2024

CELL & GENE THERAPY INSIGHTS

EDITORIAL CALENDAR

	JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE
Journal Spotlights		Induced pluripotent stem cells (iPSCs)	Non-clinical/translational tools & technologies	Vector processing & materials	Cell therapy upstream processing & materials	Viral and non-viral vector platform evolution
Channel Editions Published quarterly: Vector Supply Chain		SUPPLY CHAIN: Cryopreservation & cold chain	VECTOR: Scalability	SUPPLY CHAIN: Scaling the supply chain		VECTOR: Upstream processing
Channel Newsletters		Manufacturing Supply chain	Manufacturing Vector Analytics	Manufacturing	Manufacturing Supply chain	Manufacturing Vector Analytics
Cell and Gene Therapy Updates		Cell and gene therapy update		Cell and gene therapy update		Cell and gene therapy update

	JULY	AUGUST	SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER
Journal Spotlights	Gene therapy analytics & CMC	Innovation in cellular immunotherapy: how to reach more patients?	Scale-up/scale-out of cell & gene therapy manufacturing	Gene editing	Cell therapy downstream processing & analytics	Review of 2024 & previewing 2025
Channel Editions Published quarterly: Vector Supply Chain		SUPPLY CHAIN: Supply chain digitization		VECTOR: Downstream processing	SUPPLY CHAIN: Securing the supply chain	VECTOR: Characterization & validation
Channel Newsletters	Manufacturing	Manufacturing Supply chain	Manufacturing Vector Analytics	Manufacturing	Manufacturing Supply chain	Manufacturing Vector Analytics
Cell and Gene Therapy Updates		Cell and gene therapy update		Cell and gene therapy update		Cell and gene therapy update

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to discuss thought leadership and lead generation opportunities

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Spotlights summary

JANUARY	FEBRUARY	MARCH
	Induced pluripotent stem cells (iPSCs)	Non-clinical/translational tools & technologies
APRIL	**MAY**	**JUNE**
Vector processing & materials	Cell therapy upstream processing & materials	Viral and non-viral vector platform evolution
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CELL & GENE THERAPY INSIGHTS

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Spotlight details

Cell & Gene Therapy Insights' Spotlights provide you with fantastic opportunities to:

Educate your target market about your company's expertise, capabilities and experience

Share your latest data with organisations looking for partners and service providers in your field

Profile your executives and scientists as thought-leaders and KOLs

Generate qualified leads from across the global sector

Increase awareness of your company's role in cell and gene therapy R&D and manufacture.

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**

FEB — Induced pluripotent stem cells (iPSCs)

- What progress in addressing the preclinical-clinical translation bottleneck for induced pluripotent stem cell-derived therapeutics?
  - Learning from trailblazers in the field
  - To what extent have safety risks associated with iPSCs been successfully addressed?
- Overcoming the complexity in iPSC banking
  - What do we really know about stability and variability of iPSCs?
  - At what stages are/aren't GMP workfows needed in iPSC master cell bank creation?
  - Platform opportunities and market evolution in the iPSC cell line development space
    - What will be key specific cell lines as demand outstrips supply?
    - In-house development versus outsourcing
  - What are the main priorities and needs for standardization in the iPSC field?
- Automation and avoiding contamination in iPSC cell selection and harvesting
- Multiplex iPSC editing approaches—latest advances and lingering concerns
- Looking to the future
  - Personalized iPSC-derived therapies (e.g., iPSC-derived oocytes)
  - Should exosomes manufacture stick to standard producer cell lines or seek to harness iPSCs instead?

MAR — Non-clinical/translational tools & technologies

GUEST EDITOR: Shon Green, Adicet Bio

- What does the 'umbrella IND' mean for cell and gene therapy preclinical development? How much can you leverage from one advanced therapy product or platform to another?
- What is the future of preclinical *in vivo* testing requirements?
  - Are regulators coming round to less animal testing in practice (e.g., non-human primates)? If so, in what specific circumstances?
  - How and when will the use of organoids and other *in vitro* models become more standardized and mainstream in preclinical R&D?
  - What is the current state-of-the-art in modelling that can help to explain the difficulties in translating preclinical into clinical success for AAV-driven gene therapy?
  - How can we leverage the ever-increasing body of advanced therapy clinical data to facilitate clinical translation?
  - How far can one push the envelope in terms of a reduced preclinical package?
- Which process and analytical innovations are can streamline the transition to early-phase clinical manufacturing and beyond?
- Assessing the application of AI in non-clinical R&D—where are advances in automated bioinformatics translating into R&D insights for the cell and gene therapy field?
- How are next-generation sequencing, multiomics, and single cell analysis technologies being employed to rewrite the script for advanced therapy drug discovery?

