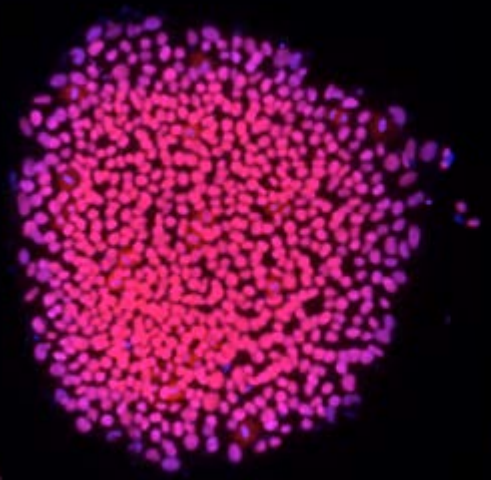
PDA
Parenteral Drug Association

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

agora

europe.pda.org/ATMPs2015

Conference | Exhibition

2-3 June 2015

Amsterdam | The Netherlands

Register by 4 May 2015 and SAVE!

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Keep thoroughly informed about our speakers
Post your question even before an event takes place
Have a look at presentations and photos
Have a quick survey of upcoming events

Welcome to the 2015 Conference on Advanced Therapy Medicinal Products!

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.

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.

This year, we are especially proud to present renowned expert speakers from Academia, Industry and these European regulatory agencies, to provide you with the latest information on the very hot topic of ATMPs:

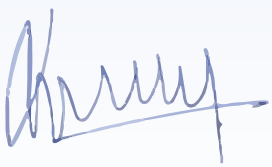
- Finnish Medicines Agency, FIMEA / Committee for Advanced Therapies, CAT
- National Authority of Medicines and Health Products, MHRA , UK
- European Directorate for the Quality of Medicines, EDQM
- Dutch Health Care Inspectorate, IGZ , The Netherlands
- Dutch Medicines Evaluation Board, CBG MEB , The Netherlands
- Paul Ehrlich Institute, Germany
- National Authority of Medicines and Health Products, Infarmed, Portugal
- Spanish Agency of Medicines and Medicinal Devices, AEMPS

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 impressive three day program.

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

Sincerely,



Dirk Groenewegen, Cells4Therapy,
2015 Conference Chair

Manufacturing and Testing Challenges of ATMPs

One of the challenges in the development of ATMPs is the transfer from the pre-clinical to the clinical stage. This workshop will address some of these challenges. Technical and regulatory (GMP-) Requirements that have to be fulfilled when preparing clinical trial material will also be considered, for example raw material selection and characterization, aseptic fill-finish operations, and testing of product and environmental conditions are just some aspects that will be presented and discussed. Part of the workshop will be dedicated to the question whether GMP activities should be outsourced. What are the pros and cons of working with a contract manufacturing partner, and what are selection criteria for or against this option. Case studies will be used as examples, and a panel discussion with experts will conclude the workshop.

Workshop Moderator

Annie Rietveld, *Dutch Health Care Inspectorate (IGZ)*

19 May 2015

Monday, 1 June 2015		**13:00-18:00**
13:00	**Welcome & Introduction**	Georg Roessling, *PDA Europe*
13:15	**The EU Agora Project, Activities & Updates**	Mark Lowdell, *Centre for Cell, Gene & Tissue Therapy*
13:45	**Pharmacopoeial Guidance**	EDQM invited
14:15	**Raw Materials in the Manufacture of Advanced Therapies Medicinal Products: Quality Attributes and Quality Assurance**	Bernd Leistler, *CellGenix*
14:45	**Fill & Finish for ATMPs**	Julien Maréchal, *Aseptic Technologies*
15:15	**Q & A, Discussion**	
15:45	**Coffee Break & Discussion**	
16:00	**Automation Strategies for Cell Therapy Production**	Andrea Traube, *Fraunhofer Institute for Manufacturing Engineering and Automation (IPA)*
16:30	**A Closed and Automated Strategy for MSCs Production: Rationale and Successful Applications**	Stefano Baila, *TerumoBCT*
17:00	**Outsourcing / Contract Manufacturing for ATMPs**	Raquel Fortunato, *Genibet*
17:30	**Q & A, Discussion**	
18:00	**Summary and Conclusion of Pre-Conference Workshop**	Georg Roessling, *PDA Europe*

PDA is pleased to invite you to a great evening at the Royal Amsterdam Rowing & Sailing Club!

Meet with conference attendees in this unique atmosphere and network while you relax.

