DOWNLOADABLE FDA GMP GUIDE

FDA GMP Guide

A Practical 21 CFR 210 & 211 Compliance Checklist

Use this guide to check whether your quality system has the evidence needed before an FDA inspection.

FOR QA • QC • PRODUCTION • VALIDATION • REGULATORY

Source basis: FDA CGMP regulations and 21 CFR Parts 210/211.

FDA GMP Inspection Readiness

What evidence must be ready before the investigator asks?

Recommended blog heading

FDA GMP Inspection Readiness Checklist

Add this section to help readers convert FDA GMP expectations into documents, records, and controls that can be reviewed during an inspection.

Checklist focus

- SOP status and document control
- Batch and laboratory record completeness
- Deviation, CAPA, and change-control evidence
- Training, validation, calibration, and supplier files

Requirement
What FDA expects the system to control.

Evidence
What records, logs, approvals, or results prove control.

Risk
What failure could affect quality, safety, data, or recurrence.

CTA copy

Download the FDA GMP Guide and check your inspection-readiness evidence before gaps become findings.

Source basis: FDA CGMP regulations and 21 CFR Parts 210/211.

21 CFR 210 vs 211

Turn regulatory scope into daily quality-system controls.

Recommended blog heading

21 CFR 210 and 211: From Regulation to Daily Controls

Part 210

General CGMP scope, definitions, and applicability. Use it to explain which products and activities are covered by the regulatory framework.

Part 211

Detailed finished-drug requirements for people, premises, equipment, production, laboratories, records, complaints, and distribution controls.

Suggested text for article

This section helps readers understand that FDA GMP compliance is not only a regulation list. It must appear in controlled procedures, approved records, trained people, validated processes, maintained equipment, reviewed data, and traceable quality decisions.

Source basis: FDA CGMP regulations and eCFR 21 CFR Part 211 scope.

What the Download Should Solve

Give readers a usable checklist, not only a regulatory summary.

Audience problem

“I know the GMP terms, but I do not know what evidence to prepare.”

Resource promise

A practical FDA GMP checklist for documents, records, controls, and inspection conversations.

Core sections

- CGMP basics and “current” expectations
- Part 210 vs Part 211 practical map
- Inspection-readiness evidence checklist
- Common FDA GMP gaps and how to prevent them
- CTA to GMP course, Career Path, and related Pharmuni resources

Source basis: FDA CGMP guidance and QMSR update for current regulatory context.