Cell Therapy Manufacturing Asia

27 February - 2 March 2018
The Westin Miyako
Kyoto, Japan

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7:45 *Registration*

8.40 **Chairperson's Opening Remarks**

The Realities of Manufacturing and Commercialising Cell Therapies in Asia and the Rest of the World

8.45 **Challenges and Opportunities for Cell Therapy in Asia**
Mickey Koh, Director-Stem Cell Transplantation, Consultant Haematologist/ Hon Senior Lecturer, **St George's Hospital and Medical School,** *UK*

9:15 **Chimeric Antigen Receptor T-Cell Therapies for Solid Tumors**
Progress in chimeric antigen receptor T (CAR T) cell therapies for hematopoietic malignancies has been stunning over the past decade, and solid tumors are only now catching up. One of the major challenges in the treatment of solid tumors with CAR T cells is the relative paucity of antigens selectively, let alone uniquely expressed by these cancers. In my talk I will briefly describe the development of the field, with an emphasis on how CAR T cell therapies have been evaluated in solid tumors, the antigens targeted; reasons why success has not been dramatic yet, and what the near future holds.
Jan Joseph Melenhorst, Director, Product Development & Correlative Sciences laboratory, **University of Pennsylvania,** *USA*

9:45 **DISCUSSION PANEL: Strategies for the Successful Commercialisation of Cell Therapies**
- What can the EU/US learn from Japan and visa versa
- What have been successes and failures in the region
- Strategies for navigating the Asian market with regards to commercialisation
- What are the biggest challenges when working in the region?
- Reimbursement and risk management strategies

10:15 **Spotlight Presentations**
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10:45 *Morning Coffee and Networking*

Bioprocessing Technologies, Automation and Closed Systems – Applications and Case Studies

11:15 **Allogeneic Stem Cell Bioprocesses for Mesenchymal and Pluripotent Stem Cells Manufacturing**
- Reprogramming & selecting human induced pluripotent stem cells on microcarriers
- Integrated Stem Cell Bioprocesses to make red blood cells
- Biodegradable microcarriers for stem cell production and tissue implantation
- New assays of cell quality and potency

Steve Oh, Director Stem Cell Bioprocessing & Institute Professor, Stem Cell Group, Bioprocessing Technology Institute, **A*Star,** *Singapore*

11:50 **Smart Cell Processing: Future of Cell Production**
We have been developing an automated closed-cell culturing system using in-process monitoring. This system guarantees the quality of the cell products during processing by applying process analytical technology (PAT). Also, through data integration system in SCP, we can analyze trends of operations and QC test data of the products in process. SCP System is revolutionizing the current outdated and costly cell manufacturing approach and bringing breakthroughs to the medical field. In this session, we are introducing SCP System as a new cell manufacturing method focusing on industrializing and commercializing cell production for the generations to come
Shin Kawamata, Director, Research and Development Centre for Cell Therapy, **FBRI,** *Japan*

12:25 **AUTOMATION EXPERT PANEL**
Informa is looking for 5 speakers to join our expert led discussion panel to talk on the below topics:
- Case studies/feedback on closed systems in general
- Is there a need to have closed systems in clean rooms?
- Process automated sampling
- What can we learn from automation for MAbs?
- How do you make thinks connectable between different devices?
- Automation linked to cost of goods

12:55 *Lunch, Networking and Live Labs*

Process Automation and Closed Systems – Applications and Case Studies

2:10 **Cell Manufacturing Based on Flexible Modular Platform**
Expansion cell culture, which is the most critical steps to realize the transplant of cells or tissues for cell therapy or regenerative medicine, respectively, will be done in terms of safety and cost-saving under the aseptic environment in the cell processing facility (CPF). The cell processing isolator system can enable cell processing in a closed aseptic chamber, which may reduce equipment and maintenance/operation costs while providing a reliable aseptic environment. handle cells collected from a large number of patients, and some believe that isolators with a function to prevent cross-contamination may be advantageous in providing a more reliable aseptic environment compared with open operation in the facilities. A novel isolator system based on a flexible Modular Platform (fMP) was designed to realize that the individual modules can connect and disconnect flexibly with keeping the aseptic environment inside each module, applying the cell processing. In addition, as it is known that the serial processes for cell processing affect the quality of the cells, the machinery processes are conducted not only to maintain an aseptic environment but also to lead to process stability in CPF. Thus, our attempts are concluded to build an advanced culture system employing isolator technology, and the adaptation of the fMP in CPF will lead to easy installation of the new modules for production line addition and/or revision through the clinical phases as well as commercial production, which contributes to the reduction of production costs.
Masahiro Kino-Oka, Professor, Department of Biotechnology, Graduate School of Engineering, **Osaka University,** *Japan*

