October 26-28, 2026 | San Diego, CA
www.rawmaterials-cgt.com

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3rd Annual

Raw Materials for Cell & Gene Therapy Summit

Benchmark Robust & Standardized Processes for Streamlined Raw Material Management

Unlock Clear, Phase Appropriate Risk Assessment, Regulatory Alignment & Vendor Management Strategies to Build a Stronger Raw Material Framework for Cell, Gene & Stem Cell Therapies

Expert Speakers Include:

Kim Raineri
Chief Technology Officer
Aspen Neuroscience

Lili Belcastro
Associate Director, Raw Materials, Drug Product Process Development
Bristol Myers Squibb

Lauren Fong
Associate Director, Raw Material Quality
Fate Therapeutics

Donald Powers
Senior Director, Advanced Therapies Supply Chain
Johnson & Johnson

Basak Clements
Independent Raw Materials Expert
USP CGT Expert Committee Member

Ben Clarke
Senior Scientist, Global Biologics
United States Pharmacopeia

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+1 617 455 4188 info@hansonwade.com
www.rawmaterials-cgt.com Cell & Gene Therapy Event Series

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Welcome to the 3rd Raw Materials for Cell & Gene Therapy Summit

3rd Annual Raw Materials for Cell & Gene Therapy Summit
October 26-28, 2026 | San Diego, CA

Cell and gene therapies (CGTs) are advancing rapidly, but the challenge of **translating scientific innovation into scalable, reliable manufacturing remains a critical barrier to success**. Raw materials sit at the centre of this challenge, directly impacting product quality, manufacturing efficiency, and regulatory approval. As more CGTs progress into late-stage trials and commercialization, small inconsistencies in materials are no longer tolerable and can trigger delays, clinical holds, and supply chain disruption.

The **3rd Raw Materials for Cell & Gene Therapy Summit** is designed to equip you with the practical, technical strategies needed to **take control of raw material variability, strengthen supplier management, and align with evolving regulatory expectations**. With material variability and supply inconsistency continuing to drive product safety concerns, manufacturing delays, and regulatory risk, gaining control is essential to protect quality and keep your programs on track.

Through real-world case studies and cross-functional discussions with **Johnson & Johnson**, **Astellas Pharma**, **Kite Pharma**, **Bristol Myers Squibb**, **Aspen Neuroscience**, and **Tr1X Bio**, you will gain clarity on how to manage material risk across the full product lifecycle, from early development through to commercial manufacturing, to ensure that your therapies are safe, easily approved, and delivered on time.

Making its way to San Diego for its third year, this meeting provides a dedicated forum to benchmark approaches, learn from late-stage and commercial experiences, and collaborate with peers across quality, MSAT, supply chain, and process development. Do not miss your opportunity to gain the insights needed to reduce risk, control costs, and ensure your raw material strategy supports long-term clinical and commercial success.

A note from our Scientific Advisory Board

"It has been a privilege to serve as co-chairs of this event since its inception. In its third year, we are thrilled to see the conference mature, attract growing support, and now expand to the West Coast. We are excited to invite colleagues to join us for the insightful content on cell and gene therapy raw materials that has become a hallmark of this gathering"

Basak Clements, Independent Raw Materials Expert
USP CGT Expert Committee Member

Lili Belcastro
Associate Director, Raw Materials, Drug Product Process Development
Bristol Myers Squibb

Key Benefits of Attending

Navigate Particulate Risk in Single-Use Systems Without Compromising Patient Safety
Join **Johnson & Johnson** to unpack how leading manufacturers are redefining particulate risk in CGT. Learn how to balance regulatory expectations with manufacturing reality, so you can protect patients while avoiding unnecessary cost, waste, and compliance risk.

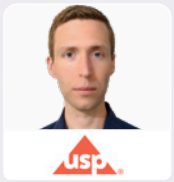
Avoid Late-Stage Delays by Planning Material Grade Transitions Early
Hear from **Astellas Pharma** and **Kite Pharma** on building a proactive material strategy from research to commercial scale. Understand how to prevent requalification setbacks, align suppliers early, and ensure your materials are ready for late-stage and regulatory expectations.

