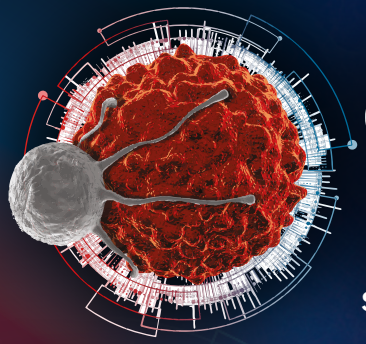
December 3-5, 2024 | Boston, MA



6th Annual

Cell Therapy Analytical Development Summit

Standardize Analytical Testing to Confidently Characterize Cell Potency, Safety & Viability

Develop Robust Analytical Methods & Tools in a Phase-Appropriate & Cost-Efficient Manner, to Improve Cell Characterization, Expedite Product Release & Gain Regulatory Approval

50+ World-Class Speakers, Including:

Haixia Wang
Head of Analytical Development
Arsenal Biosciences

Stephan Krause
Executive Director, Analytical Science & Technology, Cell Therapy Quality
Bristol Myers Squibb

Alexandre Ambrogelly
Executive Director, Analytical Operations
Kite, A Gilead Company

Jie Wei, PhD
Director, Bioanalytical Sciences
Tr1X Bio

Ramon Mendoza
Scientific Director Analytical Development & CMC Strategy
Johnson & Johnson

Connie Tsai
Associate Director, Analytical Development
Novartis

Proud to Partner With:

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Pre- Conference Workshop Day | Tuesday, December 3

7.30 Check-In & Coffee

Analytical Development

Workshop A

8.30 Optimizing Surrogate Potency Assays with Effective Implementation & Validation for Cost Effective & Streamlined Processes

Surrogate assays streamline processes and reduce costs compared to traditional cell-based methods. They offer crucial benefits such as cost and time savings, scalability, and improved efficiency, accelerating the translation of cell therapies to clinical use. However, it's essential to establish a strong correlation between surrogate methods and cell-based assays to justify their use effectively.

Join us to:

- Gain insights into how surrogate potency assays streamline processes and reduce costs, accelerating the translation of cell therapies to clinical use.
- Understand the importance of establishing a strong correlation between surrogate methods and cell-based assays for effective implementation, qualification, and validation.
- Receive practical guidance on developing surrogate potency assays, optimizing efficiency in cell therapy analytical development and looking into protein expression as a surrogate potency marker.

Connie Tsai, Associate Director, Analytical Development, **Novartis**

Ramon Mendoza, Scientific Director Analytical Development & CMC Strategy, **Novartis**

Sebastian Hymson, Scientist, **BioNtech**

Quality Control

Workshop B

8.30 Strategies & Designs for Overcoming Product Instability in Quality Control for Streamlined Regulatory Approval

Ensuring the stability of cell therapy products is essential for their safety, efficacy, and regulatory approval. However, detecting and addressing product instability poses significant challenges. This workshop will delve into innovative strategies and methodologies to navigate the complexities of product instability in cell therapy stability studies. From determining critical stability parameters to leveraging advanced analytics, gain insights into optimizing stability assessment protocols and ensuring long-term efficacy.

Join us to:

- Gain insights into critical stability parameters essential for assessing cell therapy products. Learn to establish robust stability study protocols tailored to product characteristics.
- Explore novel methodologies for detecting and addressing product instability. Discuss alternative study designs and innovative stress-inducing techniques.
- Acquire actionable strategies from industry experts. Engage in interactive discussions to exchange ideas and learn from real-world case studies.

Prachi Narayan, Global Quality Control & Clinical Science, **independent expert**

Fan Yang, Vice President of Cell Therapy, **Aisaer (IxCell Biotechnology)**

10.30 Morning Break & Networking

Workshop C

11.00 Navigating Characterization Strategies in Cell Therapy Development with Evolving Insights from FDA Guidance

In the rapidly advancing field of cell therapy, developers face significant challenges in characterizing their products to meet regulatory standards. The FDA has provided evolving guidance on what is required for effective characterization, which includes understanding product attributes, ensuring consistency, and demonstrating safety and efficacy.

