

Regulatory & Compliance Field Guide

Navigating FDA, CDC, and HHS regulatory affairs

Summary

A condensed reference for contractors and program leads working across FDA, CDC, and HHS — covering policy compliance, documentation expectations, and the common audit findings that derail awards.

The regulatory map

FDA, CDC, and HHS each carry distinct review cultures. Understanding the unwritten norms is as important as knowing the CFR sections.

Policy compliance essentials

What 'compliant' actually means in practice: traceable decisions, signed reviews, archived evidence, and a defensible chain of custody.

Top ten audit findings

Drawn from a decade of pre-award and post-award reviews. Most are preventable with three weeks of housekeeping.

Documentation that survives an audit

Templates and conventions for policies, SOPs, and decision memos that hold up under inspection.

When to escalate to counsel

Clear triggers for engaging legal — and the artifacts to bring with you when you do.

This document is a practitioner briefing prepared by Regency Consulting Group for federal program leaders. It is intended for review, internal distribution, and discussion with engagement teams. For the full appendix, templates, and implementation checklists referenced above, contact your Regency partner.