

## 21 CFR 11 – Quick Reference (Version 1)

### Kiss CSV Services

Scope: Applies to electronic records and electronic signatures used in FDA-regulated activities.

Key Principle: Electronic systems must ensure accuracy, reliability, integrity, confidentiality, and authenticity.

#### Core Controls:

- Secure, computer-generated audit trails (date/time stamped).
- System validation ensuring accuracy, consistency, and reproducibility.
- Controlled user access with unique logins and role-based permissions.
- Protect records from alteration, loss, or unauthorized access.

#### Electronic Signatures:

- Must be unique to an individual and verifiable.
- Require two-factor authentication (ID + password).
- Signature meaning must be linked to each signed record.

#### Record Requirements:

- All actions must follow ALCOA+ (Attributable, Legible, Contemporaneous, Original, Accurate).
- Records must be retained and retrievable for the required retention period.

#### - **Additional Versions Available:**

Version 2 (Intermediate): Includes diagrams, extended explanations, and practical compliance examples.

Version 3 (Professional): Full breakdown of controls, validation expectations, audit defense notes, and use-case mapping.

Both advanced versions will be available for purchase via the Kiss CSV Template Store.