



# Validation & Security Pack

For the QA and IT reviewers qualifying CMCfy as a supplier. Issued 31 October 2026.

**In short.** CMCfy runs in the browser. Files, calculations, projects and reports stay on the customer's computer or network folder; nothing is uploaded. Text is sent to a writing service only when a user presses a CMCfy Writer button and approves the exact text. Each release is versioned and fingerprinted, and an automated IQ/OQ verifies it on the customer's own computers.

|                         |                                                                                     |
|-------------------------|-------------------------------------------------------------------------------------|
| <b>Supplier</b>         | Accolade Software Products LLC, a Delaware limited liability company, United States |
| <b>Product</b>          | CMCfy™ CMC and regulatory writing software (cmcfy.com, app.cmcfy.com)               |
| <b>Contact</b>          | sales@cmcfy.com                                                                     |
| <b>Security reports</b> | sales@cmcfy.com (subject "Security"); see cmcfy.com/.well-known/security.txt        |

## 1. Data flow: what leaves the computer

| Item                                                 | Where it is handled                       | Leaves the computer?                           |
|------------------------------------------------------|-------------------------------------------|------------------------------------------------|
| <b>Files you load (Excel, Word, PDF, scans)</b>      | Read on your computer                     | Never sent                                     |
| <b>Calculations, pass/fail, statistics</b>           | Run on your computer                      | Never sent                                     |
| <b>Projects, versions, audit trail, lab notebook</b> | Saved in a folder your company picks      | Never sent                                     |
| <b>Word and PDF reports</b>                          | Written on your computer                  | Never sent                                     |
| <b>CMCfy Writer text (only when you press it)</b>    | You see and approve the exact text first  | Sent once to the writing service; no copy kept |
| <b>Your login and subscription</b>                   | Held by our sign-in and billing providers | No CMC data in them                            |

Every tool page is served with a Content Security Policy that blocks all connections except the writing endpoints, and shows a live count of network requests. An offline copy blocks every connection. IT can verify this with the browser's developer tools, or by unplugging the network.

## 2. Third-party providers

| Provider                         | Used for                                  | What it sees                                                                          |
|----------------------------------|-------------------------------------------|---------------------------------------------------------------------------------------|
| <b>Cloudflare</b>                | Hosts cmcfy.com and app.cmcfy.com         | Page requests only. Tool pages send no data back.                                     |
| <b>Anthropic (Claude models)</b> | CMCfy Writer, only when a user presses it | The approved text of that one request. CMCfy keeps no copy; not used to train models. |

| Provider                                   | Used for                                                                                      | What it sees                                     |
|--------------------------------------------|-----------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Sign-in and billing providers</b>       | Accounts and subscriptions                                                                    | Name, work email, company and plan. No CMC data. |
| <b>Your own cloud account (Enterprise)</b> | CMCfy Writer through your Anthropic, AWS Bedrock, Azure, Google Vertex, OpenAI or xAI account | Under your contract, or switch CMCfy Writer off. |

### 3. 21 CFR Part 11 and EU GMP Annex 11

| Requirement                                            | What CMCfy provides                                                                                               | What stays with the customer                       |
|--------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| <b>11.10(a) Validation</b>                             | Automated IQ/OQ (21 scripted tests) plus supplier documents VAL-01 to VAL-08                                      | You run PQ for your intended use (VAL-10 template) |
| <b>11.10(b) Accurate and complete copies</b>           | Word, PDF and CSV exports; versions read back exactly                                                             | —                                                  |
| <b>11.10(c) Protection of records</b>                  | Records are plain files in your folder; each version is fingerprinted                                             | Backup and retention of that folder                |
| <b>11.10(d) Limiting access</b>                        | Named user on every audit-trail entry and signature                                                               | Access to the project folder and computers         |
| <b>11.10(e) Audit trail</b>                            | Chained, time-stamped (UTC) entries with old and new values, user and reason; edits outside CMCfy show as altered | Review the audit trail per your SOP                |
| <b>11.10(f)–(h) Operational and device checks</b>      | Required steps and blocking checks in each tool; release fingerprint checked by IQ-01                             | —                                                  |
| <b>11.10(i) Training</b>                               | A training guide and PDF for every module                                                                         | Your training records                              |
| <b>11.10(k) System documentation</b>                   | Versioned releases with a manifest; our SOP-01 to SOP-04                                                          | —                                                  |
| <b>11.50 / 11.70 Signatures</b>                        | Printed name, date, time and meaning, bound to the content signed; a signed entry is locked                       | Your e-signature policy                            |
| <b>Annex 11 §4, §11 Validation and periodic review</b> | Each release is versioned, so you qualify one version and know it will not change underneath you                  | Periodic review                                    |
| <b>Annex 11 §7 Data storage</b>                        | No CMC data on our servers                                                                                        | Your storage and backup                            |

Summary only. The clause-by-clause assessment is document VAL-08.

### 4. Validation documents

| Document      | Title                                      | Owner                 |
|---------------|--------------------------------------------|-----------------------|
| <b>VAL-01</b> | Supplier statement and validation summary  | CMCfy                 |
| <b>VAL-02</b> | User requirements specification (baseline) | CMCfy, adopted by you |

| Document     | Title                                                                                 | Owner                  |
|--------------|---------------------------------------------------------------------------------------|------------------------|
| VAL-03       | Functional specification                                                              | CMCfy                  |
| VAL-04       | Risk assessment                                                                       | CMCfy, reviewed by you |
| VAL-05 / 06  | IQ and OQ protocols (automated on the validation page)                                | Run by you             |
| VAL-07       | Traceability matrix                                                                   | CMCfy                  |
| VAL-08       | 21 CFR Part 11 and EU GMP Annex 11 assessment                                         | CMCfy and you          |
| VAL-09 to 11 | Validation plan, PQ protocol and summary report templates                             | You                    |
| SOP-01 to 04 | Our development and change control, defects, release approval and training procedures | CMCfy                  |

The IQ/OQ runs at [app.cmcfy.com/app/validation.html](http://app.cmcfy.com/app/validation.html) and downloads a Word execution record for signature. The documents verify CMCfy's controls and calculations as supplied; the customer's validation also needs its own requirements, a PQ in its intended use, procedures and training.

