LEVERAGING SANOFI INTENSIFIED ICB PLATFORM TO ENABLE EARLY PROCESS DEVELOPMENT FOR A LABILE AND HARD-TO-EXPRESS MOLECULE

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Within the biopharmaceutics industry, tremendous progress has been made in the implementation of early development antibody platforms to achieve high volumetric productivity and consistent product quality for novel therapies. More recently, development of new modalities provide opportunities for advancing exciting new therapeutic possibilities. However, many of these modalities present new upstream and downstream development challenges, e.g., low expression, labile molecules, low recovery, and unreliable product quality. The resulting additional development requirements increase the timelines for demonstrating Proof of Concept and may even prohibit certain therapeutic candidates from reaching the clinic at all.

The Sanofi ICB platform provides opportunities to increase productivity and improve product quality, enabling manufacture of new entities previously inaccessible. Here, we present a case study of such a situation, in which the ICB platform is applied to an early-stage, labile, hard to express molecule produced from non-CHO mammalian cells. A combination of upstream and downstream high-throughput technologies have been incorporated to rapidly define a process sufficient for first-in-human studies. Process intensification enables adequate material generation within an acceptable number of batches for both development and clinical manufacturing. This case study demonstrates the strategy of using intensified perfusion platform for non-antibody modalities to support a diverse portfolio for our evolving industry.