Donor qualification requirements are located in 21 CFR 630 and 21 CFR 640 (as revised in the May 22, 2015 Final Rule) and AABB Standards for Blood Banks and Transfusion Services, current edition.

Additional requirements may be found in FDA memoranda and guidance:

FDA Memorandum, April 23, 1992: Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma, and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti HCV) in Blood Establishments. (Contains requirements related to acupuncture, ear piercing, tattooing in the absence of sterile technique)

FDA Memorandum, July 28, 1993: Deferral of Blood and Plasma Donors Based on Medications. (Contains requirements for finasteride, isotretinoin, etretinate, human pituitary-derived growth hormone and medical director responsibility to be aware of other drugs)

Acitretin (Soriatane) Safety Information: http://www.drugs.com/pro/soriatane.html


FDA Memorandum, March 10, 1995: Revision of FDA Memorandum of August 27, 1982: Requirements for Infrequent Plasma Donors. (Supports the Questions related to types of donations)


FDA Memorandum, December 14, 1995: Donor Deferral Due to Red Blood Cell Loss during Collection of Source Plasma. (Supports the Questions related to types of donations)

Blood Products Advisory Committee Meeting June 16, 2000: Update on Sexual Transmission of HCV. (Documentation for the recommendation that having sex with or living with a person with asymptomatic hepatitis C does not defer the donor)

Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods. (February 2001) (Supports the Questions related to types of donations)

Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients. (December 2002)

Guidance for Industry (corrected): Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients. (February 2003)
Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires (July 2003)


Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods. (December 2007) (Contains recommendations on drugs that affect platelet function)

Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry (May 2010)

Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc) (May 2010)


Guidance for Industry: Requalification Method for Reentry of Donors Who Test Hepatitis B Surface Antigen (HBsAg) Positive Following a Recent Vaccination against Hepatitis B Virus Infection (November 2011)

Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, including Source Plasma, to Reduce Risk of Transmission of Hepatitis B Virus (October 2012)

Guidance for Industry: Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components (May 2013)

Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk for Transfusion-Transmitted Malaria (August 2013) (Updated August 2014)

Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis (September 2014)


Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products (January 2016)