Design Control for Labs: Ensure LDT meets User Needs, Specified Requirements & Intended Use

LDT User Needs

Intended Use
Indications for Use
Disease/Condition that will be diagnosed/prevented/mitigated
Patient Population
Healthcare Practitioner Needs
Patient Needs
Clinical Guidelines, Perspectives

LDT Design Inputs

Physical & Performance Requirements
Industry Standards
Guidance Documents
Predicates, FDA feedback (Pre-Sub)
Risk Analysis
Human Factors
Clear & Concise Requirements
Tested to Pass/Fail

LDT Design Process

LDT Design Outputs

Records showing the Design Inputs have been implemented & tested.
Figures (Components)
Component Specification
Analytical Validation Reports
Production & Assembly
Instructions for Use/SOPs
Software Documentation

Verification

LDT meets Design Inputs
"Did make the LDT according to the design & standards?"
"I made the LDT correctly"

Validation

LDT meets the User Needs
"I made the correct LDT for my intended users"
Clinical Validation

Laboratory Developed Test (LDT)

Formal documented, comprehensive & systematic review @ each design stage. Meeting Minutes with Action Items & Decisions

Design History File (DHF) Store All Evidence

Summary of Required Documentation

- Intended Use & Indications For Use
- Design & Development Plan
  - *Overall laboratory approach to LDT design & development*
  - *Timelines, Milestones & Laboratory Team Responsibilities for each LDT*
- User Needs Documented (Clinical perspectives, clinical guidelines, etc.)
- Design Inputs (LDT Requirements) Documented
- Design Outputs Documentation
- Risk Management File
  - *Risk Management Plan & Risk Assessment throughout LDT Design & Development Process*
  - *Potential LDT Failure Modes, Risk Analysis, Risk Mitigation, & Risk/Benefit Analysis*
- LDT Verification (e.g., analytical validation testing) & Validation (e.g., clinical validation) Plans/Protocols & Reports
- Traceability Matrix > map design inputs to design outputs, verification (analytical) testing & validation (clinical) testing
- Formal Design Review Documentation (Decisions, Issues, Action Items, & Outcomes > Personnel to Review Design)
- Change Control Records (any LDT changes after initial approval & through the LDT lifecycle)
- Standard Operating Procedures (SOPs) & Work Instructions (WIs)
- LDT Labeling & Instructions for Use
- Training Records showing personnel are trained on design control procedures, LDT use & quality standards

“If it's not documented, it's not done”