CELL & GENE THERAPY INSIGHTS

2021 EDITORIAL CALENDAR

SPOTLIGHT

CHANNEL CONTENT or FOCUS

NEWSLETTERS

0701 JANUARY

$ Business insights

0702 FEBRUARY

Preclinical/translational tools and strategies

New vectors – update on emerging viral and non-viral delivery platforms

Clinical trends

0703 MARCH

Raw and starting materials

Manufacturing

Innovation insights

Regulatory insights

0704 APRIL

Viral vector bioprocessing

Manufacturing

Ensuring supply chain scalability for cell and gene therapy products

$ Business insights

Clinical trends

0705 MAY

Cell Therapy CMC and quality control

Cellular immuno-oncology – overcoming manufacturing and development obstacles to commercial success

Manufacturing

Innovation insights

0706 JUNE

Gene delivery platform evolution

Manufacturing

Vector characterization and analytics

Regulatory insights

0707 JULY

Clinical trial design, supply chain and operations

Manufacturing

Honing global commercial strategies

$ Business insights

Clinical trends

0708 AUGUST

Manufacturing

Innovation insights

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

0712 DECEMBER

2021 wrap-up & tools of tomorrow

Manufacturing

Starting material collection and optimization

Regulatory insights

KEY

Manufacturing channel: published monthly

Vector channel: published quarterly

Supply chain focus: published quarterly

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
Cell therapy bioprocessing and automation	2021 Wrap-up & Tools of Tomorrow

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**

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.

FEB — 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

MAR — 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.

APR — 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

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?

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

GUEST EDITOR: Fritz Fiesser, Director, C&GT 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?

JUN — 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

JUL — 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

SEP — 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

OCT — Gene therapy CMC & quality control

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?

OCT — New horizons for cell therapy: emerging platforms

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

NOV — Cell therapy bioprocessing & automation

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?

DEC — 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.

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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	

JUNE	JULY	AUGUST	SEPTEMBER	OCTOBER
Manufacturing	Manufacturing	Manufacturing	Manufacturing	Manufacturing
Vector characterization and analytics			Upstream bioprocessing	
	Honing global commercial strategies			Trends and opportunities in raw material sourcing

NOVEMBER	DECEMBER
Manufacturing	Manufacturing
Downstream bioprocessing	
	Starting material collection and optimization

Vector Channel

Frequency: 4 themed editions per year

Format: Channel content

- 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

- 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

Newsletters and Updates

NEWSLETTERS 2021

JANUARY
- $ Business Insights

FEBRUARY
- Clinical trends

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- Innovation insights
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- Innovation insights

DECEMBER
- Regulatory insights

KEY
- Regulatory insight
- Innovation insight
- $ Business insights
- 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.