Biological Sample Stability Validation Workshop

Workshop IndexDuration: 4 DAYS

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Quick Summary

Sample StabilityValidation TrainingQuality Driven

Building Reliable Stability Study and Validation Approaches for Biological Samples

Understand the purpose of biological sample stability studies in preserving analytical reliability across collection, transport, storage, and testing intervals.

Analytical ReliabilityStudy Purpose

Review factors that affect stability, including temperature, matrix, preservatives, storage duration, freeze-thaw cycles, and handling conditions.

Storage FactorsHandling Conditions

Learn how validation approaches support evidence-based sample acceptance windows and rejection criteria.

Acceptance CriteriaRejection Criteria

Examine pre-analytical and post-collection variables that introduce degradation risk and affect measurable outcomes.

Degradation RiskPre Analytical Control

Connect stability study planning with quality systems, documentation discipline, and operational decision making.

Quality SystemsDecision Making

Build practical awareness for implementing stability validation findings in clinical chemistry workflows.

Clinical ChemistryWorkflow Application

Overview

Validation StrategyProcess FocusedOperational Quality

Overview and Outcomes for Stability Study Design, Validation Logic, and Sample Control

Examine how biological sample stability programs are designed to define usable storage and transport limits.

Program DesignUsable Limits

Understand who should attend, including laboratory analysts, supervisors, quality teams, and sample management personnel.

Laboratory AnalystsQuality Teams

Recognize the importance of study endpoints, monitoring intervals, and decision thresholds in validation planning.

Decision ThresholdsMonitoring Intervals

Clarify how sample condition assessment supports defensible acceptance, retesting, or rejection decisions.

Condition AssessmentDefensible Decisions

Develop outcome-based thinking for translating study observations into routine laboratory controls.

Routine Controls **Outcome Based**

Strengthen awareness of documentation practices that support stability evidence and audit confidence.

Audit Confidence **Evidence Records**

Agenda

Scenario Based **Hands On Review** **Study Focused**

Agenda and Hands-on Review of Stability Conditions, Validation Criteria, and Result Interpretation

Cover agenda topics on stability study planning, specimen grouping, storage mapping, and monitoring schedules.

Study Planning **Monitoring Schedules**

Review stability stress conditions such as room temperature exposure, refrigeration, freezing, and repeated handling cycles.

Stress Conditions **Repeated Handling**

Use case scenarios to interpret shifts in sample quality, analyte response, and acceptance limit performance.

Quality Shifts **Acceptance Limits**

Practice documenting validation observations, deviation notes, trend summaries, and supporting conclusions.

Trend Summaries **Supporting Conclusions**

Explore hands-on review of storage records, labeling consistency, and condition-based interpretation checkpoints.

Storage Records **Interpretation Checks**

Reinforce workflows that support robust stability evidence across routine and special sample categories.

Robust EvidenceSample Categories

Deliverables

Reference MaterialValidation GuidanceProcess Output

Deliverables, Validation Guidance, and FAQs for Biological Sample Stability Programs

Receive practical guidance on study structure, storage controls, validation logic, and documentation checkpoints.

Study StructureDocumentation Checkpoints

Gain reference points for defining sample stability windows, reviewing deviations, and supporting quality decisions.

Stability WindowsQuality Decisions

FAQ topics address study frequency, sample grouping, acceptance limits, and handling of unexpected instability findings.

Study FrequencyInstability Findings

Participants can adapt outcomes to improve storage practices and reduce avoidable sample rejection risk.

Storage PracticesRejection Risk

Delivery recommendations support laboratory review meetings, validation planning, and quality monitoring discussions.

Review MeetingsQuality Monitoring

Policies emphasize careful handling, timely documentation, controlled storage, and transparent interpretation practices.

Controlled StorageTransparent Interpretation

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