May 31 – June 2, 2023 | Boston

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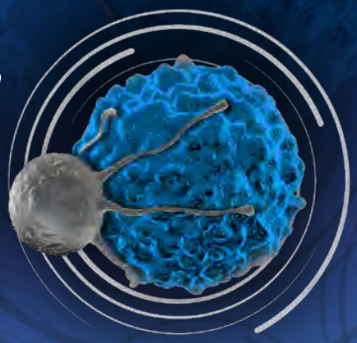
2nd Cell Therapy Potency Assay Summit

Defining Potency with Practical Assays to Satisfy Regulators



Define, Characterize & Measure Potency to Gain Regulatory Buy-In & Link Mechanism of Action to Drive Assays Predictive of Clinical Outcome

Expert Speakers Include:

Ilya Shestopalov
Senior Director & Analytical Product Lead
bluebird bio

Mariska Ter Haak
Director Analytical Development
IN8bio

Mike Sadick
Senior Director of CMC Analytical Development
Precision BioSciences

Abid Mattoo
Senior Scientist Clinical Stage Analytical Development
Takeda

Therese Choquette
Head of Analytical Sciences
Tigen Pharma

Jie Wei
Director of Analytical Sciences
Tr1x Therapeutics

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Your 24+ Industry-Leading Speakers

Yama Abassi
Associate VP, Stategic Marketing & Business Development
Agilent Technologies

Mike Lehmicke
Vice President, Science & Industry Affairs
Alliance of Regenerative Medicine

Fei Xie
Principal Scientist
Allogene Therapeutics

Emily Lowe
Senior Director Analytical Sciences
Appia Bio

Hayden Ko
Scientist, Analytical Development
Arsenal Bio

Ben Espen
Principal Quality Engineer
Avobis Bio

David Ferrick
Chief Scientific Officer
Axion BioSystems

Ilya Shestopalov
Senior Director & Analytical Product Lead
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Simina Popa
Associate Director of GDE Strategy
Bristol Myers Squibb

Xenia Peluffo Naj
Principal Scientist, Associate Director Analytical Development
Cellectis

Anna-Maria Georgoudaki
Senior Research Manager
Glycostem Therapeutics

Branimir Popovic
Associate Director, Analytical Development
IN8bio

Mariska Ter Haak
Director Analytical Development
IN8bio

Eric Smith
Associate Director
Marker Therapeutics

Anka Ehrhardt
Director of Cell Based Sciences
Merck

Nathan Hotaling
Senior Data Scientist
National Institutes of Health

Peter Velazquez
Associate Director, Analytical Development
Poseida Therapeutics

Mike Sadick
Senior Director of CMC Analytical Development
Precision BioSciences

Gopal Krishnan
Manager, Biologics
Promega

Jasmin Kristianto
Senior Scientist
Sana Biotechnology

Abid Mattoo
Senior Scientist Clinical Stage Analytical Development
Takeda

Therese Choquette
Head of Analytical Sciences
Tigen Pharma

Jie Wei
Director of Analytical Sciences
Tr1x Therapeutics

Jorge Burns
Assistant Professor
University of Ferrera

Rachel Langland
Director Analytical Development
Wugen

Pre-Conference Workshop Day:
Wednesday, May 31, 2023

7.30am Registration & Coffee Network

Cell Characterization Track

Workshop A — 8.30am - 10.30am

Outlining Clear & Strategic Motivations for Cell Characterization to Ensure Transparency with the Desired Outcome

- Determining the 'why' behind cell characterization
- Understanding what you are striving to characterize within your cell population
- Considering potency assay development when characterizing a cell population

Emily Lowe
Senior Director Analytical Sciences
Appia Bio

Revolutionizing Approaches to Potency Track

Workshop B — 8.30-10.30am

Gain, No Pain – Cell Therapy Potency Assay Development

- Highlighting the need for potency assays across cell therapeutics to assist smooth process development
- Rethinking the attitude to assay development to prioritizing potency assays as a fundamental component of drug development
- Navigating a clear path to potency assay development success to maximize clinical results

