BioProcess International Asia

October 21-23, 2024
Westin Miyako Kyoto
Kyoto, Japan

Asia's Premier Bioprocessing Summit:

Optimize, Accelerate, and Innovate Manufacturing for Your Biologics & Novel Modalities

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The Long-Awaited Return to Japan

We’re back with a bang and are excited to announce the return to Japan in October 2024. Join pioneers in the bioprocessing community as we delve into the latest innovations, successes and lessons learned.
Network with experts from across the globe in the vibrant city of Kyoto - renowned for developing many of the refined arts that are now associated with Japan.

Featured Speakers

Niki Wong

Director, Global Technical Operations CMC at AbbVie, Singapore

Wei Huang

President at Henlius Biopharmaceutical Ltd, China

Takashi Kaminagayoshi

Head of Biotherapeutics Process Development - Japan at Takeda Pharmaceutical Company Limited, Japan

Qasim Rafiq

Vice Dean (Health) Faculty of Engineering Sciences & Professor in Cell and Gene Therapy Bioprocess Engineering at University College London, UK

View All Speakers

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2024 Focuses

Next-Generation Advancements in Bioprocessing

Discover next-generation bioprocessing advancements, such as innovative cell line development and engineering techniques, optimized and scalable upstream processing for various modalities, enhanced downstream approaches for improved product quality and recovery, and cutting-edge strategies for manufacturing and commercializing cell and gene therapies.

Key Innovations for Enabling Technologies

Access key enabling technologies in bioprocessing include novel process analytical tools for real-time reaction monitoring, smart data-driven processing for improved yields and cost reduction, seamless integration of artificial intelligence and automation, and the utilization of technologies to enhance efficiency and sustainability.

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MONDAY, 21 OCTOBER 2024

(Optional) Pre-Conference Workshop Day

7:30-8:30	**Registration**
8:30-12:30	**Introduction to CDMO Management (details TBC)** Add-on this optional pre-conference workshop to your main conference registration package and gain a comprehensive overview of CDMO Management in an easy-to-follow classroom setting to help you prepare for the main conference program.
12:30-13:30	**Luncheon Provided for Main Conference + 2 Half-Day Workshop Pass Holders**
13:30-17:30	**Introduction to Cell and Gene Manufacturing |** Christopher Bravery - Consulting Regulatory Scientist, Consulting on Advanced Biologicals, UK Add-on this optional pre-conference workshop to your main conference registration package and gain a comprehensive overview of Cell and Gene Therapy Manufacturing in an easy-to-follow classroom setting to help you prepare for the main conference program. • Workshop registration begins at 12:30 pm • Afternoon Break: ~ 3:30-3:50pm **How does Cell and Gene Therapy Manufacturing Differ from other Biological Products?** • The manufacturing diversity of cell and gene products, examples. • Limitations when controlling adventitious agents • Complex starting and raw materials • Batch size, and stability

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TUESDAY, 22 OCTOBER 2024

Main Conference Day 1

8:25-8:30	**Chairperson's Opening Remarks |** Daisuke Kajihara - Senior Director of Bioprocess Technology Research Laboratories, Daiichi Sankyo., Ltd., Japan
8:30-9:00	**KEYNOTE: Advanced Biomanufacturing Facilities -** A Case Study | Takashi Kaminagayoshi - Head of Biotherapeutics Process Development - Japan, Takeda Pharmaceutical Company Limited, Japan This keynote explores the transformative potential of digital innovation and sustainability in shaping the future of biomanufacturing. It examines key considerations for establishing efficient, GMP-compliant facilities at production scale, utilizing novel single-use technologies. The discussion will highlight advancements and emerging trends in biomanufacturing.
9:00-9:30	**Case Study: Launching Singapore Biotech Product with Local Biomanufacturing -** Jack Wong - CEO and Founder at Asia Regulatory Professionals Association (ARPA), Singapore • A journey of how different team work together to make quick biotech product launch • Tips on choosing different product classification, regulatory pathway • Tips on manufacturing setup • Tips on market expansion
9:30-10:00	**Scientific Presentation from Sartorius** SARTORIUS
10:00-10:45	**Networking Refreshment Break with Exhibit and Poster Viewing**

