

2021 EDITORIAL CALENDAR

		0701 JANUARY	0702 FEBRUARY	0703 MARCH
		 SPOTLIGHT	Preclinical/translational tools and strategies	
		 CHANNEL CONTENT or FOCUS	 New vectors – update on emerging viral and non-viral delivery platforms	 Manufacturing
		NEWSLETTERS	\$ Business insights	 Innovation insights  Regulatory insights
0704 APRIL	0705 MAY	0706 JUNE	0707 JULY	0708 AUGUST
Viral vector bioprocessing	Cell Therapy CMC and quality control	Gene delivery platform evolution	Clinical trial design, supply chain and operations	
 Manufacturing	 Manufacturing	 Manufacturing	 Manufacturing	 Manufacturing
 Ensuring supply chain scalability for cell and gene therapy products		 Vector characterization and analytics	 Honing global commercial strategies	
\$ Business insights  Clinical trends	 Innovation insights	 Regulatory insights	\$ Business insights  Clinical trends	 Innovation insights
0709 SEPTEMBER	0710 OCTOBER	0711 NOVEMBER	0712 DECEMBER	KEY
Scale-up and scale-out - what do we really need and how will we get there?	Gene therapy CMC and quality control	Cell therapy bioprocessing and automation	2021 wrap-up & tools of tomorrow	 Manufacturing channel: published monthly
	New horizons for cell therapy: emerging platforms			 Vector channel: published quarterly
 Manufacturing	 Manufacturing	 Manufacturing	 Manufacturing	 Supply chain focus: published quarterly
 Upstream bioprocessing	 Trends and opportunities in raw material sourcing	 Downstream bioprocessing	 Starting material collection and optimization	 Regulatory insights
 Regulatory insights	\$ Business insights  Clinical trends	 Innovation insights	 Regulatory insights	 Innovation insights
				\$ Business insights
				 Clinical trends

Quarterly newsletters



2021 Spotlights

JANUARY	FEBRUARY	MARCH	APRIL	MAY
	Preclinical/translational tools and strategies	Raw & Starting materials	Viral vector bioprocessing	Cell Therapy CMC and Quality Control Cellular immuno-oncology – overcoming manufacturing and development obstacles to commercial success
JUNE	JULY	AUGUST	SEPTEMBER	OCTOBER
Gene delivery platform evolution	Supply Chain, Operations and Trial Designs		Scale-up and scale-out - what do we really need and how will we get there?	Gene therapy CMC and quality control New horizons for cell therapy: emerging platforms
NOVEMBER	DECEMBER	Each Spotlight Will Comprise: <ul style="list-style-type: none">▶ 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		Cell & Gene Therapy Insights' Spotlights provide you with fantastic opportunities to: <ul style="list-style-type: none">▶ 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.
Cell therapy bioprocessing and automation	2021 Wrap-up & Tools of Tomorrow			



Preclinical/translational tools & strategies

GUEST EDITOR: TBC

Assessing emerging technological innovation and collaborative strategies to drive time/cost efficiencies and valuable translational insights in non-clinical development

- ▶ As the cell and gene therapy field expands into new, more complex diseases, pathways and targets, what are the key methods and tools, and where are most pressing innovation requirements, for preclinical/translational R&D?
- ▶ Where is tangible progress being made in developing animal models that can deliver clinically translatable insights?
- ▶ How are novel/alternative non-clinical models and methods shaping up in terms of enhancing translatability to human diseases?
- ▶ Preclinical assay 101: defining the key considerations/requirements and clarifying timeframes relating to successful preclinical assay development
- ▶ Integrating early process development with preclinical/translational development



Raw & starting materials

GUEST EDITOR: Elizabeth Read, Principal Consultant, EJ Read Consulting LLC

Examining risk mitigation best practices and exploring emerging challenges/opportunities for an expanding cell and gene therapy sector

