

# Data Driven and Cellular Kinetics Approach to Mammalian Scale-up and Transfer

FUJIFILM Biotechnologies supports partners by employing an integrated model-based scale-up and transfer strategy

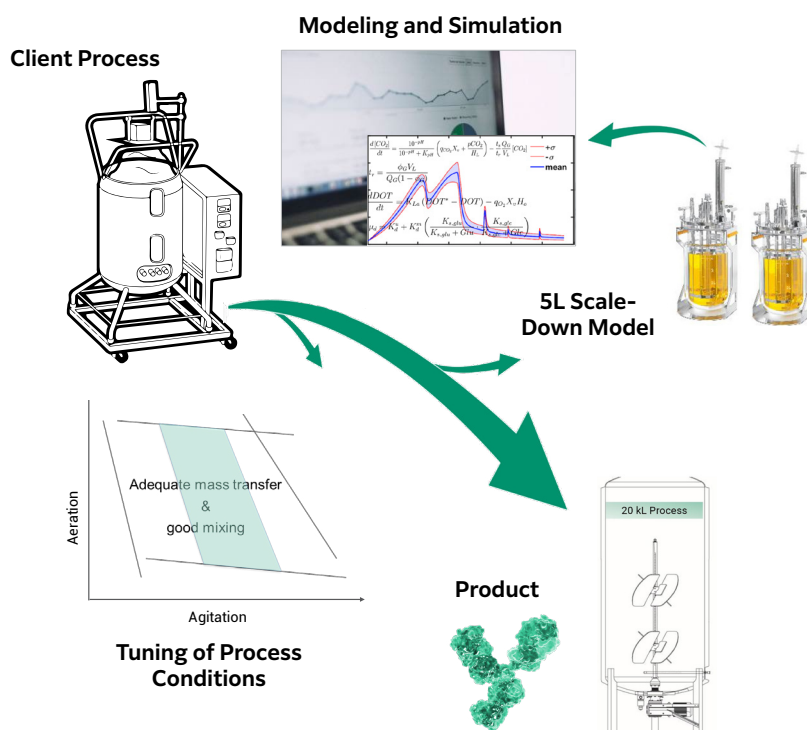
## Problem:

Biopharmaceutical demand often exceeds existing site capacity, necessitating rapid scale-up to 10,000 – 20,000 L stainless steel bioreactors. However, CHO cell culture processes are vulnerable to micro-environmental variations, which can compromise performance during transfer and scale-up.

## Solution:

FUJIFILM Biotechnologies applies a mechanistic, data-driven framework that:

- Extracts scale-independent cellular kinetics from donor data
- Assesses comparability of mass transfer and hydrodynamics coefficients vs. equipment and standards cultivation ranges
- Simulates to match donor profiles while balancing O<sub>2</sub> demand and CO<sub>2</sub> stripping
- Validate donor conditions in 5 L scale-down runs; optimize 20,000 L settings based on 5 L data.



## Impact:

This approach de-risks scale-up and improves confidence in transferring processes regardless of donor bioreactor design. It also accelerates technology transfer times and helps bridge the demand-capacity gap faster simultaneously increasing the likelihood of a successful scale-up and transfer.

Partners for *Life*

"Partners for Life" represents a transformative approach to development and manufacturing, emphasizing relationships founded on trust and transparency — founded in people-centric values, transformative science and innovation, and unprecedented delivery.

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