IS IT EVER TOO EARLY TO CLOSE AND /OR AUTOMATE MANUFACTURING OF CELL THERAPIES?

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The rapidly growing field of cell therapy is providing very promising treatments for conditions that previously were considered untreatable or whose treatments were not considered very effective. These opportunities however do not come without their own set of unique challenges. Patient Specific Cell Therapies (PSCT) can be increasingly difficult to manufacture on a large scale. Each manufactured PSCT is a batch of one, meaning that it is intended for one patient and is not for off the shelf purposes. This can lead to issues with donor variability, time, cost of goods, and ultimately quality of product. These major issues can be greatly remedied if a proper automation system is implemented. This however requires a large amount of time, man power, development, and most importantly money. All these things must be considered when deciding to transition your given therapy from the lab bench toward closed, single use, automated manufacturing.

During my presentation I will discuss the factors that will determine if a cell therapy product is ready for and can benefit from incorporating automation into the manufacturing process. The decision on when to move to a more automated process will depend on several variables. One of these variables is what stage of the development process the product is in. It may not be necessary to implement costly technology when there is little proof of concept and the product is not fully developed, however if a major change in the manufacturing process occurs too late in the clinical testing process it would cause major complications with the regulatory approval process. Patient population is also a deciding variable for when to move to a more automated manufacturing process. For example, if a condition qualifies for orphan designation (less than 200,000 cases per year) the costs and time needed to implement process automation may not be exceeded by the benefits of the technology itself. On the other hand, if a product treats a condition like lymphoma it will require a much larger scale of manufacturing where the return on investing in automation is going to be much higher. The number of steps and difficulty of the steps can also determine if automation is beneficial. A product with multiple processing days and manipulations can be heavily improved by automation by decreasing the number of skilled workers needed, the number of hours to complete the manipulation, and the risk of human error during each step. Lastly if the technology available is not sufficient to manufacture a cell therapy on a consistent and repeatable basis it may be beneficial to hold off on automating your process to avoid machine failures or inconsistency with product characteristics.

This work will discuss the above variables in detail alongside other risks that occur that may influence the decision point on when and how to automate and close a manufacturing process. This work will highlight studies that have been performed by HCATS, taking on-board over 18 years of experience with over 150 cell therapy companies. As this industry takes off such questions need to be answered with the current data set and the end goal in mind. A walk through of the questions, answers and case studies will help showcase when and how closed, automation solutions should be implemented.