APR — Vector processing & materials

GUEST EDITORS: Francesca Vitelli and **Chia Chu**, Intellia Therapeutics

- The battle to boost yields in viral vector manufacturing: where have improvements been made recently to boost yields in viral vector manufacturing?
  - Producer/packaging cell lines vs transient transfection vs helper viruses: how are they comparing and evolving in relative terms?
  - What cell lines are available beyond HEK293 and how they are performing?
  - Vector purification
- Driving down Cost of Goods for viral vector production to reach viable price points for rare and non-rare disease gene therapies
  - What does a viral vector platform actually look like, and what are the difficulties in building one?
    - Who is winning the race to find the optimal 'quick to clinic' vector manufacturing platform process?
    - What lessons can we take from the biopharma world?
    - Where in vector processing is further innovation required?
  - Reducing batch-to-batch variability
  - What are the pros and cons of harnessing synthetic raw and starting materials for gene therapy manufacture?
  - Comparing and contrasting perfusion equipment options for suspension-based production of viral vectors
  - How to capitalize on the application of design of experiments (DoE) and digital twin approaches in vector process development?

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MAY

Cell therapy upstream processing & materials

- Ensuring manufacturability: how to assemble all the pieces required for a viable cell therapy process?
- Cell sourcing
  - Enabling sourcing of allogeneic donor-derived cellular starting material
    - Optimal approaches to donor identification and characterization
    - Overcoming regulatory guidance and divergence barriers
  - Autologous cell collection
    - How to establish clear patient inclusion/exclusion criteria pre-commercialization?
    - The importance of defining the number of target cells required to manufacture a therapeutic dose
    - How to enable large-scale autologous cell collection in the decentralized outpatient setting?
    - Apheresis material characterization
    - Standardization initiatives
    - Harmonization of harvest—what are the overall requirements?
- Cell therapy upstream processing
  - Exploring recent technological innovations (e.g., automated solutions) and initiatives driving:
    - Shorter manufacturing timeframes
    - Reduced Cost of Goods
    - Enhancing process control (eg. development of non-destructive sensors)
    - Improvements in flexibility and interoperability
    - Distributed (e.g., hospital-based) manufacture
  - Transduction/transfection and expansion of allogeneic cell therapies
  - Can adaptable engineering platforms for organoid production transform the regenerative medicine field?

JUN

Viral and non-viral vector platform evolution

GUEST EDITOR: Zhenghong Gao, AskBio

- Viral delivery
  - How will we move the needle to allow sustainable success in both rare and non-rare disease settings?
  - Is the rare disease gene therapy model failing? How to address this?
  - How effectively is the AAV field addressing lingering immunogenicity and vector integration issues?
  - Profiling recent advances in viral vector engineering (lentiviral and AAV)
- Non-viral delivery
  - Nanoparticles: overcoming targeting limitations beyond the liver
    - The pros and cons of LNPs in advanced therapy applications
  - How is the toolkit of non-viral alternatives for *ex vivo* immune cell engineering evolving/improving?
  - mRNA
    - Where is it being applied currently in the therapeutic setting? What are the key gaps mRNA can fill?
    - How safe is mRNA proving to be in therapeutic application? How durable (and how viable is redosing)? How targeted?
    - What benefits can next-generation technologies deliver?
  - Extracellular vesicles/exosomes
    - What are the likely next steps in their application?
      - What lessons can we learn from viral vector development to resolve targeting issues?
    - Extracellular vesicles versus synthetic particles: will they converge? What can one field learn from the other?
  - Emerging alternatives to plasmids (e.g., dbDNA)—what can they offer the cell and gene therapy space?
  - What is the state-of-the-art in long oligos?

