NOVEL SUPPLY CHAIN AND PROCESS MODELING FOR CELL THERAPY MANUFACTURING AND DISTRIBUTION

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We present a two-level hierarchical supply chain model of (autologous) CAR-T cell therapy that serves as the basis for the development of strategies to: 1) deliver cell therapy products that are safe and have a high level of efficacy, 2) minimize fulfillment time and variability, and 3) reduce total manufacturing and logistics costs while reducing the risk of patient morbidity and mortality. The model consists of two integral components: (1) an agent-based program for a “single manufacturing facility” that simulates the manufacturing and quality control process of cell therapy; and (2) a supply chain network program that evaluates different supply chain configurations and sourcing strategies. The two-level hierarchical supply chain model can be used as a decision support system to explore manufacturing, quality assurance, and supply chain and logistics ‘what if’ questions. Using the model, we explored the impact of reagent supply chain disruptions to manufacturing and evaluated the effectiveness of different tools that can mitigate unexpected supply disruptions. We intend to use this model to support the design and operation of supply chains for end-to-end manufacturing and logistics of large-scale, low-cost, reproducible and high-quality cell therapy products.