

Additional Information:	Workshop 1: Comparability for ATMPs
	8:30am – Registration
	<p>9:00am – Workshop begins</p> <p>Christopher Bravery, <i>Director, Consulting on Advanced Biologicals Ltd</i>, UK</p> <p>Change is inevitable and necessary both in development and over the post-approval product lifecycle. Whenever changes are made it is necessary to confirm they do not adversely impact the quality and therefore safety and efficacy of the product; this requires data beyond meeting current specifications. With any biological product this is challenging, for cell, gene and tissue products that cannot be fully characterised the challenges are greater still. Concerns about comparability undertaken during development are common issues raised during review and often delay market approval or contribute to failure. This course explains what comparability is and how to develop a successful comparability protocol.</p> <p>Workshop Learning Overview:</p> <ul style="list-style-type: none"> - What is comparability? - Why is meeting existing specifications not comparability? - How do I apply the principles of comparability to highly variable products? - Case studies: Common mistakes with comparability and their consequences. - Interactive exercise: Spot the weaknesses and propose improvements to a worked comparability study.



CONFERENCE DAY ONE 27 th February 2019
8.00 am - Registration
8.50am - Chairperson's Opening remarks Steve Oh, Director Stem Cell Bioprocessing & Institute Professor, at A*Star, Singapore
Manufacturing and Process Development Strategies – Novel Technologies for Efficient Scale Up and Scale Out
9.00am – Scale-up production of human pluripotent stem cells and 3D multicellular micro-tissues with differentiated functional cells Confirmed speaker: Norio Nakatsuji, Professor Emeritus, Kyoto University and Chief Advisor, Kyoto Stem Cell Innovation, Japan
9.30am – Discussion Panel: Manufacturing Technologies and Continuous Improvement <i>This strategic panel will focus on new technologies and considerations for driving state of the art manufacturing. Topics to be discussed include:</i> <ul style="list-style-type: none">• New cell lines for therapies• Novel bioreactors• Novel microcarriers• Economy of scale considerations• Compact instrument alternatives Norio Nakatsuji, Professor Emeritus, Kyoto University and Chief Advisor, Kyoto Stem Cell Innovation, Japan Kim Raineri, Vice President of Operations, Nikon CeLL innovation Co., Ltd. Japan Antonio Lee, Global Head, Business Development, MEDIPOST CO., Ltd., CEO & Managing Director, MEDIPOST America Inc., South Korea Ohad Karnieli, CEO & Co-Founder, ATVIO Biotech Ltd., Israel
10.00am – Spotlight Presentation
10.30am - Morning Coffee and Networking
11.15am – CAR-T Cell Therapy Development for Solid Tumor Treatment —Challenges & Opportunities Confirmed speaker: Chien-Tsun Kuan, Deputy Executive Director, Institute of Biologics Development Center for Biotechnology, Taiwan
Late Morning Session Strategies and Facility Design for Commercial Manufacturing – End to end Solutions
11.45am – A forward look at the future of cell therapy manufacturing <ul style="list-style-type: none">• What does the future of manufacturing look like?• Review of different technologies out there• Where do the gaps lie? Confirmed speaker: Kim Raineri, Vice President of Operations, Nikon CeLL innovation Co., Ltd. Japan

12. 15pm – Spotlight Presentation

12.45 - Lunch, Networking and Live Labs

2.00pm – Case Study: Commercialisation Experience of a Somatic Stem Cell Product

Confirmed speaker: Antonio Lee, Global Head, Business Development, MEDIPOST CO., Ltd., CEO & Managing Director, MEDIPOST America Inc., South Korea

Early Afternoon Session

Reducing the Cost of Manufacturing – Costs of Goods Calculations, Automation and Robotics

2.30pm – Enabling commercial scale-out of T-cell manufacturing

- What are the key challenges in scaling an autologous process for commercial?
- The role of closed systems in scalability
- Understanding and controlling Key Quality Attributes

Confirmed speaker: Ohad Karnieli, CEO & Co-Founder, ATVIO Biotech Ltd., Israel

3.00pm - Spotlight Presentation

3.30pm - Afternoon Coffee

Late Afternoon Session

Regulatory Updates and Recent Progress: US, Japan and EU

4.00pm – Regenerative medicine product regulations in Japan - Enhancing the development of Advanced Therapies?

- Case study

Confirmed speaker: Colin Lee Novick, Managing Director, C.J. Partners, Japan

4.30pm - Recent regulatory innovation in cell therapy in Taiwan

In today's presentation, I will introduce the regulatory history of cell therapy medicinal products in Taiwan, then I will provide the audience with statistics regarding the current status of cell therapy clinical trials. Also, I will talk about the recent regulatory innovative measures in order to reduce the regulatory burden and facilitate the approval process of clinical trials and market authorizations.

