

DEVELOPMENT OF A NOVEL AUTOMATED PERFUSION MINI-BIOREACTOR 'AMBR® 250 PERFUSION'

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Session proposals:

- Towards other cell lines and systems – opportunities and challenges beyond CHO cells
- Pushing the Limits on Process Intensification: 10 grams/Liter and Beyond
- Process Scale Up/Down, Characterization and Control Strategy Definition

In recent years a strong trend towards continuous biopharmaceutical processing has gathered momentum, driven by the promise of process intensification, reduced cost of goods, and more consistent and better controlled product quality. Key technologies in upstream cell culture (ATF, TFF) have enabled the start of a shift towards process intensification/continuous processing in the seed train (N-1 perfusion) and main production culture (concentrated fed-batch, perfusion) for biopharmaceutical production processes. While these technologies are now available for large scale bioreactor operations, small-scale application is limited to traditional benchtop bioreactor scales and formats. Benchtop bioreactors do provide a route to developing this new wave of intensified/continuous cell culture processes, however this approach is manually intensive, relatively low throughput and cost-intensive to operate. In the last 5 years, fed-batch cell culture process development has been significantly accelerated by wide spread implementation of the ambr 15 and ambr 250 fully automated, single-use, micro and mini bioreactor systems. Case studies will be presented on the utility of the ambr 15 as a perfusion mimic, and we also present here novel performance data of a new version of the ambr 250 system 'ambr 250 perfusion'. Technical description and operating data and cell culture results presented for the novel 'ambr 250 perfusion' system outline the capacity and capability of this technology. As established with ambr 250 for fed-batch processes, ambr 250 perfusion has the potential to provide the industry with a step change in perfusion process development capacity, enabling implementation of DoE based approaches for process optimization and characterization. It is envisaged that 'ambr 250 perfusion' can therefore facilitate and significantly accelerate an industry wide transition to upstream cell culture perfusion processes for novel biopharmaceuticals currently in early development.