JUL

Gene therapy CMC & analytics

GUEST EDITOR: Stuart Beattie, Biogen

How best to leverage the expanding analytical toolkit for viral vector characterization and QC?

- Maximizing the benefits of high-performance liquid chromatography (HPLC) and liquid chromatography/mass spectrometry (LC/MS)
- Harnessing the cutting edge in capsid characterization tools
- Characterizing aggregation

- Addressing ongoing CMC challenges and associated regulatory evolution:
  - Dissecting key recent guidances—implementation and points to consider for the field
  - Where is further guidance and standardization most needed?
    - How many assays do you require for your potency assay matrix?
    - What does a phase-appropriate potency assay actually look like?
    - What if none of the your potency assays fail to correlate with a positive clinical outcome?
  - What are the keys to successfully integrating QA into viral vector manufacture?
  - Comparability—how to find the optimal balance in early development (costs vs quality)?
  - How will the empty-full-partially full capsid analysis picture continue to develop?
- Exploring key areas of need for (affordable) analytical innovation and its application
  - Priorities for future lentiviral vector-specific analytical technology innovation
  - How is the LNP QC/analytics field evolving?
  - Rapid/real-time process analytical technologies
  - Key directions for derisking vector manufacture through analytical technology
    - How can we make assays more agnostic/standard across different vectors/capsids?
    - What impact are instruments capable of multiple in-process assays having on cost and efficiency?
    - How will we continue to move towards automating data analysis and enhancing predictive abilities?

AUG

Innovation in cellular immunotherapy: how to reach more patients?

GUEST EDITOR: Nina Bauer, SmartCella

- Where and when will we see real progress in solid tumors? What is the latest clinical data telling us?
  - CAR-T (allogeneic and autologous approaches)
  - NK cell therapy
  - Macrophages
- What are the most promising approaches towards addressing issues of safety and durability of response in hematological malignancies?
- The rise of *in vivo* cellular immunotherapy—barriers to success and potential solutions
  - How will mRNA continue to influence the cellular immunotherapy field?
- Applying cutting-edge enabling technologies to overcome challenges presented by solid tumors and the TME
  - Driving advances in our understanding of functional biology in solid tumors in order to address key knowledge gaps
  - Exploring the practical application of big data analytics and AI/ML—what new insights are they providing?
  - Profiling the next wave of R&D tools—what specific capabilities will they deliver?
- Analyzing the impact of recent regulatory guidance evolution in the field, and likely next steps in this regard
- How and where to continue expanding the reach of cellular immunotherapies beyond oncology?
  - How will regulators react to an increasing number of applications in autoimmune/infectious disease therapeutic areas?
- As more and more patients are treated, how are supply chain/logistics models and tools evolving?

SEP

Scale-up/scale-out of cell & gene therapy manufacturing

- Improving and expanding advanced therapy manufacturing capabilities globally
  - Assessing collaborative solutions to remaining capacity and cost issues
  - How are commercial CAR-T suppliers moving to address the current manufacturing shortfall?
  - Targeting economies of scale to reduce cost of goods
  - How/where can we improve the sustainability of advanced therapy processes?
- AAV and lentiviral vectors: addressing remaining scalability issues
  - Transient transfection beyond 2,000 L scale—what is the optimal solution?
  - Addressing the need for rapid analytics with virus-based production systems at large-scale
  - What is the best approach to tackling scale-up challenges?
- Enabling scale-up of extracellular vesicle production
- What are the challenges when scaling-up cell therapy manufacture to the billions of cells level?
- Mitigating the impact of ongoing post-COVID supply chain limitations
- Have we reached the tipping point in the centralized vs decentralized manufacturing debate?
  - Removing obstacles to distributed advanced therapy manufacture, and key next steps for the space
- How to perform manufacturing assessments in early drug discovery to ascertain future scalability
- Shortages in the cell and gene therapy workforce. Where should workforce development efforts be aimed?

