of Day 1	
Networking Event		

Wednesday, 7 December 2011

8:00 Networking Breakfast: Linking Students to the Industry
 Since December 2011 a Sanofi "Chair" was founded in ENSTBB. Sanofi is proud to associate this Chair at the PDA conference by funding a breakfast to allow exchanges between ENSTBB students and industry.

Session 3: Process Development & Validation Part 1

Chair: Thierry Ziegler

- 9:00 Application of QbD Principles for Innovation and Compliance Irwin Hirsh, *NovoNordisk*
- 10:00 Applying Innovations to Biopharmaceutical Manufacturing Aurore Lahille, *Merck Serono*
- 10:30 **Coffee Break & Exhibition**
- 11:00 Optimization of Antibody Purification: Alternative Methods to Protein A Coupled with Host Cell Proteins Identification Xavier Santarelli and Charlotte Cabanne, *ENSTBB*
- 11:30 Questions, Answers and Discussions
- 12:00 **Lunch & Exhibition**

Session 4: Process Development & Validation Part 2

Chair: Jean-Louis Saubion

- 13:00 From Process Validation to Continuous Verification, Following the EMA Guideline Véronique Davoust, *Pfizer*
- 13:30 Points to Consider for Biotechnology Cleaning Validation (PDA TR49) PDA Taskforce Member
- 14:00 Cleaning Validation: Case Study in the Vaccine Industry Anne Rigoulot, *Sanofi Pasteur*
- 14:30 Lean Management in Life Sciences Manufacturing Environments Yvan Gouttebelle, *Co-Founder of BQG*
- 15:00 Questions, Answers and Discussions
- 15:15 **Coffee Break & Exhibition**
- 15:45 Visit of the "Genomic Platform" at ENSTBB
- 17:00 **End of Meeting**



4 WAYS TO REGISTER

- 1 **ONLINE:** <https://europe.pda.org/BioPharma2011>
- 2 **FAX:** +49 33056 23 77 77
- 3 **EMAIL:** petzholdt@pda.org
- 4 **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

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 Event Registration

All fees given in Euro and excluding VAT (19,6%)

Conference + Visit at ENSTBB (6-7 Dec) By 7 October 2011 After 7 October 2011

PDA Member	<input type="checkbox"/>	895	<input type="checkbox"/>	995
Nonmember	<input type="checkbox"/>	1145*	<input type="checkbox"/>	1245*
Govern./Health Authority/Academic	<input type="checkbox"/>	470*	<input type="checkbox"/>	500*

Training Course 1 (8 December): PDA Technical Report - Single Use Technologies

All Participants	<input type="checkbox"/>	695
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Training Course 2 (8 December): PDA Technical Report - Cleaning Validation

All Participants	<input type="checkbox"/>	695
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Conference + Visit at ENSTBB + Training Course 1 (6-8 December)

PDA Member	<input type="checkbox"/>	1395*	<input type="checkbox"/>	1495
Nonmember	<input type="checkbox"/>	1645*	<input type="checkbox"/>	1745*

Conference + Visit at ENSTBB + Training Course 2 (6-8 December)

PDA Member	<input type="checkbox"/>	1395*	<input type="checkbox"/>	1495
Nonmember	<input type="checkbox"/>	1645*	<input type="checkbox"/>	1745*

Group Registration Discount

Register 4 people from the same site as a group (at the same time) for this event and receive the 5th registration free. Other discounts cannot be applied.

Discount for Exhibiting Companies

Please mark here if your company is an exhibitor of this event. If so, you will be granted a 200 € discount of the registration fee during the early bird period, if the conference or combination with conference is booked.

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

3 Payment Options

By Credit Card American Express* MasterCard* VISA*

Total Amount (+ 19,6 % VAT) _____

Card Number _____ Exp. Date _____

Name _____
(exactly as it appears on card)

Signature _____

*All cards are charged in Euro.

By Bank Transfer

Beneficiary: PDA Europe gGmbH

Account No: 09 228 735 00

IBAN: DE73 1007 0024 0922 8735 00

BIC (SWIFT-Code): DEUTDE33

Bank Address: Deutsche Bank, Welfenallee 3-7, D-13465 Berlin, Germany

Invoice Please mark here to request an invoice from PDA. You are not considered registered for a PDA event until payment is received and a confirmation letter is issued by PDA. Should you attend an event without a formal confirmation or receipt of payment you will be required to provide a credit card as guarantee of payment.

PDA Europe VAT I.D.: DE254459362

Billing Address: Same as contact information address above.

If not, please send your billing address to: petzholdt@pda.org

Your VAT I.D.: _____

Date

Mandatory Signature

CONFIRMATION: A letter of confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. If you have submitted a purchase order or have received an invoice please be advised that you are not a confirmed registrant. You are not confirmed until payment has been received in full. Please submit payment for the prevailing rate. **SUBSTITUTIONS:** If you are unable to attend, substitutions can be made at any time, including on site at the prevailing rate. If you are a non-member substituting for a member, you will be required to pay the difference of the non-member fee. If you are pre-registering as a substitute attendee, indicate this on the registration form. **REFUNDS: Refund requests must be in writing and faxed to PDA at +49 (33056) 23 77 77** (emails are not accepted). If your written request is received on or before **4 November 2011**, 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 if your cancellation has not been received in writing on or before **14 November 2011**. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. **Refund for Courses:** If your written request is received by **18 November 2011**, you will receive a full refund less a 150 € excl. VAT processing fee. After that time, no refund or credit requests will be approved. **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 (33056) 23 77 77.

MAKING IT EASIER FOR BOTH OF US

1 Please include your member ID number on 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 Do not 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 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 by 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

THANK YOU FOR YOUR COOPERATION!