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

Devendra Mishra
Executive Director
Bio Supply Management Alliance (BSMA)
APPROVED THERAPIES

1. ABECMA - Celgene, a Bristol-Myers Squibb Company
2. BREYANZI - Juno Therapeutics, a Bristol-Myers Squibb Company
3. KYMRHIAH - 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!
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THE CALL TO ACTION

LET US COLLABORATE TO BUILD THE ECOSYSTEM WITH

PROCESSES

PEOPLE

TECHNOLOGIES

NETWORKS

SYSTEMS

BSMA IS YOUR PLATFORM For Sharing, Learning and Networking!
THANK YOU!
Let Us Begin!

BSMA
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