Apply Practical Risk Frameworks to Strengthen Raw Material Control
Through a real-world AAV case study from **Ray Therapeutics**, learn how to prioritize testing, assess risk early, and build a simple, scalable raw material control strategy suited to resource-constrained teams.

Maintain Supply Continuity While Managing Variability at Commercial Scale
Discover how **Tr1X Bio**, is addressing variability, safety risk, and process consistency in next-generation cell therapies. Gain insight into designing raw material and supply strategies that support late-stage trials and commercial manufacturing without compromizing quality.

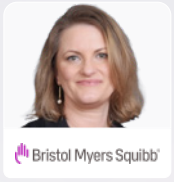
Get Excited for 2026!

Key Sessions not to Miss



1 Creating Confidence Through Raw Materials Quality Standards for Cell & Gene Therapies

Ben Clarke, Senior Scientist, Global Biologics, **United States Pharmacopeia**



2 When Materials Fail: How Risk Ranking & Supplier Engagement Transformed Our Strategy

Lili Belcastro, Associate Director, Raw Materials, Drug Product Process Development, **Bristol Myers Squibb**

3 Building Risk-Based Raw Material Strategies for Complex CGT Manufacturing

Lauren Fong, Associate Director, Raw Material Quality, **Fate Therapeutics**

4 Case Study: Reducing Safety Risk & Improving Consistency in Next Generation Allogeneic Treg Manufacturing

James Adams, Chief Technical Officer, **Tr1X Bio**

5 Reducing Process Risk by Defining the Variability You Can Still Proceed With

Aditya Dandekar, Associate Director, **Cabaletta Bio**

New Companies for 2026

Tr1X BIO · Fate THERAPEUTICS · Aspen NEUROSCIENCE · Johnson&Johnson · RAY THERAPEUTICS

Showcase Your Raw Materials Expertise

Participate in our scientific poster session to contribute to the conversation, spotlight your breakthrough discoveries and share your cutting-edge strategies with your peers working with raw materials.

Your Expert Speakers

Pharma Leaders

Alison Burkart
Director, Analytical Development
Astellas Pharma

Kien Khuu-Dong
Associate Director
Bristol Myers Squibb

Lili Belcastro
Associate Director, Raw Materials, Drug Product Process Development
Bristol Myers Squibb

Arthur Zeng
Principal Scientist II
Johnson & Johnson

Donald Powers
Senior Director, Advanced Therapies Supply Chain
Johnson & Johnson

Lindsay Pierle
Senior Manager, Lifecycle Management MSAT
Johnson & Johnson

Shawn Wang
Director, Head of Material Development
Kite Pharma

Innovative Biotechs & Industry Experts

Kim Raineri
Chief Technology Officer
Aspen Neuroscience

Aditya Dandekar
Associate Director
Cabaletta Bio

Lauren Fong
Associate Director, Raw Material Quality
Fate Therapeutics

Benjamin Cho
Technical Development Scientist II
Genentech

Basak Clements
Independent Raw Materials Expert
USP CGT Expert Committee Member

Kok-Seong Lim
Independent Expert

Mayo Pujols
Chief Technology Officer
Kyverna Therapeutics

Daniel Anaya
Associate Director, MS&T
Ray Therapeutics

James Adams
Chief Technical Officer
Tr1X Bio

Ben Clarke
Senior Scientist, Global Biologics
United States Pharmacopeia

Pre-Conference Workshop Day
Monday, October 26

Registration & Coffee 09.00

Workshop A 09.30

Managing Particulate Contamination from Single Use Materials to Reduce Patient Risk

Cell and gene therapy manufacturers are increasingly constrained by particulate contamination introduced through single use systems, without the safety net of terminal sterile filtration. At the same time, regulatory expectations continue to reflect standards written for large molecule drug products, creating a disconnect between what is technically achievable and what is formally required. This workshop focuses on how manufacturers are interpreting guidance, engaging regulators, and redefining risk in a way that prioritises patient outcomes while maintaining quality and compliance.

