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STANDARDS & GUIDANCE REPORT · UNITED STATES · REGULATION

21 CFR Parts 210 and 211

Current Good Manufacturing Practice for Finished Pharmaceuticals

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INDUSTRIES	Pharmaceutical	ONLINE	qesisbest.com/standard-21-cfr-210-211.html

IN FORCE Part 210 sets the status and applicability of the CGMP regulations; Part 211 holds the requirements for finished drug products.

What It Covers

The minimum manufacturing, processing, packing, and holding practices for finished human and veterinary drugs: organization and personnel, buildings, equipment, components, production and process controls, packaging and labeling, holding and distribution, laboratory controls, records and reports, and returned or salvaged products.

Who It Applies To

Manufacturers, packagers, labelers, testing laboratories and holders of finished drug products for the US market, domestic and foreign.

Key Requirements

- A quality control unit with the authority to approve or reject components, in-process materials, products, and procedures (§211.22).
- Written, approved procedures for production and process control, followed and documented as they are performed (§211.100).
- Laboratory controls, testing and release for distribution, and a written stability testing program (§211.160–211.166).
- Batch production and control records, reviewed by the quality unit, with every discrepancy investigated (§211.188, §211.192).
- Complaint files and an annual review of each product's quality data (§211.198, §211.180(e)).

Structure at a Glance

PART	TOPIC	WHAT IT ASKS FOR
Subpart B	Organization and personnel	Quality control unit, personnel qualifications and responsibilities, consultants.
Subparts C–D	Buildings, facilities, and equipment	Design, construction, sanitation, maintenance, cleaning, and calibration.
Subpart E	Control of components and containers	Receipt, testing, approval or rejection, storage, retesting.

PART	TOPIC	WHAT IT ASKS FOR
Subpart F	Production and process controls	Written procedures, charge-in, yields, in-process sampling, time limits, reprocessing.
Subpart G	Packaging and labeling control	Label issuance and reconciliation, packaging operations, expiration dating.
Subparts H, I	Holding, distribution, and laboratory controls	Warehousing, distribution, specifications, testing, stability, reserve samples.
Subpart J	Records and reports	Equipment logs, batch records, record review, laboratory records, complaint files.
Subpart K	Returned and salvaged drug products	Evaluation and disposition.

What an Auditor Asks to See

- Batch records for a chosen lot, with deviations and their investigations.
- Out-of-specification investigations and how their root cause was established.
- The annual product review and what changed because of it.
- Equipment cleaning, maintenance, and calibration records.

Requirements Checklist

Work down the list with the evidence in hand; write where each item is evidenced in the right-hand column.

#	REQUIREMENT	EVIDENCE ON FILE
1	Quality unit responsibilities written, staffed, and independent of production (§211.22).	
2	Training covers each person's functions and CGMP, and is current (§211.25).	
3	Equipment cleaned, maintained and calibrated to written schedules, with logs (§211.67, §211.68, §211.182).	
4	Components tested or verified before use, with supplier certificates qualified (§211.84).	
5	Master production records approved; batch records complete for every lot (§211.186, §211.188).	
6	Deviations recorded and justified; time limits for production steps set where appropriate (§211.100, §211.111).	
7	Label issuance controlled and reconciled (§211.125).	
8	Specifications, sampling plans, and test procedures scientifically sound (§211.160).	
9	Stability program supports the expiration date (§211.166).	
10	Every unexplained discrepancy or OOS investigated, extended to related batches (§211.192).	
11	Annual product review performed and documented (§211.180(e)).	
12	Complaints reviewed by the quality unit, with investigation and Field Alert evaluation (§211.198).	

Implementation Roadmap

1. Baseline	Walk the floor and the records against each subpart; list the gaps by risk to the patient.

2. Procedures	Rewrite the procedures that do not match the floor, and retire the forms they no longer use.
3. Investigations	Rebuild deviation and OOS investigation to reach and evidence a root cause.
4. Review	Run the annual product review as a decision meeting, not a compilation.
5. Mock inspection	Test the system the way an FDA investigator would, and close the findings through CAPA.

How It Fits With Other Requirements

ICH Q10 describes the pharmaceutical quality system these rules sit inside, and ICH Q9(R1) the risk management that should drive them. Part 11 governs the electronic versions of the records Part 211 requires. Combination products add Part 4. Active ingredients are covered by ICH Q7 rather than Part 211.

Findings We See Most Often

- Inadequate investigations of discrepancies and OOS results (§211.192).
- Procedures not followed, or not written (§211.100).
- Laboratory controls not scientifically sound (§211.160).
- Cleaning and maintenance records that do not support the equipment's state (§211.67).

Where Systems Fall Short

- Investigations that end at "analyst error" without evidence.
- Annual product reviews compiled late and acted on never.
- Procedures that point at forms that were retired years ago.

How QES helps. Procedure sets rewritten against the current forms and the current floor, with investigations built to reach a cause. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. eCFR — 21 CFR Part 210 — www.ecfr.gov/current/title-21/part-210; eCFR — 21 CFR Part 211 — www.ecfr.gov/current/title-21/part-211.

A summary for orientation, prepared by Quality Excellence Services. It does not reproduce or replace the standard or regulation: read the official text, which governs. Not legal advice.