

CELL THERAPY PRODUCT MANUFACTURING CONSIDERATIONS

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Cellular therapy products are defined as autologous, allogeneic, or xenogeneic cells that have been propagated, expanded, selected, pharmacologically treated, or otherwise altered in biological characteristics *ex vivo* to be administered to humans and applicable to the prevention, treatment, cure, diagnosis or mitigation of disease or injuries. This definition is broad and encompasses a diverse set of cell based products with many potential applications. While relatively few cell based therapies are currently marketed, others are in late phase clinical development. In addition, the use of cellular therapies in investigational studies has been steadily increasing. Due to the nature of these therapies, they have both great therapeutic potential and manufacturing challenges. Challenges include starting cell variability, lack of reference standards, patient specific and/or small lot sizes, limited material for testing, the need for aseptic processing, and others. Despite these challenges, cell based therapies allow manufacturers to tap into complex and living systems that may be poorly understood but can potentially repair, replace, or restore function in the patient. This talk will focus on providing a few strategies to address common manufacturing challenges by 1) applying principles of Current Good Manufacturing Practices; 2) understanding product's key Critical Quality Attributes and Critical Process Parameters; and 3) knowing how to deal with process change.