RegMedNet | Spotlight

PBS BIOTECH®

Scaling up for cell and gene therapies

KEY TRENDS

WHAT AREA ARE YOU WORKING IN?

Process/ product development	Basic research/ therapeutic discovery	Therapeutic manufacturing	Quality assurance/ control
57%	**46%**	**36%**	**14%**

MOST RESPONDENTS WORK IN CELL OR GENE THERAPY DEVELOPMENT OR PRODUCTION

Yes **79%**

No **21%**

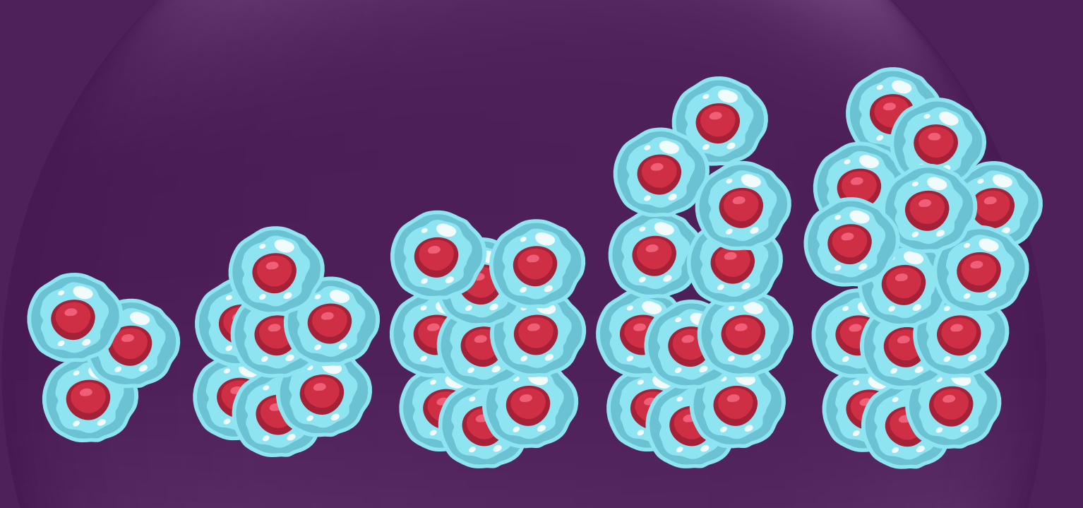
MOST RESPONDENTS WORK WITH BOTH TYPES OF CELL THERAPY

14% Autologous cell therapies

54% Both

32% Allogeneic cell therapies

WHAT CELL YIELD DO YOU REQUIRE IN YOUR WORK?



25%	**21%**	**21%**	**11%**	**21%**
< 10^9	10^9–10^{10}	10^{10}–10^{11}	10^{11}–10^{12}	>10^{12}

WHICH CELL TYPE ARE YOU PRODUCING?

54% Human primary T cells

39% Human iPSC

25% Human primary NK cells

Human primary neural stem cells **21%**

Human primary mammary epithelial stem cells **11%**

Other **25%**

Human mesenchymal stem cells
Human hematopoietic stem cells
Chondrocytes
Keratinocytes
Fibroblasts

BIOREACTOR SCALE UP: PROS AND CONS

WHAT DO YOU SEE AS THE PRIMARY ADVANTAGE OF USING BIOREACTORS FOR SCALE-UP?

28% More efficient cell expansion

28% Reduced labor

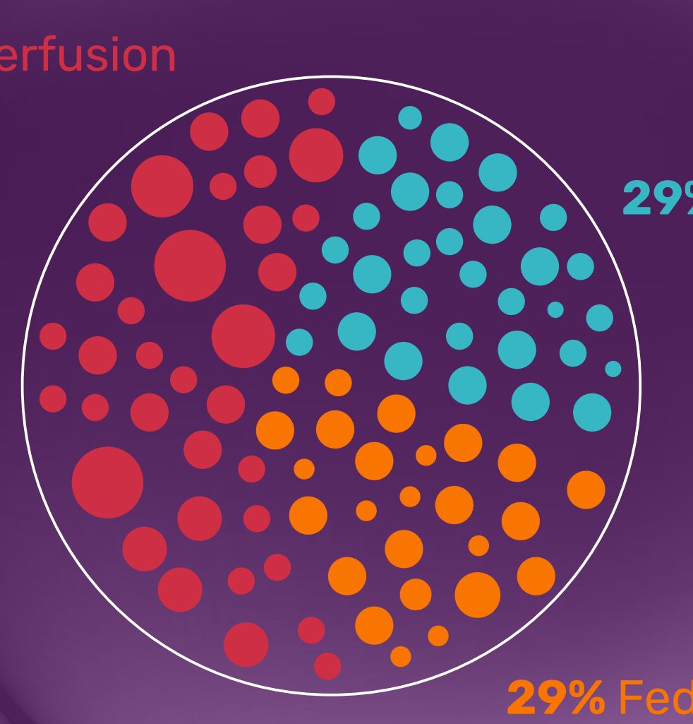
20% Greater cellular homogeneity

12% Reduced operating costs

12% Other

GMP compliance
Capacity to control and automate the process

WHAT CELL CULTURE FEEDING STRATEGY DO YOU PLAN TO UTILIZE WHEN SCALING UP?