- ▶ What lessons has the cell and gene therapy field learned about the raw and starting materials supply chain from the COVID-19 pandemic?
- ▶ What is the latest progress in ensuring a sufficient supply of starting materials for specific, rapidly expanding cell and gene therapy technology areas?
 - ▶ Eg. how are donor management strategies and cell conversion methods evolving to enable the allogeneic cell therapy field?
- ▶ Driving improvements in the consistency, reproducibility and traceability of reagents and other critical raw/ancillary materials for cell and gene therapy manufacture
- ▶ How to predict, measure and manage the impact downstream of variability in cell therapy starting materials?
- ▶ Key considerations and preparations for effectively managing materials supply risk and meeting regulatory requirements in the post-market approval setting.



Viral vector bioprocessing

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

Two decades on from the advent of commercial-scale protein therapeutics manufacture, is the viral vector space ready to make its own rapid advance towards industrialization?

- ▶ Are we ready to deliver improvements required in upstream yield and downstream throughput to finally alleviate the current bioprocessing bottlenecks affecting both AAV and lentiviral/retroviral vector production?
- ▶ Customized versus repurposed bioprocessing tools – what has been the impact on key steps in gene therapy processing from the emergence of more fit-for-purpose enabling technologies (eg. in the separation area)?
- ▶ What is the latest progress in terms of cost and time savings in viral vector bioprocessing, and what elements should we target for further gains moving forward?
- ▶ Key considerations for both in-house and outsourced viral vector manufacture in the current environment

Cell therapy CMC & quality control



Immuno-oncology: cellular – overcoming manufacturing & development obstacles to commercial success

GUEST EDITOR: Dr Christiane Niederlaender, Vice President Technical, Parexel

Learning lessons from recent setbacks, utilizing novel technological innovation, and defining key steps from early development towards delivering robust data packages

- ▶ How will evolving regulatory guidance and manufacturing strategy trends impact approaches to demonstrating comparability and potency of cell therapy products?
- ▶ Examining challenges in, and benefits from, implementing Quality by Design and Design of Experiments methodologies for cell therapy manufacture
- ▶ Technology evolution: what efficiencies and consistency/quality-related benefits are emerging process analytical tools delivering in practice to cell therapy developers and manufacturers?
- ▶ Automation and associated analytics: what is the current state-of-the-art in cell therapy?
- ▶ How to effectively harness and extract value from large analytical data sets to the benefit of cell therapy manufacturers?
- ▶ What progress in accelerating release testing to help further reduce manufacturing timeframes?

GUEST EDITOR: Fritz Fiesser, Director, C> Engineering and Informatics, GlaxoSmithKline

How sustainable are the manufacturing and commercialization models of leaders in the cellular immunotherapy field?

- ▶ What can we glean from macro investment, biopharma innovation, and cancer healthcare trends to inform future cell and gene therapy clinical development, manufacturing and commercialization strategies?
- ▶ How are leading developers of both autologous and allogeneic cellular immunotherapies and supporting tool and service providers alike addressing challenges relating to:
 - ▶ Cost of goods control?
 - ▶ Minimizing manufacturing and supply chain timeframes?
 - ▶ Optimizing bioprocess and supply chain quality/robustness?
- ▶ What has the cellular immunotherapy sector learned from the COVID-19 pandemic?



Gene delivery platform evolution

GUEST EDITOR: TBC

How are cutting-edge R&D/technological innovation and a growing understanding of human and disease biology driving the expansion of gene therapy and gene editing into new, larger markets and indications?

