2020 EDITORIAL CALENDAR

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FEBRUARY

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Suspension culture systems

Clinical trends

MARCH

Raw and starting materials: troubleshooting supply, management and optimisation issues

Manufacturing

Global cell & cene therapy supply chain strategies at commercial scale

Innovation insight

Regulatory insight

APRIL

Viral vector bioprocessing & analytics: today's key tools and innovation requirements to meet future demand

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MAY

Trends and advances in gene therapy delivery and gene editing

Clinical development strategy, tools and trial designs

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Immuno-oncology: manufacturing and commercial business models for the new decade

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Regulatory insight

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Vector characterisation and validation

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Market access: evolving commercialisation trends and strategies

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Scaling up/out: cost-effective and robust transitioning through the clinic to commercial manufacture

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New horizons in cellular immunotherapy: next-gen platforms and modalities

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NOVEMBER

Cell therapy bioprocessing and analytics: today's key tools and innovation requirements to meet future demand

Manufacturing

Critical raw & ancillary materials

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DECEMBER

Round-up of the year and expert predictions for 2021

Manufacturing

Purification

Regulatory insight

KEY

Manufacturing channel: published monthly

Vector channel: published quarterly

Supply chain focus: published quarterly

Regulatory insight

Innovation insight

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Quarterly newsletters

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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 and translational R&D insights

GUEST EDITOR: Karen Kozarsky, PhD, Founder & CSO, SwanBio Therapeutics

- *In vivo* and *in vitro* tools in application – which ones are providing the greatest depth of insight in terms of predicting clinical safety and efficacy?
  - How to address the shortfalls in current hPSC-based preclinical models?
- How to optimise integration of bioprocess development with preclinical R&D?
- Regulatory and operational best practice for preclinical-clinical translation of cell & gene therapies
  - How are regulators' expectations and requirements changing as knowledge and experience continues to build in cell & gene therapy?
  - What to outsource and what to keep in-house?

MAR — Raw and starting materials: troubleshooting supply, management and optimisation issues

GUEST EDITOR: Dr Steven Goodman, Senior Director, Drug Product Manufacturing, bluebird bio

- Starting material variability and its impact on reproducibility – managing regulatory and commercial repercussions
- Weighing up emerging allogeneic cell sources: pros and cons in practice
  - iPSCs
  - Cord blood and tissue
- Delivering apheresis/leukapheresis best practices
- Securing supply of critical raw materials through scale-up
- Ensuring maximum quality at minimal cost

APR — Viral vector bioprocessing & analytics: today's key tools and innovation requirements to meet future demand

GUEST EDITOR: Nolan Sutherland, Senior Associate Scientist, Vector/Cellular Process Development, bluebird bio

- How to boost yield and titer throughout upstream and downstream bioprocessing?
- Cutting edge closed, automated systems – can we quantify the impact on cost, quality and productivity?
- Viral vector process controls and analytics – how close are we to an era of precision manufacturing in gene therapy?
  - Assessing novel tools in practical application – how are they impacting cost, speed and quality?
  - Where are the critical remaining gaps in the toolbox?

MAY — Trends and advances in gene therapy delivery and gene editing

GUEST EDITOR: TBC

- Innovations in viral and non-viral vector engineering and bioprocessing
- Next-generation gene editing tools – assessing the relative pros and cons of novel platforms
- Pathway to the future application of gene editing platforms in clinical application
- How to tackle the issue of immunogenicity for both viral vectors and gene editing in *in vivo* applications?

Clinical development strategy, tools and trial designs

GUEST EDITOR: TBC

- How are clinical trial designs and overall strategy evolving in the rare disease arena?
- Combination therapy development in immuno-oncology – do's and don'ts in trial design.
- Clinical operations – what are the specific considerations with cell & gene therapy products, particularly for multinational trials
- Critical considerations for cell & gene therapy development in paediatric patient populations?
- Biomarkers and surrogate endpoints linked to evidence of clinical effectiveness and response to treatment: case examples in cell & gene therapy and regulatory implications
  - Harnessing clinical patient outcomes data for biomarker development
  - What is the latest progress in identifying responders and non-responders in the immuno-oncology sphere?
- The growing influence of adaptive trial designs in cell & gene therapy
- Key lessons learned from expedited regulatory pathways

JUN — Immuno-oncology: manufacturing and commercial business models for the new decade

GUEST EDITOR: Dr Usman Azam, President & CEO, Tmunity Therapeutics Inc

- Analysing early commercial experiences with cellular immunotherapies – what lessons for the next generation of product candidates making the transition from clinical to commercial? (Eg. in terms of cost control? Market and patient access strategies?)
- Enabling allogeneic approaches
  - Are iPSCs ready to step forward? What are developers', manufacturers' and regulators' key concerns?
- Cell transduction/engineering tools and techniques – what does the future hold for viral and non-viral vectors and gene editing?
- How will decentralised manufacturing models continue to evolve and emerge?
- Global supply chain optimisation

AUG

Market access: evolving commercialisation trends and strategies

GUEST EDITOR: TBC

- Global analysis of the ongoing evolution of valuation, pricing and reimbursement models
- How will cell & gene therapies compete with each other on the market, and with what impact on pricing and reimbursement?
  - What are the key differentiators and sources of competitive advantage for cell & gene therapy products in key indications and therapeutic areas such as hematological malignancies and monogenic disorders?
  - How will the First-to-Market vs. Best-in-Class question play out in cell & gene therapy?
- How are emerging markets for cell & gene therapy products (eg. China) developing, and what are the keys to accessing them?

