# QUICK GUIDE: TRANSITIONING FROM LDT TO IVD: A STEP-BY-STEP GUIDE


## Abstract

The article outlines the key steps for transitioning a Laboratory Developed Test (LDT) to an FDA-regulated In Vitro Diagnostic (IVD), focusing on regulatory submissions, quality management systems, and clinical validation. It highlights the importance of ISO 13485 compliance and risk management throughout the process. The guide provides a roadmap for successfully commercializing diagnostic products in the IVD market.



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# Transitioning from LDT to IVD: A Step-by-Step Guide

Moving from LDT to IVD involves transforming a test from a laboratory setting, where regulatory requirements may be less stringent, to a commercially viable product under FDA regulation. Key steps include understanding the regulatory landscape, implementing a compliant Quality Management System, conducting risk assessments, validating performance through clinical studies, and ensuring post-market monitoring. Collaborating with industry experts and regulatory bodies is crucial for a smooth transition. Per the new regulations, a “laboratory" LDT developer is now considered a “manufacturer” of the test, hence will need to comply to 21CFR820.

Here’s a step-by-step guide:

**1. Assess the Current LDT Status**

- **Review of the LDT's current performance**: Ensure that the LDT meets clinical performance, accuracy, precision, and reliability standards.
- **Compliance with CLIA**: Make sure the LDT complies with Clinical Laboratory Improvement Amendments (CLIA) regulations. CLIA laboratories are currently under FDA enforcement discretion. But the FDA issued a Final Rule on May 6th, 2024, that will, over the next four years, alter the landscape of the LDTs (phasing out FDA’s general enforcement discretion). The first stage of this phaseout policy for the LDTs is May 6th, 2025.

**2. Market and Regulatory Strategy**

- **Classify the IVD**: Identify the product's IVD classification based on risk—Class I, II, or III. This will determine the regulatory pathway (510(k), PMA, or De Novo or Breakthrough) for FDA clearance or approval.
- **Gap Analysis**: Conduct a gap analysis to understand the differences in requirements between LDT and IVD in terms of regulatory standards, quality systems, and market demands.
- **Regulatory Submission Path**:
    - **510(k)**: For moderate-risk devices like others already on the market.
    - **PMA (Premarket Approval)**: For high-risk devices requiring more extensive clinical evidence.
    - **De Novo**: For novel low-to-moderate risk devices without a predicate.
    - **Breakthrough**: For expediting (fast track) the development and review of medical devices and drugs that diagnose or treat serious and/or novel medical conditions.

**3. Quality Management System (QMS) Compliance**

- **ISO 13485:2016 Implementation**: Ensure that the development, production, and post-market processes adhere to ISO 13485 standards including risk assessment and mitigation (ISO 14971:2019). LDTs may not require such rigorous QMS, but IVDs must be compliant.
- **21 CFR Part 820 (FDA QSR)**: Establish a QMS in accordance with the FDA’s Quality System Regulation (QSR) for medical devices. On February 22, 2024, FDA QSR was updated to Quality Management System Regulation (QMSR) to align closely with international consensus standard for QMS for medical devices ISO 13485:2016.
- **Documentation**: Develop comprehensive design controls, including Design History File (DHF) and Device Master Record (DMR), track design, testing, and changes during development.

**4. Risk Management**

- **ISO 14971:2019 Risk Management**: Implement a formal risk management process as per ISO 14971 to identify, analyze, and mitigate risks throughout the lifecycle of the IVD.
- **Usability and Human Factors**: Ensure that human factors are integrated into product design to minimize use-related risks.

**5. Clinical Validation**

- **Clinical Studies**: Perform clinical validation studies to demonstrate safety, efficacy, and accuracy in real-world settings. For LDTs, this might be less stringent, but for IVDs, robust clinical data is essential.
- **Performance Testing**: Conduct analytical performance studies to show precision, specificity, sensitivity, reproducibility, and stability.

**6. FDA Submission**

- **Prepare and Submit Documentation**: Create and submit a 510(k), PMA, or De Novo application, including all necessary preclinical and clinical data, labeling, instructions for use, and risk assessments.
- **FDA Communication**: Engage with the FDA through pre-submission meetings (Pre-Sub) to clarify the requirements and submission pathway.

**7. Manufacturing and Supply Chain**

- **Good Manufacturing Practices (GMP)**: Transition to manufacturing under FDA GMP (21 CFR 820) for medical devices, ensuring that processes are documented, reproducible, and meet regulatory standards.
- **Supply Chain Management**: Implement rigorous supplier qualification and monitoring processes for components, especially those critical to the safety and effectiveness of the IVD.

**8. Post-Market Surveillance**

- **Post-Market Requirements**: Plan for post-market surveillance and reporting of adverse events, field actions, and device recalls in compliance with FDA requirements.
- **Continuous Improvement**: Monitor product performance and gather feedback from users to improve product quality and address emerging risks.

**9. Marketing and Labeling**

- **Marketing Strategy**: Develop a go-to-market strategy tailored to the IVD market, which may differ from the LDT customer base.
- **Labeling Compliance**: Ensure that all labeling, instructions for use, and promotional materials are compliant with FDA regulations for IVDs.

**10. Collaboration with Experts**

- **Consult Regulatory Experts**: Engage regulatory consultants or quality management consultants to help navigate the transition process. These experts can assist in preparing regulatory submissions, ensuring compliance with international standards, and guiding the clinical validation process.

**Summary**

Moving from LDT to IVD involves transforming a test from a laboratory setting, where regulatory requirements may be less stringent, to a commercially viable product under FDA regulation. Key steps include understanding the regulatory landscape, implementing a compliant Quality Management System, conducting risk assessments, validating performance through clinical studies, and ensuring post-market monitoring. Collaborating with industry experts and regulatory bodies is crucial for a smooth transition.

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**Enabling you Transition RUO Products to FDA Approved**

At QuRA Solutions, we specialize in providing comprehensive solutions for companies looking to transition their research-use-only (RUO) products to FDA-approved products. Our team of experts brings together decades of experience in regulatory affairs, quality management, and strategic marketing, ensuring a seamless journey from concept to market. Discover how our expertise can drive your product's success.

**Our Team**

Jaspreet Seth, PhD, Srileka Deka, PhD, MD, Krishnan Allampallam, PhD, MBA

**Our Services**

**Regulatory Strategy and Submission**

We guide you through the complex regulatory landscape, ensuring your product meets all necessary requirements for FDA approval.

**Quality Management Systems**

Implementation and management of robust quality systems, including ISO 13485 and cGMP compliance, CAPA processes, and internal audits.

**Product Development and Validation**

From initial concept to final product, we assist in developing, validating, and documenting your product to meet regulatory and market standards.

**Market Entry and Commercialization**

Our strategic marketing expertise ensures a successful market entry, leveraging global marketing strategies and go-to-market plans tailored to your product.

**Clinical and Regulatory Compliance**

We provide comprehensive support for clinical trials, regulatory submissions, and interactions with Institutional Review Boards and Scientific Review Committees.

**Why Choose Us?**

Combining decades of experience in regulatory affairs, quality management, and strategic marketing, our team offers unparalleled expertise and support. We understand the challenges of transitioning RUO products to FDA-approved products and are dedicated to guiding you through every step of the process, ensuring your success in the market.

Partner with us to transform your innovative ideas into market-ready products. Contact us today to learn more about how we can support your journey from research to regulatory approval

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