# 2019 Editorial Calendar

## January
- **Spotlight**
- **Channel content**
- **Focus**

## February
- **Cell Therapy Quality/CMC & Analytics**
- **Vectors: Purification**

## March
- **Raw and Starting Materials**
- **Upstream Bioprocessing Technology Update**
- **Manufacturing**

## April
- **Manufacturing**

## May
- **Vector Process Characterization & Validation**

## June
- **Cellular Immunology 2.0**
- **Global Regulatory Update**

## July
- **Meeting Preclinical Data Requirements For Cell & Gene Therapies**
- **Vectors: Suspension Culture Methods**

## August
- **Market & Patient Access**
- **Downstream Bioprocessing Technology Update**

## September
- **Manufacturing**

## October
- **Decentralized Manufacture**
- **Vectors: Raw Materials**

## November
- **Clinical Trial Designs For Advanced Therapies**
- **Synthetic Biology/Tools of Tomorrow**
- **Vectors: Adherent Culture Methods**

## December
- **Vectors: Assays & Titering**
- **Quarterly Supply Chain Focus: Materials Collection & Logistics at the Clinical Point of Care**
- **TBA**
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

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 organizations 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.

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

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**Cell Therapy Quality/CMC & Analytics**

*Guest Editor: Greg Russotti, Vice President, Technical Operations, Celgene Cellular Therapeutics*

A perennially challenging area for cell therapy, product characterization/CMC has lately come to the fore as perhaps THE next critical manufacturing-related obstacle that must be properly addressed. Heavily funded consortia and renewed investment (from established tool providers and new faces on the cell therapy scene alike) are helping to drive technological innovation, regulatory guideline development and standardization efforts. But fundamental questions remain: which assays and solutions do you really need to employ? Whose product characterization standards should you meet? And what is the most cost-effective way to strengthen and accelerate Quality Control processes for novel cell therapies approaching commercialization?

- Recent evolution in product characterization tools (eg. flow cytometry, live cell imaging, single cell analysis)
- How to reduce the heavy burden of QC and release testing on production timelines and Cost of Goods?
- How are regulators’ expectations and requirements evolving as cell therapies continue to advance into the commercial sphere – for instance, in regard to potency and comparability?
- What is the state-of-the-art – and practical utility of – in-process analytics today?

**Raw and Starting Materials**

*Guest Editor: Rob Piperno, Director Cell and Gene Therapy QA, GlaxoSmithKline*

As the cell & gene therapy space continues to grow at a rate of knots, there is perhaps no greater bottleneck on the horizon than the supply of critical raw materials. Add in the hefty contribution they can make to overall Cost of Goods, plus a dizzying array of technological, practical, logistical, regulatory and educational challenges, and you have a potential minefield. However, materials producers/suppliers and manufacturers of both autologous and allogeneic cell & gene therapies are bringing novel innovations to the fore to ensure that raw and starting materials can be a vital source of insight, confidence and competitive advantage.

- Troubleshooting apheresis and leukapheresis processes and management
- Interrogating the predictability of raw and starting materials to inform subsequent bioprocessing
- Regulatory compliance and standardization
- Next-generation raw materials (serum-free media)

**Upstream Bioprocessing Technology Update**

*Guest Editor: TBA*

Optimizing and automating scalable bioreactors and cell culture platforms for the reliable, high quality production of cells and viral vectors alike is an area of tremendous activity and innovation in cell & gene therapy. However, this is driven by a most pressing need to advance beyond current technological limitations in order to meet burgeoning demand and to better control manufacturing costs, timelines and quality.

- Towards stable vector production platforms
- Relative pros and cons of the latest automated upstream bioprocessing unit operations and all-in-one devices
- Insights into scale-up success factors
Guest Editor: Professor R. Jude Samulski, University of North Carolina at Chapel Hill

The landmark approval of Spark Therapeutics' Luxturna changed the landscape of gene therapy forever and brought many lingering and emerging issues into sharp relief – not least, the need for viral and non-viral vector manufacturing to advance to a stage where it is genuinely fit for commercial purpose. As the current capacity crunch intensifies, the onus is on efficiency in product development and manufacture as never before.

- Advances in gene therapy characterization and QC
- Keys to successfully validating vector bioprocesses
- Latest regulatory guidance

Guest Editor: TBA

With Novartis and Kite, busying themselves with the roll out of Kymriah and Yescarta, it is timely to examine the latest progress in addressing long-standing manufacturing and supply chain-related challenges facing the cellular immunotherapy field, particularly at clinical and commercial scales.

- Assessing the latest strategic and technical solutions for autologous cellular immunotherapy product development and scalable manufacture (including automation technology)
- Next-generation CAR-T platforms, TCRs & combination approaches and enabling technologies
- Focus on the convergence of immuno-oncology and gene editing
- Progressing allogeneic cancer immunotherapy

Guest Editor: TBA

The past few years have witnessed an unprecedented increase in the range of expedited regulatory pathways potentially available to cell & gene therapy developers across the world. From RMAT to PRIME, and from Breakthrough Designation to the PMD Act, a weight of experience and insight now exists to help you capitalize on the benefits whilst avoiding the pitfalls.

