

Will the FDA accept the Excel software in the Qualification Kits as valid - FAQ

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The short answer is: you should consult your internal regulatory or quality assurance team for a definitive answer based on your specific compliance framework.

However, in general, the FDA does accept data generated and managed in Excel, provided that your organization applies its standard internal controls—such as version control, access restrictions, audit trails, and validation procedures—to ensure data integrity and compliance with 21 CFR Part 11 or other applicable regulations.

Excel remains a widely used tool in regulated environments, but its acceptance hinges on how it is implemented and controlled within your quality system.

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