Mariska Ter Haak
Director Analytical Development
IN8bio

Branimir Popovic
Associate Director, Analytical Development
IN8bio

Morning Break 10.30am - 11.00am

Workshop C — 11.00am - 1.00pm

Developing a Time Efficient & Cost Effective Method of Characterizing Cells Prior to Potency Assay Development

- Outlining common mistakes across the cell therapy industry in relation to funding spent on cell characterization
- Minimizing time spent on cell characterization whilst producing results of paramount importance to process development
- Adopting good habits across cell characterization from early stage of development to reduce time and money spent unnecessarily

Anka Ehrhardt
Director of Cell Based Sciences
Merck

Workshop D — 11.00am-1.00pm

Adopting an Early Planning Approach to Cell Therapy Potency Assay Development

- Identifying the necessary steps required to maximize success in regulatory approval of the potency assay
- Following a scalable approach to potency assay design to adapt to product growth
- Discovering cost effective methods of potency assay design to assist companies in their infancy

Jorge Burns
Assistant Professor
University of Ferrera

Lunch Break 1.00pm - 2.00pm

Workshop E — 2.00pm - 4.00pm

Leveraging Characterization Data to Understand which Elements of Potency Assays are Predictive

- Deconstructing the benefit and potential of characterization data
- Exploring how results obtained from characterization can be optimally applied to potency assay analysis
- Developing a greater understanding of the potency assay through parallel analysis with cell characterization

Therese Choquette
Head of Analytical Sciences
Tigen Pharma

Workshop F — 2.00pm-4.00pm

Platforms & Approaches for Enabling Translational Science with a Case Study in Non-Invasively Predicting Potency, Identity, & Safety of a Tissue Engineered Therapy for Macular Degeneration

- Improving the robustness, efficiency, and replicability of traditional and machine/deep learning analysis pipelines
- Interoperable Computational Tool standard for multi-institute collaboration
- iPSC derived tissue engineered scaffold

Nathan Hotaling
Senior Data Scientist
National Institutes of Health

4.00pm End of Pre-Conference Workshop Day

Conference Day One
Thursday, June 1, 2023

7.15 **Registration & Coffee Networking Opens**

8.15 **Chair's Opening Remarks**

Evaluating the Industry Definition of Potency to Create Standards Across Cell Therapy

8.30 **Roundtable discussion - Defining Optimal Potency Outcomes Through High-Level Analytical Strategy to Support Assay Development**

Fei Xie
Principal Scientist
Allogene Therapeutics

- Highlighting the importance of a well-constructed potency assay
- Rethinking potency as an accelerator to process development
- Determining what stability looks like with a potency assay
- Differentiating potency assays against other assays implemented across process development

9.00 **Implementing Clear Strategy to Determine the Aims of the Potency Assay in Use**

Jie Wei
Director of Analytical Sciences
Tr1x Therapeutics

- Ensuring clarity in outline of objectives prior to potency assay design
- Utilizing cell characterization data to inform understanding of what the potency assay intends to validate
- Aligning potency assay design with clinical data and stage of clinical trials

9.30 **Benchmarking Successful Potency Assays to Create a Unifying Vision of Best Practice**

Abid Mattoo
Senior Scientist Clinical Stage Analytical Development
Takeda

- Challenges to successful development of cell therapy potency assays
- Progressive potency assay implementation
- Honing evaluative measures to understand the success of potency assay.
- Striving for the golden standard of cell therapy potency assays

10.00 **Real-Time Measurement of Immune Cell Cytotoxicity & Metabolic Fitness and Persistence: Robust Potency Assays Meeting the Demands of Cell Therapy Discovery, Process Development & QC/Release Criteria**

Yama Abassi
Associate VP, Stategic Marketing & Business Development
Agilent Technologies

- Overview of the general challenges around designing robust potency assays satisfying the needs of analytical development in cell therapy manufacturing setting
- Evaluation of cell fate, function and fitness using real-time cytotoxicity assays as well as metabolic assays
- Identification and optimization of critical process parameters (CPPs) using real-time metabolic and cytotoxicity readouts

10.30 **Morning Refreshments & Speed Networking**

Bump elbows with your fellow potency assay experts! Back by popular demand, this is your opportunity to network and forge new contacts with peers in the industry. Join speed networking to meet a broad spectrum of attendees at the summit, and exchange details to catch up later in the event.

