

ATMP Hybrid Conference – An Irish Perspective

The Parenteral Drug Association (PDA) is the leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical community. Founded in 1946 as a non-profit organisation, PDA is committed to developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise of its near 10,000 members worldwide. Conferences, meetings, and courses bring together pharmaceutical manufacturers, suppliers, users, academics, and regulatory officials to discuss and boost issues of mutual interest. These exchanges of technical knowledge, expertise, and best practices assist the advancement of pharmaceutical science and technology in the interest of public health.



PDA Ireland Chapter, Event Committee



Guest Speakers



Valerie Mulholland, GMP Services Ltd, MC



Guest Speakers

Recently, the design and development of a modern health policy in the field of regenerative medicine leads to the formation of a new and integrated cognitive field, which requires systematic research and study to produce innovative answers and best practices. Advanced therapy medicinal products (ATMPs) are a new product category, which is at the heart of concern since it has to deal with diseases in which traditional medicine has proven to be ineffective so far.

The ATMPs consist of three basic categories of products: 1) gene therapy (gene therapy medicinal products (GTMPs)); 2) somatic cell therapies; and 3) tissue engineering products, as well as any combination of the above. These are products that use human cells and tissues which have undergone gene or other treatment or modification in the laboratory. The donor and the recipient of the cells/tissues may be the same individual (autologous use) or different (allogeneic use). Cell therapy and gene therapy are overlapping fields of biomedical research and treatment. Both therapies aim to treat, prevent, or potentially cure diseases, and both approaches have the potential to alleviate the underlying cause of genetic diseases and acquired diseases.

PDA's Ireland Chapter organised the ATMP Hybrid Conference on the 26th of November 2021 in Dublin.

An attendance of more than 250 people both in-person & remotely, gathered to discuss the importance of ATMP as the next wave of therapeutics and enhance the contribution that the biopharma sector makes to the Irish economy as well as deliver solutions to unmet and existing medical needs.

"I believe Ireland is very well positioned and with a very strong pharmaceutical and biopharmaceutical industry worth around over €140B in exports. Most of the main companies in the world manufacture here (Ireland). I think we do have all the components of what a very successful sector in the future should be", affirms Matt Moran, Director at BioPharmaChem Ireland. Moran adds: "The Covid-19 pandemic has had a huge impact and we now have an mRNA vaccine, which is a new technology. And it is proven to be very successful in the treatment or prevention of Covid-19 through vaccination. And what I think is very encouraging about this new technology is that it has got huge potential to be used in other therapeutic areas as well as dealing with new variants of the Covid-19."

The main aim of the event sponsored by renowned organisations like IPS, Bioquell, Koerber, Pharmalex, Steris & SteriTech was an ideal meeting ground to provide comprehensive information on ATMPs, which could be applied in various regenerative medicine and tissue engineering applications. Moreover, ATMPs could be a valuable tool for the physicians for the proper administration of life-threatening diseases, thus could be applied in personalized regenerative medicine.

The event gave us a sense of returning to normality after two years of disruption. Although the pharmaceutical industry has never stopped, social gatherings and face-to-face events which have been vital to knowledge sharing & key partnerships had come to an abrupt halt. This conference was vital to regenerate a sense of purpose in the drug discovery and development world. It was also vital to highlight the role which Ireland can play in a global setting.

"Bioquell Ecolab solutions are just delighted to be back here, to see people face-to-face again is just so important and we are so happy to support this industry. PDA Ireland events have always been brilliant events and always well attended. It's just brilliant for us to get in front of

these people again and to reconnect.” Says Kristen McKeown at Bioquell, one of the main sponsors of the event.

True to PDA’s mission to promote the exchange of rapidly evolving information on the latest technology and regulations, the ATMP Hybrid Conference hosted topics like A Fully Integrated Ecosystem for Manufacturing Gene Therapies from Clinical through Commercialisation, mRNA Vaccines – An Overview of the Manufacturing Challenges & Bottlenecks, New Momentum for Advanced Therapies: How Regulators can help.

