

COMPUTATIONAL FLUID DYNAMICS MODELING FOR FERMENTATION RISK REDUCTION DURING TECHNOLOGY TRANSFER AND PROCESS UNDERSTANDING

Tracie Spangler, Merck
tracie_saunders@merck.com
Michael Ray, Merck
Kristen Potuck, Merck
Matthew Flamm, Merck

Key Words: Computational Fluid Dynamics, Fermentation, Commercialization, Scale-Up, Facility Fit

Computational Fluid Dynamics modeling and in-depth scaling calculations have been utilized in partnership to generate data to support equipment design and facility fit during commercialization of a fermentation and primary recovery process for a vaccine candidate across multiple technical transfers. This analysis utilizing representative computer models for tank configurations, supplemented with traditional computational scaling approaches (ungassed P/V, gassed P/V, k_La , etc.), ensures full knowledge of a tank's mixing and oxygen transfer capabilities allowing process understanding and robust manufacturing across technology transfer to multiple sites. Implementation of this approach across process steps as well as manufacturing sites allows increased knowledge prior to use in a process and/or prior to construction of a new vessel, therefore contributing to successful process transfer with reduced risks upon scale-up/scale-down and new facility introductions.