

## ADVANCED BIOREACTORS FOR APPLICATION IN CLINICAL MEDICINE

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Cell therapy and tissue engineering hold great promise; however, current manufacturing methods constrain economic viability, especially for 'patient-scale' production

Despite significant production constraints in terms of clinical scale-up, autologous and matched allogeneic treatments continue to find considerable clinical interest due to the ability to avoid immunologic complications. In these clinical models, 'patient-scale' production is the term adopted for autologous or matched allogeneic cell therapy procedures where the size of the cell production event is necessarily matched to the requirements of a single therapy.

We examine five critical issues in the successful clinical delivery of patient-scale cell therapy and evaluate potential solutions based on the use of advanced bioreactors. The high cost of cell therapy production protocols is considered in the context of automation where electronic instrumentation linked to disposable bioreactors creates production efficiencies. The adoption of such bioreactor-based platforms combined with flexible instrumentation programming allows cell production centers to produce cell therapy treatments for diverse clinical conditions. Furthermore, the incorporation of biosensors as essential monitoring aids in the bioreactor environment provides the opportunity for pre-validated software to effect discrete process changes to accommodate inherent variability in cell performance on a patient-by-patient basis. The use of such electronic protocols and biological feedback implicitly drives the availability of comprehensive electronic batch records, which enhance GMP traceability and support the complex clinical logistics inherent in autologous processes.

Through the use of automated processes delivered by bioreactor-based production platforms, we propose new clinical models for patient-scale cell production that address today's demanding expectations for reliable biological performance, effective GMP logistics, and economic viability.