The event, moderated by Valerie Mulholland, started with a welcome speech from Ann McGee, PDA Ireland President, and Matt Moran, Director BioPharmaChem Ireland. Between face-to-face and online presentations, some important names of the industry gave their insights into some topics, like Bertie Daly at Takeda who talked more about the contamination control strategy for cell therapy manufacturing facility and Dr. Christian Schneider, who spoke about how regulators can help in advanced therapies, between others.

The event enabled attendees to:

- Discuss business-related questions with regulators, industry, and academic organisations
- Ignite conversation, collaboration, and change in how we improve access to innovative treatments by accelerating their way to the market and ultimately to patients
- Gain practical knowledge on how to best navigate the complex access landscape of advanced therapies
- Create solutions in various formats with plenary sessions and interactive sessions

By the end the event the feedback from all the attendees was excellent. “It’s a delight to be sponsoring the PDA event. There was a sense of joy from people, from seeing the familiar faces and some unfamiliar ones also. It was just great to be back “mentions Bernard Flynn at Elis Cleanroom. Brian O’Connor from MeiraGtx, exclaimed “It is Immediately clear from the interaction you get from before and after the presentation. People will come and chat with you. Something you can’t necessarily do online. You can’t be in person and get that face-to-face interaction”

Please find more at:

www.pda.org/chapters/europe/Ireland

Name: **Brian O’Connor, Director of Quality Assurance**



Company: **MeiraGTX Ireland**

Feedback: “Thank you Kevin, and all the PDA Ireland team, for the privilege to speak among such an esteemed panel of speakers. It is clear that the development of ATMP manufacturing in Ireland has great momentum and it was inspiring to hear first-hand the details on the projects happening across academia and industry.”

Name: **Niall Barron, Principal Investigator, Cell Engineering Lab**



Company: **NIBRT**

Feedback: “Thank you Kevin and co at PDA Ireland. Great event and really looking forward to seeing Ireland go from strength to strength in the production and delivery of ATMPs!”

Name: **Christian K Schneider, M.D., Head of Biopharma Excellence/Chief Medical Officer (Biopharma)**



Company: **Biopharma Excellence**

Feedback: “Also from my side thank you so much for having me in the conference. Brilliant speakers, and the conference highlighted what power the Irish ATMP life sciences community has. I really hope to learn more in the future!”

Name: **Matt Moran – Director BioPharmaChem Ireland**



Company: **BioPharmaChem Ireland**

Feedback: “Great presentation Bertie and Aidan – fascinating to see the challenges that you have overcome to deliver this product – a whole new ball game!”

Name: **Kevin Smyth, IPS**



Company: **IPS-Integrated Project Services GmbH**

Feedback: “IPS were delighted to be the main sponsor of the fantastic event. The PDA Ireland committee successfully managed to provide us with top class international ATMP expert speakers from Ireland, the UK and mainland Europe. In addition to the excellent speakers and presentations, the open floor Q&A sessions were very informative and highly interactive. Everybody who attended this conference established new contacts and learned more about the fascinating and rapidly developing ATMP Biopharma Industry. Well done to all the organisers, presenters and delegates.”

Name: **Trevor Brett, Director, Business Development**



Company: **PharmaLex UK**

Feedback: “Thank you for PDA arranging such an insightful and enjoyable ATMP event: scores 11 out of 10! The talks by Takeda and Meira were totally awesome.”

Name: **Catherine Jomary, PhD., Technology Lead ATMPs**



Company: **IPS-Integrated Project Services GmbH**

Feedback: “Thank you very much for your kind invitation to the meeting, for introducing me to the Dublin IPS Team and to Ireland experts in ATMPs. I really enjoyed the meeting, and congratulations for the organisation!”

Name: **Bertie Daly, Manufacturing Head Cell Therapy**



Company: **Takeda**

Feedback: “It was my pleasure to present with Aidan at the prestigious PDA event. Great meeting with the SME’s on the panel sharing their knowledge and expertise on the various presentations. Special mention to the organizers, Aidan Harrington for providing the opportunity to present and of course Valerie Mulholland our moderator for making the event such a success.”