

For any approach, documentation of the review of data and the decision made, using Quality Risk Management principles must be prepared and approved using local or regional procedures prior to the elimination of any testing.

Special attention must be given to materials intended for use in sterile applications based on global regulatory requirements, as some countries/regions may not allow reduced testing of materials used in sterile products.

Consideration must also be given if the material is used in more than one product. In this case, the more conservative approach needs to be adopted unless the material is shown to be non-critical to the quality of all affected products.

A. Elimination of Analytical Tests Performed Only at the User Site
(see Figure 1)

- (1) Determine if the test is necessary from a scientific perspective (*e.g., is the data obtained required in order to provide confidence of a satisfactory process and/or product(s).*)
 - i. If the test is scientifically necessary, continue testing.
 - ii. If the test is not needed, determine if it is required in any regulatory application.
- (2) If the test is confirmed to be a **regulatory** requirement, evaluate if the effort (resources, variation fees, etc.) required to make the regulatory change results in an overall benefit.
 - iii. If a regulatory change will provide significant benefits, initiate internal and external change control procedures to eliminate the test with supporting documentation justifying the change.
 - iv. If there is no significant benefit, continue testing.
- (3) If the test is a **non-regulatory** requirement and is considered not to be scientifically necessary, initiate change control procedures to eliminate the test, with supporting documentation justifying the change.

Figure 1: [Regulatory and Non-regulatory Tests Elimination Process Flow](#)

B. Acceptance of a Vendor COA (refer to Figure 2)

(1) Materials from other sister sites

For materials manufactured, tested and released by other sister sites, testing at the receiving site may be reduced to visual inspection and ID testing from only one

- (1) Container of each lot received (*refer to Appendix A for scope and rationale*) including those materials intended for marketing in the European Union (EU).