

DEVELOPING A UNIVERSAL SINGLE-USE SKID FOR CONTINUOUS PURIFICATION OPERATIONS

Chad Varner, Purification Development, Mammalian CMC Dev, Sanofi
Chad.varner@sanofi.com

Xhorxhi Gjoka, Purification Development, Mammalian CMC Dev, Sanofi

Shashi Malladi, Purification Development, Mammalian CMC Dev, Sanofi

Michael Coolbaugh, Purification Development, Mammalian CMC Dev, Sanofi

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Continuous purification approaches such as multiple column chromatography, single-pass tangential flow filtration, and inline buffer adjustments can significantly decrease the size and overall footprint of downstream processes, thus enabling fully single use downstream processing equipment. Further, by intensifying the downstream process, multiple continuous unit operations require the same pump/flow ranges, hardware elements, and sensors. Recent advances in single use skid design and automation have demonstrated that a single skid can operate multiple unit operations. However, an appropriately sized single use solution for continuous purification operations is not yet commercially available. We have developed a prototype single use skid that can perform all downstream unit operations in a continuous purification process. Single use flow path considerations such as individual step versus global optimization and universally conserved flow path sections will be presented. Initial performance testing for multiple unit operations will be shared. A single use skid that can perform all the unit operations in a continuous purification process presents a flexible and modular approach to bioprocessing and can, thus, have significant impacts on supply chain, maintenance, and validation efforts, and increase facility flexibility and utilization.