Join us to:

- Understand how cell therapy developers are adapting their characterization strategies in response to evolving regulatory requirements, identifying areas for innovation and improvement in current practices.
- Delve into recent FDA guidance on cell therapy characterization, exploring strategies for effectively interpreting and implementing these expectations.
- Discuss approaches for aligning characterization strategies with FDA expectations to ensure compliance and facilitate regulatory approval.

Chris Rold, Vice President, Vector Development & Quality Control, **Adicet Bio**

Yunes Kunes, VP Analytical Development and Quality Control, **Prime Medicine**

Workshop D

11.00 Strategies for Potency-Driven Quality Control in Cell Therapy to Maximize Therapeutic Efficacy

Ensuring the effectiveness and safety of cell therapy is critical as the field progresses. Central to this is potency evaluation, encompassing vital functions like mechanism of action, cell-based killing, and more. Crafting robust quality control (QC) strategies involves navigating complexities to align with regulatory standards and therapeutic goals. Translating QC findings to clinical settings is essential for predicting therapeutic outcomes.

Join us to:

- Explore the multifaceted landscape of potency evaluation, delving into vital functions such as mechanism of action, cell-based killing, degranulation, release, proliferation, and persistence, crucial for determining therapeutic efficacy.
- Navigate the complexities of QC strategy formulation, understanding how to select and prioritize functions for monitoring, ensuring alignment with regulatory requirements and therapeutic objectives.
- Gain insights into the translation of QC findings to clinical settings, elucidating the significance of robust potency assessments in predicting cell performance and therapeutic outcomes in patients.

Kato Shum, Director of Quality Control, **CARGO Therapeutics**

Anu Vasudevan, Associate Director, Analytical Development, **CARGO Therapeutics**

Pre- Conference Workshop Day | Tuesday, December 3

1.00 Lunch Break & Networking

Analytical Development

Workshop E

2.00 Optimizing Analytical Development for Scalable & Efficient Cell Therapy Manufacturing

Optimizing analytical development for scalable and efficient cell therapy manufacturing is essential for ensuring product quality and regulatory compliance. Challenges include the complexity of cell therapies, scalability of methods, integration with manufacturing, and regulatory standards. Developing robust analytical methods that align with manufacturing needs and regulatory requirements is critical for accelerating the translation of cell therapies from research to clinical use.

Join us to:

- Gain insights into how analytical methods evolve throughout cell therapy development, from research to commercialization.
- Learn strategies for aligning assays with manufacturing, enhancing efficiency and product consistency.
- Explore best practices for transitioning from quality assurance to quality control, ensuring adherence to regulatory standards.

Laura Pierce, Biomedical Engineer, **NIST**

Aarohi Thakkar, Senior Scientist Process Development Drug Substance, **Satellite Bio**

Quality Control

Workshop F

2.00 Establishing Robust Acceptance Criteria for Improved Product Quality

Establishing acceptance criteria for cell therapy products is crucial for ensuring safety and efficacy by defining standards for parameters like cell viability, identity, potency, and stability during development and testing. However, this process is challenging due to the complex nature of living cells and the lack of standardized methods. While regulatory guidelines provide frameworks, their application requires careful consideration of each product's unique characteristics. Developing robust acceptance criteria is essential for maintaining product quality.

Join us to:

- Understanding the regulatory guidelines and expectations for establishing acceptance criteria in QC processes, ensuring compliance with industry standards and regulatory requirements.
- Learning practical methodologies, strategies, and risk assessment techniques for defining acceptance criteria, enabling participants to implement effective QC protocols tailored to their specific product development needs.
- Gaining insights into industry best practices, continuous monitoring and evaluation and challenges related to acceptance criteria establishment, providing valuable guidance for optimizing QC processes and enhancing product quality and safety.