## 5. Release control and guidance currency

Each release has a date, a build fingerprint and a manifest of every page; IQ-01 checks the fingerprint. Customers qualify one version and know it will not change underneath them.

We check every guideline CMCfy cites against the agencies' own sites. When a new version comes into force, the tools, the review checklists and the training guides are updated within 30 days, and the change is listed on the update log. Citations last checked: 30 October 2026.

| Expected by             | Guideline revision being watched                                                 | What is changing                                                                                                                                                                                         |
|-------------------------|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>30 November 2026</b> | Stability testing (Q1A(R2), Q1B, Q1D, Q1E; Q5C for biologics)                    | ICH Q1 consolidated revision (merges Q1A–Q1F and Q5C): Step 2 draft April 2025; Step 4 planned at the ICH Assembly, Prague, 17–18 November 2026                                                          |
| <b>31 December 2026</b> | Residual solvents Q3C(R9)                                                        | Q3C(R10): revised PDEs for DMF, dichloromethane and ethylene glycol; Step 4 planned December 2026                                                                                                        |
| <b>31 January 2027</b>  | Directive 2001/83/EC and Regulation (EC) No 726/2004                             | EU pharma package (new Directive and Regulation repealing 2001/83/EC and 726/2004): adoption and Official Journal publication expected late 2026; most provisions apply 24 months after entry into force |
| <b>31 March 2027</b>    | EU GMP Part I, Annex 1 (2022), Annex 11 (2011), Annex 15 (2015), Annex 16 (2016) | Revised Annex 11, Chapter 4 and new Annex 22 (artificial intelligence): drafts July 2025, consultation closed October 2025; final texts awaited                                                          |

| Expected by              | Guideline revision being watched                                                                                                                                                                                    | What is changing                                                                                                                                                     |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>30 June 2027</b>      | Validation of analytical procedures Q2(R2) and analytical procedure development Q14                                                                                                                                 | USP <1225> revision aligned with Q2(R2)/Q14 proposed in Pharmacopeial Forum 51(6); USP <1225> as published stays official until then                                 |
| <b>30 June 2027</b>      | CTD quality M4Q(R1)                                                                                                                                                                                                 | M4Q(R2) restructures Module 2.3 and 3: Step 2 draft May 2025; consultation closed March 2026; Step 4 planned June 2027                                               |
| <b>31 August 2027</b>    | Container Closure Systems for Packaging Human Drugs and Biologics                                                                                                                                                   | Draft Container Closure Systems for Human Drugs and Biological Products (FDA-2026-D-7957, 14 August 2026) will replace the 1999 guidance and the 2002 Q&A when final |
| <b>30 September 2027</b> | Pesticide registration: FIFRA section 3, 40 CFR 152 (procedures, data citation), 40 CFR 158 (data requirements), 40 CFR 160 (GLP), 40 CFR 156 (labeling), 40 CFR 180 (tolerances); PR Notices 86-5 and 98-5; PRIA 5 | PRIA 5 fee and decision-time tables run to 30 September 2027; reauthorisation (PRIA 6) expected before then                                                          |

## 6. Recent releases

| Date                   | Change                                                                                                                                                                                                                                                                                                                                                 |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>31 October 2026</b> | Trust Center and Validation & Security Pack: One page and one PDF for your QA and IT reviewers: where data goes, the providers we use, how CMCfy maps to 21 CFR Part 11 and EU GMP Annex 11, and the validation documents.                                                                                                                             |
| <b>31 October 2026</b> | Lab Notebook: Record experiments from templates, attach any file, sign and witness entries, and send signed results straight into the matching report tool.                                                                                                                                                                                            |
| <b>31 October 2026</b> | Write the report with CMCfy: CMCfy Writer drafts the narrative from your data and protocol, lists the gaps for you to accept or ignore, and takes edits in plain words. Numbers still come from fixed rules.                                                                                                                                           |
| <b>31 October 2026</b> | Stability Studio: several tests at once: Assay, impurities, dissolution and other attributes evaluated together, each with its own ICH Q1E shelf life.                                                                                                                                                                                                 |
| <b>31 October 2026</b> | Release protection: Tool code is minified and fingerprinted per release; stricter security headers on every tool page.                                                                                                                                                                                                                                 |
| <b>30 October 2026</b> | All citations checked against the agencies' sites: Every guideline cited by the tools, the review and the training guides was checked. New in force: EU variations guidelines C/2025/5045 (from 15 January 2026, new Q-codes), FDA nitrosamine less-than-lifetime guidance (24 September 2026), ICH E6(R3) Annex 2 and the FDA QMSR (2 February 2026). |
| <b>30 October 2026</b> | "Guidances applied" in every tool and report: Each tool page and every Word or PDF report lists the guidelines and versions the data was compared with.                                                                                                                                                                                                |
| <b>30 October 2026</b> | FDA inspections: Mock inspection readiness, Form 483 and warning letter responses, a remediation tracker and FDA citation trends.                                                                                                                                                                                                                      |

Full log: [cmcfy.com/updates](https://cmcfy.com/updates). This document describes the software as supplied; drafts produced with CMCfy must be reviewed and approved by the customer's qualified people.