# Are You Audit-Ready? The 2026 MoCRA Compliance Checklist

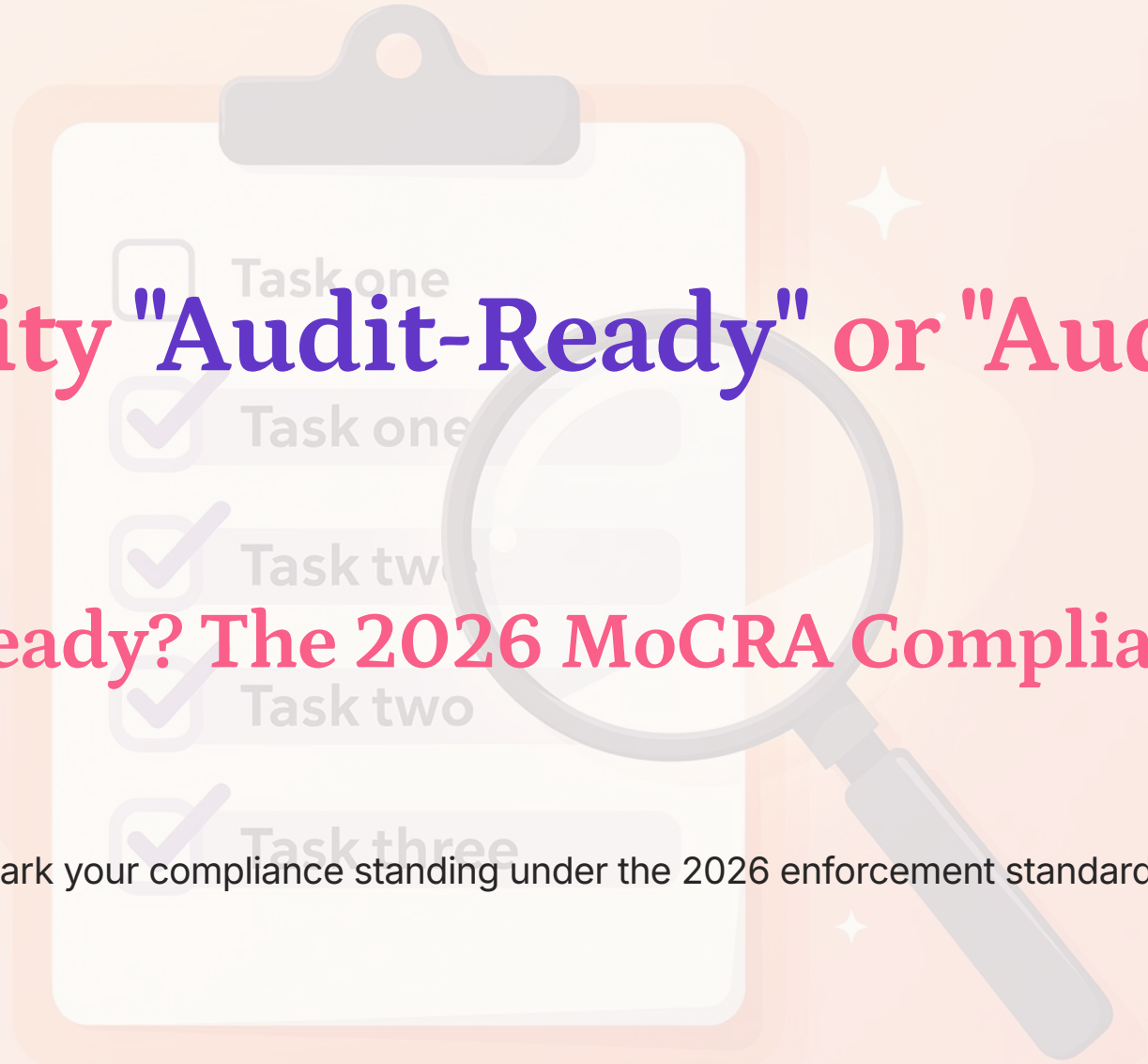
Transforms complex 2026 FDA regulations into a series of actionable "Yes/No" benchmarks.

DOWNLOADABLE PDF

# Is your facility "Audit-Ready" or "Audit-Risky"?

## Are You Audit-Ready? The 2026 MoCRA Compliance Checklist

Use this definitive guide to benchmark your compliance standing under the 2026 enforcement standards.



Phase 1

# Facility & Product Fundamentals

**Compliance is no longer optional.** Under MoCRA, your right to manufacture depends on these being current.

- **Is your facility currently registered with the FDA?**
- **Do you have a comprehensive product listing for all U.S.-marketed SKUs, including ingredient and allergen disclosures?**
- **Have you clearly identified the Responsible Person (RP) for every product line?**
- **Is your small business exemption (revenue <$1M, no high-risk products) properly documented?**


Phase 2

# Safety Substantiation (The "Dossier")

The FDA now has the authority to request your safety data during any routine inspection.

- [ ] **Do you have documented scientific evidence proving product safety for every SKU?**
- [ ] **Have you reviewed fragrance and color additives against 2026 prohibited/restricted lists?**
- [ ] **Do you have current stability reports for all products to support shelf-life claims?**
- [ ] **Can your team produce safety records within 24 hours of an FDA request?**

Phase 3

# Post-Market Vigilance (15-Day Clock)

Adverse event reporting is the #1 trigger for mandatory recalls in 2026.

- **Do you have a written SOP for adverse event complaints?**
- **Is there a digital system for 15-day Serious Adverse Event reporting?**
- **Is your staff trained to recognize "Serious Adverse Event" criteria?**
- **Are adverse event records retained for the mandatory 6-year period (3 for small businesses)?**


Phase 4

# Labeling & Transparency

Labels must now act as a bridge between the consumer and the manufacturer.

- Does every label include U.S. contact info (address, phone, or website) for adverse event reporting?
- Have you updated labels to disclose 2026 FDA-identified fragrance allergens?
- Do professional-use products explicitly state 'For Professional Use Only'?

Phase 5

# The Digital Spine (GMP & Data Integrity)

In 2026, the FDA prioritizes **"ALCOA+" data integrity**: Attributable, Legible, Contemporaneous, Original, and Accurate.

- Are batch records signed and timestamped in real-time?
- Does your manufacturing software maintain an immutable audit trail for every change?
- Can you perform a "Mock Recall" and trace a raw material lot in under 4 hours?
- Is equipment cleaning and calibration documented digitally and linked to batches?

# 📉 Your Readiness Score

### 18-21 "Yes" Checks: Leader

You are likely in the top 5% of compliant manufacturers.

### 12-17 "Yes" Checks: At Risk

You have the fundamentals, but a single "Serious Adverse Event" could trigger an audit you aren't prepared for.

### <12 "Yes" Checks: Critical

Your facility is vulnerable to mandatory recall authority and stop-sale orders.

## Next Step: Close the Gap with Batch Buddy

Don't let manual paperwork be your single point of failure. Batch Buddy was built to automate the "Digital Spine" of your facility, ensuring that every batch is MoCRA-compliant and GMP-ready from day one.

Report generated by Batch Buddy

## About This Report

This report was produced by Batch Buddy, the leading manufacturing intelligence platform for CPG brands. Our mission is to transform lab chaos into shelf certainty through AI-powered formulation, compliance, and production management.

Visit Batch Buddy | Explore More CPG Resources