TUESDAY, 22 OCTOBER 2024

Main Conference Day 1

10:45-11:45	**Panel Discussion: Managing and Fostering Successful Cross-Continental CDMO Relationships** | Niki Wong - Director, Global Technical Operations CMC at AbbVie, Singapore & Wei Huang - President at Henlius Biopharmaceutical Ltd, China Setting expectations from the outset to ensure clear communication of timelines; How can you create trust with both parties to ensure a successful working relationship?; Key pitfalls and successes; Choosing the right partners
11:45-12:45	**An Efficient One Batch Calibration using Raman for Monitoring of CHO mAb Cell Cultures** | Minh Tran - Global Head of Automation, PAT and Analytics Software at Merck KGaA MERCK The use of Raman spectroscopy as a PAT solution is showing many tremendous opportunities for real time process monitoring capabilities. Historically, the most challenging part of implementing Raman spectroscopy as a PAT solution for real time process monitoring is establishing the chemometric models to monitor the cell culture critical process parameters and critical quality attributes. This chemometric model building process would require multiple batches (4-5) and data points (50-70). During this talk, I will be sharing recent breakthrough of a proprietary and simplified one batch calibration method to easily establish the whole process of chemometric model building
12:15-13:45	**Networking Luncheon with Exhibit and Poster Viewing**
13:45-13:50	**Chairperson's Opening Remarks**
13:50-14:20	**Root Cause Analysis for GMP Nonconformities and CAPA Management** | Kevin Jonggu Kim - Quality Lead, External Manufacturing Large Molecules at Sanofi, South Korea Regulatory Requirements and Definitions; Investigation Tools for Root Cause Analysis; Problem Solving Options for CAPA and Evaluation for Effectiveness Check; Suggestions for handling Deviations and CAPAs

TUESDAY, 22 OCTOBER 2024

Main Conference Day 1

14:20-14:50	**Cell Line Development for Biologics** | Dr Yasuhiro Takagi - Senior Director at Astellas Pharma Inc., Japan
14:50-15:20	**Cell Line Engineering (Talk Title TBC)**
15:20-15:50	**Manufacturing of Human MSCs and iPSCs with an Automated Instrument with Process Analytical Technologies** | Haruki Takeuchi - Department Manager & Senior Engineer, Medical Engineering Center at Sinfonia Technology Co., Ltd., Japan SINFONIA Critical quality attribute of MSCs is sustained homeostatic replication and those of iPSCs are self-renewal and differentiation susceptibility. Since quality fluctuation of stem cells is primarily caused at culturing, their expansion has long been undertaken by skilled and experienced staffs with large efforts and labors. Simple automatization would not be their solution since process monitoring and analyzing are indispensable to secure quality of unstable stem cells. We have applied CellQualia Intelligent Cell Processing (ICP) System, a fully closed cell manufacturing instrument with process analytical technologies, to both MSCs and iPSCs and compared their quality with those from manual operation. The results showed the quality comparability of the cells from automated and manual expansion. On the other hand, only ICP System enabled us to monitor and record cell manufacturing process as numerical indexes. The data thus obtained is expected to be used in applying Quality-by-Design concept to manufacturing of those cells and base for their in-process qualification. We hope the results of our study would be cue for shifting from manual to automated cell manufacturing at practical level.
15:50-16:20	**Networking Refreshment Break with Exhibit and Poster Viewing**

TUESDAY, 22 OCTOBER 2024

Main Conference Day 1

16:20-16:50	**Digital Twins to Optimize Feeding Strategies and Achieve Process Robustness using Model Based Control** | Christoph Herwig - Fr. Professor for Biochemical Engineering, Senior Scientific Advisor at Körber Pharma Austria GmbH, Austria Cell culture and microbial cultivation processes are complex and difficult to control, because of the biological variability and many process parameters which also interact. The results are batch to batch variations, batch failure and missing economy. However MC process understanding must be demonstrated in regulatory filing, which is currently targeted by many explorative experiments using DoE. This contribution demonstrates the usefulness of process modelling and the deployment of the models as digital twins for process optimization and achieve process robustness. We will show, • How process models can be set up using a good modelling practice workflow • How digital twins are used to optimize feeding strategies by model-based design. • Which data architecture is needed to deploy digital twins in real time? • How to achieve robustness and optimized process conditions by digital twin-based feedback control?
16:50-17:20	**Computational Approach to Accelerate Culture Media Optimization for New Modalities** | Zach Pang - Group Leader at A*STAR Bioprocessing Technology Institute, Singapore Culture culture media optimization plays a vital role in bioprocess development. Achieving an optimal formulation for the culture media is crucial as it enables maximum cell growth and subsequently yields the highest possible cell density. The current workflow involves experimental Design of Experiments (DOE) to determine the optimal culture media formulation. A paradigm shift is underway in the optimization of culture media, wherein a modelling approach can be employed to accelerate culture media optimization. In this talk, I will introduce a computational approach involving genome-scale metabolic modelling and model-guided DoE approach, and how this workflow can help the industry, particularly for new modalities, to accelerate culture media design and optimization.
17:20-18:20	**Networking Cocktail Reception with Exhibit and Poster Viewing**