Benjamin Espen, Principal Quality Engineer**, Avobis Bio**

Prachi Narayan, Global Quality Control & Clinical Science, **Independent expert**

4.00 End of Workshop Day

> "With constantly evolving therapies and their regulations, it is important to have a space like this for the stakeholders to come together and share their knowledge and experiences"
>
> Senior Scientist, Process Development Drug Substance**, Satellite Bio**, **2024 Speaker**

Conference Day One | Wednesday, December 4

7.30 Check-In & Coffee

8.30 Chair's Opening Remarks

Navigating Analytical & Regulatory Frontiers to Propel Cell Therapy Development Forward

8.40 **Industry Leaders' Fireside Chat: Pioneering Analytical Frontiers to Overcome the Complexities of Cell Therapy Products – Insights from Cell Therapy's Foremost Analytical Minds**

- Delve into the key obstacles and complexities currently facing analytical development in cell therapy:
  - Representative material for method development
  - Regulatory expectations and phase appropriateness
  - Comparability challenges across analytical methods
- Discuss the latest advancements and innovations in analytical techniques and methodologies and their applications in cell therapy development.
- Share insights and strategies for overcoming current challenges and maximizing the potential of analytical development in advancing cell therapy research and clinical applications.

Renee Hart
President & Chief Business Officer
Lumacyte

Ramon Mendoza
Scientific Director Analytical Development & CMC Strategy
Johnson & Johnson

Stephan Krause
Executive Director, Analytical Science & Technology, Cell Therapy Quality
Bristol Myers Squibb

Alexandre Ambrogelly
Executive Director Analytical Operations
Kite, A Gilead Company

9.30 **Navigating the Path to Successful CGT Assay Development**

Dirk Windgassen
Director, Analytical Development
Miltenyi Biotec

- Identify and address common pitfalls: Avoid the frequent challenges faced in CGT assay development by employing these strategies to mitigate these issues early in the process.
- Optimize reproducibility and data integrity: Best practices for implementing robust flow-based methods that ensure consistency and reliability across different assays.
- Implement efficient workflow strategies: Reduce time to market and improve overall project outcomes.

9.45 **Leveraging the MACSQuant® Analyzer to Optimize Assays for Analytical Development**

Alex Villalba
Senior Research Associate
Tr1x

- Automate for efficiency: Explore how one-way automated compensation on the MACSQuant Analyzer can streamline workflows and reduce manual errors commonly associated with traditional flow cytometry methods.
- Seamlessly transfer technology: Learn about effective R&D tech transfer strategies to MACSQuant Analyzer, including the practical implications of converting assay panels and ensuring instrument compatibility.

10.00 **Enhancing Potency Assay Strategy for CGT: Unlocking Precision & Reliability for Regulatory Approval**

Kelly Bowen
Associate Principal Scientist, Analytical Development
KSQ Therapeutics

Shreya Mehta
Senior Director, Regulatory Affairs
KSQ Therapeutics

- Delve into the new potency assurance guidance and understand how to align potency methods with regulatory requirements to meet expectations and ensure compliance. Explore effective strategies to mitigate risks to a product's potency.
- Discover how collaborative initiatives streamline compliance efforts and facilitate the adoption of best practices, particularly in addressing the complexities of new regulatory guidance and ensuring alignment with evolving expectations.
- Learn effective strategies for engaging with regulators early and continuously throughout the cell therapy development process.

Ankita Burke, PhD
Product Manager, Clinical Instruments
BD Biosciences

10.30 Standardize Cell Analysis for Cell Therapy Development & Transfer to Manufacturing QC

- At BD Biosciences, we partner globally, across all stages of the drug development process, to support leading biopharmaceutical companies and CDMOs from discovery to market approval and commercialization. BD's automation solutions can accelerate multisite collaboration and drive standardization.

This talk will demonstrate:

- -the efficiency improvements in flow cytometry workflows when sample preparation and staining is automated,
- -the reproducibility of flow cytometry data with easy assay transfer across BD FACSLyric™ instruments,
- -the advantages of automating flow cytometry data analysis, with the BD ElastiGate™ auto-gating feature onboard the BD FACSLyric™ Flow Cytometer with few training files

11.00 Speed Networking

As this community reunites, this session will provide valuable networking time with your peers, enabling you to forge new and lasting connections.

