

THE FACTS ABOUT...

QSEAL INDUSTRY STANDARDS

A comprehensive, rigorous initiative to strengthen the continued safety and quality of life-saving, plasma-derived and recombinant analog therapies (collectively referred to as plasma protein therapies) worldwide, the Quality Standards of Excellence, Assurance and Leadership (QSEAL) certification represents steadfast industry commitment to producing safe plasma-derived therapies worldwide.

Safety is the number one priority of the plasma protein therapeutics industry. People around the world depend on therapies derived from human plasma proteins to treat conditions such as hemophilia, primary immunodeficiencies, alpha-1 antitrypsin deficiency, and other life-threatening diseases or serious medical conditions, including burns and shock.

The Plasma Protein Therapeutics Association (PPTA), on behalf of the manufacturers of these life-sustaining therapies, supports efforts by regulatory agencies to establish requirements to ensure the safety of these products. Nevertheless, PPTA has adopted voluntary standards that go beyond established government regulatory requirements and further define the regulations as they apply to the production of plasma protein therapies.

The QSEAL certification is based on an independent, third-party evaluation and recognizes strict adherence to a set of voluntary standards, which underscore the industry's quality and safety commitment to patients who rely on essential plasma protein therapies.

In order for a manufacturer of plasma therapies to become QSEAL certified, each one of its facilities must pass inspection by an independent auditor for adherence to the QSEAL Standards. To maintain QSEAL certification, audits are required every two years.

The primary focus of the QSEAL audit is to assess adherence to the following standards:

QUALIFIED DONOR

Potential donors must pass two separate medical screenings and be tested for HIV, hepatitis B and hepatitis C on two different occasions. Only after those satisfactory screenings and negative test results does that person become a Qualified Donor. If a donor does not return within six months, that person loses his/her Qualified Donor status and must qualify again.

This standard means that plasma from a one-time-only donor (even when all test results are nonreactive) cannot be used for further manufacturing. The standard results in committed donors and eliminates the risk that so-called "test-seekers" are accepted.

VIRAL MARKER

It is important that donations are collected from a low-risk donor population. Although every donation is tested for transmissible disease, the Viral Marker Standard represents an industry continuous quality improvement measure by assuring that donor centers are attracting healthy donors.

QSEAL-certified Companies

- Baxter BioScience
- Biotest AG
- CSL Behring
- Grifols, S.A.
- Talecris Biotherapeutics



Under this standard, each donor center must report the number of positive test results it receives each month. These data are then compared against a national standard to assure the safety of the donor population. If a donor center exceeds the national standard, corrective action must be taken or it will risk losing its QSEAL status.

INVENTORY HOLD

The inventory hold standard requires that each plasma donation be held in inventory for a minimum of 60 days prior to being used in the production of plasma protein therapies. This robust standard allows for the identification, retrieval, and destruction of any plasma donation as a result of post-donation information. In light of the comprehensive screening criteria for plasma donors, there could be many reasons for retrieving and destroying a plasma donation. For example, a donor may have received a tattoo or piercing that would have disqualified him/her at the time of the original donation, or perhaps the donor failed to report foreign travel to certain parts of the world that would have disqualified him/her. Regardless of the reason, the Inventory Hold Standard offers a strong, important measure of quality control to the production of plasma protein therapies.

NUCLEIC ACID AMPLIFICATION TECHNOLOGY (NAT) SCREENING

The use of Nucleic Acid Amplification Technology (NAT) screening uses state-of-the-art technology to allow for the earliest possible detection of transmissible disease. NAT screening compliments regulatory requirements for serology testing (an antibody test), which occurs most often at the donation level. NAT testing, which can detect disease, is done at the donation or pool level and is an additional safety measure for final therapies.

“The safety of blood and plasma derived products remain a high concern for people affected by bleeding disorders. By adopting the voluntary standards of the QSEAL program, which exceed the requirements of regulatory agencies, manufacturers have taken important extra steps to ensure these products remain safe for patients who need them.”

— Glenn Mones, VP for Public Policy
National Hemophilia Foundation

INTERMEDIATES STANDARD

The intermediates standard is another layer of QSEAL that further assures the consistency, quality and traceability of intermediate products being incorporated into final therapies by manufacturers. An intermediate is a plasma-derived starting material that must undergo further manufacturing steps, before it becomes a final therapeutic product. The exchange of intermediates allows producers to focus on the production of their specific products, while not wasting precious material that can benefit other patients. As an additional quality control measure, a “chain of custody” must exist between the supplier and the purchaser of any intermediate subject to QSEAL.

PARVOVIRUS B19 TESTING

All plasma that is used for therapeutic purposes also is tested for Parvovirus B19, a common infection that is often asymptomatic. The goal of the NAT in-process testing component of the QSEAL standard is to further reduce the risk of Parvovirus B19 transmission through plasma-derived therapies, without affecting current protective antibody titers (a measurement of how much an antibody is produced in the body) that patients need. The standard, which addresses this common virus, represents an exceptional level of safety and quality.

All companies that participate in the QSEAL certification process demonstrate their commitment to produce safe therapies.

Information as of May 2009

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