Adoptive Immunotherapy, the transfer of autologous T cells that have been genetically modified ex vivo and given back to the patient for the treatment of cancer and other immune-related disorders, is an exciting and emerging field that has grown significantly in the past five years. What was once considered a boutique therapy with minimal potential has demonstrated the potential to be an effective and durable treatment and has certainly gotten the attention of multiple drug development companies. Although this is good news, as these therapies are finally getting the attention they deserve, it is important to understand the complexity and challenges associated with developing and scaling up such therapies. Unlike traditional drug development, where the starting material is the same every time, with autologous cellular therapies, the starting material for manufacturing the drug is different for each patient. Therefore understanding patient-to-patient variability is critical. In addition, for such therapies to be successful, it is important to shift the paradigm of traditional drug development, and for scientists, clinical investigators, regulatory agencies and payers alike to come together to think of novel ways to bring these potentially life-changing therapies to market. Due to the nature and complexity of the manufacturing process, it is important that activities such as process characterization are considered earlier in the development process. Some key challenges, aside from patient-to-patient variability, that are associated with developing autologous cellular therapies include availability of patient material for development, availability of qualified assays, cost of goods, technical expertise, manufacturing and disposition times, and establishing appropriate scale-down models.