

# FACTBIRD

**21 CFR Part 11**

Validation Support Package

[factbird.com](https://factbird.com)

For customers using Factbird in  
FDA-regulated environments

# 21 CFR Part 11

## Validation Support Package

# 21 CFR Part 11 Validation Support Package

Factbird E-signature Compliance Statement  
For customers using Factbird in FDA-regulated environments

### What is this document?

This document describes how Factbird's e-signature functionality supports customer compliance with 21 CFR Part 11, Electronic Records; Electronic Signatures.

It is intended to help you understand what Factbird provides and what your organization needs to do.

### How Factbird E-signatures Work

When an operator completes an Activity that requires a signature:

1. They select their identity from a list of Operator Profiles
2. They enter their 6-digit PIN
3. The system validates the PIN and records the signature
4. The signed record becomes read-only

If a correction is needed later, the original record stays unchanged and a new version is created (also requiring a signature).

### About Factbird

Factbird is a cloud-based platform. Your organization controls who has access to your records through Factbird's user and operator management. All data is encrypted in transit and at rest.

### Compliance Mapping

This table shows how Factbird features map to 21 CFR Part 11 requirements.

What the regulation requires	How Factbird addresses it	What you need to do
System validation (§11.10a)	We provide this document to support your validation.	Validate the system for your intended use.
Audit trails (§11.10e)	Automatic, always-on audit trail for all signed records. Captures who, what, when. Server timestamps (UTC).	Review audit trails per your procedures.

# 21 CFR Part 11

## Validation Support Package

What the regulation requires	How Factbird addresses it	What you need to do
Access controls (§11.10d, g)	Role-based permissions control who can manage the system. Operator Profiles are signing identities only, not login accounts. Only authorized Factbird users can create or manage Operator Profiles.	Configure roles appropriately. Control who has access.
Signature shows name, date/time, meaning (§11.50)	Every signed record displays: Full name, Employee ID, Timestamp, Signature meaning (e.g. "Completed by").	Define what signature meanings you need.
Signature linked to record (§11.70)	Signatures are permanently attached to the specific record version. Cannot be removed or copied.	N/A
Each signature unique to one person (§11.100a)	Each Operator Profile represents one individual. Employee ID must be unique.	Ensure one profile per person. Verify identity before creating profiles.
Identity verified before signature issued (§11.100b)	Supervisor confirmation required when creating an e-signature.	Establish identity verification procedure.
Two-component signature (§11.200)	Component 1: Identity selection Component 2: 6-digit PIN	Train users on PIN confidentiality.
PIN management (§11.300)	PINs are hashed (never stored in plain text). Configurable expiry (1-24 months). Lockout after 5 failed attempts.	Define PIN policy. Establish reset procedures.

# 21 CFR Part 11

## Validation Support Package

What the regulation requires	How Factbird addresses it	What you need to do
Operational system checks (§11.10f)	The system enforces permitted sequencing of steps. Required fields must be completed before submission. Corrections always create a new version.	Define which fields are required. Document intended use procedures.
Authority checks (§11.10g)	Only users with an active, non-expired, non-locked e-signature can sign. Only authorized Factbird users can create, activate, deactivate, or reset operator e-signatures.	Regularly review who has signing authority. Deactivate profiles promptly when operators leave or change roles.
Exporting records (§11.10b)	Activities can be printed. Data can be exported to Excel. Exports include signature details, timestamps, and audit trail information.	Establish a procedure for producing and storing record copies when needed.
Device checks (§11.10h)	Factbird is a cloud-based web application accessible via HTTPS. Access requires authenticated login credentials.	Ensure devices are managed and secured per your IT policy.
Personnel qualifications (§11.10i)	Factbird provides compliance documentation and user-facing guidance. Only users with verified signing identities can sign records.	Ensure personnel have required education, training, and experience. Maintain qualification records.
Training (§11.10j)	Factbird provides compliance documentation and guidance on e-signature procedures.	Train all users who create, modify, or sign records. Maintain training records.
System documentation controls (§11.10k)	Factbird maintains documentation for system operation. Signed records and audit trails cannot be modified or deleted.	Maintain records of how the system is configured and used. Document changes to templates, profiles, or permissions.

# 21 CFR Part 11

## Validation Support Package

### What the regulation requires

Record retention  
(§11.10c)

### How Factbird addresses it

Factbird stores all records and audit trails while your subscription is active. Records cannot be accidentally deleted.

### What you need to do

Define how long records need to be kept. Export and archive records if you leave Factbird.

### Technical Details

Item	Specification
PIN format	6 digits
PIN storage	Hashed (not stored in plain text)
Lockout threshold	5 failed attempts
Validity period	Configurable: 1-24 months (default: 12)
Timestamps	Server-generated, UTC with timezone offset
Audit trail	Always enabled, cannot be disabled

### Responsibilities

#### Factbird provides:

- E-signature functionality as described above
- Audit trail generation and storage
- This compliance documentation
- Record integrity (signed records cannot be modified)

#### Your organization is responsible for:

- Validating the system for your intended use
- Creating and maintaining SOPs for e-signature use
- Verifying operator identity before creating profiles
- Managing user access and permissions
- Training users on e-signature procedures and PIN confidentiality
- Defining PIN policies
- Reviewing audit trails
- Determining which Activities require signatures
- Defining how long records need to be kept
- Having written policies that hold individuals accountable for actions taken under their e-signature
- Notifying the FDA (if required) that your electronic signatures are intended to be legally binding

# 21 CFR Part 11

## Validation Support Package

### Definitions

Term	Meaning
Operator Profile	A user identity for someone who signs Activities (has name, Employee ID, location)
E-signature	The PIN-based credential attached to an Operator Profile or User
Activity	A checklist, form, or SOP execution in Factbird
Activity Template	The configuration that defines what an Activity contains

### Questions?

Contact your Factbird account representative or [support@factbird.com](mailto:support@factbird.com).