This workshop will discuss:

- Assessing the real clinical risk of visible and subvisible particles in cell and gene therapy products
- Interpreting legacy particulate standards and test methods that were not designed for cell and gene therapies
- Balancing regulatory expectations with manufacturing limitations and patient access pressures
- Defining what clean enough means for single use systems without driving unsustainable cost or waste

Workshop Leaders

Donald Powers
Senior Director, Advanced Therapies Supply Chain
Johnson & Johnson

Lindsay Pierle
Senior Manager, Lifecycle Management MSAT
Johnson & Johnson
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Lunch Break & Networking 12.30

Workshop B 13.30

Planning Material Grade Transitions Early to Avoid Late-Stage Requalification & Delayed Timelines

Moving from research to GMP and then to commercial materials is a common source of delay and regulatory risk when this strategy is not planned early. Many teams discover too late that materials used in early development cannot scale, or that supplier controls are not aligned with late-stage expectations. This workshop focuses on how to plan material grade transitions proactively so your scale up journey can progress without disruptive requalification or friction in your process changes.

This workshop will discuss:

- Identifying materials that will not scale beyond research or early GMP use
- Assessing supplier readiness and grade roadmaps before phase three
- Aligning material grade strategy with development phase to reduce requalification work
- Discussing the transition from late-stage to commercial and long-term life-cycle monitoring via the CPV process and improvements to raw materials

Workshop Leaders

Alison Burkart
Director, Analytical Development
Astellas Pharma
NEW COMPANY

Shawn Wang
Director, Head of Material Development
Kite Pharma
NEW COMPANY

Mayo Pujols
Chief Technology Officer
Kyverna Therapeutics
NEW COMPANY

End of Pre-Conference Workshop Day 16.30

Conference Day One
Tuesday, October 27

08.00 Registration & Coffee

08.50 **Chair's Opening Remarks**

Developing Practical, Risk-Based Strategies to Build Scalable & Resilient Raw Material Control Across Development Stages

09.00 **Panel Discussion: Building a Robust Raw Material Strategy for Advanced Therapies**

- Establishing a phase-appropriate raw material strategy that supports both early development flexibility and late-stage regulatory expectations
- Navigating evolving regulatory expectations for raw materials
- Evaluating supplier strategies, including sole vs dual sourcing, to mitigate supply chain risk while maintaining product comparability and regulatory compliance

Kim Raineri
Chief Technology Officer
Aspen Neuroscience
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Basak Clements
Independent Raw Materials Expert
USP CGT Expert Committee Member

Daniel Anaya
Associate Director, MS&T
Ray Therapeutics
NEW COMPANY
CASE STUDY

09.45 **AAV Gene Therapy Case Study: Building an Overall Raw Material Control Strategy**

- Setting up a simple and structured raw material risk approach suitable for small and growing organizations
- Prioritizing testing and qualification effort when time, data, and resources are limited
- Assessing risk early to avoid downstream delays and rework

10.15 Morning Break & Speed Networking

Accelerating Development Timelines Through Phase Appropriate Material Qualification That Balances Speed with Robust Quality

Benjamin Cho
Technical Development Scientist II
Genentech

11.15 **Balancing Quality with Speed & Efficiency to Create a Phase Appropriate Material Qualification Strategy**

- Qualifying multiple materials to enable parallel testing during early development
- Aligning early-stage work with the requirements for transfer into stage two
- Balancing speed with quality to support a reliable and effective transition

Lauren Fong
Associate Director, Raw Material Quality
Fate Therapeutics
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11.45 **Roundtable Discussion: Building Risk Based Raw Material Strategies for Complex CGT Manufacturing**

- Exploring how companies prioritize raw materials using risk-based frameworks
- Comparing approaches to material qualification, sampling strategies, and CoA expectations
- Discussing regulatory experiences shaping raw material decisions across development stages

Conference Day One
Tuesday, October 27

12.30 Lunch Break & Networking
Private lunch hosted by Instant Systems, please inquire at info@hansonwade.com for more information

