EDITORIAL CALENDAR **2025**

CELL & GENE THERAPY INSIGHTS

FEBRUARY
Expanding cellular immunotherapy
Manufacturing scale-up
Manufacturing
Supply Chain
Cell and gene therapy update

MARCH
Induced pluripotent stem cells (iPSCs)
Raw/starting materials
Manufacturing
Vector
Analytics

APRIL
Gene therapy analytics and CMC
Manufacturing
Cell and gene therapy update

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Upstream processing
Manufacturing
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Cell and gene therapy update

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Distributed advanced therapy manufacturing and delivery
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OCTOBER
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Characterization and validation
Manufacturing
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DECEMBER
Non-viral delivery: research, design, and engineering
Supply chain AI and digitization
Manufacturing
Vector
Analytics
Cell and gene therapy update

SPOTLIGHTS
Offering an in-depth exploration of the fundamental themes shaping the cell and gene therapy landscape in 2025, detailing the latest research breakthroughs, technological advancements, and emerging trends.

CHANNEL EDITIONS
Vector
Supply Chain

CHANNEL NEWSLETTERS
Delivering regular direct-to-inbox, personalized updates on topics spanning analytics, supply chain, manufacturing, and vectors in a digestible format.

CELL AND GENE THERAPY UPDATES
Providing up-to-the-minute news and commentary on the stories and breakthroughs of the day from across the cell and gene therapy field, with insights across regulatory navigation, business updates, clinical trends, and cutting-edge innovation.

Contact **Nicola McCall** on **+44 (0)7711 350195** or **n.mccall@insights.bio**
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EDITORIAL CALENDAR **2025**

CELL & GENE THERAPY INSIGHTS

JOURNAL SPOTLIGHTS

Expanding the range of cellular immunotherapy — FEB

- **Tracking the continued migration and growth of cellular immunotherapies beyond cancer and rare diseases**
  - What can we deduce about the field's prospects in the autoimmune diseases area from the latest preclinical and clinical data?
    - What lessons from the successes seen in hematological malignancies can be applied to autoimmune disease applications?
  - What will be the next key indication or therapeutic area for the cellular immunotherapy field?
- **Advancing the CAR-T cell therapy field**
  - How to overcome the remaining obstacles facing allogeneic/off-the-shelf CAR-T cell therapies?
  - *In vivo* CAR-T cell therapy—a progress report
    - What can we divine from the latest data in terms of future prospects and timeframes for further advancement in the *in vivo* CAR T cell therapy space?
      - To what extent will advances in *in vivo* CAR-T cell therapy address remaining challenges in the field, such as toxicity and antigen escape?
  - How can we continue reducing the cost and complexity of CAR-T cell therapy manufacture?
  - How and where is progress being made in reducing manufacturing timeframes to ensure rapid delivery of cellular immunotherapies to patients?
  - Demystifying CAR-T cell safety
    - How will the field cope with hesitancy related to insertional mutagenesis and tumorigenesis concerns?
    - How are on-target off-tumor effects being addressed?
- **What is needed to finally move the needle for cellular immunotherapy in solid tumors?**
  - How are technologies involved in the modulation of the physical, chemical, and biological hurdles in the tumor microenvironment evolving?
  - How do we improve efficacy and persistence in solid tumors? (e.g., repeat dosing? enabling earlier lines of treatment?)
  - Can a theranostics approach be integrated as part of patient treatment to help us further understand the solid tumor environment?
- **Leveraging the cutting-edge cellular immunotherapy R&D toolkit—what new insights can it provide?**
  - Exploring advances in matching cell type to indication—enabling the use of NK cells, T-regs, macrophages, and other immune cells as alternatives to CAR-Ts
  - How can R&D tools and technologies be platformed to help reduce preclinical and clinical development costs and timelines?
- **Does the NK cell therapy space require a reappraisal?**
  - How can we overcome the issues in scaling NK cell therapy production to commercial?
- **With the first tumor-infiltrating lymphocyte-based therapy on the market, what's next for the TILs field?**

