- What previously used procedures are available for reference purposes?

FDT.03200 Procedure Revision Review **Phase II**

All changes are dated and initialed by the laboratory director.

FDT.03300 Retained Procedures **Phase II**

Copies of all procedures (paper or electronic) and the effective dates are retained for reference.

FDT.03400 Procedure Manual **Phase II**

There is a complete procedure written for each analytical test.

NOTE: Information must include, where appropriate:

1. *Principles of each test*
2. *Preparation of reagents, standards/calibrators, and controls*
3. *Protocol for performing the analysis*
4. *Directions for calibration and calibration verification*
5. *Derivation of results (ie, direct readout, calibration from a standard or against a multi-point curve, definitions for semi-quantitative readout)*
6. *LOQ, linearity of quantitative methods and the course of action taken if results exceed this linearity*
7. *Limit of detection (LOD)*
8. *Specificity of the method (ie, interferences)*
9. *Cutoff values used for screening and confirmation*
10. *How to report when the result is below the cutoff value*
11. *Controls used in the assay*
12. *Criteria for unacceptable result*
13. *Notes, special requirements, safety precautions, etc.*
14. *Carryover potential and the actions to take when carryover is detected*
15. *Pharmacokinetic information about the drug or drug group*
16. *References*

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Developing and Managing Laboratory Documents*. 7th ed. CLSI guideline QMS02. Clinical and Laboratory Standards Institute, Wayne, PA; 2024.

FDT.04700 Procedure Manual Index **Phase II**

The procedure manual has an index or it is organized in a fashion that allows for quick retrieval of information.

SPECIMEN HANDLING

Review the written procedures and thoroughly inspect the specimen handling in the laboratory. This may require a prearranged inspection during the evening or night shifts in some laboratories. Particular attention should be paid to specimen receipt, verification of identity, accessioning, external and internal chain-of-custody, labeling, specimen examination, evaluation of sample volume, any adulteration and dilution checks, evaluation of integrity