DELIVERING A TOOLBOX OF FLEXIBLE PLATFORMS FOR CLINICAL AND COMMERCIAL BIOPROCESSING PRODUCTION:
‘DEFINING THE BUSINESS DRIVERS FOR DEVELOPMENT AND IMPLEMENTATION’

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Despite the growing success, the biopharmaceutical industry continues to face competitive challenges from multiple sources. The cost pressures include evolving reimbursement, global competition and loss of drug exclusivity. As a result, there is a significant drive to boost the overall productivity of bio therapeutic programs by shortening development timelines and lowering both development and production costs, while maintaining product quality. Low cost production solutions must be aggressively pursued due to the large number of drug candidates in development, and their relatively high dosing requirements. The industry is facing an expanding range of modalities such as bispecifics and nanobodies, that provide a more heterogeneous product pipeline and a wider range of product demand (kg/yr). In addition supply chains need to be more responsive to the patient needs in a more personalized approach.

These industry challenges need flexible solutions that can provide agility and lower cost. The presentation will discuss the business case, development and implementation of such a toolbox of low cost flexible platform solutions to meet a range of scenarios faced in clinical development, that also provide a line of sight to commercial. Examples will include the simple single use fed batch process for low demand processes versus advanced integrated/continuous automated processing for higher demands. The implementation strategy through the clinical phases to commercial will be discussed for commodity mAb production using a fully automated continuous process with product attribute control and real time release. This provides a supply responsive approach to rapid changes in demand to provide a ‘supply on demand’ process. This production synchronization should provide a responsive approach to changing drug demand, shorten clinical and commercial timelines and minimize inventory costs. These cost reduction initiatives, in combination with regional manufacturing, should help to expand patient accessibility to biologics and vaccines.