

FAQs

AABB CSM Qualification Value



Cellular Starting Material
Qualified Facility

What is AABB's Cellular Starting Material Qualification?

AABB's Cellular Starting Material (CSM) qualification is designed to accelerate supplier qualification for biotherapies companies relying on AABB-accredited facilities to support advanced therapies.

It is a new recognition for AABB-accredited facilities that want to highlight their expertise, capacity and practices related to collecting CSM to biotech companies and research facilities looking for qualified suppliers.



Are all CSM-qualified facilities also AABB accredited?

Yes. Only AABB-accredited facilities are eligible to obtain CSM qualification. This process ensures that a facility has undergone a rigorous review of compliance with applicable AABB standards, including a thorough review of key areas related to cellular starting materials.

What is AABB Accreditation?

AABB accreditation demonstrates a commitment to the highest standards of quality and safety and a dedication to continuously improving operations. AABB-accredited facilities can be found in more than 50 countries worldwide, and AABB has been leading the field in ensuring high-quality assessment and accreditation since 1957.

AABB's accreditation process is based on its renowned quality systems approach that helps to optimize existing processes. Facilities that achieve AABB Accreditation demonstrate compliance with applicable AABB standards. AABB standards require facilities to follow applicable federal, state, and local laws and regulations. AABB accreditation helps facilities attain and, in many cases, exceed federal and state requirements. In addition, AABB is one of only a few accrediting bodies in the U.S. to have obtained the distinguished International Society for Quality in Health Care (ISQua) Association International External Evaluation Accreditation (IEEA).

You can read more about AABB accreditation [here](#).

What is the value of CSM qualification for biotherapies companies?

Biotherapies companies struggle to find and validate qualified CSM supplies needed to ramp-up to commercialization. AABB's CSM qualification database provides access to the largest, most comprehensive list of qualified CSM providers. CSM qualification enables biotherapies companies to find and verify sites faster at lower costs with the goal of expanding to commercialization with greater speed.

Facilities achieving AABB's CSM qualification are assessed by independent professionals who evaluate the facilities' quality management system, including policies, procedures, and practices. The CSM qualification demonstrates that a facility has a comprehensive quality management system that addresses the following areas:

- Facility organization and demographics;
- Resource management;
- Equipment;
- Supplier and customer issues;
- Process control;
- Documents and records;
- Deviations, non-conformances, and adverse events;
- Assessments: internal and external;
- Process improvement through corrective and preventive action; and
- Facilities and safety.

What does achieving CSM qualification demonstrate?

AABB-accredited facilities achieving CSM qualification have demonstrated that their quality system meets or exceeds AABB's evidence-based standards for the donor qualification, collection, storage and/or processing of cellular starting materials in compliance with 21 CFR 1271 and better practices. That means AABB-accredited facilities achieving the CSM qualification meet standards of quality and safety.

Are the AABB's CSM qualification facilities assessments trustworthy?

AABB assesses CSM-qualified facilities every two years by independent, professional assessors who evaluate that the facility has a comprehensive quality management system for the cellular starting material.

Assessments associated with CSM qualification are performed by professional AABB experts employed by AABB and credentialed in quality auditing. All AABB assessors are required to complete assessor training. Each assessment team is carefully formed to fulfill regulatory requirements, provide subject matter expertise and avoid conflicts of interest.

The AABB assessor training program is itself accredited by IEEA, and is one of only a few accredited training programs in the world. AABB professional assessors are among the most qualified professionals in the field.

What happens if a facility does not comply with current standards?

As a part of the accreditation assessment process, AABB may identify areas where a facility was not found to comply with current standards. These are referred to as nonconformances. In such cases, the issue must be resolved before closing the assessment, and the facility is awarded accreditation. Nonconformances are resolved through a robust process, including a written corrective action plan, evidence of corrective and preventive measures, and supporting evidence (e.g., changes in policies, processes, and procedures). All nonconformances are reviewed by two independent AABB staff technical specialists and vetted by an expert committee if discrepancies are noted. Accreditation is not awarded until all corrective action plans are completed. Thus, biotherapies companies can be confident that AABB-accredited facilities comply with AABB standards.

How many facilities are currently CSM qualified?

Hundreds of AABB-accredited facilities have earned the CSM qualification and hundreds more are in the application process.

How can I search for CSM-qualified facilities?

Biotherapies companies can easily search facility listings by name, address, city, state, zip code and country on [AABB's CSM-qualified facilities directory](https://aabb.org/csmq).