



Biotherapies Gap Analysis

AABB Consulting Services is a leader in providing expertise worldwide in quality management systems and process improvement solutions in the fields of blood banking and transfusion medicine, cellular therapy, cord blood banking, translational research and regenerative medicine.

A division of AABB, Consulting Services has more than 50 years history and experience in the blood and biotherapies field. Our innovative assessment methods are effective in identifying specific challenges and opportunities unique to each facility, matching implementation plans with institutional requirements and resources.

AABB Consulting Services offers collaborative, custom-designed consultations and technical assistance to deliver the best possible outcomes, on time and within budget. Committed to the highest level of professionalism, we provide exceptional results while guiding clients to achieve sustainable goals.

Expansion in Cellular Starting Material Collection

Example of Our Work

AABB Consulting Services was approached by a facility that was implementing a new program to collect cellular starting material with a framework for improving their quality system. The facility was able to successfully attain AABB accreditation, signifying its overall implementation of quality management system.

THE CUSTOMER: The facility recently decided to expand its business by collecting cellular starting material.

CHALLENGE: The facility needed to be able to show prospective customers that the cellular starting material it provides is of the highest quality. High-quality material processed according to regulations directly impacts customers' speed to market. Therefore, a quality system needed to be in place to be better able to meet this demand.

SOLUTION: AABB's consultants initiated the remote discovery phase of the project to determine the optimal next steps. After the remote evaluation, consultants visited the

“As a future supplier of raw materials in the cell and gene therapy environment, AABB worked with our operations, regulatory and quality teams to ensure that we are on the right track with processes, documents and infrastructure. The consultation with AABB has helped us meet and exceed the requirements of industry to support future therapies.”

– AABB Consulting Services Customer

collection and manufacturing facility for an in-depth review of operations. The consultants also used this visit as an opportunity to provide education to staff and leadership on quality system essentials and ways to meet these requirements in their workflow.

The AABB consultants submitted a comprehensive written report, summarizing results of the technical and quality system review and outlining general recommendations for staff development. The detailed report also included a correction action/preventive action plan to address quality system nonconformances.

The Outcome

The facility was able to implement solid quality fundamentals and quickly improve operations. In a few weeks, the facility was able to apply for AABB Accreditation using the Standards for Cellular Therapy Services. This accreditation will allow it to attract and retain critical partners in the biotherapies field.

Contact us:

consulting@aabb.org

aabb.org/Consulting