DEVELOPMENT OF A FLEXIBLE AND MODULAR APPROACH FOR INTEGRATED CONTINUOUS BIOMANUFACTURING

Michael Coolbaugh, Sanofi, USA
michael.coolbaugh@sanofi.com
Chad Varner, Sanofi, USA
Shashi Malladi, Sanofi, USA
Xhorxhi Gjoka, Sanofi, USA
Matt Stundtner, Sanofi, USA
Bob Flynn, Sanofi, USA
Raja Jagadesan, Sanofi, USA
Jason Walther, Sanofi, USA
Kevin Brower, Sanofi, USA

Key Words: flexibility, manufacturing, modular, facility-of-the-future

The implementation of an integrated, closed, and end-to-end continuous process will be a key enabler in the realization of the biomanufacturing facility-of-the-future. Previously, we have successfully executed a proof-of-concept for an end-to-end continuous process, from perfusion bioreactor through formulated drug substance, at the pilot-scale. Building on that demonstration, we have identified an opportunity for the end-to-end downstream train to be applied universally across our processes, irrespective of the modality, cell culture format, or production scale. Realization of this vision will enable a transformation of our manufacturing network.

To enable this vision, we are developing flexible and modular manufacturing systems and approaches to facility design. The flexible manufacturing system (skid) consists of a standard set of hardware (pumps, valves, utilities, etc.) that is designed to accommodate all traditional downstream unit operations with a wide turndown ratio. The physical system is then combined with a unit-operation-specific single-use flowpath to create a flexible manufacturing module. These flexible modules are then deployed in any number of potential configurations within a manufacturing facility to accommodate multiple products and process architectures with minimal change-over in physical equipment.

Here we will describe the design principles and capabilities of the flexible manufacturing system, review key performance data from a prototype universal skid, and demonstrate the flexibility of the system to accommodate multiple unit operations. We will then further discuss specific case-studies of how these manufacturing systems could be deployed in a flexible facility to enable manufacturing of a variety of molecules across a range of production scales. Finally, we will present the transformative impact of implementing this flexible and modular manufacturing approach to a diverse product pipeline.