LOCATION
K.A.R.&Z.V. De Hoop
Weesperzijde 1046A
1091 EH Amsterdam

2 June 2015

MEETING POINT
VU University
Main Entrance
at 19:10 h

BUS SHUTTLE
From
VU University
leaving at 19:15

Tuesday, 2 June 2015

9:00	**Welcome & Introduction**	Georg Roessling, *PDA Europe*

Session 1: Regulatory Update — *Moderator:* **Wilfried Dalemans,** *Tigenix*

Since Regulation of advanced therapies in the European Union came into force, a number of gene and cell therapy medicinal products have applied for marketing authorization application through the centralized procedure. Few medicinal products have been approved so far and several are under evaluation. Advanced therapy medicinal products pose specific regulatory challenges as compared to other medicines throughout development. These aspects will be reviewed and discussed.

9:15	**Latest News from the CAT – Progresses and Challenges**	Paula Salmikangas, *FIMEA /Chair of the Committee for Advanced Therapies (CAT)*
9:45	**ATMP Development: An Industry Perspective**	Wilfried Dalemans, *Tigenix*
10:15	**Coffee Break & Exhibition**	
10:30	**European Regulation of ATMPs: Quality Assessments**	Marcel Hoefnagel, *Dutch Medicines Evaluation-Board, CBG MEB*
11:00	**Quality of Raw Materials for the Production of ATMPs: Ph Eur Recommendations**	Jaana Vesterinen, *Fimea / EDQM*
11:30	**Panel Discussion with Regulators**	
12:00	**Lunch Break & Exhibition**	

Session 2: Pre-Clinical & Clinical ATMP Progress — *Moderator:* **Margarida Menezes-Ferreira,** *Infarmed*

Slowly but progressively more ATMPs are reaching the market and a significant number are getting closer to a marketing authorisation submission. Approval of these complex multifactorial products, mostly under a conditional path, is often based on a sufficiently established intended action, cross referencing results gathered through the process and product characterization studies, the relation with proof of concept and non-clinical safety studies and more importantly on the results obtained for appropriately defined clinical end points. Advantages of a well-targeted product definition supporting an adequate development for well defined patient population(s) will be considered in this panel.

13:00	**The Long and Winding Way to ATMP Approval**	Graziella Pellegrini, *University of Modena*
13:30	**Exploring Proteomics Toolbox: Human Cardiac Stem Cells Characterization and Rational Therapy Design**	Patricia Gomes-Alves, *iBET & ITQB-UNL*
14:00	**Cell-based Therapies for Cardiac Repair: A European Regulatory View**	Martina Schuessler-Lenz, *Paul Ehrlich Institute (PEI)*
14:30	**Q & A, Discussion**	
15:00	**Coffee Break & Exhibition**	

PARALLEL SESSIONS

Auditorium

Session 3: Non-Commercial GMP

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

The customary trial and registration route for ATMP-products is extremely laborious, time and money consuming, hence a major bottleneck for academic institutions and other non-commercial entities. At the same time there is an increasing innovation output from such parties. Consequently, clinicians and scientists around the globe are attempting to find alternative routes for getting earlier access to promising experimental therapies. For cost and legislative reasons, most of the ATMP-products intended for experimental therapies will be produced in the own GMP-facilities of such parties. In this session, we will hear from and discuss with top GMP-experts the specific issues concerning non-commercial GMP-production.

15:30	**Mark Lowdell,** *Centre for Cell, Gene & Tissue Therapy* **Academic Development of ATMP's - Ethics of GMP Compliance**
16:00	**Ineke Slaper Cortenbach,** *Utrecht University Medical Center* **Development of ATMP's in the University Medical Center Utrecht, and the Regulatory Environment in Europe**
16:30	**Lutz Uharek,** *Charité Berlin* **Industrial and Non-Commercial GMP, Living Apart Together**

Room Aurora

Session 4: GMP & Contract Manufacturing

Moderator: **Giovanni Migliaccio,** *ISS*

From a strategic point of view, a manufacturer may decide to manufacture in-house or subcontract a CMO. In the latter case, compatibilities of the quality systems of the developer and the CMO need to established. Companies need to make a choice regarding the role of the CMO, as sole product manufacturer or as an integrated partner of process development and validation. Technology transfer to the CMO, and product segregation at the CMO's site are other factors that need to be taken into consideration. The translation to GMP manufacturing itself contains a number of possible pitfalls that differ for Cell and Gene Therapies as well as Tissue Engineering. Selected case studies will illustrate how these different situations can be or have been handled.

