

BatchBuddy.AI — PLM-ERP Platform for CPG Manufacturers

FDA 21 CFR Part 11 Compliance Whitepaper

Electronic Records, Electronic Signatures — Platform Compliance Statement

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SCOPE: This document covers BatchBuddy.AI's Enterprise plan features. Core Part 11 controls (audit trails, access controls, record integrity) are present on all paid plans. Electronic Batch Records (EBR) and digital e-signatures are Enterprise-tier features.

Executive Summary

This whitepaper documents how BatchBuddy.AI's PLM-ERP platform satisfies the requirements set forth in Title 21 of the Code of Federal Regulations, Part 11 (21 CFR Part 11), governing Electronic Records and Electronic Signatures for FDA-regulated industries.

BatchBuddy.AI is purpose-built for supplement, cosmetic, and food manufacturers who operate under FDA oversight. Every production run on the platform automatically generates a complete, immutable electronic batch record with full audit trail, operator e-signatures, and lot-level traceability — the precise controls required by Part 11 and enforced during FDA inspections.

1. Regulatory Background

1.1 Overview of 21 CFR Part 11

21 CFR Part 11, published by the U.S. Food and Drug Administration, establishes the criteria under which the FDA considers electronic records, electronic signatures, and handwritten signatures executed on electronic systems to be trustworthy, reliable, and equivalent to paper records and handwritten signatures.

Part 11 applies to records that are: (a) created, modified, maintained, archived, retrieved, or transmitted under any FDA regulation, and (b) submitted to the FDA in electronic form. For supplement and food manufacturers, this encompasses batch production records, laboratory records, distribution records, and quality control documentation.

1.2 Scope of Application for CPG Manufacturers

Supplement manufacturers operating under 21 CFR Parts 111 (Current Good Manufacturing Practice for Dietary Supplements) must maintain electronic records that comply with Part 11 if those records are used in place of paper records. BatchBuddy.AI's Electronic Batch Records and audit trail features are designed to meet these requirements

natively.

2. Part 11 Requirements — Compliance Mapping

2.1 Subpart B — Electronic Records

21 CFR Part 11 Requirement	Regulation	BatchBuddy.AI Feature	Status
System validation — accuracy, reliability, and performance	§11.10(a)	Validated SDLC; automated test suite; staged release pipeline	✓ Compliant
Generate accurate and complete copies of records	§11.10(b)	PDF export of batch records, COAs, and audit logs	✓ Compliant
Protection of records for accurate and ready retrieval	§11.10(c)	Immutable record storage; indexed for instant retrieval	✓ Compliant
Limiting system access to authorized individuals	§11.10(d)	Role-based access control (RBAC); unique user credentials; session timeout	✓ Compliant
Secure, computer-generated, time-stamped audit trails	§11.10(e)	Automated audit trail on every data write; UTC timestamps; tamper-evident log	✓ Compliant
Operational checks to enforce permitted sequencing	§11.10(f)	Production workflow state machine; QC gates enforce step sequencing	✓ Compliant
Authority checks to ensure valid access	§11.10(g)	Permission matrix enforced at API level; per-action authorization	✓ Compliant
Device checks to determine validity of data input source	§11.10(h)	Session-bound authentication; all actions tied to authenticated user	✓ Compliant
Education and training of personnel	§11.10(i)	In-app training resources; admin-managed user onboarding documentation	✓ Supported
Written policies and adherence controls	§11.10(j)	Policy documentation templates; compliance policy library in resource center	✓ Supported
Controls over system documentation	§11.10(k)	Version control on all formulation documents; change history with attribution	✓ Compliant

2.2 Electronic Signatures — §11.50 and §11.70

21 CFR Part 11 Requirement	Regulation	BatchBuddy.AI Feature	Status
Printed name of signer in signed records	§11.50(a)(1)	E-signature captures full legal name, user ID, and role at time of signing	✓ Compliant
Date and time of signature in signed records	§11.50(a)(2)	UTC timestamp recorded at signature event; displayed on batch record	✓ Compliant
Meaning of signature in signed records	§11.50(a)(3)	Signature meaning configured per workflow step (e.g., Reviewed, Approved, Released)	✓ Compliant
Electronic signatures unique to one individual	§11.100(a)	One-to-one user account to identity mapping; no shared credentials permitted	✓ Compliant

21 CFR Part 11 Requirement	Regulation	BatchBuddy.AI Feature	Status
Identity of individual verified before e-signature	§11.100(b)	Re-authentication required at point of signature; password confirmation enforced	✓ Compliant
Signed records linked to their respective electronic records	§11.70	Cryptographic binding of signature to record; tampering detected and flagged	✓ Compliant