11.30 Morning Break & Refreshments

"I have been a regular attendee at this conference and it's always been a spot to meet new cell therapy SMEs and reconnect with some others"

Head of Analytical Development, **Takeda, 2024 Speaker**

Conference Day One | Wednesday, December 4

Track A – Cell Based Assay

Chair: Renee Hart, President & Chief Business Officer, **Lumacyte**

Unravelling Potency by Overcoming Complexities in Assessing Therapeutic Efficacy

12.00 Timing & Challenges of Potency Assessment in Cell Therapy Development

- Learn how to effectively balance the need for robust and validated potency assays with the practicalities of clinical trial timelines and resource allocation, optimizing both development speed and product quality.
- Explore strategies for meeting regulatory expectations on potency assays early in development while maintaining flexibility for product optimization, ensuring compliance without stifling innovation.
- Discuss the impact of the evolving understanding of mechanisms of action on potency assays, and how to adapt these assays to capture critical therapeutic attributes throughout the product lifecycle.

Christian Aguilera-Sandoval, Independent Expert

12.30 Quantitative Cell Characterization Using Laser Force Cytology™ (LFC): Predictive Insights into CAR T Donor Variability

- Label-free analysis of intrinsic biochemical and biophysical properties of cells provides real-time insights into cellular changes occurring throughout a manufacturing process. Additionally, ensuring robust cellular fitness of starting material is a crucial component to manufacturing and treatment success
- Learn how Laser Force Cytology™, a label-free, quantitative precision PAT enables real-time monitoring of CQAs and CPPs delivers insights into complex manufacturing processes through its optical force univariate and multivariate machine learning predictive capabilities
- Exciting new data on the correlation of CAR T potency with donor cellular starting material as well as T-cell activation road mapping using LumaCyte's Laser Force Cytology™ will be shared

Colin Hebert, SVP, Scientific & Business Operations, **Lumacyte**

Track B - Immunophenotype Assay

Chair: Alexandre Ambrogelly, Executive Director Analytical Operations, **Kite, A Gilead Company**

Navigating Complexities in Assay Qualification for Immunophenotyping for Enhanced Consistency & Repeatability

12.00 Strategies for Validating Reference Standards in Immunophenotyping Assays to Ensure Consistency

- Explore the complexities of creating robust and universally accepted reference standards for immunophenotyping assays, crucial for maintaining consistency and accuracy.
- Discuss the challenges in achieving consistent results across different laboratories and studies, emphasizing the need for standardized protocols and reference materials.
- Highlight innovative approaches and best practices for validating reference standards, ensuring reliable and reproducible data in immunophenotyping research and clinical applications.

Ruud Hulspas, PhD., Director Process Development, Cell Manipulation Core Facility (CMCF), **Dana-Farber Cancer Institute**

12.30 Reproducible & Efficient Phenotyping for Cell Therapy Manufacturing Using the Automated Flow Cytometer Platform: Accellix

- Accellix Platform demonstrates comparability to traditional flow cytometers.
- The platform reduces operator involvement and bias through workflow automation.
- PBMC composition and enumeration is reproducible across operators, sites, and devices.
- Suitable for in-process analytical assessments within GMP manufacturing environments.

Track C - Molecular Assay

Chair: Laura Pierce, Biomedical Engineer, **NIST**

Enabling Expedited Release of Cell Therapy Products with Accelerated Testing Timelines

12.00 Develop a Quality Control-Friendly Cytokine Independent Growth Assay

- Introduction of cytokine independent growth release method
- Selection of proper assay controls
- Method validation and training

Snow Xuezhou Hou, Principal Scientist, **Bristol Myers Squibb**

12.30 Up the Release of Cell Therapies by Reducing the Time to Detection of Slow-Growing Microorganisms

- Understanding the challenges to develop a robust analytical approach
- Adapting an existing platform to optimize detection times
- Outlining the implementation strategy with a standardized approach

Nadia Ward, Senior Business Development Manager, **Biomerieux**

1.00 Lunch Break & Networking

Conference Day One | Wednesday, December 4

Leveraging Automation & Technology to Streamline Processes & Speed Up Assay Development

2.00 Automation in Cell-Based Assays for Enhanced Efficiency & Reproducibility

- Explore how automation reduces human error and increases throughput, accelerating assay development processes.
- Discover the impact of liquid handling robots, scheduling software, and organs-on-a-chip on improving assay workflows.
- Learn how automation ensures reproducibility and scalability, enhancing the reliability of potency testing in cell therapy development.