WEDNESDAY, 23 OCTOBER 2024

Main Conference Day 2

8:25-8:30	**Chairperson's Opening Remarks** | Mark Duerkop - Chief Executive Officer at Novasign, Austria
8:30-9:00	**KEYNOTE: Novel Technology in Biomanufacturing - A Case Study** | Dr Wei Huang - President at Henlius Biopharmaceutical Ltd, China The application of novel technologies in biopharmaceutical manufacturing and their benefits and challenges will be discussed. Case studies include use of continuous manufacturing, on-line multivariable monitoring and feedback control and use of robotic appartus in fill and finish
9:00-9:30	**Digital-Twin-assisted Manufacturing: Guideline to Accelerate Development Timelines and Automated Process Control** | Mark Duerkop - Chief Executive Officer at Novasign, Austria In the slowly evolving landscape of bioprocess development and manufacturing, digital bioprocess-twins have emerged as potential accelerators. While advanced algorithms are at the heart of this endeavor, they are just one piece of the puzzle. The talk delves into key discussion points that are integral to this paradigm shift. The foundation of accelerated process development and automated process control starts with a clever experimental design, in-time data accessibility combined with powerful modeling algorithms. The talk will highlight the advantages of using hybrid modeling, while emphasizing the other critical aspects on his journey. Several industrial relevant upstream showcases for microbial and mammalian cell lines will be highlighted. Thereby, concepts to save experimental effort by up to 70% will be elaborated, and the modeling structure created in the late-stage development will be reused for real-time monitoring and control in the later stages. Additionally, a downstream optimization showcase for UF/DF/SPTFF will be highlighted.
9:30-10:00	**Advanced Analytical Technologies for Better, Faster, and more Integrated PAT** | Olivier Henry - Program Director for Life Science & Medical Device Technologies at imec, Belgium Bioprocesses involve complex process flow that require to be monitored at every step. Traditionally, this has been accomplished through time-consuming tests, either conducted on-site or in specialized off-site laboratories. However, advances in micro- and nano-technologies realized over the past decade have led to the development of highly miniaturized and performing sensors. These sensors can be deployed in situ for real-time monitoring or at-line for swift testing at the point of need. This technological progress supports the industry's shift towards continuous manufacturing, real-time release of therapeutic products, and meeting process intensification requirements. Imec, a globally renowned research and innovation centre in nanoelectronics and digital technologies, leverages the power of chip technology to revolutionize healthcare and life sciences. Collaborating with partners in life sciences, pharma, biotech, and MedTech, imec focuses on developing next-generation technologies that demand extreme sensitivity, massive parallelization, and miniaturization enabling breakthrough impact. This talk showcases recent breakthroughs in this domain, including a compact, multiparameter sensor chip designed for in-situ monitoring of critical process parameters. Additionally, we introduce a rapid immunosensor array tailored for at-line contaminant quantification and a multiplexed PCR chip coupled with lens free imaging for at-line bioburden monitoring. These advancements represent significant advances towards efficient and real-time monitoring in bioprocessing, opening new avenues for enhanced productivity and product quality.