3. Technical Architecture Supporting Compliance

3.1 Audit Trail Architecture

BatchBuddy.AI implements an append-only audit log that captures every system event affecting regulated data. The audit trail records:

- User identity (unique user ID and display name)
- Timestamp in Coordinated Universal Time (UTC)
- Nature of action (create, modify, delete, approve, sign)
- Before and after values for any modified field
- IP address and session identifier
- Record ID and record type affected

The audit log is written to an isolated, append-only data store logically separated from the primary application database. Application-layer code cannot modify or delete audit entries. Access to raw audit data is restricted to system administrators with explicit audit access roles.

3.2 Electronic Batch Record Generation

Upon closure of a production run, BatchBuddy.AI automatically generates a complete Electronic Batch Record (EBR) that includes:

- Batch number, formula name, and batch size
- All ingredients used with exact lot numbers, quantities, and supplier information
- FIFO lot selection rationale and expiry dates
- Operator identity for each production step
- Yield calculations and deviation records
- QC test results with pass/fail determinations
- E-signatures for each required sign-off step
- Complete tamper-evident audit trail for the batch lifecycle

EBRs are stored in immutable format. Once a batch record is closed and signed, no modifications are possible. Any discrepancies must be logged as deviations with their own audit trail.

3.3 Role-Based Access Control

Role	Access Permissions
Administrator	Full system access including user management, audit log access, compliance configuration, and all production data.
Quality Manager	Review and approve batch records, access all QC data, generate COAs, initiate deviations. Read-only access to formulations.

Role	Access Permissions
Production Operator	Start and close production runs, record QC data, sign assigned batch record steps. Cannot modify formulations or inventory master data.
Formulator	Create and modify formulations, manage ingredient library. Cannot access financial data or production sign-offs.
Read-Only / Auditor	View all records and audit trails without modification capability. Designed for compliance officers and third-party auditors.

4. Data Integrity and Record Retention

4.1 Immutability and Tamper Evidence

All regulated records in BatchBuddy.AI are stored with cryptographic integrity checks. Any unauthorized modification to a record will be detected and flagged by the system. Records cannot be deleted by any user, including system administrators, once they are part of a closed batch record or signed document.

4.2 Backup and Disaster Recovery

BatchBuddy.AI maintains automated daily backups with point-in-time recovery capability. Backup data is encrypted at rest using AES-256 and stored in geographically redundant locations. Recovery Time Objective (RTO) is under 4 hours; Recovery Point Objective (RPO) is under 24 hours.

4.3 Record Retention

BatchBuddy.AI retains all electronic records for a minimum of 7 years, consistent with FDA GMP requirements for supplement manufacturers under 21 CFR Part 111. Enterprise customers may configure longer retention periods as required by their specific regulatory obligations. All retained records remain fully searchable and exportable throughout the retention period.

5. Customer Responsibilities

While BatchBuddy.AI provides the technical controls required by 21 CFR Part 11, regulated manufacturers retain responsibility for the following procedural elements of compliance:

- Establishing written policies and SOPs governing use of electronic records and signatures
- Conducting user training and maintaining training records
- Performing periodic access reviews to ensure only authorized personnel hold active accounts
- Conducting system validation activities appropriate to the risk level of the application
- Reviewing and acting upon audit trail exceptions and anomalies
- Ensuring their specific use of the platform meets all applicable regulatory requirements

NOTE: BatchBuddy.AI provides a Validation Support Package to Enterprise customers that includes an Installation Qualification (IQ) and Operational Qualification (OQ) template protocol, supporting customer validation activities consistent with GAMP 5 guidelines. Contact compliance@batchbuddy.ai to request the package.

6. Conclusion

BatchBuddy.AI is designed from the ground up for manufacturers who operate in FDA-regulated environments. The platform's Electronic Batch Records, tamper-evident audit trails, role-based access controls, and electronic signature

capabilities collectively satisfy the technical requirements of 21 CFR Part 11 for electronic records and signatures.

Manufacturers using BatchBuddy.AI's Enterprise plan can approach FDA inspections with confidence that their electronic production records are complete, attributable, legible, contemporaneous, and accurate — the ALCOA principles that define data integrity in regulated manufacturing.

Questions about compliance documentation?

compliance@batchbuddy.ai · batchbuddy.ai/trust · batchbuddy.ai/register?plan=enterprise