42% Perfusion

29% Batch

29% Fed batch

WHAT DO YOU CONSIDER TO BE THE GREATEST CHALLENGE IN THE USE OF BIOREACTORS TO SCALE UP CELL YIELD?

24% Media cost

24% Lack of scalable inoculation protocols

8% Lack of scalable harvesting protocols

16% High shear stress

4% Unfavorable hydrodynamic conditions

4% Regulatory hurdles

4% Other

Lack of ability to control cell physiology during extended expansion

BIOREACTOR SCALE UP: APPROACHES AND SPECIFICATIONS

WHICH BIOREACTOR METHOD DO YOU USE FOR THE SCALE UP OF CELL YIELD?

2D (plates/flasks /cell factory) **53%**

Horizontal impeller **27%**

Rocking-wave mixing **32%**

Vertical wheel **12%**

Paddle **6%**

DO YOU USE SINGLE-USE SYSTEMS?

Yes **88%**

No **12%**

HOW COULD THE USE OF YOUR BIOREACTOR/SCALE-UP METHOD BE IMPROVED?

53% Ease of harvesting

29% Single-use sensors

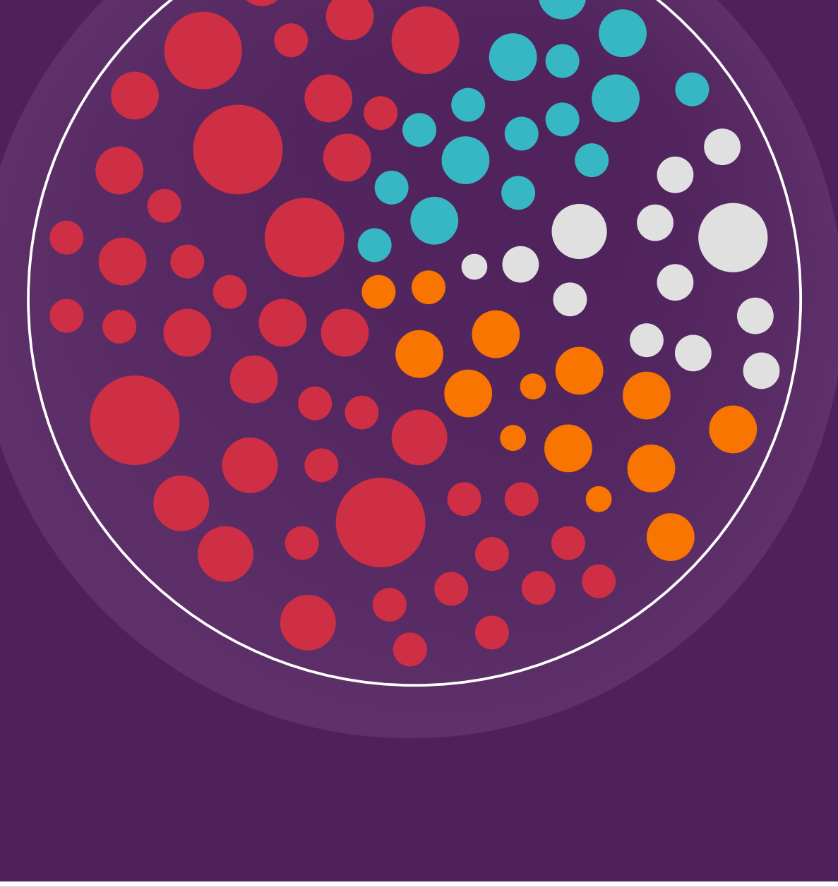
29% Better protocols

24% Closed system

24% Added ports

18% Ease of sampling

WHICH INOCULATION STRATEGY DO YOU USE?



59% Single-cell inoculation

18% Clump seeding

12% Preformed aggregate inoculation

12% Automated

SETTING UP EFFICIENT SCALE UP FOR CELL AND GENE THERAPIES

THE MOST IMPORTANT HYDRODYNAMIC CRITERIA

Distribution of turbulent energy dissipation rate **33%**

Fluid flow pattern **27%**

Fluid shear force **20%**

The volumetric gas-liquid mass transfer coefficient **13%**

Mixing time **7%**

THE MOST IMPORTANT CELL-SPECIFIC CRITERIA

Cell proliferation rate **40%**

Cell-cell adhesion strength **33%**

Cell type: anchorage dependent vs single-cell suspension **20%**

Other **7%**

phenotype

WHAT TECHNIQUES DO YOU USE TO INVESTIGATE OPTIMAL BIOPROCESS HYDRODYNAMICS?

56% Computational fluid-dynamics modeling

44% Physical testing

DEMOGRAPHICS

LOCATION

33% North America

16% Asia

40% Europe

ORGANIZATION

Pharma/Biotech **42%**

Academic **25%**

CRO/CDMO **17%**

Hospital/Clinic **17%**

Government/NGO **8%**

JOB TITLE

Researcher/Scientist **42%**

Clinician/Surgeon **8%**

Other healthcare or medical professional **17%**

Managing Director/Senior management **25%**

Student **8%**

RegMedNet | Spotlight

PBS BIOTECH®