



FDA Audit Readiness Checklist

For Life Sciences Companies

“Be Prepared. Be Compliant. Be Confident.”

Why This Checklist Matters:

FDA audits can happen with little warning, and the risks are high—product delays, warning letters, fines, or worse. This checklist helps life sciences companies quickly assess their audit readiness across compliance-critical areas.

10-Point Audit Readiness Checklist:


- ☐ Do you have up-to-date SOPs for clinical trials, labeling, quality control, and manufacturing?
- ☐ Are all adverse events (AEs) and complaints properly logged and categorized?
- ☐ Have all corrective and preventive actions (CAPAs) been documented and implemented?
- ☐ Are training records complete and current for all relevant staff?
- ☐ Are all marketing and promotional materials approved and archived?
- ☐ Do you have traceable batch records and quality assurance logs?
- ☐ Are internal audits conducted regularly and documented?
- ☐ Is there a documented response protocol for 483s or warning letters?
- ☐ Is your regulatory correspondence centralized and audit-ready?
- ☐ Is your leadership team briefed and prepared for audit interviews?


Quick Self-Assessment:

If you answered 'No' or 'Unsure' to 2 or more items above, your organization may be vulnerable to FDA enforcement actions. Now is the time to address these gaps.

Need Help Getting Audit-Ready?

At Regulis Legal, we specialize in building customized compliance programs and audit defense strategies for FDA-regulated companies. Let’s talk about how we can support your team.

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