SEP

Scaling up/out: cost-effective and robust transitioning through the clinic to commercial manufacture

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

- Examining current trends in in-house and outsourced manufacture – where is the cell & gene therapy space heading, and why?
- Where are the key opportunities to target cost of goods reductions in both cell therapy and gene therapy today? How to capitalise upon them?
- In process and release testing – how are next-generation analytics driving improvements in product quality and accelerating manufacturing timelines?
- How to demonstrate comparability with both cell therapy and gene therapy products through the transitions between early clinical, pivotal trial and commercial phases?
- Continuous manufacture: is it likely to impact the cell & gene therapy space? If so, how and where?
- Standardisation: what are the critical next steps to further enable cell & gene therapy manufacturing?

OCT

New horizons in cellular immunotherapy: next-gen platforms and modalities

GUEST EDITOR: Dr David Morrow, ATMP & Vaccine Scientific Programme Manager, Translational Medicine & Drug Development, EATRIS

- New horizons in immuno-oncology:
  - How are emerging autologous and allogeneic approaches and immune cell types performing in preclinical and early clinical studies?
    - What is the evidence to date that they can improve rates and durability of response and address lingering safety concerns?
    - Next steps in targeting and tackling solid tumours: what have we learned from earlier approaches?
  - Preclinical to clinical translatability: overcoming *in vivo* hurdles for immuno-oncology therapies
  - Window on future enabling technologies: what impact will tools such as genome and epigenome editing have on the immuno-oncology space moving forward?
  - How are novel therapeutics combinations performing in clinical applications?
- The dawn of cellular immunotherapy in non-cancer: evaluating the promise of novel approaches in tolerisation, autoimmune diseases and diabetes.

NOV

Cell therapy bioprocessing and analytics: today's key tools and innovation requirements to meet future demand

GUEST EDITOR: John Tomtishen, Director of Manufacturing, CMC Technical Operations, Legend Biotech USA Inc.

- Step-by-step assessment of cell therapy bioprocessing tools – showcasing the state-of-the-art (including closed, automated systems and single-use technologies) for:
  - Isolation
  - Transduction
  - Expansion
  - Harvest, concentration and washing
  - Formulation and fill-finish
  - Packaging and cryopreservation
- GMP in a box: what will the next wave of 'all-in-one' solutions look like?
- Cell therapy process controls and analytics – where is progress being made in improving robustness and accelerating timelines in cell therapy manufacture?
  - How is the latest innovation in QC analytics helping reduce release testing waiting times?

DEC

Round-up of the year and expert predictions for 2021

A wrap-up of the year focused variously on different geographical regions, cell & gene therapy technology areas, indications and functions. Thought leaders from across the cell & gene therapy community will reflect on the significant events and talking points of 2019 and share their expectations for 2020 and beyond.

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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	Manufacturing
Vector channel: published quarterly	Suspension culture systems			
Supply chain focus: published quarterly		Global cell & cene therapy supply chain strategies at commercial scale		

JUNE	JULY	AUGUST	SEPTEMBER	OCTOBER
Manufacturing	Manufacturing	Manufacturing	Manufacturing	Manufacturing
	Vector characterisation and validation			Adherent culture systems
Biopreservation & cold chain logistics			Starting material optimisation	

NOVEMBER	DECEMBER
Manufacturing	Manufacturing
	Purification
Critical raw & ancillary materials	

Vector Channel

Frequency: 4 themed editions per year

Format: Channel content

- Suspension Culture
- Vector Characterisation and Validation
- Adherent Culture
- Purification

Supply Chain Channel

Frequency: 4 themed editions per year

Format: Channel content

- Global Cell & Gene Therapy Supply Chain Strategies at Commercial Scale
- Biopreservation and Cold Chain Logistics
- Starting Material Optimisation
- Critical Raw & Ancillary Materials

Newsletters and Updates

NEWSLETTERS
2020

JANUARY
- $ Investor Insight

FEBRUARY
- Clinical trends

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Innovation Insight
Frequency: Quarterly or Bimonthly

Format: Newsletter

Evaluating the latest innovations from across the sector: what platforms, tools and technologies are entering the market, and what is the potential of emerging therapeutic or delivery modalities?

Regulatory Insight
Frequency: Quarterly

Format: Newsletter

Collating the latest regulatory news from across the globe, and providing a layer of expert commentary from our Regulatory Advisory Panel.

Clinical Trends & Data Updates
Frequency: Quarterly

Format: Newsletter

Clinical Insight newsletter themes:

- Oncology
- Cardiology
- Neurology and CNS
- Ophthalmology

An overview of the latest clinical trial outcomes, with commentary and analysis from a Guest Editor. Interviews with Key Opinion Leaders and PIs provide a layer of expert insight into the trends and data.

$ Investor Insight
Frequency: Quarterly

Format: Newsletter

Collating the latest financial and investment news and analysis published in Cell & Gene Therapy Insights' Investor Corner, enhanced with expert commentary from leading investors and analysts.