Deconstructing Regulatory Guidelines for Cell Therapy Potency Assays

11.30 **Highlighting Common Regulatory-Orientated Delays Due to Typical Potency Assay Development Approaches**

Mike Lehmicke
Vice President, Science & Industry Affairs
Alliance of Regenerative Medicine

- Reflecting on the feedback received on potency assays from successful vs. unsuccessful regulatory submissions
- Rethinking the primary focuses when addressing a potency assay
- Revolutionizing a streamlined approach to developing an approved potency assay

12.00 **Evaluating Analytical Strategy Following Regulatory Input to Provide Clarity to the Industry**

Ilya Shestopalov
Senior Director & Analytical Product Lead
bluebird bio

- Establishing cell therapy-specific guidelines for potency assay development
- Exploring how potency assay approval has evolved over the past year
- Reaffirming the primary elements of attention required to maximize regulatory approval

Conference Day One
Thursday, June 1, 2023

12.30 **Lunch & Networking**

Creating Quantitative Measurements of Potency to Conduct a Thorough Assessment

David Ferrick
Chief Scientific Officer
Axion BioSystems

1.30 **Tools for Quantitative Potency Testing from Discovery to Manufacturing**

- Label-free cell growth and killing assays
- One platform for every step of development
- Save time, cut costs, and simplify your workflow

Ben Espen
Principal Quality Engineer
Avobis Bio

2.00 **Navigating Error Analysis Data to Comprehend the Outcomes of a Potency Assay**

- Utilizing a novel lack-of-fit assessment as a tool of error analysis
- Deploying predictive statistical formulas to tackle variance
- Locating the source of discrepancies highlighted from error analysis data

2.30 **Afternoon Poster Session & Networking**

Exploring Cell Manufacturing Options to Leverage Potency Assay Development

Gopal Krishnan
Manager, Biologics
Promega

3.00 **Bioluminescent Bioassays for the Discovery and Development of Molecular and Cellular T-Cell Redirecting Cancer Therapy**

- Redirected T cell therapies represent a new paradigm for cancer treatment. T cell therapies, such as CAR-T and TCR-T, are a promising frontier in the treatment of cancer.
- Bioluminescent cell-based bioassays provide a rapid and simple method for potency quantification of T cell redirecting viral vectors, allowing for in-process testing that reflects effectiveness of the final CAR-T.

Eric Smith
Associate Director
Marker Therapeutics

3.30 **No Wash, No Rest Potency Assay for Cryopreserved CAR-T Therapies**

- Assessment of CAR-T killing without removal of cryopreservation medium
- T-cell assessment over multiple days without disruption
- Multi-parameter characterization of T-cells and target cells

Anna-Maria Georgoudaki
Senior Research Manager
Glycostem Therapeutics

4.00 **Maintaining GMP Standards Across Cell Manufacture into Potency Assay Development to Follow a Licensed Approach**

- Developing GMP standards for quantitatively testing potency and biological activity
- Setting the expectations of routine potency release testing to GMP standards
- Relating GMP testing and method to the mechanisms of action of the cell therapy

4.30 **Chair's Closing Remarks**

4.45 **Hanson Wade Drinks Reception**

5.45 **End of Day One**

Conference Day Two
Friday, June 2, 2023

8.15 **Registration & Coffee Networking Opens**

9.15 **Chair's Opening Remarks**

Managing Phase Development Considerations for Cell Therapy Potency Assays to Promote a Unified Approach

Peter Velazquez
Associate Director, Analytical Development
Poseida Therapeutics

9.30 **Phase Appropriate Approach to Potency Strategy, Phase I Through Phase II Pivotal**

- Design, development and Implementation (PreQual, Tech Transfer and Qual) of Lot Release Assay for Potency, Phase I plus improvements going into Phase II pivotal
- A biology-based approach to characterization
- Phased approach to expanding on product characterization

