APPLICATION BRIEF

Scaling Up Vaccine Production

Scaling up vaccine production from beaker to bioreactor is critical for inoculating global populations against disease. In most instances, vaccine development begins in a small beaker on a lab bench and must be rapidly scaled up — initially to meet the requirements of clinical trials and subsequently, when approved, to immunize billions of people. Of course, in an ideal world, we could simply manufacture bigger beakers capable of mixing more vaccine. Unfortunately, as nonlinear laws of physics govern fluid flow, scaled-up vaccine production necessitates more than a beaker on steroids: It requires vastly different industrial equipment and operating parameters. Scaling up is a high stakes process: Improperly designed or operated bioreactors can cause months-long delays and cost millions of dollars in wasted raw materials. Engineers use field-tested Ansys computational fluid dynamics (CFD) simulations to scale up bioreactors for vaccine production and other applications.

Products Used:

Ansys Fluent
Ansys CFD

/ Solution

Successful vaccine manufacture requires effective mixing. Ansys Fluent and Ansys CFD solve the fundamental nonlinear flow physics found in bioreactors. This simulation capability is used throughout the industry to reduce risk and improve productivity in bioreactors. Common bioreactor scale-up issues include:

Blend time simulation is a universal metric for successful mixing that affects the bioreactor holistically. Blend time is often used to ensure nutrient addition will not locally change pH too extensively in cell cultures. Mixing non-Newtonian materials is supported. Power per unit volume, turbulence, swirl, shear rate, velocity and other foundational bioreactor scale-up factors are predicted and may be optimized with a blend-time analysis.

Mass transfer coefficient (kla) prediction drives dissolved oxygen content in fermentations and cell cultures. The effect of stripping gas is supported. Bubble size distribution and concentrations at all locations in the bioreactor are other useful outputs of the simulation. The effects of sparger type, placement and gas flow are often optimized as part of the digital bioreactor investigation.

Dissolution or particle suspension rates can be bottlenecks in bio-processing. Time-consuming buffer preparation steps have been streamlined by Ansys customers. The same class of physics may also be used to ensure that micro-carriers stay suspended in growth media, do not agglomerate and are not damaged by shear.

In addition, all Ansys simulation tools allow for parametric design exploration. Using a digital “what if” analysis, rigorous DOE or goal-seek optimization to verify your equipment produces a successful bioreactive environment. Optimization in a digital bioreactor can eliminate poor scale-up productivity and lost batches.

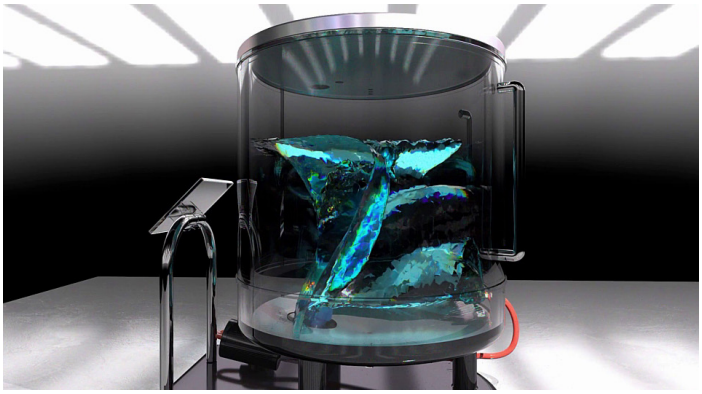

Figure 1: Ansys Fluent bioreactor simulation of blend time. Acidic components (blue-green) mix into the bulk of the vessel.

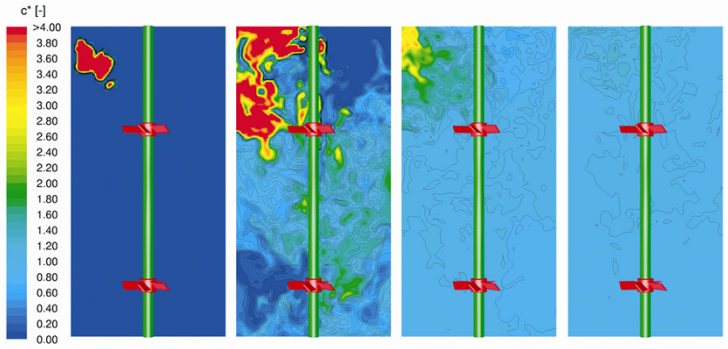

Figure 2 : Cross-sectional simulation snapshots from a blend-time analysis. Low pH material flows through the vessel and is colored red at high concentration. Images from left to right were taken at approximately 0.5, 2, 5 and 10 seconds.

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Disclaimers
These simulations were designed to replicate physical behaviors under specific circumstances. They should not be considered medical guidance and do not account for environmental variants, such as wind or humidity.