

# FDA 21 CFR Part 211 - Subpart J: Records and Reports

## **Official Source (Always Valid):**

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-J>

## **Scope of Subpart J (Records & Reports):**

This section defines FDA requirements for documentation, traceability, and reporting in GMP pharmaceutical manufacturing systems.

## **Key Regulatory Requirements:**

- §211.180 – General requirements for records & retention
- §211.182 – Equipment cleaning and use logs
- §211.186 – Master production and control records
- §211.188 – Batch production and control records
- §211.194 – Laboratory records (critical for data integrity)
- §211.198 – Complaint files and investigations

## **Inspection Focus (FDA Perspective):**

- Data integrity (ALCOA+ principles)
- Traceability of batch records
- Timeliness and completeness of deviations
- Laboratory raw data review
- Complaint trending and investigation quality

## **Deviation & Change Control Linkage:**

Deviation → Investigation → CAPA → Change Control → Effectiveness Check → Trending Review

## **Common FDA Findings:**

- Missing raw data or incomplete batch records
- Backdated entries in logs
- Inconsistent laboratory documentation
- Weak complaint investigation systems