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A single use platform for expansion of cellular therapeutics

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Human cellular therapies are used extensively in clinical studies and as drug discovery tools. Current culture methods involve cumbersome multilayer flatbed culture and roller bottle systems. Several groups previously demonstrated an expansion paradigm that uses a scalable, single use, stirred tank bioreactor for cell expansion. A bioreactor system enables direct monitoring for the specific cell characteristics at any point during the expansion, thus assuring product quality and consistency. In addition, a bioreactor provides ease of use in handling and lower medium volume requirements. Cells cultured in bioreactors were evaluated to assess a variety of markers that confirm identity and purity. No differences were observed in protein markers. Finally, we evaluated concentration technologies and found that good recovery of viable cells is achievable. In this work, we verified that the cells expanded in the single use stirred tank bioreactor and subsequently harvested were identical to those grown in traditional systems.

Cancer immunotherapy-regulatory challenges for clinical studies

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Some of the challenges relating to proof of concept, immune monitoring, patient section and clinical endpoints when developing therapeutic cancer vaccines will be discussed. While the expected main mechanism of action of cancer immunotherapy differs from standard chemotherapies, the need to show a clinically relevant benefit remains the ultimate goal of treatment. When one of the mechanisms of action can be shown, this aids in biomarker identification, proof of concept studies and dose finding. Some of the challenges in interpreting results from immune monitoring will be highlighted. The need for adequate proof of concept studies prior to initiating phase 3 trials will be discussed.