Using Data to Define Variability Acceptance Limits & Material Qualification Decision Making

Aditya Dandekar
Associate Director
Cabaletta Bio
CASE STUDY

13.30 Reducing Process Risk by Defining the Variability You Can Still Proceed With

- Defining acceptance criteria based on process characterization rather than supplier specifications
- Understanding when variability can be absorbed and when it becomes a process risk
- Disqualifying lots with confidence using data instead of assumptions

14.00 Audience Discussion: Benchmark Your Approach to Variability Management

This interactive session will create space for peer-to-peer exchange on how teams are managing raw material variability, qualification, and process risk in practice. Through structured discussions, attendees will share approaches, compare challenges, and explore how to make more confident, data led decisions across development stages.

- Exploring approaches to defining and managing acceptable material variability
- Comparing strategies for material qualification and release decisions
- Sharing practical insights on using data to improve confidence and reduce process risk

14.45 Afternoon Break & Poster Session

Turning Material Failures into Stronger Strategies to Improve Resilience & Decision Making Across Complex Supply Chains

Lili Belcastro
Associate Director, Raw Materials, Drug Product Process Development
Bristol Myers Squibb
CASE STUDY

15.45 When Materials Fail: How Risk Ranking & Supplier Engagement Transformed Our Strategy

- Turning raw material failures into a catalyst - redefining supplier strategy through a centralized, data-driven MRC model
- Applying integrated risk scoring (beyond PRAM) to pinpoint and prioritize highest-risk suppliers
- Deployment of targeted technical due diligence visits to shift from reactive firefighting to proactive risk mitigation

16.15 Review & Reflect: Consolidating Key Learnings from Day One

This interactive working session brings together the key discussion points surfaced across the day's presentations to explore where approaches align and where they differ.

In small groups, you'll examine shared challenges across raw material selection, qualification, and control, drawing on real-world experience from across functions including QC, MSAT, and supply chain. The session will close with group feedback to capture collective insights, helping you refine your approach and carry forward key learnings into day two.

16.45 End of Day One

Conference Day Two
Wednesday, October 28

08.45 Registration & Coffee

09.20 **Chair's Opening Remarks**

Developing Regulatory Confidence Through Stronger Quality Standards & Material Risk Assessment

Ben Clarke
Senior Scientist, Global Biologics
United States Pharmacopeia

09.30 **Creating Confidence Through Raw Materials Quality Standards for Cell & Gene Therapies**

- Discussing USP Chapter <1043> on ancillary material quality, risk assessment and material qualification
- Noting recent developments in compendial methods for raw materials

Ben Clarke
Senior Scientist, Global Biologics
United States Pharmacopeia

10.00 **Interactive Discussion: Ask the USP**

- Opening up discussion on proposed revisions to USP Chapter 1043, with a focus on the 4-tier risk assessment system
- Bringing together differing views on the tiered approach, encouraging participants to share perspectives and challenge assumptions
- Exploring what these potential changes mean in practice for raw material risk assessment and decision-making

10.45 Morning Break & Networking

Ensuring Manufacturing Consistency & Supply Continuity to Improve Safety & Reduce Disruption

James Adams
Chief Technical Officer
Tr1X Bio

NEW COMPANY
CASE STUDY

11.45 **Reducing Safety Risk & Improving Consistency in Next Generation Allogeneic Treg Manufacturing**

- Enabling mid process purification to achieve best-in-class drug product purity
- Reducing graft versus host disease risk through tighter process control
- Designing raw material and supply strategies with late-stage trials and commercial scale in mind

12.15 **Panel Session: Navigating Supplier Diversification to Reduce Risk & Maintain Product Continuity**

- Addressing challenges in qualifying secondary suppliers for critical materials
- Understanding comparability and change control requirements when switching vendors
- Balancing supply chain flexibility with IP constraints

Shawn Wang
Director, Head of Material Development
Kite Pharma

Lili Belcastro
Associate Director, Raw Materials, Drug Product Process Development
Bristol Myers Squibb

