



Connecting People,
Science and Regulation®



The Parenteral Drug Association presents:



2015 PDA Europe Conference Advanced Therapy Medicinal Products

1 June | **Manufacturing and Testing Challenges of ATMPs**
Pre-Conference Workshop in cooperation with the
AGORA Project, the European Open Access Research Alliance

europe.pda.org/ATMPs2015

Conference | Exhibition

2-3 June 2015

Amsterdam | The Netherlands



Register by
4 May 2015
and SAVE!

Welcome to the 2015 PDA Conference on Advanced Therapy Medicinal Products!

Scientific Planning Committee

Dirk Groenewegen, *Chair,*
Cells4Therapy

Fabio D'Agostino,
Newcastle University

Wilfried Dalemans,
Tigenix

Giovanni Migliaccio,
Istituto Superiore di Sanità (ISS)

Michele Myers,
GSK

Valerie Pimpaneau,
Voisin Consulting

Sol Ruiz,
AEMPS

Georg Roessling,
PDA Europe

After prior successful events in Madrid and Florence, this time Amsterdam will host the 2015 PDA Europe Advanced Therapy Medicinal Products Conference on 2-3 June 2015 in Amsterdam, The Netherlands.

Where other general conferences leave discussions open, this will be your unique opportunity to learn about the latest information on Pre-Clinical & Clinical ATMPs, Contract Manufacturing, First-In-Human Trials, Process & Product Development, and to discuss on-site with national, European and FDA regulators.

ATMP represent a most promising class of products for treating highly complex medical conditions. First generation products have obtained regulatory approval and the field is rapidly moving towards even more complex second generation products. Clearly there is a need for discussing the many challenges involved in developing, testing, producing and registration of ATMPs.

This conference has established itself as a unique interactive discussion platform that offers plenty of opportunities for knowledge exchange between representatives of industry, academia and regulatory authorities, both from Europe and the USA. Selected podium presentations and a series of case studies encompassing a broad range of product types and approaches will illustrate how ATMPs are currently being developed and tested. Examples will come from both the academic world and industry and will cover cell therapy, gene therapy, and tissue engineering products.

Prior to this two-day conference, PDA Europe offers a pre-conference workshop specifically dedicated to the Manufacturing & Testing Challenges of ATMPs. This pre-conference workshop will be held in cooperation with the AGORA Project, the European Open Access Research Alliance. Go visit them here agora-gmp.org and join our open forum on 1 June!

Panel Discussions, luncheons, dinners and a networking event in Amsterdam will complete this three day program.

Don't be late and mark your agenda for this exciting event in Amsterdam, 1-3 June 2015!

Why travel far when you can focus on ATMPs in Amsterdam!

Sincerely,



Dirk Groenewegen, *Cells4Therapy*,
2015 Conference Chair

Tuesday, 2 June 2015

Regulatory Update

Moderator: **Wilfried Dalemans**, *Tigenix*

- ▶ MHRA / CAT
- ▶ Dutch Agency CBG MEB
- ▶ FDA

Pre-Clinical & Clinical ATMP Progress

Moderator: **Margarida Menezes-Ferreira**, *Infarmed*

- ▶ Proteomics
- ▶ Cardiac Repair

Non-Commercial GMP

Moderator: **Dirk Groenewegen**, *Cells4Therapy*

- ▶ Utrecht University Medical Center
- ▶ Centre for Cell, Gene & Tissue Therapy, London
- ▶ Charité University Clinic, Berlin

Downstream Processing & Final Formulation

Moderator: **Fabio D'Agostino**, *Newcastle University*

Networking Event in Amsterdam

Wednesday, 3 June 2015

Process Development & Characterization

Moderators: **Sol Ruiz**, *AEMPS*
Manuel Carrondo, *iBET*

- ▶ Novartis
- ▶ Advanced Biologicals

Challenges in Demonstrating Comparability for Cell and Gene Therapy Products

Moderators: **Michele Myers**, *GSK*
Valerie Pimpaneau, *Voisin Consulting*

- ▶ Bluebird Bio
- ▶ GSK
- ▶ Pluristem Therapeutics

GMP & Contract Manufacturing

Moderator: **Giovanni Migliaccio**,
Istituto Superiore di Sanità (ISS)

- ▶ Genibet
- ▶ Genethon
- ▶ IZI Fraunhofer Leipzig

Contacts

For additional conference information please contact:

Antje Petzholdt

Membership Management

petzholdt@pda.org

Membership Management

Interest Group

General Event Information

Call for Papers

Presentations

Speaker Biographies

Event Agenda

Committee Information

Sylvia Becker

Program Coordinator

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Creixell Espilla-Gilart

Exhibition & Sponsorship
Manager

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Exhibition Information

Sponsoring Opportunities

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.

Please see the Exhibition Floor Plan on our website:

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

General Address

PDA Europe gGmbH

Adalbertstr. 9

16548 Glienicke/ Berlin, Germany

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

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

Venue of Conference

VU University Amsterdam

Room: Auditorium

De Boelelaan 1105

1081 HV Amsterdam

Hotel

For hotel accommodation at a special rate, please visit our website **europe.pda.org/ATMPs2015**.