- Strategic pros/cons and practical considerations with accelerated development and conditional approval pathways
- Keys to remaining nimble and flexible with clinical trial designs and parallel product/process development
- Step-by-step guides to making successful pathway applications

Guest Editor: TBA

The application of novel animal models, cutting edge in vitro and in silico tools and innovation in the biomarkers realm all hold the potential to drive cell & gene therapy product candidates into First-in-Human trials. But how are regulators’ requirements evolving as the field and its technologies mature? And which tools and techniques will deliver the clinical insights critical to longer term success?

- Current and likely future preclinical requirements for established and emerging cell & gene therapy modalities
- Accelerating toxicology studies
- Addressing the need for predictive tools in immunotherapy

Guest Editor: TBA

Recent product approvals have only increased the sense of urgency to find viable pricing and reimbursement models for cell & gene therapies. They have also brought into sharper focus the need to educate and work with a wide variety of healthcare sector stakeholders – and of course, patients themselves - to ensure society benefits fully from such novel, disruptive therapeutic technologies.

- Evaluating the suitability of evolving P+R models
- Dissecting the market and patient access approaches of cell & gene therapy sector leaders
- Multiple stakeholder engagement strategies

Guest Editor: TBA

As the need for rapid, robust and cost-effective downstream processing of cell & gene therapies has increased, so the sector’s enabling technology providers and their industrial and academic partners have invested and collaborated as never before to develop novel solutions, repurpose existing ones, and to seek clarity in regulatory guidelines and standards. Understanding exactly what benefits and advantages emerging options can offer – for example, automated and single-use tools – has never been more vital.

- Product purification and polishing (of both cell-based therapies and viral vectors)
- Fill & finish and preparation for biopreservation
- Release testing
Decentralized Manufacture

Guest Editor: TBA

Does decentralized manufacturing represent the future for commercial autologous cell & gene therapy products, and if so, where will it sit on a spectrum that stretches from regional facilities to the patient's bedside itself? The potential benefits are manifold, but imposing challenges remain – not least the issue of regulatory oversight and QC the closer one gets to the point of care. However, the will and, increasingly, the technological solutions are emerging to make this a reality.

› Making the business case for decentralized manufacturing
› Defining fit-for-purpose regulatory compliance models
› The role of automation in enabling local and point of care bioprocessing

Clinical Trial Designs For Advanced Therapies

Guest Editor: Dr Timothy Miller, President & CEO, Abeona Therapeutics

The dramatic recent growth of a dedicated clinical tools and services sector signals both the rapid maturation of the advanced therapies space, and a growing awareness that specific, fit-for-purpose clinical trial protocols are needed to cater for the nuances of this field with its widely varying component technology platforms and target indications.

› Clinical trial protocols to prepare patients for in vivo and ex vivo gene therapy
› Blueprints for clinical operations and patient recruitment success
› Utility of adaptive trial designs in cell & gene therapy

Synthetic Biology/Tools of Tomorrow

Guest Editor: TBA

Exploring the promise of synthetic biology in the cancer immunotherapy space in particular, this special edition will focus on enabling technologies at the bleeding edge with the potential to boost both safety and efficacy.

› Gene editing
› Microfluidics
› On/off switches to control T cell activation

Supply Chain Quarterly Focus

The Cell & Gene Therapy Insights quarterly focus on Supply Chain will be specifically themed and designed to provide an invaluable information source and reference point for anyone seeking to develop and implement an optimal supply chain for advanced therapy products. Covering:

› MAR: Cold Chain Management
› JUN: Data Management & Integration
› SEP: Biologistics Strategy for Scale-Up
› DEC: Materials Collection & Logistics at the Clinical Point of Care

Vector Insight

Vector Insight provides the latest news and in-depth analysis of current talking points in viral and non-viral vector engineering and manufacture, as well as gene therapy R&D and gene editing. With regular features on each major vector type, this is your one-stop-shop to stay fully up-to-date throughout the year:

› JAN: Non-Viral Delivery Mechanisms
› FEB: Purification
› JUL: Suspension Culture Methods
› OCT: Raw Materials
› NOV: Assays and Titering
› DEC: Adherent Culture Methods

Manufacturing Insight

Dedicated to advancing the discussion around the commercialization challenges faced by the sector, Cell and Gene Therapy Insights features peer-reviewed articles, interviews, news and webinars year-round, tackling the critical issues across the manufacturing pathway.

The Manufacturing Insight channel highlights the latest manufacturing-related content, with a monthly newsletter distributed to our database of 4,100 manufacturing contacts within the cell and gene therapy sector.

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