

Is the Excel template included in the Chemical Solutions Qualification kits CFR Part 21.11 compliant - FAQ

Date: 1-MARCH-2024 Last Updated: 5-JULY-2025

In the strictest regulatory sense, no Excel-based tool can be fully 21 CFR Part 11 compliant on its own. Compliance with 21 CFR Part 11 requires a validated, closed system with features like:

- Secure user access
- Full audit trails
- Electronic signature controls
- Oversight by a qualified Quality Assurance (QA) system

What Does This Mean for the Excel Template?

The Excel template included with our **Chemical Solutions Qualification Kits** is not a standalone 21.11-compliant system. However, it is:

- Locked and protected to prevent accidental or unauthorized changes
- Validated to ensure accurate calculations for precision, linearity, and other qualification metrics
- Designed to work with data generated from your 21.11-compliant HPLC software

This means your original qualification data remains compliant, and the Excel tool simply processes that data in a controlled and reliable way.

QA Acceptance

Our spreadsheet is designed to meet the expectations of most Quality Control (QC) and QA departments. A validation report is available upon request to support internal review and documentation requirements.

 Click [HERE](#) for PQ Kit™ ordering information