13.00 Lunch Break & Networking

Conference Day Two
Wednesday, October 28

Building Stronger Buyer–Supplier Alignment to Enable Reliable, Scalable Raw Material Strategies

Kok-Seong Lim
Independent Expert

14.00 **Roundtable Discussion: Defining What Biopharma Needs from Raw Material Suppliers to Enable Scalable, Reliable CGT Manufacturing**

- Aligning expectations on material quality, data transparency, and change control to reduce downstream risk
- Understanding where current supplier offerings fall short across development through commercial scale
- Defining what strong partnerships look like in practice, from early engagement to long-term collaboration

Arthur Zeng
Principal Scientist II
Johnson & Johnson

14.30 **Strengthening Shelf-Life Strategies for Raw Materials**

- Aligning shelf-life approaches across sites and CDMOs while leveraging supplier data and scientific justifications
- Assessing chemical sensitivities and microbial risk in order to support the shelf-life decisions
- Developing strategies to mitigate gaps in supplier stability data

Kien Khuu-Dong
Associate Director
Bristol Myers Squibb

15.00 **Improving Visibility Across Multi-Layer Raw Material Supply Chains**

- Why visibility fails today?
- Understanding where variability is introduced upstream
- Solution framework to improve multi-layer visibility

15.30 **End of the 3rd Raw Materials for Cell & Gene Therapy Summit**

> "The quality and depth of knowledge from the speakers stood out, as did the engagement and interest from all participants."
>
> Senior Engineer, Process Manufacturing Science & Technology, **AskBio**, 2024 Attendee

2026 Partners

Hosting Partner – Instant Systems

Instant Systems specializes in single-use supplies designed to enhance and optimize cell therapy processes. Our product lineup, including transfer tubing sets, in-line filters, manifolds, waste bags, freezing bags, overwraps, and conical tube sets, ensures closed, safe processes and effective therapy production. We provide comprehensive solutions that meet the highest standards of quality and compliance, supporting every step of process development.

www.instantsystems.com

Exhibition Partner – Boston BioProducts

Boston BioProducts is a leading provider of biological buffers, media, and solutions for the life sciences. With 30 years of experience in buffer and reagent manufacturing, our dedicated team of formulation scientists and in-house manufacturing capabilities support multiple applications including molecular biology, assay development, and bioprocessing

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"The meeting was very collaborative between suppliers and end-users. Typically, at conferences, vendors are seen more as pests and salesy but there was a genuine interest from pharma to speak with us and hear our opinions."

Chief Executive Officer, **Boston BioProducts**, 2025 Partner

Get Involved

Angus Booth
Partnerships Director
Tel: +1 617 455 4188
Email: sponsor@hansonwade.com

Partner With Us

Your Dedicated Forum for Strengthening Existing Partnerships & Forging New Connections with CGT Decision-Makers

Secure Direct Access to Qualified Buyers in CGT Manufacturing

Engage senior decision-makers across quality, MSAT, supply chain and process development who are actively selecting, qualifying and managing raw material suppliers. Position your solutions in front of teams from companies including **Johnson & Johnson**, **Kite Pharma**, **Bristol Myers Squibb** and **Astellas Pharma** at the point where purchasing and sourcing decisions are being shaped

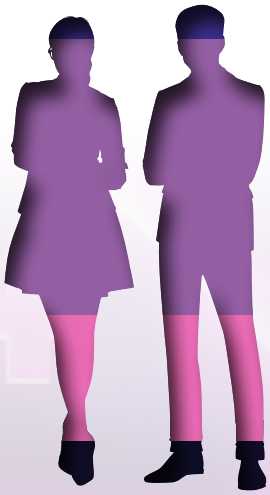
Influence Material Strategy as Developers Prepare for Commercialization

As CGT companies face increasing pressure to control variability and meet regulatory expectations, this meeting brings together teams actively refining their raw material strategies. Build early relationships, demonstrate technical credibility and align your offering to the evolving needs of late-stage and commercial programs

