# LDT Regulatory Guidance

*US Food and Drug Administration Requirements in 21 CFR Parts 820.198, 803, and 806 for Laboratory-Developed Tests, Stage One*

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## Introduction

The US Food and Drug Administration (FDA) 21 CFR Parts 820.198,[1] 803,[2] and 806[3] requirements apply to enforcement discretion for laboratory-developed tests (LDTs), which begins on May 6, 2025. This document intends to provide guidance for preparing a laboratory to adhere to the FDA requirements when establishing and implementing LDTs.

This document contains the following sections:

**Section 1: General**

- Suggested Workflow for FDA LDT Requirements in 21 CFR 820.198, 803, and 806
- FDA LDT General Requirements Checklist

**Section 2: Complaints (21 CFR 820.198)**

- FDA LDT Complaints Checklist
- Supplemental Information on Complaints (21 CFR 820.198)

**Section 3: Medical Device Reporting (21 CFR 803)**

- FDA LDT Medical Device Reporting Checklist
- Supplemental Information on Medical Device Reporting (21 CFR 803)

**Section 4: Corrections and Removals (21 CFR 806)**

- FDA LDT Corrections and Removals Checklist
- Supplemental Information for Corrections and Removals (21 CFR 806)

**Section 5: Postimplementation Review and Internal Audit**

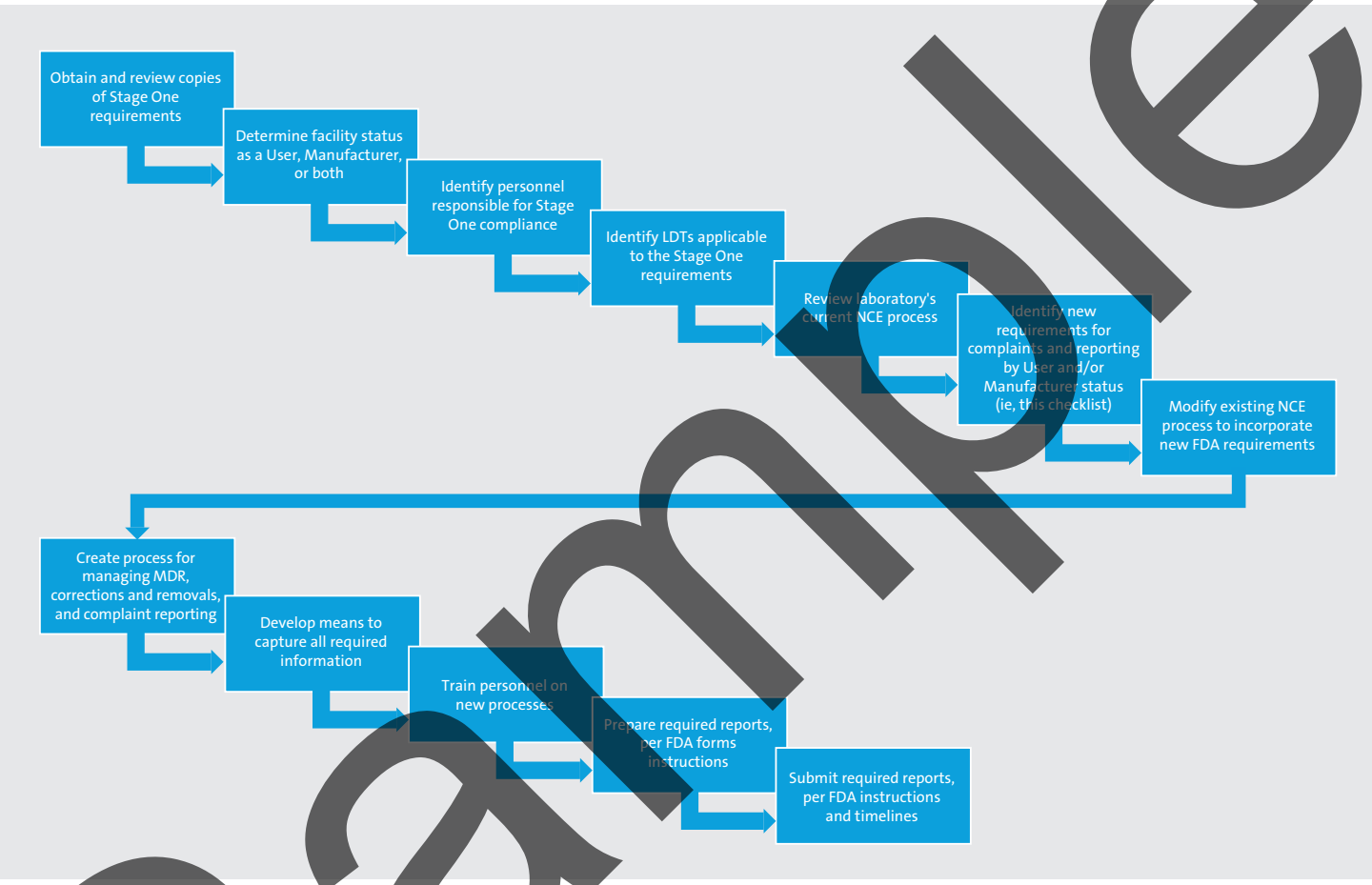
- Postimplementation Review
- Using the FDA LDT Checklists as an Internal Audit Tool

**NOTE:** In this and future LDT-stage specific documents, the FDA requirements are abbreviated with a section symbol (§) before the CFR code.

The FDA's 21 CFR regulations for Complaints, Medical Device Reporting, and Corrections and Removals are not presented in the sequence that a laboratory would follow to fulfill these requirements. Therefore, the process flow shown below provides a suggested workflow to fulfill the FDA requirements in a logical order.

## Section 1. General

The suggested workflow for FDA LDT requirements in 21 CFR 820.198, 803, and 806 can be seen in Figure 1 below.




Abbreviations: FDA, US Food and Drug Administration; LDT, laboratory-developed test; MDR, medical device reporting; NCE, nonconforming event.

**Figure 1. Suggested Workflow for FDA LDT Requirements in 21 CFR 820.198, 803, and 806**