

CHANGES TO AATB STANDARDS FOR TISSUE BANKING
14th Edition

SECTION K
QUALITY ASSURANCE

Current (14th Edition)

K1.000 Quality Assurance Program

K1.200 Qualification, Verification, and Validation Requirements

Each *tissue bank shall*:

- 1) develop, document, and implement protocols for the *qualification, verification, or validation* of significant components of:
 - a) facilities;
 - b) processes;
 - c) equipment;
 - d) reagents;
 - e) *labels*;
 - f) *containers*;
 - g) packaging materials;
 - h) *electronic systems*; and
 - i) *donor* eligibility criteria.
- 2) perform process *validations* for processes whose results cannot be fully *verified* by subsequent inspection and test;
- 3) assess process changes and perform *revalidation* as appropriate; and
- 4) evaluate parameters tested and determine the adequacy of the study to demonstrate necessary outcomes.

Elements or items that *must be qualified, verified, or validated shall* be determined from a risk assessment that has been approved by the *tissue bank's quality* department and the frequency of these activities will be determined by the risk assessment and results of the initial and follow up *validations*.

With Amendments

K1.000 Quality Assurance Program

K1.200 Qualification, Verification, and Validation Requirements

Elements or items that *must* be *qualified*, *verified*, or *validated shall* be determined from a risk assessment that has been approved by the *tissue bank's quality* department and the frequency of these activities will be determined by the risk assessment and results of the initial and follow up *validations*.

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 - h) *electronic systems* including *quality management systems*; and
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For information and guidance on validations, see *Process Validation: General Principles and Practices* (Jan. 2011) FDA Guidance for Industry, AATB Guidance Document No. 5 *Microbiological Process Validation & Surveillance Program*, and AATB Guidance Document No. 9 *Qualification of Packaging and Validation of Shipping and Transport Procedures*.

As Amended

K1.000 Quality Assurance Program

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Approved by the Board of Governors on April 4, 2018

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