2:45 **3D Suspension Culture for Scalable Cultivation of Pluripotent Stem Cells**
Katsuhisa Matsuura, Associate Professor, Department of Cardiology, **Tokyo Women's Medical University,** *Japan*

3:20 **SPOTLIGHT PRESENTATION: Enabling Technologies for Scalable Manufacturing of Allogeneic Cell Therapy Products**
Scalable biomanufacturing platforms are needed to meet the anticipated demands of allogeneic cell therapy products. Two-dimensional (2-D) planar technologies have proven inadequate for large-scale manufacturing. Growing cells on microcarriers or in aggregates suspended in bioreactors is considered the most viable option for scaling up the manufacturing process. Bioreactors with horizontal impellers require relatively high agitation power in order to fully suspend microcarriers or aggregates which can inhibit cell growth and/or cause early cell death. Anchorage dependent cells grown on microcarriers or in aggregates are known to be more sensitive to fluid shear stress than suspended single cell cultures. In addition, the cells respond to their growth environment in ways that may affect product quality, safety, and potency. This makes it more challenging to identify the acceptable range of agitation rates to achieve satisfactory cell growth and quality attributes. This problem often becomes worse as the size of bioreactor increases. New case study data for scale up from 500 mL to as high as 50 L working volumes for adult and pluripotent stem cell applications will be presented.
Brian Lee, President and Co-Founder, **PBS Biotech, USA**

3:50 *Afternoon Coffee*

Reducing the Cost of Manufacturing – Costs of Goods Calculations and Considerations

4:20 **DUAL DIALOGUE: Cost of Goods Calculations for Cell Therapy Products** CASE STUDY
Informa is looking for 2 speakers to present back to back on carrying out cost of goods calculations when manufacturing cell therapy products
Kim Raineri, Vice President Operations, **NIKON CeLL innovation Co., Ltd.,** *Japan*

4:55 **Redirecting T Cells Towards Epitope/HLA Complexes for the Treatment of Hematological Cancers; Our Experience of WT1-siTCR-T Cell Therapy**
WT1 is constantly expressed in leukemic cells of acute leukemia and myelodysplastic syndrome (MDS). A T-cell receptor (TCR) that specifically reacts with WT1 peptide in the context of HLA-A*24:02 has been identified. The safety and cell kinetics of WT1-specific TCR-gene transduced T cells in patients with acute myeloid leukemia (AML) and MDS were investigated in the first-in-human trial. In this talk, I will introduce our clinical trial and briefly overview the current status of redirecting T cells towards epitope/HLA complex for the treatment of hematological cancers including some of our own attempts.
Hiroshi Fujiwara, Senior Assistant Professor, Department of Hematology, Clinical Immunology and Infectious Diseases at Graduate School of Medicine, **Ehime University,** *Japan*

5:30 **Chairperson's Closing Remarks**

5:35 **Networking Dinner in Kyoto**
Join fellow attendees in a fantastic networking and dining opportunity at a local restaurant in beautiful Kyoto. Space is limited and an additional fee applies. Please indicate when you register if you plan to join the dinner.

8.30 *Registration*

8.55 **Chairperson's Opening Remarks**

International and Asian Regulatory Perspectives

9:00 **The Observation of Regulatory Requirement and Development Status of Cell Therapy**
- Regulatory and industrial development status in China
- Regulatory requirement and industrial development status in Taiwan
- The challenges and key success factors

Lily Lien, Senior Project Manager, **TOT BIOPHARM,** *China*

9:20 **Conditional and Time-Limited Approval Systems for a New Regenerative Medicinal Product in Japan**

Colin Lee Novick, Managing Director, **CJ Partners Inc.,** *Japan (Invited)*

9:40 **DISCUSSION PANEL: What Can We Do to Work Towards Regulatory Harmonisation?**
- A look at regulatory strategies in both Asia and the EU/US
- What can the regions learn from one another
- What work's well and what doesn't?