Rachael Cohen, Associate Director, Plate Based Assays & Lab Automation, **Prime Medicine**

2.30 Panel Discussion: Future Prospects of Automation & Technologies in Cell-Based Assays for Cell Therapy

- Discuss how next-generation automation systems and AI technologies will enhance assay efficiency, precision products, and reproducibility, driving faster and more reliable cell therapy development.
- Cost-Effective Implementation: Discussing how and when to integrate automation into cell therapy workflows, balancing initial investment costs with long-term scalability, reproducibility, and operational efficiency.
- Learn how automation will support scalable, flexible, and standardized production processes, ensuring regulatory compliance and consistent quality control in the manufacturing of cell therapy products.

Rachael Cohen, Associate Director, Plate Based Assays & Lab Automation, **Prime Medicine**

Mahmoud Ahmadi, Analytical Development Principal Research Scientist, **Vertex Pharmaceuticals**

Haixia Wang, Head of Analytical Development, **Arsenal Biosciences**

Overcoming the Challenges of Immunophenotype Assays with Robust Data Strategy

2.00 Navigating Data Challenges in Cell Therapy Analytical Development & Improving Overall Product Quality

- Exploring strategies for optimizing data collection, storage, and analysis to enhance product understanding and process optimization in cell therapy development.
- Highlighting the importance of robust data management and curation practices to derive meaningful insights and inform decision-making in cell therapy analytical development.
- Addressing the need to stay updated and flexible in data interpretation amidst rapidly evolving research and technological advancements, emphasizing the role of data platforms in facilitating informed decisions.

Benjamin Espen, Principal Quality Engineer, **Avobis Bio**

2.30 Enhancing Predictive Value in Immunophenotyping for Cell Therapy Efficacy

- What are the main obstacles in establishing a direct correlation between immunophenotyping data and therapeutic outcomes in cell therapy?
- How can we develop and implement standardized guidelines for immunophenotyping to ensure consistent and reliable results across different contexts?
- What innovative methodologies or technologies could enhance the assessment of inflammation and immune activity, thereby improving the predictive value of immunophenotyping in therapeutic settings?

Elizabeth Eill, Analytical Development Lead, **Verismo**

Transitioning from Conventional Approaches to Enhance Cost Effectiveness & Efficiency

2.00 Characterization of Genomic Integrity of GE products for a Cell Therapy

- •Discussing the technologies to assess the genomic integrity: WGS, etc.
- Improving WGS analysis with both short-read and long-read NGS.
- Discussing the challenges and considerations in the characterization of genomic integrity.

Gun Lee, Senior Scientist, **Shoreline Biosciences**

2.30 Expert Discussion: Innovative Molecular Assays through Revolutionizing Genomic Analysis in Cell Therapy Development

- Harnessing the power of next-generation sequencing for comprehensive genomic profiling, enabling precise characterization of genetic variations, gene expression profiles, and molecular pathways relevant to cell therapy efficacy and safety.
- Exploring the applications of digital PCR in quantitative nucleic acid analysis, offering enhanced sensitivity, accuracy, and reproducibility for detecting rare mutaons, monitoring gene expression levels, and assessing viral vector integration sites.
- Discuss the regulatory landscape for CRISPR-based gene therapy, exploring potential risks, recent FDA guidance, and the ethical balance between stringent regulations and patient autonomy.

Wendy Nie, Principal Scientist, Analytical Development, **Arsenal Biosciences**

Hui-wen Liu, Principal Scientist, **Affini T**

Conference Day One | Wednesday, December 4

3.00 **Afternoon Break & Poster Session**

This is your opportunity to contribute to the conversation and share your cutting-edge research with this community, while discovering exciting work carried out by your peers.

