

### FOREWORD

## Spotlight on: The Integration of Manufacturing and Delivery into Healthcare Systems

Chris Mason & Elisa Manzotti

In **Part One** of our Cell & Gene Therapy Manufacturing Pathway spotlight series we focused on the early stages of product development, examining the key attributes that will eventually impact commercial viability. **Part Two** takes us on a step to evaluate potential solutions to the core manufacturing and logistical challenges involved in cost-effectively delivering cell and gene therapies to patients.

Working with our expert Guest Editors – **Dr Gregory Russotti** (Celgene Cellular Therapeutics, USA), **Dr Stephen Ward** (Cell Therapy Catapult, UK), and **Dr Peter Zandstra** (Univ. Toronto, Canada) – we have selected world-leading authors from multiple stakeholder groups: academic centers, translational institutions, cell and gene therapy manufacturers, and equipment and

service providers; all of whom are invested in progressing the translation of this promising new technology.

### Integration of manufacturing & delivery into healthcare systems

While cell and gene therapy products share the same goal for their cold chains as standard pharmaceutical and biological products, namely to ensure the product is maintained within appropriate temperature specifications en route to the patient, there are specific features of cell therapy products that make their cold chains uniquely challenging. **Francis Meacle**, **Ian Harris** (Cell Therapy, Janssen R&D), **Jeff Salkin**, **Meredith Rice Harris** (Janssen Supply Chain) discuss the unique challenges and advances in the cold-chain logistics

for cell and gene therapy products, highlighting some of the current technologies and innovative approaches being developed to facilitate the process.

**Phil Vanek** (GE Healthcare) discusses the challenges the pharmaceutical industry faces in translating laboratory research into commercially manufacturable products. He shares with us his vision for the manufacturing supply chain of the future and the critical steps along the path to achieving this.

We then examine the manufacturing and administration challenges within the point of care setting, from the perspective of the healthcare facility and the manufacturer. First **Isabelle Riviere** (Memorial Sloan Kettering Cancer Center) shares her thoughts on the key considerations and challenges

of manufacturing and administering cell and gene therapies within the clinical setting. **Brian Murphy** (Celgene Cellular Therapeutics) provides insight into the industry perspective on clinical preparation and administration of cell therapies and shares key learnings to date.

**Juergen Branke** (University of Warwick, UK), **Suzanne S. Farid** (UCL, UK) and **Nilay Shah** (Imperial College, London) provide their expert insights on the ways to improve responsiveness in the manufacturing sector, with a focus on Industry 4.0, a data-driven integrated system. The article explores what this technology-driven vision has to offer the biopharmaceutical industry, and in particular, cell and gene therapies.

Cell and gene therapies offer the potential to move towards an era of personalized medicine. **Damian Marshall, Michaela Sharpe and Stephen Ward** (Cell & Gene Therapy Catapult, UK) discuss the emerging role of personalized medicine in various cell and gene therapies, its role in health economics and challenges to its implementation.

### Innovator Insight

Our Innovator Insight articles let you hear directly from the experts in Cell & Gene Therapy Manufacturing sector, their experience and perspective on the challenges the industry faces.

**Eric Kunkel** (BioCision) discusses the translational challenges of cell therapies and the downstream path from cell therapy manufacturing through to administration into patients in the healthcare setting.

**Kevin O'Donnell & Aby Mathew** (BioLife Solutions, Inc) discuss the threats faced by cell and gene therapies during the transportation process and share with us some insight into the innovative approaches being designed to try to mitigate this effect.

We hope you enjoy the **Cell & Gene Therapy Insights** spotlight on integration of manufacturing and delivery into healthcare systems. You can access all content free of charge on the [CGTI website](#), in addition to a host of other useful content, videos and webinars in our [Manufacturing Resource Center](#).

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