

Validation notes

No Part 11 / audit / e-sign in codebase; controlled install, licenses, methods, exports.

Honest scope for QA / CSV / IT: what Quanto does **not** claim, and what labs can still control.

What was not found in the codebase

Quanto does **not** implement 21 CFR Part 11-style **audit trail**, **electronic signature**, or dedicated electronic-record controls as product features. Do not document or market the desktop app as Part 11 compliant on the basis of this release.

Instrument licensing ([Licensing](#)) and prerelease expiry are **not** substitutes for Part 11 controls.

What labs can still do

Practical controls that do not require inventing missing features:

Control	How
Controlled install	Fixed path <code>C:\Program Files\Quanto</code> ; silent deploy (Silent deploy); pinned build
License folder	Shared <code>LicenseFolder</code> / Public Documents license path; restricted write
Method packages	Versioned <code>.qtm</code> on a controlled share; Replace vs Append discipline
Batch packages	Study folder + <code>QuantoResults*.qtb</code> next to raw data; backup policy
Export evidence	Excel / PDF report export with baked plots (Reports)
Permissions	NTFS on Program Files, license folder, study shares (Installation)
Reset / support	Shift+splash recycle; Recovery zips under Local AppData

Prerelease expiry

Alpha / prerelease binaries expire **60 days after build** (`SplashIdentity.ExpirationDaysAfterBuild`). That is separate from instrument serial licenses. Plan upgrades before expiry; do not treat expiry as a validation audit feature.

Related

- [Licensing](#)
- [Installation and folders](#)
- [Compatibility](#)