

CELL THERAPY MANUFACTURING: IT'S ABOUT "TIME"

Donald Powers, Janssen Technical Operation
DPowers2@ITS.JNJ.COM

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The Cell Therapy industry is poised to take the next steps in its evolution as it prepares to transition from the realm of clinical trials into the world of commercial manufacturing. There are approximately 2500 CT based clinical trials currently underway worldwide. If even a fraction of these succeed the demand for CT manufacturing capability will skyrocket. The promise of these therapies have the potential to be life altering to so many patients as long as we can produce enough to supply the markets. *It's about time* we got serious about how to manufacture Cell Therapies at scales that can support these commercial demands. One of the biggest hurdles that need to be address is "time" itself. CT manufacturing does not have the luxury of long hold steps or extensive purification processes. The process has to be quick, efficient, reproducible, safe and compliant or the resulting cell product will have low viability and/or decreased potency. We must begin to discuss and address these constraints immediately as this is an issue that impacts all cell therapies not just certain ones and the issues only worsen as we add in the complexity of scaling up. This talk will highlight specific process steps that can be problematic and time consuming along with ideas and mitigation strategies that can help speed up the process while diminishing potential product impact.