WEDNESDAY, 23 OCTOBER 2024

Main Conference Day 2

10:00-10:45	**Networking Refreshment Break with Exhibit and Poster Viewing**
10:45-11:15	**End to End Digital Twins Provide an Agile Control Strategy for Real Time Release |** Christoph Herwig - Fr. Professor for Biochemical Engineering, Senior Scientific Advisor at Körber Pharma Austria GmbH, Austria Acceleration of commercialization of biologics including the filing of a robust control strategy is of utmost importance for biosimilars up to new modalities. Digital twins capture CMC knowledge and allow multiple deployments. This contribution shows how end-to-end digital twins. • Save 50% of experimental effort by incorporating drug substance specification when designing CMC control strategies for the process chain and • Allow for the identification of critical process parameters, which influence the process chain holistically. • Allow for prediction and control on process performance in real time application and therewith allow for real time release testing and avoiding batch failures.
11:15-11:45	**Viral Safety of Biological Products, the Need for a Holistic Approach |** Christopher Bravery - Consulting Regulatory Scientist at Consulting on Advanced Biologicals, UK Lessons from history; Viral testing; no one method is perfect; Viral inactivation and removal; How does viral control differ for cell and gene products?
11:45-12:15	**3D Printed Chromatography the Successor to Expanded Bed Adsorption |** Sean Feast - CEO & Founder at Precision Chroma, New Zealand Expanded bed adsorption promised to revolutionize downstream processing by combining clarification and capture chromatography into one step. However, due to the reliance on a perfectly fluidized bed this technology faced significant issues including poor and unstable fluidization due to complex feed streams, fouling and ultimately bed collapse. This concept has been reimagined in the form of a stable, monolith structure containing an array of uniform self-supporting channels. Printed Monolith adsorption (PMA) is a 3D printed chromatography column capable of direct purification of biological molecules from both whole cell culture and crude cell lysate. This talk describes both the use of this technology on the purification of his-tagged proteins from crude bacterial cell lysates and antibodies from high density mammalian cell culture. PMA purifications show equivalent purity to a traditional downstream clarification and capture chromatography process while significantly shortening purification time by up to two thirds. Routine lab-based purification can be completed within one hour from cell culture to highly pure product. PMA has also reached pilot scale with column volumes of 1 L with discussion regarding reaching the next column size of 10 L for the future of preparative chromatography.

WEDNESDAY, 23 OCTOBER 2024

Main Conference Day 2

12:15-12:45	**Scientific Presentation by IDBS** IDBS
12:45-13:55	**Networking Luncheon with Exhibit and Poster Viewing**
13:55-14:00	**Chairperson's Opening Remarks**
14:00-14:30	**Achieving Process Intensification for High Titer mAb Processes using Inline Concentrators and Next Gen Virus Filtration Technologies |** Sanjay Nilapwar - Principal Scientist I, Purification Development, BioProcess Development, Operations Science & Technology – Biologics at Abbvie, USA Improvement in cell culture titers has directed demands on process intensification to reduce the bottleneck in downstream manufacturing facilities. Accordingly, in-process volume during downstream operations has risen significantly, straining capacities on the downstream unit operations. To address these challenge inline ultrafiltration technologies for volume reduction as modification to platform purification technologies scheme seems promising. We evaluated competing technologies: one based on countercurrent flow channels with a built-in fixed retentate restrictor, and second one with traditional 3X membrane PES based ultrafiltration membrane cassettes with added retentate restriction by plate dividers. Lab study studies showed that 3 membrane configuration gives the best outcome and was used for estimation of flux mAb concentration at constant feed flow rate and mAb load. Factors impacting volumetric concentration factor (VCF) were also evaluated to assess SP-TFF fit to downstream process in manufacturing prior to the AEX (Q) step. Results suggested that both competing technologies perform similarly in terms of VCF, inlet TMP or residence time showed the greatest impact on the VCF factor, with no impact on the product quality seen. Studies suggest that SP-TFF can be implemented as a process intensification tool to reduce in-process volumes significantly and can be implemented without much changes to a purification platform. UFDF modelling was also performed using Dynochem in-built tools and with modified recirculation loop. Modelling study shows that the VCF impact due the viscosity modulation within 10-40 g/L mAB concentration range is minimal. This technology has the potential to be an efficient process intensification tool for the high titer mAB processes and for controlling in-process volumes.