Induced pluripotent stem cells (iPSCs) — MAR

- **Overcoming challenges associated with the creation of master cell banks (MCB) and comparability between working cell banks**
  - Examining trends, challenges, and breakthroughs in gene editing of iPSCs (e.g., multiplex editing)
  - How can novel iPSC cell lines help to alleviate the lack of a single, universal cell line?
  - Analyzing the decision-making process between in-house and outsourced iPSC development and production
- **How can we establish a reliable and reproducible method of differentiating iPSCs to limit the risk of mutation?**
  - Developing techniques to control the differentiation of iPSCs when used as the basis for an advanced therapy
  - Exploring platform opportunities for the end-to-end manufacture of iPSCs, including closed, automated processing
- **Troubleshooting key regulatory challenges in the iPSC field**
  - Addressing ongoing issues with tumorigenicity and safety profile of iPSC-derived immune cells
    - To what extent have existing safety concerns been addressed?
    - Addressing the necessity for more targeted and less toxic conditioning regimens
- **Breakthroughs in iPSC-based in vitro models of human disease—where are they being applied, specifically, and what are the pros and cons in doing so?**
- **Can we overcome the scale-up and cost of goods challenges related to producing the high volumes of iPSCs required to reach a broader range of indications?**
- **Considering alternative stem cells—could embryonic stem cells fill the gaps in the current generation of stem cell therapies?**

Gene therapy analytics and CMC — APR

- **Assessing the gene therapy analytical toolkit—do we know enough about our vectors? Where are the current shortfalls in our knowledge?**
  - Where is progress being made in reducing product development and process timelines and costs—e.g., through in-line testing technologies, and rapid QC/release assays?
  - How can assay sensitivity and robustness be increased to meet the requirements of evolving regulatory CMC guidance?
  - Addressing the need for universal reference standards to identify assay variability
  - Employing orthogonal methods across ddPCR/qPCR and ELISA, cryo TEM, HPLC, AUC, SDS-PAGE, and flow cytometry for enhanced viral vector characterization
  - How will next-generation sequencing (NGS) and other emerging analytical tools reshape the gene therapy analytical space?
  - Employing platform analytical approaches to viral vector manufacturing
  - How can laboratory testing be optimized and automated to reduce timelines and COGs to ultimately increase gene therapy accessibility?

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EDITORIAL CALENDAR **2025**

JOURNAL SPOTLIGHTS

CELL & GENE THERAPY INSIGHTS

- Establishing rapid in-line testing technologies to reduce the required number of process development runs
- **Sharing best practices to enable CQA identification in early development**
- **Navigating the evolving landscape of regulatory CMC guidance**
  - Understanding and meeting current regulatory expectations relating to empty-full-partially full capsid analysis
  - What are the key areas of regulatory divergence impacting the gene therapy field today, and how can we navigate them with harmonized solutions?
  - How to effectively develop an early-stage Target Product Profile (TPP) to inform product development and CMC compliance strategies?
- **Given the swiftly growing analytical toolbox, can the field reach a universal agreement on the analytical methods required for release assays?**
  - Fulfilling the need for rapid and reliable release sterility/contamination assays
  - What is the impact of hcDNA on stability?
- **Stability studies of GMP-compliant and non-GMP-compliant plasmids—assigning an appropriate use period**

Cell therapy manufacturing and bioprocessing — MAY

- **Addressing lingering and emerging challenges with cellular starting materials and critical raw materials**
  - Streamlining and optimizing autologous cell collection to maximize manufacturing success and final product efficacy
  - Honing your allogeneic cell sourcing strategy
    - Donor cell sourcing
    - iPSCs
    - Overcoming funding issues associated with cord blood banking and transplantation to drive the field forward
  - Troubleshooting the supply of consistent, high-quality critical raw materials
    - How and where can emerging alternative materials reduce risk in cell therapy manufacturing?
      - Human serum—are we close to replacing it?
- **What upstream and downstream processing technology innovations are delivering the cost and time savings and improvements in quality/consistency required to allow cell therapies to reach wider patient populations?**
  - Analyzing the growing range of available closed, automated cell therapy manufacturing solutions
    - How will all-in-one, 'GMP-in-a-box' technologies perform in the commercial setting?
  - Making gains in achieving affordable, scalable process development for cell therapies
  - How can we work to close and automate processes whilst retaining the ability to make real-time decisions?
  - Closing the gaps between R&D/PD and PD/manufacturing through earlier considerations of late-stage and commercial processes
  - How can the field continue migrating away from traditional multi-step processes involving manual handling and towards automized production on a single platform?
  - Process integration technology—how can the upstream and downstream processes be seamlessly integrated to ensure overall streamlined manufacturing?
    - How can process integration technology be applied to autologous cell therapies in a personalized context?
  - Profiling recent innovations and remaining needs in final formulation and fill-finish
    - Can we establish the automated backfilling technologies needed for large-scale allogeneic manufacturing?
- **Cell therapy 4.0—where are we now?**
  - How can bioreactor systems with integrated intelligent controls become standard, rendering expansion processes self-adaptive?
  - Harnessing novel algorithms to enable the adaptation of autologous processes to the needs of specific patients at scale
- **Best practices for end user/tool provider collaborations to cost-effectively road-test emerging manufacturing technologies**
- **Enabling the re-emergence of tissue engineered products**

