

STANDARDS DEVELOPMENT IN ACTION

Cell Collection Standards for Cell Therapies

CHALLENGE



When patients' lives rely on a manufactured cell or gene therapy arriving exactly when and where it needs to, it is essential to ensure each step of the critical supply chain is managed as efficiently as possible. Cellular starting material collection is at the beginning of that supply chain, making cell collection processes vital to ensuring the quality and safety of these therapies. However, **cell collection requirements for different treatments and companies vary and are often nuanced, raising the potential for error.** Additionally, cell collection practices and capabilities between collection centers differ. These variations can lead to an increased potential for human error, delayed delivery of starting material, and collections with unpredictable cell quality, which could result in decreased efficacy of treatments.

SOLUTION



As an organization that works with both cell and gene therapy companies and cell collection centers to support the supply chain, **Be The Match BioTherapies®** saw firsthand the critical need for standardization in starting material collection protocols and practices. **Be The Match BioTherapies** contacted the **Standards Coordinating Body (SCB)** for support with developing and implementing standardized practices to create a more efficient system for the development and delivery of cell and gene therapies and support patient safety.

SCB coordinated a stakeholder workshop and **established a working group** to discuss cell collection standardization needs and opportunities. Through this working group and additional industry feedback via an online survey, the team is **identifying existing cell collection protocols** that can be leveraged during standards development and **defining consistent cell collection processes** that could be implemented across the regenerative medicine community. **SCB** is also helping **preserve the intellectual property of companies** working on the standard initiative by anonymizing company-specific data to compare processes across companies.

The work on advancing cell collection standards is ongoing. **Be The Match BioTherapies** will continue collaborating with **SCB** and the working group to identify a relevant standards developing organization (SDO) and coordinate the advancement of cell collection standards.

IMPACT



Standardizing common aspects of cell collection protocols and processes can improve cell collection center employee efficiency and accuracy, reduce the financial burden on centers as new therapies emerge, and ultimately **increase the quality of starting materials to enable more powerful and reliable cell therapies.**

LESSONS LEARNED



When advancing standards, **Be The Match BioTherapies** emphasizes the importance of **identifying the challenges most broadly impacting regenerative medicine stakeholders**, as well as leveraging existing processes and protocols whenever possible to inform standards development. These steps help to ensure that a standard will not only be feasible to implement, but will also gain essential industry buy-in. A key priority for **Be The Match BioTherapies** in this role is encouraging participation and information sharing from all involved in the development and delivery of next generation cell and gene therapies to ensure that the standards developed present the most efficient and effective solutions possible.

Get Involved in Standards Development through SCB

As a coordinating body, **SCB** helps streamline the standards advancement process by driving momentum, aligning stakeholder efforts, and helping projects overcome obstacles.

Individuals can provide feedback to **SCB** on needed standards or join **SCB**-coordinated projects to advance standards that benefit the broad regenerative medicine community.

Contact SCB today to get involved.

www.standardscoordinatingbody.org



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