FASTFACTS

# Cell collection in cell therapy — quality matters

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**When time is spent upfront to optimize and standardize apheresis collections, it will have positive effects at each step along the cell therapy continuum and may lead to greater success in cell and gene therapies. This poster provides details about how data analytics can help to standardize and optimize cell collections done on the Spectra Optia® Apheresis System.**

## THE CELL THERAPY MANUFACTURING CYCLE

Cell collection by apheresis is one of the critical first steps of the cell therapy manufacturing cycle **(Figure 1)**. Cell collection influences the rest of the cycle and is vital to ensure the successful manufacturing of life-saving drug therapies to the highest quality standards. Apheresis collection plays an important role in producing a high-quality starting material for cell and gene therapies.

## VARIABILITY IN THE CELL COLLECTION ECOSYSTEM

Achieving consistently high yield and quality cell products during apheresis has proven challenging. There are several critical factors that contribute to the success of an apheresis collection **(Figure 2)**.

Cell collection is an inherently variable process due to patient variation, which can be further complicated by blood-related malignancies. Other patient or donor factors to consider include the preparatory regimen and vascular access.

**Figure 1.** Solutions provided by Terumo Blood and Cell Technologies for the cell therapy manufacturing cycle.

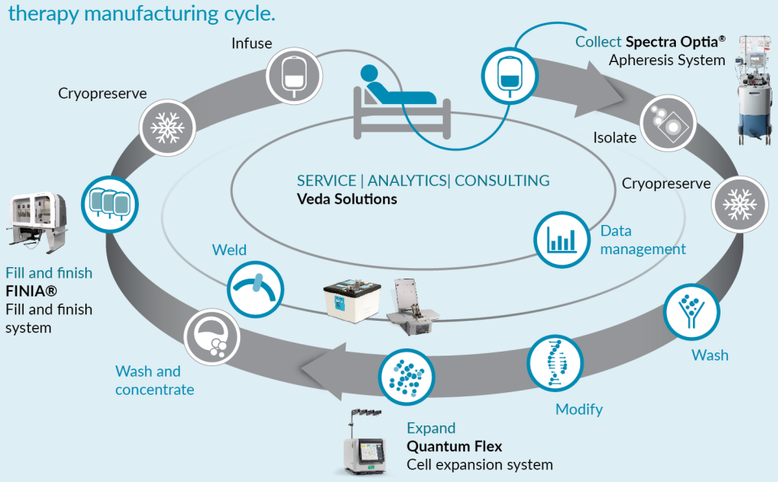
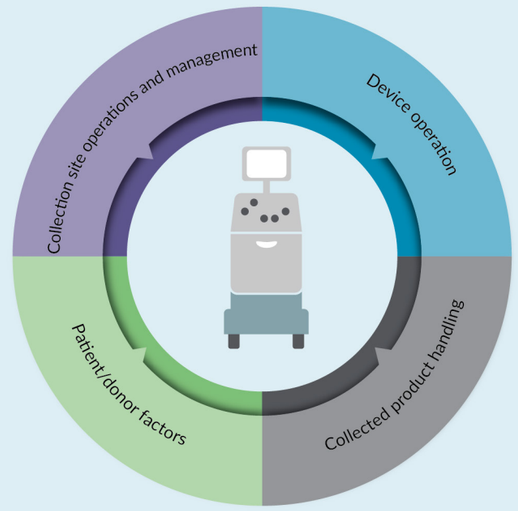



**Figure 2.** Major components of the cell collection ecosystem.




The operation of the device itself also plays a significant role in cell collection. Optimization for cell type, patient physiology, minimization of off-target contamination, targeting the desired yield, concentration and volume goals, and management of procedural issues are all important factors to consider.

The processing of the product after it is collected, including anticoagulation and clumping prevention, cryopreservation, and handling and shipping, also contributes to collection success.

Finally, other considerations include collection site operations and management, as cell collections occur at multiple sites, each of which shows variability. Ideally, a collection site should offer GMP compliance, experience managing varied patient populations, and willingness to facilitate data analysis.

## VISIBILITY AND CONTROL THROUGH DATA

Data plays a critical role in achieving visibility and control over the cell collection process. Data connects cell collection sites and manufacturers to help optimize cell collections for consistency and accuracy, standardize protocols with collection sites, and improve the quality of the starting material.

The Spectra Optia Apheresis System logs data during each procedure, allowing for the optimization and troubleshooting of individual collections or a larger group of procedures across multiple sites. This data analysis can bring predictability to the cell collection process to create more consistent and higher-quality starting material for cell and gene therapies. The device data does not contain patient-identifiable information and the Spectra Optia Apheresis System software is GDPR compliant.

Terumo Blood and Cell Technologies offers Veda Solutions cell collection services. These services help cell manufacturers that are getting their starting material from the Spectra Optia Apheresis System do so in the most efficient, optimized, and standardized way possible **(Figure 3)**.

**Figure 3.** Veda Solutions cell collection services.

**CELL COLLECTION SERVICES**

| Cell collection ecosystem training | Cell collection optimization | Prediction algorithm analysis | Apheresis consulting |
|---|---|---|---|
| Overview of apheresis and the Spectra Optia device | Site, device, and operator comparison | Customized procedure endpoint calculation tool | Apheresis manual/ SOP development and review |
| Understanding the sources of procedure variabilities | Benchmarking across multiple sites | Plan collections to meet the target goal based on a patient's precount | Process optimization consulting |
| Troubleshooting and optimization | Single and multi-procedure analysis | | |
| Power of data | Comprehensive analysis from pre-procedure data through final therapy results | | |

CELL & GENE THERAPY INSIGHTS

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