- ▶ Predicting next steps for gene therapy R&D in the traditional stronghold of rare monogenic diseases
- ▶ Continuing the drive of gene editing into clinical application:
 - ▶ How are genome editing platforms evolving in the context of their applications in the burgeoning allogeneic cell therapy field?
 - ▶ Reviewing emerging gene editing platforms and their relative pros and cons versus established tools
- ▶ How successfully are current R&D approaches, such as next-gen vector engineering, at tackling key obstacles to the widespread and long-term success of in vivo gene therapy?
- ▶ Brave new world: assessing evidence of early progress in terms of gene therapies delivering both clinical efficacy and safer delivery strategies in larger indications



Supply chain, operations & trial designs

GUEST EDITOR: TBC

Ensuring strategic and operational excellence in the increasingly competitive world of cell and gene therapy clinical development

- ▶ Assessing the longer-term repercussions of the COVID-19 pandemic for cell and gene therapy clinical development
- ▶ How is competition for patients in key indications driving innovation in patient recruitment within the cell and gene therapy space?
- ▶ Weighing up the pros and cons of recent innovation in both clinical development tools and trial designs
 - ▶ How should the cell and gene therapy field capitalize on the potential of Patient Reported Outcomes to bring both efficiencies and increased robustness to clinical development?
 - ▶ Adaptive trial designs
 - ▶ Biomarkers and surrogate markers linked to evidence of clinical effectiveness and response to treatment in cell and gene therapy: Recent progress and regulatory implications.
 - ▶ Capitalizing on increasing interaction and convergence between the cell and gene therapy, *in vitro* diagnostics, and medical device fields



Scale-up & scale-out: what do we really need & how will we get there?

GUEST EDITOR: Dr Jan Thirkettle, Chief Development Officer, Freeline Therapeutics

Identifying and addressing critical scalability bottlenecks in cell therapy and viral vector bioprocessing and supply chain to enable large-scale manufacture of advanced therapies

- ▶ Considerations for effective viral vector scale-up and scale-out with both insect and mammalian cell culture systems
- ▶ Improving the scalability of allogeneic cell therapy platforms (eg. iPSCs, extracellular vesicles)
- ▶ What should the future of scaled-out commercial autologous cell therapy manufacture actually look like?
 - ▶ Assessing the advantages and limitations of current tools and processes through this lens
- ▶ How to ensure that PAT-derived data management and integration doesn't apply the handbrake to rapid, robust scale-up/-out?
- ▶ What progress in delivering turnkey manufacturing platforms and solutions for the cell and gene therapy space to enable a stronger early-stage focus on scale-up?
- ▶ Key do's and don'ts for an effective integrated approach to materials supply chain and bioprocess scale-up



Gene therapy CMC & quality control

GUEST EDITOR: Christine Le Bec, Head, CMC, Gene Therapy, Sensorion

Is recent innovation in analytical tools delivering the required improvements in cost, speed and accuracy for vector manufacturing?

- ▶ How and where are process analytical tools being successfully incorporated/integrated into viral vector bioprocess tools/steps, and where is further innovation required in this regard?
- ▶ What is the state-of-the-art in accelerated release testing for gene therapy products?
- ▶ Manufacturer and regulator perspectives on viral vector purity testing requirements and the utility of current tools
- ▶ How will evolving regulatory guidance and manufacturing strategy trends impact approaches to demonstrating comparability and potency of gene therapy products?
- ▶ Examining challenges in, and benefits from, implementing Quality by Design and Design of Experiments methodologies for gene therapy manufacture
- ▶ Is it time to prepare for continuous manufacture of gene therapy products? If so, what are the initial steps?



New horizons for cell therapy: emerging platforms

GUEST EDITOR: Tamara Laskowski, Scientific Project Director at MD Anderson Cancer Center

An exploration of the cutting-edge in next-gen cell therapy technology platforms and applications spanning the cellular immunotherapy and stem cell therapy realms

- ▶ Update on preclinical and early clinical-stage cell therapy platforms, with analysis of data generated to date, and discussion of how specific challenges and considerations relating to their ongoing development will be addressed – to include:
- ▶ Cellular Immunotherapies (eg. novel CAR T, TCR and NK cell therapy approaches)
 - ▶ Progress on the migration into solid tumor indications – how are obstacles presented by the tumor microenvironment being approached? What is the latest thinking on the potential role/utility of cellular immunotherapy in the combination therapy setting?
 - ▶ Profiling the continuing expansion of engineered cells (eg. T cells, NK cells, macrophages) into non-cancer therapeutic areas and indications
- ▶ Are MSCs back for the long-term?
- ▶ Exosomes



