2022

CELL & GENE THERAPY INSIGHTS

EDITORIAL CALENDAR

	JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE
Journal Spotlights		**Preclinical and translational tools and strategies**	**Raw and starting materials**	**Vector bioprocessing**	**Gene delivery/gene editing platform evolution**	**Industrializing immuno-oncology product manufacture and supply chain**
Channel Editions Published quarterly: -Vector - Supply Chain - Analytics		VECTOR: Enhancing vector bioprocess scalability	ANALYTICS	SUPPLY CHAIN: Best practices for ensuring cell and gene therapy supply chain scalability	VECTOR: Vector characterization	ANALYTICS
Channel Newsletters		Manufacturing Vector	Manufacturing Vector Analytics	Manufacturing Vector Supply chain	Manufacturing Vector	Manufacturing Vector Analytics
Reports		$ Business Insights	Clinical Trends; Innovation Insights	Regulatory Insights	$ Business Insights	Clinical Trends; Innovation Insights
Podcast series			Tomorrow's cell and gene therapy workforce			Licensing and partnering in cell and gene therapy

	JULY	AUGUST	SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER
Journal Spotlights	**Global regulatory update**	**New horizons in cellular immunotherapy**	**Cell and gene therapy manufacturing scale-up/ scale-out**	**Gene therapy CMC and analytics**	**Cell therapy bioprocessing**	**Tools of tomorrow**
Channel Editions Published quarterly: -Vector - Supply Chain - Analytics	SUPPLY CHAIN: Driving the digitization of cell and gene therapy supply chains	VECTOR: Upstream Bioprocessing	ANALYTICS; SUPPLY CHAIN: Optimizing raw materials quality	VECTOR: Downstream bioprocessing	SUPPLY CHAIN: Starting materials sourcing and management	ANALYTICS
Channel Newsletters	Manufacturing Vector Supply chain	Manufacturing Vector	Manufacturing Vector Analytics	Manufacturing Vector Supply chain	Manufacturing Vector	Manufacturing Vector Supply chain Analytics
Reports	$ Business Insights	Innovation Insights	Clinical Trends	Innovation Insights	$ Business Insights; Clinical Trends	Regulatory Insights
Podcast series			Digitally enabling cell and gene therapy			The potential of mRNA for advanced therapies

Contact Nicola McCall on +44 1732 463215 or n.mccall@insights.bio to discuss thought leadership and lead generation opportunities