10:00 **Spotlight Presentations**

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10:20 *Morning Coffee*

Manufacturing and Process Development Strategies – Solutions for Efficient Scale Up and Scale Out

11:05 **CAR-T Therapy Induced Remission of r/r B-ALL Patients Pre-Treated with HSCT**

Ting He, CEO, **ImmunoChina Pharmaceuticals Co. Ltd.,** *China*

11:40 **Allogeneic T Cell Therapies – from Bench To Bedside**

Michael Leek, Chief Executive Officer, **TC Biopharm,** *UK*

12:15 **Development of Serum-Free Culture Conditions for CAR T Cell Expansion**

Expansion of T cells was a critical step for preparing chimeric antigen receptor (CAR) T cells for therapy. Although serum was widely applied in the culture or expansion of T cells, the quality of serum could be varied from batch to batch, leading to the variation of T cell expansion and quality. In addition, the safety of pathogens from serum was required to be considered. To overcome the disadvantages of serum application in T cell culture, serum-free and xeno-free culture conditions were required. Here, we developed a rapid serum-free culture condition for the expansion of immune T cells ex vivo. Human T cells were isolated from the PBMCs of healthy donor using a density gradient medium followed by CD3+ magnetic cell separation. The isolated CD3+ T cells were applied into serum-free medium supplied with IL-2. After a 2-week culture, T cells could expand more than 100-3,000 folds, and the cell viability in all samples was above 90%. The T cell pollutions could be controlled at averagely about 40% of CD8+ T cells and averagely about 55% of CD4+ T cells after culture. These conditions could be applied in the expansion of CAR T cells for cell therapy to support the minimum requirement of blood or cell samples from patients.

Hsin-Lin Lu, Research Fellow, Bioengineering Group, Institute of Biologics, **Development Centre for Biotechnology,** *Taiwan*

12:45 *Lunch and Networking*

Production Considerations – Facilities Linked to Manufacturing Strategies

2:00 **In vivo Gene Therapies - the Need for Process Scale Up and Production** CASE STUDY

What production facilities can be used for the production of vectors and viruses?

2:35 **CDMO EXPERT LED PANEL: How Do You Choose Your Development Partner?**

Informa is looking for 5 speakers to join this panel discussion looking at the below topics:
- How do you choose your CDMO
- What capabilities should they have?
- Centralised manufacturing
- Regional manufacturing
- Local manufacturing
- Considerations for autologous, allogeneic and gene therapy products
- Tech transfer of processes to new facilities

Kim Raineri, Vice President Operations, **NIKON CeLL innovation Co., Ltd.,** *Japan*

Kunihiko Suzuki, Vice Chairman and Member of the Board, **MEDINET Co., Ltd.,** *Japan*

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3:40 *Afternoon Coffee*

Logistics, Supply Chain, and Cryopreservation Techniques

4:10 **Transportation Strategies from Manufacture to the Patient: Elevating Bottlenecks**
- Logistics of the transfer from manufacture to patient
- Current systems used for transport/cryogenically freezing
- Preparing samples for use
- Systems used to track shipments
- What improvements can be made
- Storage and packaging

Hsiu-ling Hsiao, Chief Scientific Officer, **Ever Supreme Bio Technology Co., Ltd.,** *Taiwan*

4:45 **LOGISTICS ROUNDTABLES: Analysing Where the Gaps Lie**

Informa is looking for 4 round-table leaders to host round-tables on the below topics:
- Product distribution
- Injection technologies/ Administration techniques
- Thawing technologies
- Global supply chain strategies (including raw materials)
- Forward thinking and preparations for commercialisation

5:20 **Chairperson's Closing Remarks**

5:25 *End of Day Two*

TUESDAY, FEBRUARY 27, 2018
PRE-CONFERENCE WORKSHOP

9:00 - 17:00

Comparability Testing for ATMPs

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

- Introduction to comparability
- Regulatory framework
- Process and product characterisation
- Comparability expectations during clinical development and post-approval
- Examples of changes and comparability strategies
- Case study exercise

FRIDAY, MARCH 2, 2018
POST-CONFERENCE WORKSHOP

9:00 - 15:00

Characterising ATMPs

Understanding Potency and Developing Potency Assays for ATMP

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

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Share your company's scientific research by presenting a poster at Cell Therapy Manufacturing Asia 2018. Be sure to sign up for a poster space when you register and submit your abstract online by February 2, 2018.