

## **DIRECT INOCULATION OF A PERFUSION BIOREACTOR WITH A FROZEN INTERMEDIATE SEED TRAIN**

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**Key Words:** High cell density culture, frozen intermediate seed train, perfusion, direct inoculation

Flexibility in cell culture manufacturing via a reduction in the process duration is a key strategy to execute cell culture manufacturing campaigns quickly in a multi-product facility. A major bottleneck is the seed train, which can add weeks to the timeline of the production culture. Seeding production bioreactors with a direct, cryopreserved CHO cell inoculum could possibly eliminate the need for a lengthy continuous seed train and provide other numerous benefits.

Previous efforts have shown that high-density (HD) cell banking can be an effective means to reduce the number of seed-train steps required and also improve operational success in seed-train processes. This study demonstrates that it is possible to remove the entire seed train during routine operations by using an intermediate frozen seed train. This involves cultivating cells to high cell density in a perfusion bioreactor, and cryopreserving cells in multiple disposable bags. Each run for a manufacturing campaign would then come from a thaw of one or more of these cryopreserved bags directed inoculated in the N-1 bioreactor.

The data gathered during the development and optimization of the different steps during the generation of a frozen intermediate seed train using various approaches and technologies, will be presented. As well as the extensive data set that has been generated to demonstrate that the new process scheme delivered the same performance as the conventional seed train process.