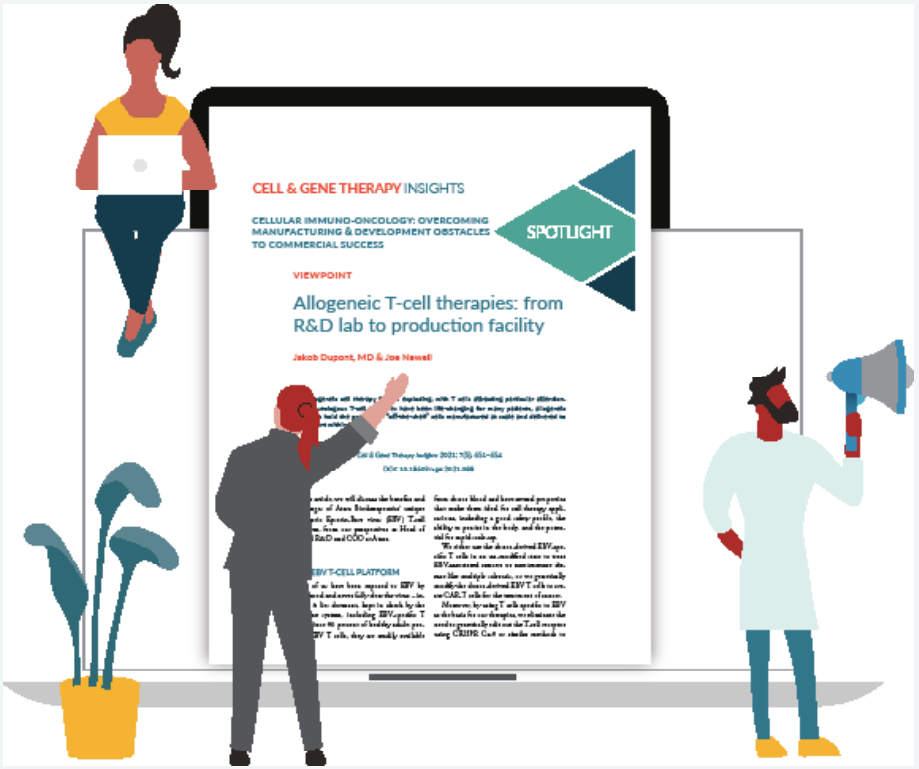
2022

CELL & GENE THERAPY INSIGHTS

EDITORIAL CALENDAR

Spotlights summary

JANUARY	FEBRUARY	MARCH
	Preclinical and translational tools and strategies	Raw and starting materials
APRIL	**MAY**	**JUNE**
Vector bioprocessing	Gene delivery/gene editing platform evolution	Industrializing immuno-oncology product manufacture and supply chain
JULY	**AUGUST**	**SEPTEMBER**
Global regulatory update	New horizons in cellular immunotherapy	Cell and gene therapy manufacturing scale-up/ scale-out
OCTOBER	**NOVEMBER**	**DECEMBER**
Gene therapy CMC and analytics	Cell therapy bioprocessing	Tools of tomorrow



Contact Nicola McCall on +44 1732 463215 or n.mccall@insights.bio to discuss thought leadership and lead generation opportunities

2022

CELL & GENE THERAPY INSIGHTS

EDITORIAL CALENDAR

Spotlights 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 — Preclinical and translational tools and strategies

- Joined-up assays: defining best practices for an integrated approach to early-stage potency assay R&D, keeping the eventual goal of marketing application in mind
- Use of organoids, tissues on-a-chip, and other emerging *in vitro* and *in silico* tools to support preclinical data packages and provide genuinely predictive clinical insights
  - Standardization in the manufacture and usage of *in vitro* models
- Biomarkers and surrogate marker development: regulatory acceptance criteria and implications for first-in-human trial designs
- Computational biology and big data analytics tools for cell/gene therapy target identification/validation and non-clinical development
- PK/PD modeling applied in the cell/gene therapy field
- Testing for immunotoxicity or genotoxicity: safety testing where *in vivo* models are unavailable
- Addressing the lack of good non-clinical models for allogeneic cell therapy development
- To what extent can we address long-term clinical efficacy through redosing of *in vivo* gene therapy products in preclinical models?

MAR — Raw & starting materials

GUEST EDITOR: Gary du Moulin, former VP, Quality Operations, Genzyme Biosurgery & Senior Director of Quality Aseptic Control, Genzyme (A Sanofi Company)

- Regulatory agency expectations for raw and starting materials
  - Qualification of raw materials
  - Regulatory disharmony between different national and multinational jurisdictions
- Evolving risk management considerations and best practices
  - Long-term upstream supply chain strategies: anticipating and preparing for raw material and consumables shortages and challenges in obtaining starting materials related to COVID-19
- Increasing consistency, scalability, and standardization - and reducing costs of raw materials
- Analytical tool development to support material changes
- Production of materials in-house vs outsourcing
- Steps to removing a complex biological material from your process and replacing it
- Control of starting materials for autologous and allogeneic cell therapies
  - Cell line development upstream of allogeneic cell banking
  - Cell sorting and selection for optimized manufacture

APR — Vector bioprocessing

GUEST EDITOR: Franz Gerner, Chief Technology Officer, Excision BioTherapeutics

- Analysis of the rapidly evolving competitive landscape in vector manufacturing
  - Viral vector capacity issues (AAV and LV)
  - Future supply and demand trends in light of the current pandemic
- Viral vector process intensification and streamlining production through automation and reduction in process steps
- Production platforms
  - Pros and cons of producer cell lines
- Technological trends and advancements in vector purification
- Shortfalls in the established bioanalytical toolkit
- Viral clearance in viral vector processing
- Reducing timeframes for process development activities and earlier process-related decision-making
- How to protect your GMP vector production from COVID-19?
- What does phase-appropriate GMP look like in practice?

MAY — Gene delivery/gene editing platform evolution

GUEST EDITOR: Louise Rodino-Klapac, EVP, Head of R&D, Chief Scientific Officer, Sarepta Therapeutics

- Gene editing platform/application evolution
  - How and where are next-generation gene editing platforms being applied and with what benefit?
  - Predicting future trends in gene editing platform evolution
- Engineering/innovating around long-standing issues for AAV vectors as the field expands into larger patient populations
  - Pre-existing immunity
  - Redosing
  - Enhancing specificity/tissue tropism: systemic delivery
  - Improving AAV vector efficiency/potency to enable dose reduction and an improved toxicity profile?
- Third-generation LV vectors in *ex vivo* and *in vivo* settings
  - Have safety issues now been sufficiently addressed?
- Non-viral delivery platforms: benefits, obstacles, and their potential future impact on the cell and gene therapy space
  - mRNA delivery in the light of the approved COVID-19 vaccines
  - Lipid nanoparticles
  - Exosomes
  - Electroporation