Navigating the Analytical Lifecycle for Strategic Management & Streamlined Product Development

Liselotte Brix
Chief, Scientific Officer
Immudex

3.40 **Artificial Antigen Presenting Scaffolds - New Analytical Tool for TCR-T Cell Potency Testing**

- Evaluate Activation of engineered T Cells
- Expansion of MHC-peptide specific cells
- QC release testing of engineered T cell products

Jie Wei, PhD
Director, Bioanalytical Sciences
TR1X Bio

3.50 **Expanding Perspectives on Potency Assays in Cell Therapy: Beyond Primary Mechanisms**

- Explore the evolving definition of potency assays beyond traditional metrics like cell-based killing, delving into engineered attributes crucial for therapeutic efficacy.
- Discuss the need for functional assays to evaluate engineered functions such as evading the host immune system, aligning with evolving FDA guidance and label claim requirements.
- Delve into the role of protein expression as a surrogate marker for potency.

Despina Lymperopoulou
Senior Manager, Pharma Analytics Research & Development
BioProduction Group
Purification & Pharma Analytics
Thermo Fisher Scientific

4.20 **Effective Analytical Solutions for Ensuring Quality & Efficiency in Cell Therapy**

- Explore innovative analytical techniques for cell therapy manufacturing and learn how they can be applied to various stages of the production process
- Develop a comprehensive understanding of the advantages of analytical kits in cell therapy production
- Discover ways to overcome bottlenecks and reduce time constraints in sterility testing and mycoplasma detection

Vaibhav Patel
Director of Quality Assurance & Regulatory Affairs
University of Minnesota

4.50 **Adapting Analytical Development Strategies Across Clinical Trial Phases**

- Delve into the shifting landscape of analytical development strategies from early clinical trials to post-approval phases, highlighting the evolving needs and challenges at each stage.
- Explore the unique challenges encountered during transitions between clinical trial phases and discuss strategies for adapting analytical methodologies to address changing requirements effectively.
- Focus on post-approval analytical strategies aimed at maintaining product efficacy and safety over the long term, emphasizing the importance of continuous monitoring and refinement in response to real-world data and feedback.

5.20 **Chair's Closing Remarks**

5.20 **Drinks Reception**

6.30 **End of Conference Day One**

Conference Day Two | Thursday, December 5

8.30 Check-In & Coffee

9.25 Chair's Opening Remarks

Overcoming Ongoing Analytical Development Hurdles in Cell Therapy to Accelerate Therapeutic Advancements

Stephan Krause
Executive Director, Analytical Science & Technology, Cell Therapy Quality
Bristol Myers Squibb

9.30 **Optimizing Analytical Validation for Commercialization Success in Product Development**

- Exploring methods to strategically validate assays, minimizing the number required for commercialization while ensuring regulatory compliance.
- Discussing the transition towards PAT to accelerate testing timelines, with a focus on stability assessments and early data acquisition.
- Investigating innovative approaches to obtain stability data earlier in the manufacturing process, enabling expedited release of the final drug product.

Natalia Romero
R&D Director, Workflow Development
Cell Analysis Division
Agilent Technologies

10.00 **Agilent's Cell-based Analytical Solutions for Process Development & Manufacturing of Immune Cell Therapies**

- Overview and performance analysis of Agilent's real-time, label-free cell analysis platforms for assessment of critical quality attributes of cell therapy products
- Discuss the advantages of metabolic fitness and immune cell killing functional assays during the evaluation of critical process parameters for manufacturing of engineered immune cells
- Explore using in-process monitoring of cell identity, potency and metabolic fitness to shorten cell therapy manufacturing process

10.30 Morning Break & Networking

Conference Day Two | Thursday, December 5

Track A – Cell Based Assay

Developing Standardized Protocols for Characterization Across the Cell Therapy Modalities

11.15 Round Table: Standardizing Cell-Based Assays for Diverse Cell Therapy Modalities to Ensure Consistency & Reproducibility

- Investigating techniques to ensure methodological consistency across cell-based assays.
- Exploring quality control measures such as assay validation, inter-laboratory proficiency testing, and data normalization techniques.
- Discussing the integration of advanced technologies such as automation, microfluidics, and high-throughput screening platforms.

