

EDITORIAL CALENDAR



SPOTLIGHT

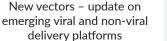


CHANNEL CONTENT or FOCUS

0701 JANUARY

0702 FEBRUARY

Preclinical/translational tools and strategies





Manufacturing

0703 MARCH

Raw and starting materials

NEWSLETTERS

\$ **Business insights**



Clinical trends

0707 JULY

Clinical trial design, supply chain

and operations



Innovation insights Regulatory insights

0708 AUGUST

0704 APRIL

Viral vector bioprocessing

control

overcoming manufacturing and development obstacles to



Cell Therapy CMC and quality

Cellular immuno-oncology commercial success



Manufacturing



Gene delivery platform evolution



Manufacturing

Honing global commercial

strategies



Manufacturing

Ensuring supply chain scalability for cell and gene therapy products

Manufacturing

Business insights



Clinical trends



Innovation insights



Regulatory insights

Manufacturing

Vector characterization and

analytics



Business insights Clinical trends

0712 DECEMBER

2021 wrap-up & tools of

tomorrow



Innovation insights

KEY

Manufacturing channel:

published monthly

Vector channel: published

quarterly Supply chain focus:

published quarterly

0709 SEPTEMBER

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



Manufacturing



Upstream bioprocessing



Regulatory insights

0710 OCTOBER

Gene therapy CMC and quality control

New horizons for cell therapy: emerging platforms



Manufacturing



Trends and opportunities in raw material sourcing



Business insights Clinical trends



0711 NOVEMBER

Cell therapy bioprocessing and automation



Manufacturing



Downstream bioprocessing



Innovation insights



Manufacturing



Starting material collection and optimization

Regulatory insights



Regulatory insights

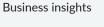






Clinical trends









2021 Spotlights

JANUARY	FEBRUARY	MARCH	APRIL	MAY	
				Cell Therapy CMC and Quality Control	
	Preclinical/translational tools and strategies	Raw & Starting materials	Viral vector bioprocessing	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:	Cell & Gene Therapy Insights' Spotlights provide you with fantastic		
Cell therapy bioprocessing and automation	2021 Wrap-up & Tools of Tomorrow	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	 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. 		



Preclinical/translational tools & strategies



Raw & starting materials

J J APR

Viral vector bioprocessing

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

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.

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



Gene delivery platform evolution

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/qualityrelated 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-theart 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, biophama 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?

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



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



Gene therapy CMC & quality control

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

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

GUEST EDITOR: TBC

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



Cell therapy bioprocessing & automation



2021 wrap-up/tools of tomorrow

GUEST EDITOR: TBC

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

GUEST EDITOR: TBC

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?

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.

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to discuss thought leadership and lead generation opportunities associated with the Spotlights

Channels

	KEY	FEBRUARY	,	MARCH		APRIL		MAY	
O	Manufacturing channel: published monthly			Manufacturing	\bigcirc	Manufacturing		Manufacturing	
	Vector channel: published quarterly	New vectors – upo emerging viral and r delivery platfor	non-viral						
6 9	Supply chain focus: published quarterly					ring supply chain scalabilit or cell and gene therapy products	У		
	JUNE	JULY		AUGUST	S	EPTEMBER		OCTOBER	
\bigcirc	Manufacturing	Manufacturin	ng	Manufacturing		Manufacturing		Manufacturing	
	Vector characterization and analytics					Jpstream bioprocessing			
		Honing global com strategies	mercial				F Tre	ends and opportunities in raw material sourcing	
	NOVEMBER	DECEMBER		Vector Chann	el	R	Supply Cha	in Channel	
O	Manufacturing	Manufacturin	Form	uency: 4 themed editions per yea at: Channel content		Frequency: 4 themed editions per year Format: Channel content			
	Downstream bioprocessing		de ▶ Ve	 New vectors - update on emerging vector delivery platforms Vector characterization and analytics Upstream bioprocessing 		products Honing globa		ply chain scalability for cell and gene therapy al commercial strategies apportunities in raw material sourcing	
		Starting material colle optimization	ection and	ownstream bioprocessing		 Starting material collection and optimization 			

Newsletters and Updates





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.



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.



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.



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.