JUN — Industrializing immuno-oncology product manufacture and supply chain

- Lessons learned during the second wave of approved CAR T cell therapies from the roll of out Kymriah and Yescarta.
  - Improving cost effectiveness, with market and patient access in mind
  - Difference between clinical and commercial CAR T cell therapy manufacturing
  - What is the best approach to ensure such novel and personalized medicines find their patients – and the physicians who prescribe them?
- Delivering cellular immunotherapy to larger patient groups
  - Capacity and infrastructure requirements to enable widespread patient access
- Supply chain improvements required by emerging cellular immunotherapy modalities (eg. TILs)
- What will the cellular immunotherapy products we are manufacturing in 3–5 years' time look like – and what does this means for today's facility design?

JUL — Global regulatory update

GUEST EDITOR: Alexis Cockroft, Director & Regulatory Consultant, Lex Regulatory Ltd

- National and global updates on novel and forthcoming guidance
- Learnings from regulator knock-backs of BLAs/MAAs
- Regulator perspectives on the evolving cell therapy and gene therapy CMC landscapes
- Impact of the EMA's 'principles of GMP for manufacturing of starting materials of biological origin used to transfer genetic materials for the manufacture of ATMPs'
- Managing different regulations in countries receiving centrally manufactured modified cell products and gene therapies
- Expedited development pathways (eg. EU PRIME)
- Regulations regarding combination products
- Environmental Risk Assessment (ERA) for medicinal products containing/consisting of genetically modified organisms
- Regulating unproven stem cell treatment/medical tourism
- Disconnects between science and ethics

AUG — New horizons in cellular immunotherapy

- Impact on CoGs, product quality, and manufacturing cycle time and complexity of the range of cell engineering platform options
- Emerging technologies to improve targeting of the tumor microenvironment and reduce toxicity issues
  - Multiomics, single cell sequencing/analysis, non-invasive spatial imaging, novel in vitro cell/tissue models, computational biology and big data analysis, machine learning and AI
- Next generation cellular immunotherapy modalities
- T cell immunotherapies: what improvements are being made in enhancing safety, efficacy, and durability?
  - Optimization approaches for allogeneic cell therapies
  - Non-T-cell CARs (eg. NK-CARs, CAR macrophages)
  - Optimization of tumor infiltrating lymphocyte autologous therapies
  - Innovation in alternative cell therapy molecular design and multiplex cell engineering
- How to approach antigen discovery in the solid tumor setting?
- Current trends and future directions in combination therapy selection
- How far away is *in vivo* gene immunotherapy?

SEP — Cell and gene therapy manufacturing scale-up/scale-out

- Increasing availability of 'right-sized', built-for-purpose cell and gene therapy bioprocessing technology on scale-up/-out approaches
- Viral vector scale-up/scale-out: progress in scaling manufacturing platforms and boosting yields to enable the ongoing migration to larger indications
  - Facilities designed for <2,000 L production capacities: challenges at large production scales
    - Safeguarding against over- and under-sizing vector manufacturing facilities
  - Scale-up of adherent bioreactors
  - Improving scalability of transient transfection processes
- Exploring scalability-related pros and cons of emerging non-viral gene delivery platforms
- Allogeneic cell therapy scale-up
- Autologous cell therapy scale-out: centralized vs decentralized
- Addressing the shortage in adequately trained/experienced personnel

OCT — Gene therapy CMC and analytics

GUEST EDITOR: Anindya Dasgupta, Director, Vector Development, Expression Therapeutics

- Improving the speed and cost-effectiveness of vector bioprocessing and the identification and measurement of quality attributes using cutting edge analytical tools
  - PAT to accelerate bioprocess monitoring/testing
  - Throughput-related issues
  - Empty/full capsid ratio: assessing current tools and methodologies
  - Next-generation sequencing in gene therapy product development and manufacture
  - Measuring the impact of AAV vector engineering methods on the capsid and its transduction profile
  - Standards and assay options for viral clearance and adventitious agent control in gene therapy manufacture
  - Reducing the amount of final vector product required for QC and release testing
  - In-process analytics and controls in the gene therapy field
- CMC data required for an ultra-rare disease indication
  - 'Plug-and-play' gene therapy platforms for ultra-rare indications
- How is regulatory evolution reshaping the gene therapy CMC space?
  - Changes in CMC guidance
  - Potency assays

NOV — Cell therapy bioprocessing

- Cost of goods reduction and streamlining/simplifying manufacture
  - Allogeneic cell therapy
  - Reducing manufacturing process cycle times
  - Managing the number and complexity of gene edits
  - Industrializing manufacture of extracellular vesicle/exosome-based therapies
- Automation and fully closed systems for cell therapy manufacturing
  - CoGs analysis for closed/automated cell therapy bioprocessing tools
  - Modular options to automate individual steps of the process
- Cell differentiation approaches for cell therapy
- Pros and cons of novel fill-finish platforms
- Ensuring reduced timeframes for process development activities alongside earlier process-related decision-making
- What does phase-appropriate GMP look like in practice?
- Protecting GMP cell therapy manufacturing from COVID-19
  - What will GMP manufacturing in the 'new normal' look like?