Helen Sarantis, Principal Scientist, Analytical & Quality Control, **BlueRock Therapeutics**

11.45 Single-Cell Multi-omic Assessment of Gene Editing Outcomes, Toxicity, & VCN for High Resolution Characterization of Cell Therapies

- Despite advancements in cell therapy engineering, conventional methods for measuring gene transfer and gene editing techniques lack the resolution and representation to truly reflect sample composition and either report a population average (bulk) or involve laborious and time-consuming clonal outgrowth.
- Mission Bio has developed an end-to-end solution from panel design to data analysis for single-cell targeted DNA sequencing to interrogate transgenes to confirm the distribution of vector copy number (VCN).
- Additionally, the solution simultaneously measures the co-occurrence and zygosity of on-target edits, off-target edits, translocations between predicted edit sites, as well as the genomic CNV landscape (including focal CNV) in over thousands of cells in parallel to reveal potential genotoxicity events in a single-cell context.

Nori Ueno, PhD, Director, Business Development, **Mission Bio**

11.55 Panel Discussion: Contrasting Characterization Strategies Across Cell Therapy Modalities to Understand the Diversity of Cell Therapy Platforms

- Explore the unique challenges and considerations in characterizing immunotherapy products, including antigen specificity, T-cell functionality, and cytokine secretion profiles.
- Compare and contrast characterization approaches between autologous and allogeneic cell therapies, examining donor variability, immune compatibility testing, and scalability considerations.
- Explore the complexities of characterizing gene therapy products, including the need for precise vector identity, potency, and purity assessments

Abid Mattoo, Senior Scientist CMC Analytical Development, Independent Expert

Elisha Fielding, Associate Director, **Sail Biomedicines**

Christian Aguilera-Sandoval, Independent Expert

Kelly Bowen, Associate Principal Scientist, Analytical Development, **KSQ Therapeutics**

Track B - Immunophenotype Assay

Chair: Liselotte Brix, Chief Scientific Officer, **Immudex**

Optimizing Sample Management & Handling for Enhanced Immunophenotype Assays

11.15 Process Analytical Utility of Raman Microscopy for Allogeneic Cell Therapy Manufacturing

- Continued advances in laser technology and data analytics are increasing the process analytical utility of spectroscopy.
- Cell composition changes measured by Raman micro-spectroscopy distinguish many cell types, even the accumulation of insulin in cells to treat diabetes.
- Information-rich, non-invasive spectroscopic technologies should complement conventional quality assurance methods.

Jamie Piret, Professor Michael Smith Laboratories, **University of British Columbia**

11.45 Rapid Growth-Based Sterility Results in Hours, Not Weeks

- Rapid sterility testing of cell and gene therapies (CGTs), using activated pan T-cells spiked with organisms with accurate results within 48 hours, improving batch release and patient safety.
- Mango technology detected colonies for six of seven organisms in under eight hours and identified Cutibacterium acnes within 30–40 hours—significantly faster than traditional methods. Its CFU counts were comparable to the compendial spread plate method.
- The Mango platform demonstrated potential as a rapid, accurate sterility test for CGTs, achieving results within 48 hours while maintaining precision.

Simon Nielsen, Chief Technology Officer, **Mango**

11.55 When Less is More: Advantages & Pitfalls of Cell-Based Assays Miniaturization

- Analyzing the current landscape of miniaturization efforts in analytical assays and the driving factors behind the push for smaller sample volumes.
- Discussing the technical challenges associated with miniaturizing assays, including maintaining sensitivity, reproducibility, and accuracy while reducing sample volume.
- Evaluating the need for standardized approaches to miniaturization in analytical assays, exploring potential solutions, and addressing the lack of uniformity across the industry.

Guillaume Cornelis, Associate Director, Principal Scientist, Analytical Development, **Cellectis**

Conference Day Two | Thursday, December 5

12.25 Lunch Break & Networking

Strategies to Address Variability in Cell-Based Assays for Enhanced Reliability

1.25 Approaches to Activate Human Gamma-Delta T Cells for Immunotherapy Treatment

- Human gamma-delta T cell activation and suppression.
- Tumor cell killing and immune evasion.
- Gamma-delta T cell-based immunotherapy.