Pre-Conference Workshop

in cooperation with the Agora Project **www.agora-gmp.org**



Special offer: Discounted travel with Lufthansa Group Airlines

Lufthansa Group Partner Airlines offer a comprehensive global route network linking major cities around the world. We offer special prices and conditions to participants, visitors, exhibitors, invited guests as well as employees of the Contracting partner and their travel companions. To make a reservation, please click on **www.lufthansa.com/event-booking_en** and enter the access code **DEZEWLD** in the "Access to Your Special Lufthansa Offer" area. This will open an online booking platform that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

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

These promotional fares are also available through your IATA / ARC travel agent. Travel agents can obtain ticketing instructions by sending an email to **lufthansa.mobility@dlh.de** and providing the access code as a reference.



Mobile Tagging:
To go directly to PDA website, simply download any QR Code App and then scan this code with your Smartphone or Tablet.

**4 WAYS
TO REGISTER**

- 1 **ONLINE:** europe.pda.org/ATMPs2015
- 2 **FAX:** +49 33056 23 77 77
- 3 **EMAIL:** petzholdt@pda.org
- 4 **MAIL:** PDA Europe, Adalbertstr. 9, 16548 Glienicke/Berlin, Germany

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

1 Your Contact InformationIf 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 subscription form

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.

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).

2 Registration

No PDA membership included

EARLY BIRD DISCOUNT ☐ Book by 4 May to receive
€ 150 off the conference fee only

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

Conference (2-3 June)

PDA Member

net

☐ 1495

Nonmember

☐ 1745

Govern./Health Authority/Academic

☐ 750**Student rate available, upon request. Please contact: petzholdt@pda.org****Manufacturing and Testing Challenges of ATMPs (1 June)**

Pre-Conference Workshop

This pre-conference workshop will be held in cooperation with the AGORA Project, the European Open Access Research Alliance (agora-gmp.org).

The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be provided. The fee does not include the hotel accommodation. PDA Europe has secured a limited number of rooms at a special group rate.

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.

☐ **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). This special rate does not include one-year PDA membership.

3 Payment Options☐ **By Credit Card**☐ American Express☐ MasterCard☐ VISA**For your credit card information safety:****Please send your details by fax only (+49-33056-23 77 77) or register online.**☐ **By Bank Transfer****Beneficiary:** PDA Europe gGmbH**IBAN:** DE73 1007 0024 0922 8735 00**BIC (SWIFT-Code):** DEUTDE33HAN**Bank Address:** Deutsche Bank, Welfenallee 3-7, D-13465 Berlin, Germany☐ **By Purchase Order** Purchase Order Number**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 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)

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.** You must have a written confirmation (including invoice) to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. Payment must be received or guaranteed by Purchase Order or credit card details on 1st day of event, at the very latest. **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 **4 May 2015**, 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 work 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 (33056) 23 77 77. **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.



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 VAT ID number if European-based Company

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. Changes in the billing address (if induced by participating company) will be charged 25,- € if imposed 3 weeks prior to the start of the event.

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 if payment had been done by credit card and details are available. Refunds to bank accounts can be done if payment had been done by bank transfer and the following details are provided:

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

9 Substitutions

If a participant is unable to attend, substitutions are welcome at any time. Changes are free of charge until 3 weeks prior to the start of the event. After this date, there will be a charge of € 50 per name change.

10 For assistance contact: Antje Petzholdt, PDA Europe

Tel: +49 (0)33056 2377-10

Email: petzholdt@pda.org

THANK YOU FOR YOUR COOPERATION!

The Parenteral Drug Association presents...

PDA Europe Upcoming Activities and Events

2015

22-23 January	Extractables & Leachables	Workshop	Seoul Republic of Korea
22-23 January	GMP for APIs (ICHQ7)	Training Course	Seoul Republic of Korea
17-18 February	Pharmaceutical Microbiology	Conference, Exhibition	Berlin Germany
3-4 March	Parenteral Packaging	Conference, Exhibition	Frankfurt/Main - Bad Soden Germany
14-15 April	Aseptic Manufacturing	Conference, Exhibition	Berlin Germany
2-3 June	Advanced Therapy Medicinal Products	Conference, Exhibition	Amsterdam The Netherlands
9-11 June	Virus/ TSE Safety Forum	Conference, Exhibition	Lisbon (Cascais) Portugal
23-24 June	Quality & Regulation Conference	Conference, Exhibition	Brussels Belgium
15-16 September	Pharmaceutical Freeze Drying Technology	Conference, Exhibition	Munich Germany
22-23 September	8 th Workshop on Monoclonal Antibodies	Workshop, Exhibition	Berlin Germany
6-7 October	Pharmaceutical Cold & Supply Chain Logistics	Conference, Exhibition	Amsterdam The Netherlands
3-4 November	The Universe of Pre-filled Syringes & Injection Devices	Conference, Exhibition	Vienna Austria
17-18 November	Outsourcing / Contract Manufacturing	Conference, Exhibition	Copenhagen Denmark
1-2 December	Vaccines	Conference, Exhibition	Berlin Germany

For latest info: <https://europe.pda.org>

Subject to change

Shortlist 15 Jan 2015

Additional training courses will accompany most conferences. For details, please use the QR-Code or go to www.europe.pda.org

Get a quick overview of all PDA Europe activities with the myPDA-WebApp.
For Apple iPhone & iPad, Android and Windows Mobile7 smartphones: www.my-pda.eu



**For general information
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**For exhibition information
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