SAFETY & QUALITY A TOP PRIORITY

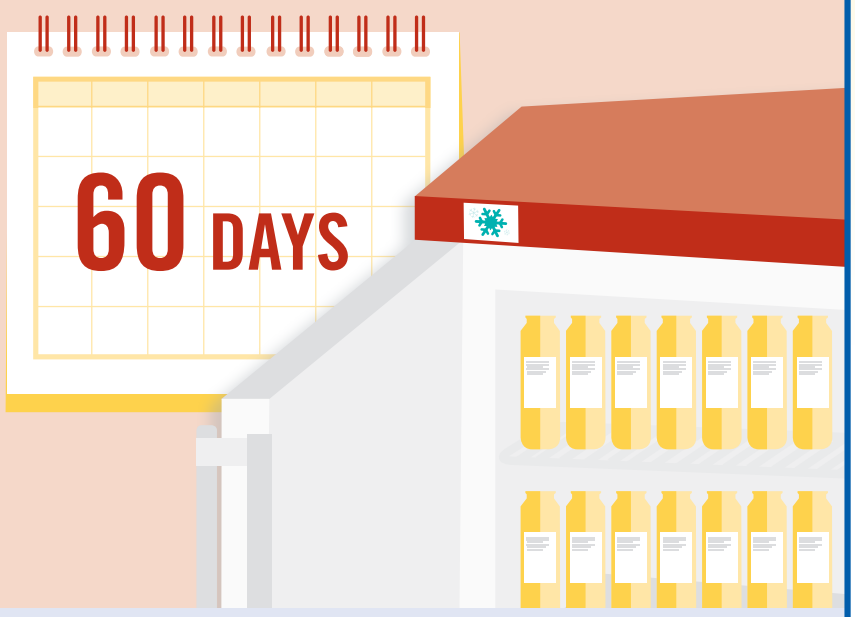
SOURCE PLASMA used for manufacturing plasma protein therapies is different from plasma used for direct transfusion. After collection, a Source plasma donation is frozen and shipped to a state-of-the-art facility for manufacture into life-saving plasma protein therapies. The **QUALITY STANDARDS OF EXCELLENCE, ASSURANCE AND LEADERSHIP (QSEAL)** program provides voluntary standards for incoming plasma manufactured into life-saving therapies.

QSEAL

QUALITY STANDARDS OF EXCELLENCE, ASSURANCE & LEADERSHIP

SOME QSEAL STANDARDS INCLUDE:

INVENTORY HOLD



Collected source plasma is held in inventory for **AT LEAST 60 DAYS** after donation, allowing for retrieval and destruction of a disqualified donation.

CONTROLS ON INCOMING PLASMA

The plasma protein therapy **MANUFACTURER** must demonstrate that all plasma pools **MEET QUALITY AND SAFETY PARAMETERS**.

NUCLEIC ACID AMPLIFICATION TECHNOLOGY TESTING

Requires Nucleic Acid Amplification Technology (NAT) **TESTING** for HIV, Hepatitis B (HBV), Hepatitis C (HCV) at both the **DONATION** and **PLASMA POOLING LEVELS** and includes in process testing for **HEPATITIS A (HAV)** and **PARVOVIRUS B19**.

RECOVERED PLASMA SPECIFICATION

Provides acceptance criteria for both the **COLLECTOR AND MANUFACTURER** of recovered plasma.

PPTA Plasma Protein Therapeutics Association

INTERNATIONAL PLASMA AWARENESS WEEK

FOR MORE INFORMATION AND WAYS TO DONATE, VISIT:
WWW.DONATINGPLASMA.ORG OR CONTACT 202-789-3100.

OCTOBER 2016