Ultra Scale-Down (USD) Technologies for a Scaleable and Informed Biomanufacturing

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Manufacturing-scale processes are known to have an impact on macromolecules. However, this is not often evident in the typical laboratory-scale experimentation performed during bioprocess development. This presentation will feature case studies on the ultra scale-down (USD) technologies which can be used in developing bioprocess options and assess the impact of manufacturing operations on bioprocess materials using only millitre quantities. The USD technologies have been developed over 10 years at the Advanced Centre for Biochemical Engineering, University College London, and are a combination of specifically designed devices and methodologies that mimic larger-scale operation. These have been developed with the understanding of the engineering environment that dominates the manufacturing operations. The USD technologies enable the manufacturability characterisation of drug candidates early in the drug development process and facilitate the study of different bioprocess options with minimal costs. The risk of scale up, and the cost of performing scale-up studies, are minimized by gaining process insights early on and ensuring that laboratory experimentation are mimics of the larger scale operation. The ability to conduct such studies with minimal quantities of material allows for the integration of laboratory scale bioreactors with ultra scale-down technologies of the subsequent processing stages such as centrifugation or depth filtration. The research presented will include bioprocessing of antibodies, antibody fragments, and verification of findings at larger scale operation, and will include an assessment of the value of this technology in terms of potential cost savings in bioprocess development.