STANDARDS DEVELOPMENT IN ACTION
CASE STUDY

STANDARDS COORDINATING BODY
REGENERATIVE MEDICINE

Cryopreservation of Cells

CHALLENGE

Cryopreservation is often needed to extend the life of cell therapy products for sterility testing; transport between donation, manufacturing, and administration facilities; or temporary storage. To demonstrate that products are safe and effective after thawing, cell therapy manufacturers must be able to achieve 70 percent viability of cryopreserved cells. Viability of cryopreserved cells depends on complex factors—including media choice, freezing rates, and thaw temperatures—**and there is currently no broad consensus on the best methods for ensuring optimal product quality and potency for cryopreserved cell products**. Manufacturers often work in isolation to develop solutions to this complex challenge, which results in duplication of work and makes it difficult to improve safety and viability outcomes across the field.

SOLUTION

Pluristyx—a biotechnology company that manufactures stem cells for regenerative medicine therapies—frequently received requests from other companies to provide advice on optimal cryopreservation methods. After helping multiple groups individually, the team at **Pluristyx** saw an opportunity to contribute their knowledge and experience in cryopreservation techniques and their impact on viability outcomes to **help develop a set of common cryopreservation best practices for the regenerative medicine community**. To achieve this, **Pluristyx** initiated a cryopreservation standard development effort through the **Parenteral Drug Association (PDA)** with support from the **Standards Coordinating Body (SCB)**.

IMPACT

The standard under development will equip product manufacturers with a **flexible decision-making framework for selecting the best cryopreservation methods** for their products' needs, which can save time and resources, reduce product variability, and help speed the time to market for new therapies. **Pluristyx** has chosen to take an active role in regenerative medicine standards development as a way of **accelerating the advancement of the regenerative medicine field** as a whole through the sharing of knowledge and safety innovations.

LESSONS LEARNED

Based on their experience, **Pluristyx** encourages others interested in supporting standards advancement to **view the challenge from a high-level perspective** and examine their underlying assumptions. For example, before it was possible to determine the best methods for cryopreservation, the working group needed to ask **when to measure viability** (e.g., immediately after thawing or closer to administration) to arrive at the most meaningful result. Once this question was answered, they could look at cryopreservation factors that can optimize the measured value.

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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