15:30	**Jean Stanton,** *J&J* **Contract Manufacturing: Challenges for a Changing Landscape**
16:00	**Raquel Fortunato,** *GenIbet* **Case Study: Use of Isolator Technology on Aseptic Filling of Final Products for Clinical Trials**
16:30	**Matthias Hebben,** *Genethon* **AAV Vector Manufacturing and Control: Points to Consider during the Development Phase**
17:00	**Jean-Sebastien Parisse,** *Aseptic Technologies* **Scaling up for Commercial Manufacturing of an Allogeneic Product**

17:30 **Panel Discussion with European Regulators**

Moderator: **Margarida Menezes-Ferreira,** *National Authority of Medicines and Health Products, Infarmed, Portugal*

Paula Salmikangas, *Finnish Medicines Agency, FIMEA / Chair of CAT*

Ian Rees, *National Authority of Medicines and Health Products, MHRA, UK*

Jaana Vesterinen, *Finnish Medicines Agency, FIMEA / EDQM*

Annie Rietveld, *Dutch Health Care Inspectorate, IGZ*

Marcel Hoefnagel, *Dutch Medicines Evaluation Board, CBG MEB*

Sol Ruiz, *Spanish Agency of Medicines and Medicinal Devices, AEMPS*

Martina Schuessler-Lenz, *Paul Ehrlich Institute, Germany*

18:30 **End of Day 1**

19:30 **Networking Event in Amsterdam**

Wednesday, 3 June 2015

Session 5:	**GMP Manufacturing & Regulatory Compliance**	*Moderator:*	**Georg Roessling,** *PDA Europe*
8:00	**Challenges of Manufacturing of ATMPs for Clinical Trials**		Gerno Schmiedeknecht, *Fraunhofer Institute for Cell Therapy and Immunology (IZI)*
8:30	**Lesson Learned from Audits of ATMPs Manufacturers and Associated Critical Raw Materials Suppliers**		Paul Fiorio, *Novartis*
9:00	**MHRA's Regulatory Inspection Observations of Cell & Gene Therapy Facilities**		Ian Rees, *MHRA*
9:30	**Panel Discussion on Inspections featuring:** Dutch Health Care Inspectorate, IGZ Medicines & Healthcare Regulatory Agency, MHRA Paul Ehrlich Institute, PEI National Authority of Medicines and Health Products, Infarmed	*Moderator:*	Georg Roessling, PDA Europe
10:00	**Coffee Break & Exhibition**		
Session 6:	**Downstream Processing & Final Formulation**	*Moderator:*	**Fabio D'Agostino,** *Newcastle University*

The specific nature of cell therapy medicinal products, being complex, of large size, and living entities, makes the downstream processing of these products a real challenge. Standard purification and sterilization methods cannot (readily) be applied. Nevertheless, the presence of particulates and pathogens must be prevented. Moreover, the choice of excipients for the final product formulation along with packaging and transportation conditions need to be tailored in order to guarantee the viability and potency of the shipped cell therapy medicinal product. Currently, at an early stage, an increasing number of downstream processing options are becoming available for cell therapy. The selected presentations will address these final process steps and illustrate how efficient solutions can be/have been found.

10:30	**Application of Filtration Methodologies for the Concentration and Washing of Human Mesenchymal Stem Cells**	Barbara Cunha, *iBET & ITQB-UNL*
11:00	**Manufacturing Challenges of ATMPs**	Francis Meacle, *Janssen Cilag*
11:30	**The Impact of Cryopreservation on Mesenchymal Stromal Cells (MSCs): To freeze or not to freeze?**	Johanna Nystedt, *Finnish Red Cross Blood Service*
12:00	**Lunch Break & Exhibition**	

Session 7:	**Process Development & Characterization**	*Moderators:*	**Sol Ruiz,** *AEMPS* **Manuel Carrondo,** *iBET*

The need for process development for medicinal products is a given. Nevertheless, translating classical concepts of PD to Cell and Gene Therapy products necessitates a good understanding of the specifics of these products, both from the process side as well as from the product side. Process validation needs e.g. to take into account the autologous or allogeneic nature of the product as well as inherent biological variability of a living drug substance. Given the complex and adaptive nature of biological activity, it will ultimately be key to broadly characterize the product from different angles so to be able to control the consistency of the product batches.