Non-viral delivery: manufacturing and analytics — JUN

- **Driving the development and establishment of scalable, plug-and-play processing tools and workflows for non-viral vector-based cell and gene therapy**
  - What are the keys to streamlining non-viral cell therapy manufacturing workflows while fulfilling safety requirements and regulatory expectations?
  - Future directions for non-viral-based engineered cell therapy manufacturing
    - How can non-viral gene delivery systems (e.g. exosomes, extracellular vesicles, pDNA, electroporation) exceed transfection efficiencies with improved safety profiles compared to viral gene delivery platforms?
- **Optimizing non-viral vector production to capitalize on potential cost, scalability, and safety advantages**
  - Enabling fully closed and automated non-viral vector manufacturing
  - Learning lessons from the mRNA COVID-19 vaccines: how can large-scale RNA-LNP manufacturing be made accessible globally?
- **Developing effective, tailored, robust, and reproducible assays for non-viral vector production**
  - Enabling real-time monitoring and control: increasing manufacturing efficiency through the adoption of at-line and in-line analytical tools
- **Rethinking cell and gene therapy regulatory approaches to fit novel synthetic gene delivery platforms**
- **Where, and to what practical end, are novel AI/ML tools being implemented in non-viral technology manufacturing and analytics?**

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EDITORIAL CALENDAR 2025

JOURNAL SPOTLIGHTS

CELL & GENE THERAPY INSIGHTS

Distributed advanced therapy manufacturing — JUL

- **Analyzing and comparing strategic models across the full spectrum of distributed cell and gene therapy manufacturing, including point-of-care manufacture, close-to-point-of-care manufacture, and manufacture utilizing CDMOs**
  - What specific indications or technologies/therapeutic modalities are a 'best fit' for a distributed model?
  - Can a 'hub and spokes' model for cell and gene therapies be applied globally?
- **What enabling tools and technologies would facilitate a distributed manufacturing model?**
  - What cell sourcing, fill-finish, QC, and analytics technologies will be optimal for a successful distributed manufacturing model, considering equipment footprint and viability?
    - What would QC testing for point-of-care manufacturing actually look like?
  - What would a robust supply chain for decentralized manufacturing look like?
  - How can closed and automated platform systems enable high-grade manufacture in hospital settings?
  - How can GMP compliance be maintained across point-of-care facilities?
- **Meeting regulatory requirements: how can regulatory bodies and product developers and manufacturers alike ensure comparability, consistency, and compliance across distributed manufacturing sites?**
- **Addressing further key obstacles to enabling distributed manufacturing in hospitals and medical centers**
  - How to ensure the availability of a suitably trained workforce at individual sites, and successful knowledge transfer between sites?