Cell therapy bioprocessing & automation

GUEST EDITOR: Qasim Rafiq, Associate Professor of Cell & Gene Therapy Bioprocess Engineering at University College London

How recent technological advances and economic/healthcare/regulatory evolution have helped ignite the centralized versus distributed manufacturing debate

- ▶ How far have we come in automating cell therapy manufacture, and how far have we got to go? Assessing successes and setbacks to date, as well as key areas for future focus
 - ▶ How has the 'unit operations vs. GMP-in-a-box' debate moved on over recent times? And where next for either approach?
 - ▶ Automation of analytics – reviewing recent advances in enabling fully closed system manufacture, and creating the feedback loops necessary for true manufacturing automation
- ▶ What do the latest cost analyses for centralized and various distributed cell therapy manufacturing models tell us about their current relative efficiency? How is this picture evolving?
- ▶ Just how far away – and how desirable – is point-of-care manufacturing? Healthcare sector, industry, academic and regulatory perspectives
- ▶ Exploring the interface between tool development and trends in cell therapy manufacturing facility design – what do they mean for the cell factory of the future?




2021 wrap-up/tools of tomorrow

Cell & Gene Therapy Insights' annual review of the year just gone, with trends analysis providing pointers to the likely big stories and developments in the 12 months ahead. Combined with an exploration of enabling tools and therapeutic technology platforms likely to make a splash in 2022.

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

Channels

KEY	FEBRUARY	MARCH	APRIL	MAY	
 Manufacturing channel: published monthly		 Manufacturing	 Manufacturing	 Manufacturing	
 Vector channel: published quarterly	 New vectors – update on emerging viral and non-viral delivery platforms				
 Supply chain focus: published quarterly			 Ensuring supply chain scalability for cell and gene therapy products		
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 Manufacturing	 Manufacturing	 Manufacturing	 Manufacturing	 Manufacturing	
 Vector characterization and analytics			 Upstream bioprocessing		
	 Honing global commercial strategies			 Trends and opportunities in raw material sourcing	
NOVEMBER	DECEMBER	 Vector Channel Frequency: 4 themed editions per year Format: Channel content <ul style="list-style-type: none"> ▶ New vectors – update on emerging viral and non-viral delivery platforms ▶ Vector characterization and analytics ▶ Upstream bioprocessing ▶ Downstream bioprocessing 		 Supply Chain Channel Frequency: 4 themed editions per year Format: Channel content <ul style="list-style-type: none"> ▶ Ensuring supply chain scalability for cell and gene therapy products ▶ Honing global commercial strategies ▶ Trends and opportunities in raw material sourcing ▶ Starting material collection and optimization 	
 Manufacturing	 Manufacturing				
 Downstream bioprocessing	 Starting material collection and optimization				


Newsletters and Updates

NEWSLETTERS 2021		JANUARY	FEBRUARY	MARCH
		 Business Insights	 Clinical trends	 Innovation insights  Regulatory insights
APRIL	MAY	JUNE	JULY	AUGUST
 Business insights	 Innovation insights	 Regulatory insights	 Business insights	 Innovation insights
 Clinical trends			 Clinical trends	
SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER	KEY
 Regulatory insights	 Business insights	 Innovation insights	 Regulatory insights	 Regulatory insight  Innovation insight  Business insights  Clinical trends
	 Clinical trends			

 **Innovation Insights**

Frequency: Quarterly or Bimonthly
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: Quarterly
Format: Newsletter

Your opportunity to get updated on the very latest evolution in 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 brand new blend of CGTI's Investor Insights and Commercial Insights reports, this novel quarterly will also host our market access coverage for 2021.