MOVING OFF-THE-SHELF INTO PATIENTS; DEVELOPMENT OF PLURIPOTENT CELL-BASED IMMUNOTHERAPEUTICS

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As patient-specific genetically engineered cell-based therapies begin to show efficacy in treating hematological malignancies, and potentially a far broader range of indications, attention has turned to developing methods to efficiently manufacturing such therapies. Products that are manufactured on a patient-by-patient basis can easily inherit the differences that are evident in the clinical presentation of individual patients, and as such may display vastly differing safety and efficacy profiles in different individuals. One solution to this problem lies in the ability to identify the critical to safety and efficacy attributes of patient-specific therapies and engineer these attributes into continuous cell lines that can subsequently be manufactured indefinitely in a consistent manner. This presentation will detail the unique challenges and opportunities associated with the clinical development of genetically-engineered human induced pluripotent cell line-based natural killer and T cell-based therapies. It will also outline manufacturing processes that are designed to be immune to patient-to-patient variation, can reproducibly result in consistent safety and efficacy profiles and can facilitate on-demand availability of cost efficient cell-based therapies for a broad patient base.