WEDNESDAY, 23 OCTOBER 2024

Main Conference Day 2

14:30-15:00	**Integrating Continuous Operations for Cell and Gene Therapy Enhancement |** Manuel Carrondo - Vice President at Instituto de Biologia Experimental e Tecnológica (iBET), Portugal • Substantially improved product quality. • Significantly higher productivity. • Markedly lowered costs. • Appreciably lower footprint. • Closed system, facilitating sterile operation.
15:00-15:30	**Building a CAR-T Centre of Excellence in New Zealand |** Darja Nelson - Commercialisation Manager - Biotech at Bridgewest Ventures, New Zealand Bridgewest Ventures is partnering with the government, researchers and entrepreneurs in New Zealand to change the status quo. By creating a decentralized model for accelerating the development and manufacture of cutting-edge therapeutics that could save patients lives, worldwide. Bridgewest is building an end-to-end ecosystem for biomanufacturing of CAR-T cell and cell therapies by creating and investing in start-ups which fit into the value chain. The incubated ventures are able to leverage the broader Bridgewest Group portfolio, creating a unique end-to-end CAR T-cell development and manufacture offering. “This ecosystem could cut the development of novel cancer immunotherapies from an average of 3 years to just 9 months and make it available in New Zealand at a fraction of the current cost”
15:30-16:00	**New Bioprocess Strategy with Fiber Chromatographic Clarification Platform from Discovery to Manufacturing |** Dr Masa Nakamura - Bioprocess Science Senior Specialist at Solventum We will explore how novel clarification technology, based on advanced synthetic fibrous chromatography materials, will enable new bioprocess strategies to address critical challenges in process simplification and intensification. We will illustrate how this platform can offer seamless implementation of chromatographic clarification from discovery to clinical and commercial manufacturing, providing consistent and high-quality clarified fluid and enhancing commercialization productivity

WEDNESDAY, 23 OCTOBER 2024

Main Conference Day 2

16:00-16:30	**Networking Refreshment Break**
16:30-17:00	**Pandemic Readiness, Sa-mRNA and LNP Technology Transfer, a US - Japan Collaboration |** Hamid Trimech - mRNA/LNP Project Leader at Arcalis Inc., Japan In November 2023, MLHW, Japanese Health Authorities, approved the world's 1st Sa-mRNA Covid-19 vaccine, Kostaive™. As part of the Japanese government pandemic readiness initiative, this new vaccine, developed in collaboration by Arcturus Therapeutics, CSL Seqirus and Meiji Seika Pharma will be manufactured locally in Japan. In September of 2023, a technology transfer of both the mRNA and LNP technologies to a newly established CDMO, ARCALIS Inc. was initiated with a target of completion by fall 2024. This presentation shares how mRNA and LNP manufacturing capability was established in record time and the methodology implemented, issues faced, and lessons learned throughout the transfer of Sa-mRNA/LNP technology to Japan.
17:00-17:30	**Process Intensification and Adaptive Manufacturing Strategies for Cell & Gene Therapies |** Qasim Rafiq - Vice Dean (Health) Faculty of Engineering Sciences & Professor in Cell and Gene Therapy Bioprocess Engineering at University College London, UK • Approaches to reduce the variability and address scalability challenges of advanced therapies • Demonstrating the consistent and scalable expansion of CAR-T cells from multiple donors in stirred-tank bioreactors • Establishment of novel process control strategies to achieve cell therapy process intensification • Role and scope for adaptive manufacture in the development of novel advanced therapies • Integration and implementation of artificial intelligence and digital twins to support process modelling and cell therapy manufacture

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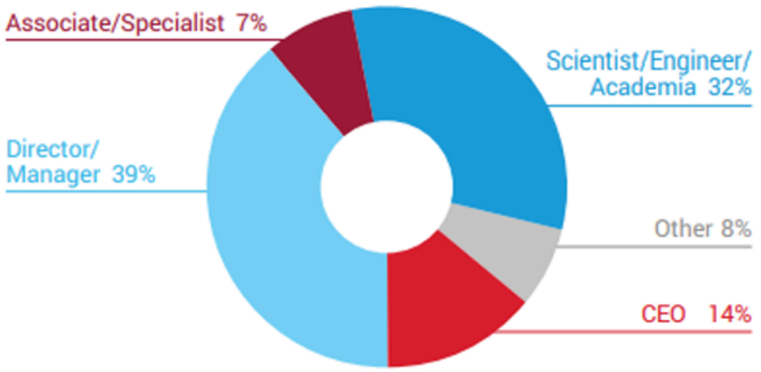

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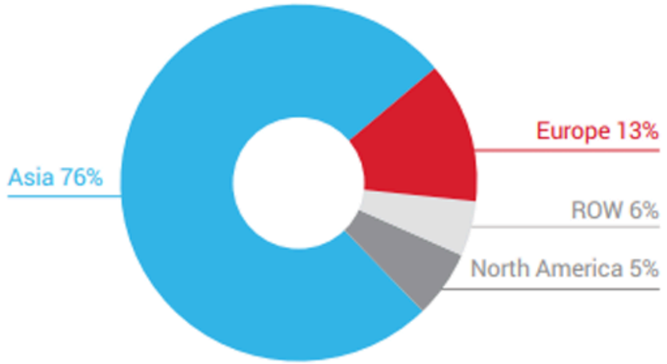

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