Simina Popa
Associate Director of GDE Strategy
Bristol Myers Squibb

10.00 **Phase-appropriate potency assay requirements from first in human, to pivotal, to commercial stages of a product for both vector and cellular drug product**

- Factors to consider in potency strategy of early phase programs when balancing fast timelines with right first time
- Transition to GMP QC analytical potency methods in pivotal and commercial stages and strategies for method lifecycle management
- Utilization and choice of reporter genes as a functional bioassay and demonstration of MoA relevance
- Method development considerations for accuracy, precision and QC friendliness (eg. relative potency) as well as method performance characteristics (eg. specificity, linearity, accuracy, precision).

10.30 **Audience Discussion: The Automated Future for Potency:**

- Discussing the future scope for potency assay development platforms
- Minimizing the risk of human error when analyzing assay results
- Advancing technology in assay development whilst minimizing cost

Jorge Burns
Assistant Professor
University of Ferrera

11.00 **Morning Refreshments & Networking**

Exploring the Varying Approaches to Potency Assay Design with a Thorough Validation of the Method

Rachel Langland
Director Analytical Development
Wugen

11.30 **Wielding Potency Assays in Early Clinical Development**

- The utility of potency in stability assessments
- CDMO qualification for early-stage trials
- Comparability of potency data between laboratories

Xenia Peluffo Naj
Principal Scientist, Associate Director Analytical Development
Cellectis

12.00 **Implementing Potency Assay with Platform Approach across CAR T Cell Products**

- Considerations for potency assay design and choice of analysis model
- Leverage DOE to test and potentially optimize assay robustness
- Planning ahead: retro-planning for reference material and critical reagents

Conference Day Two
Friday, June 2, 2023

Mike Sadick
Senior Director of CMC Analytical Development
Precision BioSciences

12.30 **Matrix Approach to CART Potency Assessment. *How do I test thee? Let me count the ways.***

- Working definition of 'potency' for CART 'Precedent' for CART potency assessment – single point assessment of IFNg
- Revision of approach to "full-curve relative potency analyses"
- Alternative CART responses/activities to harness as potency measurements Proliferation
- Target cell cytotoxicity (potentially more MoA reflective)
- Not enough data to recommend one response measurement over the other

1.00 **Lunch & Networking**

Communicating Effectively Between the Roles Across Process & Analytical Development

Jasmin Kristianto
Senior Scientist
Sana Biotechnology

2.30 **Spotlighting the Mechanisms of Action of a Therapeutic from R&D to Assist Potency Assay Design**

- Developing an understanding of biological functions of cell therapies
- Translating animal model and preclinical data into the theory behind potency assay design
- Tackling the multi-modal nature of cell therapies and dealing with the breadth of mechanism of action

Jorge Burns
Assistant Professor
University of Ferrera

2.00 **Osteogenic Potency Assay, Reproducibility from the Ground Up**

- The quest for osteogenic potency assay biomarkers
- Measurements and microenvironments
- Reproducibility across two independent laboratories
- Roadmap for improvements

Hayden Ko
Scientist, Analytical Development
Arsenal Bio

3.00 **Generating Potency Assays to Achieve a QC-Friendly Standard**

- Creating a streamlined approach to potency assay transfer which is understood across varying disciplines
- Understanding what makes a potency assay QC-friendly
- Relating the signals between the clinic and QC

3.30 **Chair's Closing Remarks**

3.45 **Close of Summit**

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Exhibition Partner

Avance Biosciences is a leading CRO/CTL providing GLP & GMP-compliant assay development, assay validation, and sample testing services to support biological drug development and manufacturing activities world-wide. We work with many clients across multiple modalities for potency assay development, method transfer, validation and sample testing. I addition we can support long term stability studies with potency testing and compendial assay testing for pH, sterility, mycoplasma, endotoxin, appearance and others. Our platforms include flow cytometry, ELISA, MSD-ECLA, ddPCR, qPCR, NGS and cell-based assays.

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GET INVOLVED

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