OCT

Gene editing

- Tackling remaining safety concerns as the era of commercial genome editing-based therapeutics arrives
  - On- and off-target editing analysis—which tools/models should we use?
  - What is the current state-of-the-art in the area of multiplex editing analysis?
- Analysis of the pros and cons of genome editing and gene writing platforms as next-generation approaches enter the clinic
  - To what extent is promising preclinical data being borne out in humans?
  - What are the key opportunities to utilize CRISPR knockout and how to capitalize?
- Gene editing delivery: the benefits and challenges in applying viral and non-viral platforms
- What improvements can recent innovations in the enzymes area deliver?
  - What are the pros and cons of next-generation Cas technologies in application?
- Predicting future developments in gene editing and its application
  - What can we expect in the way of further regulatory guidance for the field? What are some of the key areas of convergence/divergence to look out for?
  - Assessing the epigenome editing opportunity: what is possible currently in the realm of epigenetic modulation, and what might the future hold in the context of both combinatorial and synergistic therapeutic approaches?

NOV

Cell therapy downstream processing & analytics

- Cell therapy downstream processing
  - Exploring recent technological innovations and initiatives driving shorter manufacturing timeframes, reduced Cost of Goods, improvements in flexibility and interoperability, and distributed manufacture
  - Optimizing cell therapy fill-finish: what are the key innovation gaps?
- How are developers interpreting and responding to recent regulatory guidance regarding potency assays?
  - Can we identify any best practices, particularly in terms of potency assay matrix development?
  - What are the preclinical 'must-do's' to prepare for potency assay success?
  - How can we advance to improved, standardized analytical toolkit to allow developers to implement potency assay matrixes that correlate with clinical outcomes?
- Comparability: what exactly do we need to show, and how to prepare from an early stage?
  - Finding the optimal balance between product development and speed to patient post-IND
  - What knowledge can we leverage from cell therapy products that have already been through the clinic in terms of how best to approach process changes?
- What does phase-appropriate analytical control of cell therapy manufacture look like?
- Are novel cell therapy analytical tools and technologies delivering the required degree of repeatability and precision?
- How can we move further towards the automation of data analysis in cell therapy manufacture?
- How are regulatory CMC compliance strategies and analytical toolkit innovation evolving to address the ever-increasing complexity of engineered cell therapy products?
  - What do/don't we understand about the associated risk?
  - How and where specifically can off-the-shelf therapy developers leverage the fund of autologous cell therapy-derived CMC knowledge to help advance the allogeneic cell therapy field?
- Dissecting critical areas of international regulatory divergence impacting cell therapy CMC and QC

DEC

Review of 2024/previewing 2025

- Examining the major advances and setbacks, stories and trends from the past 12 months—what will be likely repercussions for the cell and gene therapy field moving forward?
- Profiling key enabling technology innovation trends and advances for the year(s) to come

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Channel Newsletters	Manufacturing Vector Supply chain Analytics	Manufacturing Vector	Manufacturing Vector	Manufacturing Vector Supply chain Analytics	Manufacturing Vector	Manufacturing Vector Supply chain

Vector Channel

Frequency: 4 themed editions per year and 12 newsletters per year
Format: Channel content
Vector scalability
Upstream processing
Downstream bioprocessing
Vector characterization and validation

Supply Chain Channel

Frequency: 4 themed editions and newsletters per year
Format: Channel content
Cryopreservation and cold chain
Scaling the supply chain
Supply chain digitization
Securing the supply chain

Analytics Channel

Frequency: 4 editions and newsletters per year
Format: Channel content

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Bimonthly Cell and Gene Therapy Update

Providing up-to-the-minute news and opinion on the stories and breakthroughs of the day from right across the cell and gene therapy field.
Covering everything from R&D innovation to regulatory affairs, and from business/commercial strategy to clinical trends.

	JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE
Reports		Cell and Gene Therapy update		Cell and Gene Therapy update		Cell and Gene Therapy update

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Reports		Cell and Gene Therapy update		Cell and Gene Therapy update		Cell and Gene Therapy update

Cell and Gene Therapy Updates will contain content from each of the areas below:

Innovation Insights

Providing updates from the scientific and technological cutting edge of advanced therapies

Regulatory Insights

Keeping you up to date with 'need to know' guidance evolution, and a repository of advice on how to navigate regulations on a global basis

Clinical Trends

Putting recent clinical data in context and providing solutions for the clinical development challenges of the day

Business Insights

Commentary on key issues and trends in financing, market access, and licensing & partnering in the cell and gene therapy space

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