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How current and new technologies can overcome challenges in adherent scale-up

Like any new and evolving technology area, there are growing pains and challenges that must be solved to facilitate progress in cell and gene therapy. Some pain points that are top of mind for the industry are scalability, automation, cell type flexibility and how all of these factors can affect time to market and production costs.

CHALLENGES AND HOW WE CAN OVERCOME THEM

Scalability and yield
Platforms and processes that can go from research to production while minimizing technology transfer and re-development

Automation
Monitoring and control that helps minimize opportunities for human error, reduce labor costs and increase consistency

Cell type flexibility
Platforms that support multiple cell types and workflows, maximizing utilization and training efficiency

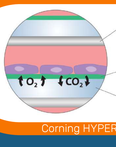
Time to market
Higher yield efficiency may mean fewer runs required, shorter production time

Production costs
Fewer runs can result in lower labor, media and reagent costs

HOW ARE WE ADDRESSING THESE HURDLES?

Let's take a look at some technological innovations enabling efficient scale-up strategies in cell and gene therapy.

1 Corning® HYPERFlask® Cell Culture Vessels



Corning HYPER Technology

- Scalable and reduced production costs - 1720 cm² growth area in the footprint of a traditional 175 cm² flask
- Multilayered gas-permeable growing surface for efficient gas exchange
- Reduced time to market - 10-fold higher cell yields
- Automation compatible

Corning CellSTACK Cell Culture Chamber (10-layer)

2 Corning® CellSTACK® Culture Chambers

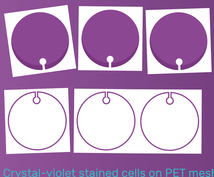
- Choice of surface treatment for efficient workflow
- Reduced time to market and production costs – greater chamber durability and cleanliness

3 Corning® HYPERStack® Cell Culture Vessel

- Scalable – 5x growth surface area of a traditional cell culture vessel of comparable footprint
- Reduced time to market and production costs - multiple size offerings to support scale up and scale out

4 Corning® Ascent™ Fixed Bed Bioreactor System

- High-density platform delivers high yield/m² and fewer required runs -- > 90% transfection efficiency, harvest recovery and cell viability



Crystal-violet stained cells on PET mesh substrate before and after harvest

Ascent FBR bioreactor disks before and after harvest. These show >90% cell recovery and >95% viable cell yield.

- High yield – innovative bioreactor design facilitates uniform media flow and uniform high-density cell growth
- Automated control, parameter monitoring -- reduces labor costs, risk of human error
- Linear scalability – multiple Ascent FBR systems, from a 1 - 5m² Process Development system to 1000m² Production system
- Cell type flexibility – enables viable cell harvests for seed train and total viral particle capture and a path for other applications, e.g. stem cell therapy workflows

This infographic was created as part of the RegMedNet In Focus on scale-up in association with Corning.

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