Differentiate Your Offering Through Technical Collaboration

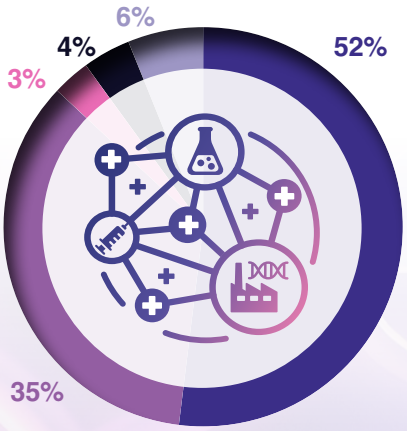
Position your company as a strategic partner by contributing to discussions on material variability, supplier qualification and co-development. Showcase your expertise in a forum designed for practical problem-solving, where biopharma teams are actively seeking partners to improve consistency, reliability and supply security

Seniority of Attendees



- C-Level: 6%
- Director/VP: 61%
- Scientist/Team Leader: 24%
- Other: 9%

Type of Companies Attending



- Biopharma Drug Developers
- CDMOs / CROs
- Consultants
- Regulatory Bodies
- Other

Statistics taken from the 2nd Raw Materials for Cell & Gene Therapies Summit

Get Involved

Angus Booth
Partnerships Director
Tel: +1 617 455 4188
Email: sponsor@hansonwade.com

Ready to Register?

3 Easy Ways to Book

www.rawmaterials-cgt.com/register/

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Email: info@hansonwade.com

STRENGTHEN your approach to supplier management and material qualification through proven strategies that reduce risk across program phases

ALIGN with evolving regulatory expectations by understanding how to manage raw material changes throughout the product lifecycle

CONNECT with peers across quality, MSAT, supply chain and process development to benchmark approaches and share real-world lessons from cell and gene therapy programs

Drug Developer Pricing*	Register & Pay by July 10 to save $1,000	On the Door Price
Conference + Workshop Day	$3,397 **(Save $1,000)**	$4,397
Conference Only	$2,599 **(Save $500)**	$3,099

Academic Pricing**	Register & Pay by July 10 to save $1,000	On the Door Price
Conference + Workshop Day	$2,797 **(Save $1,000)**	$3,797
Conference Only	$2,199 **(Save $500)**	$2,699

Vendor Pricing	Register & Pay by July 10 to save $1,000	On the Door Price
Conference + Workshop Day	$4,297 **(Save $1,000)**	$5,297
Conference Only	$3,299 **(Save $500)**	$3,799

*To qualify for the drug developer rate your company must have a public drug pipeline, and not offer pay-for services. Please visit the website for full pricing options or email info@hansonwade.com

Do you work for a Not-for-Profit organization? Email us at info@hansonwade.com to inquire about attending

**To qualify for the academic & research rate you must be full time academic. Please visit the website for full pricing options or email info@hansonwade.com

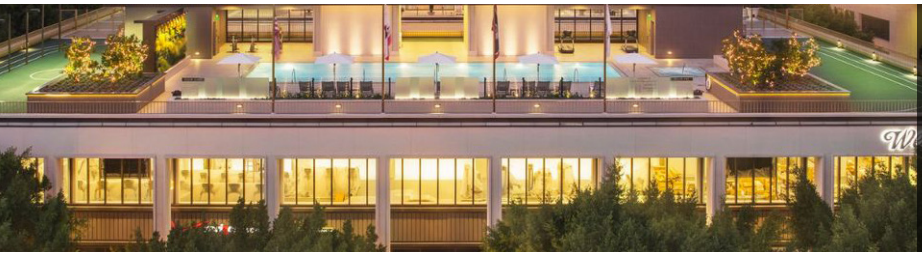
Team Discounts***

- **10% discount – 2 Attendees**
- **15% discount – 3 Attendees**
- **20% discount – 4+ Attendees**

***Please note that discounts are only valid when two or more delegates from one company book and pay at the same time.

Discounts cannot be used in conjunction with any other offer or discount. Only one discount offer may be applied to the current pricing rate.

Contact: register@hansonwade.com



Venue

The Westgate Hotel
1055 2nd Ave, San Diego, CA 92101
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