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Challenges in the development and adaptation of platform process to existing pipeline

Edmund Scarfo
Takeda Pharmaceutical

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Nandita Vishwanathan, Ed Scarfo, Christopher Brown, Christine Collins and Chris Campbell

The development and use of platform processes have been adopted as an industry-wide strategy for enabling faster timelines for early clinical stages. However due to increasing product demands and the competitive landscape of antibody therapeutics in the industry, the development and use of a highly productive and economic upstream platform process has also become an adopted strategy. In keeping with industry standards, Takeda's platform has evolved from upstream processes capable of achieving protein titers from 0.7-1.2 g/L to highly productive processes achieving titers in the range of 4.0-7.0 g/L. Unlike these earlier, low titer processes for the same molecules, the platform has also evolved to incorporate proprietary process mediums which are protein-free and animal component-free . For earlier versions of the newer platform, the concentrations of the feed media components were determined by estimating their consumption rates relative to the glucose consumption rate. However, this process involved administration of three different feed media being delivered at different times. The process was further refined to consolidate feeds for the ease of operation and for the purpose of manufacturing process transfer.

Takeda has amassed a variety of drug candidates over the past few years which have used this newly refined platform. However, each drug candidate can present unique challenges of expression, production and quality characteristics, during adaptation to our platform process. Our approach towards achieving consistency in critical product quality attributes using media additives and process adjustments will be presented. Such challenges and a history of evolution for the platform process for three different candidates will be discussed.