Confirmed speaker: I-Ning Tang, Team Leader, Center for Drug Evaluation (CDE), Taiwan

<p>5.00pm – Discussion Panel: Working towards a cooperative framework for regulatory harmonisation across Asia</p> <p>Confirmed speakers:</p> <ol style="list-style-type: none"> 1. Colin Lee Novick, <i>Managing Director, C.J. Partners, Japan</i> 2. I-Ning Tang, <i>Team Leader, Center for Drug Evaluation (CDE), Taiwan</i> 3. Antonio Lee, <i>Global Head, Business Development, MEDIPOST CO., Ltd., CEO & Managing Director, MEDIPOST America Inc., South Korea</i>
5.30pm - Chairperson’s Closing Remarks
5.35pm - Networking Drinks and Evening Social Event

<p>CONFERENCE DAY TWO 28th February 2019</p>
8.50am – Chairperson’s Opening Remarks
<p>Regional Spotlight Session – Case Studies and Pipeline Updates</p>
<p>9.00am – Allogeneic Mesenchymal Stromal Cell Therapy: feasibility using HLA matched donors</p> <p>Mesenchymal Stem Cells (MSCs) are considered immunoprivileged because they express HLA-Class I but not Class II antigens. Consequently, HLA-matching is considered unnecessarily in clinical applications using allogeneic MSCs, although there have been very few studies to compare the results of matched vs mismatched major histocompatibility complex (MHC) expression.</p> <p>However, recent human clinical studies often showed that results using allogeneic MSCs seemed not as well as using autologous MSCs. Meanwhile, substantial evidence now exist to prove with multiple studies documenting specific cellular & humoral immunoresponse against donor follow administration of these cells. Industrial allo-MSC product failure analysis also suggested that the role of immunogenesis cannot be neglected.</p> <p>We propose that the immunoprivilege property of MSCs should be re-evaluated, while the feasibility using HLA-matched allogeneic MSCs should be considered.</p> <p>Confirmed speaker: YaoChang Chen, <i>Professor of Emeritus, National Taiwan University, College of Medicine, Taiwan</i></p>
<p>9.30am – Basic technologies for CAR-T cell therapy (tentative)</p> <p>Confirmed speaker: Keiya Ozawa, <i>Director, Center for Gene & Cell Therapy; Professor, Division of Genetic Therapeutics, The Advanced Clinical Research Center, The Institute of Medical Science, The University of Tokyo, Japan</i></p>
<p>10.00am – Spotlight Presentation</p>

10.30am - Morning Coffee
Late Morning Session Regional Spotlight Session – Case Studies and Pipeline Updates
11.15am – hES Case Study Confirmed speaker: Hideto Yamaguchi, Executive Director, Head of Technical Operations, Astellas Institute for Regenerative Medicine (AIRM), Japan
11.45am – CART/ CAR product case study Confirmed speaker: Ting He, CEO, ImmunoChina Pharmaceuticals Co. Ltd., China
12.15pm – Spotlight Presentation
12.45pm - Lunch and Networking
Early Afternoon Session Regional Spotlight Session – Case Studies and Pipeline Updates
2.00pm – Ex vivo NK expansion without allogeneic feeder cells, viral factors, and non-human components Confirmed speaker: James Chieh-Liang, Director, Science and Innovation Department, Medigen Biotechnology Corp., Taiwan
2.30pm – TriCAR-T / gp100 program for the treatment of melanoma – case study Confirmed speaker: Peter Sun, Head of Global Partnering, Beiike Biotech Ltd., CEO, TIMMUNE, China
3.00pm – Spotlight Presentation
3.30pm - Afternoon Coffee
Late Afternoon Session Regional Spotlight Session – Case Studies and Pipeline Updates
4.00pm – Stem Cell Case Study Confirmed speaker: Steve Oh, Director Stem Cell Bioprocessing & Institute Professor, at A*Star, Singapore

4:30pm - IL-7 and CCL19 expression in CAR-T cells improves immune cell infiltration and CAR-T cell survival in the tumour

Confirmed speaker: Koji Tamada, *Professor and Chairman*, Department of Immunology, Yamaguchi University Graduate School of Medicine, Japan

5.00pm - End of Day Two

POST CONFERENCE WORKSHOP

1st March 2019

Characterising ATMPs

09.00am – Understanding Potency and Developing Potency Assays for ATMP

Christopher Bravery, *Consulting on Advanced Biologicals Ltd., Member*, ISCT EU Legal and Regulatory Affairs Committee, UK