DEC — Tools of tomorrow

- Cell & Gene Therapy Insights' annual exploration of enabling tools and therapeutic technology platforms likely to make a splash in 2023.

2022

CELL & GENE THERAPY INSIGHTS

EDITORIAL CALENDAR

Channel editions and newsletters

	JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE
Channel Editions Published quarterly: -Vector - Supply Chain - Analytics		VECTOR: Enhancing vector bioprocess scalability	ANALYTICS	SUPPLY CHAIN: Best practices for ensuring cell and gene therapy supply chain scalability	VECTOR: Vector characterization	ANALYTICS
Channel Newsletters		Manufacturing Vector	Manufacturing Vector Analytics	Manufacturing Vector Supply chain	Manufacturing Vector	Manufacturing Vector Analytics

	JULY	AUGUST	SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER
Channel Editions Published quarterly: -Vector - Supply Chain - Analytics	SUPPLY CHAIN: Driving the digitization of cell and gene therapy supply chains	VECTOR: Upstream Bioprocessing	SUPPLY CHAIN: Optimizing raw materials quality ANALYTICS	VECTOR: Downstream bioprocessing	SUPPLY CHAIN: Starting materials sourcing and management	ANALYTICS
Channel Newsletters	Manufacturing Vector Supply chain	Manufacturing Vector	Manufacturing Vector Analytics	Manufacturing Vector Supply chain	Manufacturing Vector	Manufacturing Vector Supply chain Analytics

Vector Channel

Frequency: 4 themed editions per year and 12 newsletters per year

Format: Channel content

Enhancing vector bioprocess scalability

Vector characterization

Upstream bioprocessing

Downstream bioprocessing

Supply Chain Channel

Frequency: 4 themed editions and newsletters per year

Format: Channel content

Best practices for ensuring cell and gene therapy supply chain scalability

Driving the digitization of cell and gene therapy supply chains

Optimizing raw materials quality

Starting materials sourcing and management

Analytics Channel

Frequency: 4 editions and newsletters per year

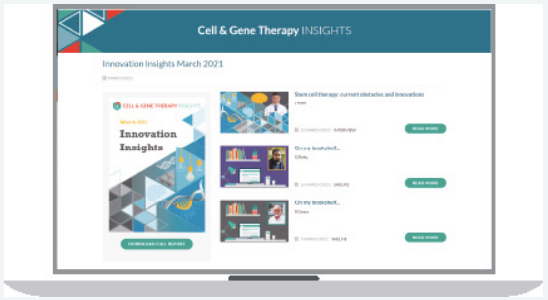
Format: Channel content

2022

CELL & GENE THERAPY INSIGHTS

EDITORIAL CALENDAR

Reports



	JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE
Reports	$ Business Insights	Clinical Trends Innovation Insights	Regulatory Insights	$ Business Insights	Clinical Trends Innovation Insights	

	JULY	AUGUST	SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER
Reports	$ Business Insights	Innovation Insights	Clinical Trends	Innovation Insights	$ Business Insights Clinical Trends	Regulatory Insights

Innovation Insights

Frequency: Quarterly

Format: Newsletter

CGTI's quarterly review of the latest technological and scientific advances and breakthroughs across the cell and gene therapy space.

Regulatory Insights

Frequency: biannually

Format: Newsletter

Latest regulatory guidance relating to cell and gene therapy development and manufacture from around the globe. Includes commentary and navigational advice from the regulators themselves, as well as expert analysis of the true significance for the field of specific guidelines and legislation.

Clinical Trends & Data Updates

Frequency: Quarterly

Format: Newsletter

Providing a regular update on the key clinical stories and data read-outs from the preceding quarter, this report also offers commentary and insights from some of the cell and gene therapy world's foremost translational and clinical R&D experts.

Business Insights

Frequency: Quarterly

Format: Newsletter

A blend of *CGTI*'s Investor Insights and Commercial Insights reports, this novel quarterly will also host our market access coverage.

Contact Nicola McCall on +44 1732 463215 or n.mccall@insights.bio to discuss thought leadership and lead generation opportunities