Next steps in the gene editing revolution — AUG

- **CRISPR/Cas9: where next for gene editing's poster child?**
  - In the wake of the first *in vivo* gene editing product approval, how can a new frontier in data collection and monitoring lead the next generation of CRISPR-based therapeutics to commercial success?
  - How will the field address remaining safety challenges in CRISPR-mediated gene editing, including unexpected immune reactions and off-target effects?
  - Are alternatives to Cas9 proving more effective and causing fewer off-target edits in conjunction with CRISPR?
  - CRISPR/Cas9 applications in xenotransplantation—addressing associated legal, operational, and biosecurity challenges
- **How are novel platforms and tools revolutionizing the field of genome editing (e.g., prime editing, base editing, gene writing, synthetic DNA, AI/ML)?**
  - As prime editing nears the commercialization stage, what will it mean for the gene editing, and for the advanced therapies field as a whole?
  - What techniques will aid the necessary increase in editing efficiency to enable *in vivo* use, thus bringing down COGs?
  - Can employing doggybone DNA with polymerase ensure high fidelity?
  - Can the use of safe harbor loci reduce the likelihood of off-target editing?
  - What tools will enable further genomic analysis/large human data set exploration?
- **How can we overcome existing delivery challenges to enhance target specificity of gene editing therapeutics?**
  - How can we improve nuclear uptake gene editing payloads?
  - Which delivery technologies (e.g. lipid nanoparticles) are proving most effective in helping to minimize translocation rearrangements and other unwanted effects?
- **Optimizing gene editing-based therapeutics manufacture**
  - How to enhance scalability? Consistency? Cost effectiveness?
- **What does the future hold in terms of functional CMC and other specific regulatory guidance for gene editing?**
  - What are the specific issues and considerations with transferring existing CMC/regulations from the gene therapy space into gene editing?
- **How can we increase patient understanding and accurate knowledge sharing around gene editing?**
- **Demystifying the IP space around gene editing for developers and investors**
  - Understanding the Cartagena Protocol on biosafety and the GMO dossiers required

Scale-up/-out of cell and gene therapy manufacturing — SEP

- **Safeguarding scalability in viral vector manufacture**
  - What are the keys to minimizing process development timelines while ensuring scale-up success?
- **Scaling process and analytical technologies in cell therapy manufacturing**
  - How do we upscale the bioprocessing of human, patient-specific cells in a way that maintains batch-to-batch consistency in potency and functionality?
  - Tackling key scalability barriers to the commercial launch of allogeneic cell therapies
- **How can scalable platform technologies create more streamlined, cost-effective manufacturing workflows to ultimately increase patient access to cell and gene therapies?**
  - How can platforms and standards be established to speed up the development and scale-up/scale-out of customized or bespoke advanced therapies, including in rare and ultra-rare diseases?
- **Closing the gaps between preclinical, process development (PD), and commercial manufacturing stages**
  - How to embed the future requirements of clinical translation earlier into process development to smooth the path from academic to industry settings?
  - How to improve manufacturing capacity utilization—including equipment, resources, and staffing?
  - How can scalable automation be implemented earlier in processes to streamline the path to commercialization and alleviate manufacturing scalability issues?
- **How can we ensure we have the data robustness required to facilitate the implementation of digital infrastructure and AI when operating at scale?**

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CELL & GENE THERAPY INSIGHTS

JOURNAL SPOTLIGHTS

- Identifying and addressing the key skills gaps in cell and gene therapy field from bench to point of care
- What are the key next steps to ensuring equitable access to cell and gene therapies on a global scale?
- Managing the impact of geopolitical and biosecurity issues on advanced therapies from a global perspective

Viral vector manufacturing and platform evolution — OCT

- Addressing remaining process-related challenges to ensure AAV-based gene therapy's future as a competitive modality
  - How can we increase efficiency and productivity in AAV upstream processing?
    - Enabling further improvements in terms of yield, titer, and quality
  - Optimizing downstream processes
    - What are the keys to successfully scaling empty/full separation, including limiting partially full capsids?
      - Optimizing affinity capture
      - Enabling removal of empty and partially full capsids after the affinity step
  - Overcoming the continuing lack of standardization in AAV manufacturing
  - Reducing batch-to-batch variability
- Key challenges and next steps for lentiviral vector processing
  - How do we overcome the loss of vector particles when utilizing anion exchange methods?
  - How to manage the low stability of lentivirus and limit both the pH and salt window and mechanical stress/shear to retain infectivity throughout processing?
- How can platform-based technologies be further implemented and established in viral vector production?
- Expanding the gene therapy field's focus beyond AAV and lentivirus: what are the key manufacturing challenges and considerations relating to novel and emerging gene therapy vectors (e.g., VSV, HSV, anelloviruses, non-AAV parvovirus, Newcastle disease virus)

