



**“COMMERCIALIZATION OF CELL &
GENE THERAPY: ADVANCING
TECHNOLOGY AND INNOVATION”**

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Executive Director

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APPROVED THERAPIES

- 1. ABECMA - Celgene, a Bristol-Myers Squibb Company
- 2. BREYANZI - Juno Therapeutics, a Bristol-Myers Squibb Company
- 3. KYMRIAH - Novartis
- 4. LUXTURNA - Spark Therapeutics
- 5. PROVENGE - Dandreon
- 6. TECARTUS - Kite Pharma
- 7. YESCARTA - Kite Pharma

FDA PROJECTIONS of CGT THERAPIES

FDA anticipates approving Cell and gene therapies per year by 2025

10–20:

FDA says it will hire New clinical reviewers

50:

FDA expects to see new drug applications per year by 2020

200:

UNPRECEDENTED NATURE OF THE SUPPLY CHAIN OF CGT

Batch Size of 1
Personalized Medicine
Zero-Defect Environment
S&OP Challenge Formidable
Scale Out and Scale Up of Manufacturing
Chain of Custody & Monitoring Imperative
Extreme Temperature Control for Distribution
100% Demand-driven Patientcare
Life or Death Reality
Exorbitantly Expensive Treatment
Stringent Regulatory Requirements

AGENDA for TODAY

- New Technology
- Supply Chain Challenges
- Apheresis Centers
- Strategic Sourcing
- Scale Out of Manufacturing Processes
- Labeling, Packaging & Temperature-controlled Distribution
- The Road Ahead!

SPEAKERS



Timothy Moore
President,
PACT Pharma



Aileen Baquiran
Vice President,
Supply Chain,
Orchard
Therapeutics



Chris Bogart
Vice President,
Supply Chain,
Bayer



Dawn Henke
Senior Technical
Program
Manager,
Standards
Coordinating
Body (SCB)



Gary Hutchinson
President,
Modality
Solutions



Olive Sturtevant
Sr. Admin Dir.,
Dana-Farber
Cancer
Institute



Gregg Bodnar
Senior Client
Engagement
Manager, Be
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BioTherapies



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Let Us Begin!



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