Kok Fei (Jimmy) Chan, Research Fellow, **Olivia Newton-John Cancer Research Institute**

1.55 Functional Characterization of Cell Therapies with Real-Time Live Cell Analysis for Accelerated Efficacy Assessment

- Discover cutting-edge tools that simplify and enhance CAR T-cell research and manufacturing workflows, providing efficient and scalable options for functional characterization and therapeutic assessment.
- Learn how the Maestro Z platform enables robust, non-destructive evaluation of CAR T cells by supporting real-time, label-free monitoring of cytotoxicity.
- Explore new data on a streamlined protocol that enables rapid bioactivity assessment using an impedance-based assay, supporting accelerated decision-making in cell therapy development.

Danielle Califano, Business Development Manager, **Axion Biosystems**

2.05 Roundtable Discussion: Navigating Inherent Limitations in Cell-Based Assays: Strategies for Improved Reliability & Reproducibility

- How can we better understand in mitigate the sources of variability in cell-based assays to improve reliability and reproducibility of results?
- What alternative assay formats or technologies can be employed to complement or replace cell-based assays in situations where variability poses significant challenges?
- What quality control measures and best practices can be implemented to minimize test-retest variability and enhance the robustness of cell-based assays for analytical testing?

Jose Pena, Principal Scientist, **Arsenal Biosciences**

Advancing Immunophenotype Assays with Technologies & Methodologies for Cell Therapy Excellence

1.25 Strategies for Designing Quality Control-Friendly Flow Cytometry Panels in Cell Therapy Development

- Explore strategies for designing flow cytometry panels that balance the need to cover product characteristics and impurities while adhering to quality control-friendly limitations, such as color restrictions.
- Examine the implications of the recent FDA potency assay draft guidelines on cell therapy development programs, including the importance of studying mechanism of action from early phases and ensuring compliance with evolving regulatory standards.

Giorgio Sarkis, Senior Scientist, Quality Control Supervisor, **KSQ Therapeutics**

1.55 Fit for Purpose Immunophenotype Characterization in Cell Therapy Development, from Draw-to-Thaw™

- Characterization of donor variability to assure optimal cell sourcing.
- Characterization of starting material to assure identity and quality.
- Monitoring the identity and cell health during manufacturing to improve success rate.
- Release testing of critical quality attributes to assure the quality of final product.

Eva Morschl, PhD, Associate Director of Analytical Development, **Comprehensive Cell Solutions**

2.05 Overcoming Challenges in Qualifying Flow Cytometry Assays for Cell-Based Therapies

- Ensuring reproducibility is challenging due to the complexity and heterogeneity of cell populations and the variability in sample preparation and instrument performance.
- Developing robust, standardized protocols and maintaining regular calibration and maintenance schedules for flow cytometers are essential to achieving consistent and reliable results.
- Utilizing advanced data analysis tools, consistent gating strategies, and early engagement with regulatory bodies can help manage the complexity of data and ensure compliance with regulatory standards.

Masoud Golshadi, Senior Scientist, **Takeda**

2.35 Afternoon Break & Networking

Conference Day Two | Thursday, December 5

Scott R. Burger, MD
Principal
Advanced Cell & Gene Therapy, LLC

3.05 Use of Cell Mimics as In Process & Potency Controls in Cell Therapy Development

- Explore the limitations of biological controls examining variability and resource demands that compromise reproducibility in validation assays.
- Discuss the application of cell mimics as scalable, reproducible solutions that address the limitations of biological materials
- Demonstrate how cell mimics help standardize key aspects of the cell therapy process and support regulatory compliance

Natalie Fekete
Manager for Science & Industry Affairs
Alliance for Regenerative Medicine

3.35 Roundtable Discussion: Top Five Regulatory & CMC Highlights to Advance the Field in 2024

- Decentralized/distributed manufacturing.
- Potency assays and assurance.
- New designations - AMTD and PTD.
- Acceleration of CMC in advent of expedited clinical programs.
- iPSC-based therapies.

4.05 Chair's Closing Remarks

4.10 Close of Conference

Notes

Notes

Notes

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