Cell therapy analytics and CMC — NOV

- What emerging analytical assays, platforms, and workflows are emerging to help drive the requisite improvements in the quality and consistency of cell therapy manufacturing?
  - Leveraging integrated real-time/online monitoring systems
  - How and where are AI/ML technologies and approaches having an impact on cell therapy analytics?
  - Can platform technologies meet the need to reduce assay turnaround time and labor intensity?
  - How can the field implement process analytical technologies (PAT) to enable widespread access to cell analysis (without the need for highly skilled personnel)?
  - Is the need for improved microbiological and mycoplasma detection methods being fulfilled?
  - Exploring the analytical/QC components of 'all-in-one' process solutions and automated systems—do they pass muster?
- How can we drive down assay COGs, particularly reagent costs?
- How to assess leukapheresis consistency, and quality assurance of cellular starting materials in general, for both autologous and allogeneic cell therapies?
- Honing regulatory CMC strategy in the cell therapy space
  - Identifying and negotiating key current gaps between rapidly advancing science and technology and regulatory CMC guidance
  - Addressing the need for increased scientific rigor in data collection for IND submission
  - Furthering understanding and industry confidence in AI/ML tools to assist in functional regulatory analysis of novel cell therapy technologies
  - Driving the development of physical standards and reference materials for cell therapy products

Non-viral delivery: research, design, and engineering — DEC

- Examining progress in developing non-viral delivery vehicles with the requisite payload capacity and tropism beyond the liver to drive future growth in the field
  - How can existing challenges in lipid nanoparticle (LNP)-based delivery systems (e.g., extrahepatic delivery, targeting selectivity, instability in vivo) be overcome to ensure their potential is realized?
    - Overcoming challenges associated with the delivery of exogenous mRNA using LNPs for systemic indications
      - Employing receptor-mediated internalization and cell-type targeting of nanoparticles
      - Overcoming endosomal escape as a bottleneck to LNP-mediated therapeutics
  - Where should ongoing efforts to enhance and augment oligonucleotide-based delivery be directed?
  - Optimizing electroporation-based techniques to enable improved efficiency with reduced payload
  - To what extent can extracellular vesicles/exosomes enable cell-specific tropism?
  - Comparing and contrasting the prospects of novel technologies (e.g., nano straws/spikes, branched polymers) to improve targeting and control of gene delivery
- Addressing remaining barriers to repeated and patient-specific dosing with non-viral methods
- Enabling increased efficiency of non-viral delivery methods through innovation in payload engineering and therapeutic cassette design
- How to build the datasets required for AI/ML utilization in the development of non-viral vectors?

Cell & Gene Therapy Insights Spotlights

Each spotlight will comprise:

- Peer-reviewed Reviews and Expert Insight articles written by leading experts in the field
- Webinars, featuring industry speakers and sponsors discussing key topics specific to the Spotlight
- Podcast, written and video interviews with key opinion leaders
- On demand roundtable discussions

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CHANNEL EDITIONS

CELL & GENE THERAPY INSIGHTS

FEBRUARY

Manufacturing scale-up

As clinical and commercial demands grow, we identify how vector manufacturing processes can be scaled to increase yield, whilst ensuring consistency and quality in addition to addressing regulatory and logistical challenges.

MARCH

Raw/starting materials

We delve into the importance of sourcing consistent, high quality raw and starting materials for cell and gene therapies, tackling supply chain hurdles from donor cell-variability to considerations surrounding reliably sourcing critical raw materials.

MAY

Upstream processing

We delve into the initial stages of vector manufacture, assessing the current state-of-the-art in cell culture expansion, transfection, and viral vector production, and exploring associated manufacturing hurdles and trends.

JUNE

Cryopreservation

This edition details the complexities of cryopreservation and the cold chain for advanced therapies, and the challenges faced in reaching and maintaining freezing temperatures from formulation to distribution and delivery.

AUGUST

Downstream processing

We dive into the intricate world of vector downstream processing, observing vectors as they move through harvest and clarification, purification, formulation, and fill/finish, and assessing the tools and technologies used throughout.

OCTOBER

Vein-to-vein supply journey

This special Supply Chain Channel Edition will tell the story of the cell and gene therapy vein-to-vein supply chain journey from start to finish, highlighting recent strategic evolution and emerging technological innovation influencing each step.

The edition will include dedicated features examining cell collection/apheresis, digital track and trace/security, orchestration systems, transportation/logistics, cold chain management, and more.

NOVEMBER

Characterization and validation

This edition examines the cutting-edge analytical techniques and rigorous QC/QA and CMC testing at the forefront of the vector analytics space to ensure the precision, safety, and efficacy of vector-based therapeutics.

DECEMBER

Supply chain AI and digitization

Here, we explore how AI and digitization present a new frontier to the management of existing challenges across the cell and gene therapy supply chain, evaluating everything from omics solutions to machine learning tools.

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