13:00	**Autologous Product Development using Patients' Starting Materials: What is possible, what is feasible, and what are the challenges?**	Karin Hoogendoorn, *Novartis*
13:30	**Justification of Specifications (JOS)**	Christopher Bravery, *Advanced Biologicals*

14:00	**Preparing for Comparability: Quantification of Process Input Variation**	David Williams, *Loughborough University*
14:30	**Coffee Break & Exhibition**	

Session 8: Challenges in Demonstrating Comparability for Cell and Gene Therapy Products

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

Changes in the production process, analytical procedures, manufacturing equipment and/or facilities are inevitable during clinical development. The challenge is to demonstrate that the specific CMC changes have not drastically impacted identity, strength, quality, purity or potency of the product without additional clinical or pre-clinical studies. During the course of clinical development, our understanding of product quality is bound to evolve. The focus of the comparability exercise is to determine the relationship between product quality and safety as we move along the different clinical development phases. For cell and gene therapies, this challenge is further amplified by inherent product and process variability and our relatively limited ability to fully characterize the product. Speakers during this session will share their experience and provide examples to illustrate how, despite the challenges, they have successfully designed comparability studies and associated analytical tools to confirm the consistent safety and effectiveness of the product throughout development.

15:00	**Autologous Gene Therapy Manufacturing Comparability: Meeting the Challenge through Process Understanding and Product Characterization**	Michael Paglia, *Bluebird Bio*
15:30	**Case Study: Demonstrating Comparability of Clinical and Commercial Processes for an ADA-SCID Autologous HSPC Gene Therapy**	Smaragda Angelidou, *GSK*
16:00	**Case Study: Comparability of MSC's during Scaling Up – From Design to Approval**	Ohad Karnieli, *Pluristem Therapeutics*
16:30	**Q & A, Discussion**	
17:00	**Closing Remarks & Farewell**	

Contacts

For additional conference information please contact

Melanie Decker Director Events & Exhibitions **decker@pda.org**	**Conference** **Venue** **Hotel Accommodation**
Antje Petzholdt Membership Management **petzholdt@pda.org**	**Membership Management** **Interest Group** **General Event Information**
Sylvia Becker Manager Programs & Events **becker@pda.org**	**Call for Papers** **Speaker Management** **Conference Agenda**
Elke von Laufenberg Manager Training & Education **laufenberg@pda.org**	**Education Program** **Faculty Management**
Creixell Espilla-Gilart Manager Exhibition & Sponsorship **espilla@pda.org**	**Exhibitor Management** **Sponsorship 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.

General Address
PDA Europe gGmbH
Am Borsigturm 60
13507 Berlin
Tel: +49 (30) 4365508-0
Fax: +49 (30) 4365508-66

Venue of Conference

VU University Amsterdam
Room: Auditorium
De Boelelaan 1105
1081 HV Amsterdam

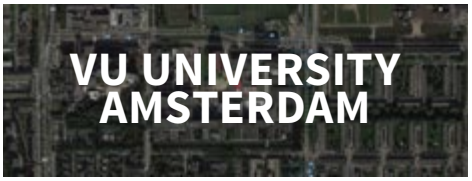
Hotel

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**

How to find the venue:



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Advanced Therapy Medicinal Products

2-3 June | Amsterdam / The Netherlands

Your Contact Person is
Antje Petzholdt at PDA Europe
petzholdt@pda.org

4 WAYS TO REGISTER

1. **ONLINE: https://europe.pda.org/ATMPs2015**
2. **FAX: +49 30 4365508-66**
3. **EMAIL: petzholdt@pda.org**
4. **MAIL: PDA Europe, Am Borsigturm 60, 13507 Berlin, Germany**

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

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* 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

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

Conference (2-3 June)	net
PDA Member	☐ **1495**
Nonmember	☐ **1745**
Govern./Health Authority/Academic /Student	☐ **750**
Start-Ups / SMEs	☐ **950**

Manufacturing and Testing Challenges of ATMPs (1 June)

Pre-Conference Workshop

All Participants ☐ **400**

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

Members of the Agora Project participate for FREE!

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.

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Please send your details by fax only (+49-33056-23 77 77) or register online.

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IBAN: DE73 1007 0024 0922 8735 00
BIC (SWIFT-Code): DEUTDEDBBER
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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.:

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2 Do not send money in advance

Please wait until we send our invoice to you.
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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
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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

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THANK YOU FOR YOUR COOPERATION!

The Parenteral Drug Association presents...

PDA Europe Upcoming Activities and Events

2015

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 & Regulations	Conference, Exhibition	Brussels Belgium
30 June - 1 July	Managing Risk in Aseptic Processing	Conference	Tel Aviv Israel
10-11 September	Particles in Injectables	Conference, Exhibition	Berlin Germany
15-16 September	Pharmaceutical Freeze Drying Technology	Conference, Exhibition	Munich Germany
22-23 September	8th 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 19 May 2015

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

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