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Jessica Olson
MSD, USA

Greeshma Manomohan
MSD, USA

Alyssa Brown
MSD, USA

Christopher Lee
MSD, USA

Samantha Moyer
MSD, USA

See next page for additional authors

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Authors

Jessica Olson, Greeshma Manomohan, Alyssa Brown, Christopher Lee, Samantha Moyer, and Marc Wenger

AMBR® 250 HT SYSTEM: A KEY PROCESS DEVELOPMENT TOOL FOR NEW LIVE VIRUS AND MICROBIAL VACCINE CANDIDATES

Jessica Olson, Vaccines Process Development, MSD, USA
Jessica_olson@merck.com
Greeshma Manomohan, MSD
Alyssa Brown, MSD
Christopher Lee, MSD
Samantha Moyer, MSD
Marc Wenger, MSD

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Vaccine development requires accurate scale down models that can provide both qualitative and quantitative data that can be utilized for process development. With such data, time to pilot scale can be minimized and provide cost and time savings.

The ambr®250 high-throughput (HT) system is a multi-parallel, single-use mini bioreactor system with automated liquid handling and automated controls. Implementation of the ambr®250 HT system was evaluated as a potential scale-down model for several microcarrier production system vaccine candidates and one microbial production system vaccine candidate.

Many live virus vaccines utilize anchorage-dependent cell lines grown on microcarrier beads. This presents unique challenges to cultivation in scale down systems and has the potential to complicate scaling models and generate data that is not representative of the pilot or commercial scale. Initially, the ambr250®HT system did not generate representative data due to the suspension requirements of the microcarriers and distribution through the reactors. These challenges were largely addressed through vessel modifications, improvement in motor speed control, and careful liquid handling practices. The microbial vaccine candidate demonstrated good comparability to standard lab scale systems following evaluation of several scale-up methods and sampling method improvement.

The ambr®250 HT system has become a valuable vaccines process development tool, although more work must be done to fully understand some process performance differences across scales.