# Food and Drug Administration CFR Title 21 Part 11 United States

## Microsoft helps customers comply with these US Food and Drug Administration regulations.

### Microsoft and FDA CFR Title 21 Part 11

Microsoft enterprise cloud services undergo regular independent third-party SOC 1 Type 2 and SOC 2 Type 2 audits and are certified according to ISO/IEC 27001 and ISO/IEC 27018 standards.

Although these regular audits and certifications do not specifically focus on FDA regulatory compliance, their purpose and objectives are similar in nature to those of CFR Title 21 Part 11, and serve to help ensure the confidentiality, integrity, and availability of data stored in Microsoft cloud services. Our qualification approach is also based on industry best practices, including the International Society for Pharmaceutical Engineering (ISPE) GAMP series of Good Practices Guides and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Practices for Computerized Systems in Regulated GxP Environments.

In addition, qualification guidelines for Microsoft Azure and Microsoft Office 365 provide a detailed explanation of how Microsoft audit controls correspond to the requirements of CFR Title 21 Part 11, guidance for implementing an FDA qualification strategy, and a description of areas of shared responsibility.

### Microsoft in-scope cloud services

Although there is no certification for complying with FDA CFR Title 21 Part 11, the following Microsoft enterprise cloud services have undergone independent, third-party audits that may help customers in their compliance efforts. These services include:

- Azure: Cloud Services, Storage, Traffic Manager, Virtual Machines, and Virtual Network
  Learn more
- Dynamics 365 and Dynamics 365 U.S. Government
  Learn more
- Office 365 and Office 365 U.S. Government
  Learn more

### Audits, reports, and certificates

The audit reports for in-scope Microsoft cloud services for SOC 1 and SOC 2 Type 2, ISO/IEC 27001, and ISO/IEC 27018 standards attest to the effectiveness of the controls Microsoft has implemented and may help customers in their compliance with FDA CFR Title 21 Part 11.

### How to implement

- **Azure GxP Guidelines**
  A comprehensive toolset for using Azure while adhering to GxP best practices and regulations.
  Learn more
- **Title 21 Part 11 Qualification Guides**
  Get help establishing a qualification strategy that complies with FDA guidelines for electronic records.
  - Azure
    Learn more
  - Office 365
    Learn more

## About FDA CFR Title 21 Part 11

The Code of Federal Regulations (CFR) contains the rules and regulations for executive departments and agencies of the US federal government. Each of the 50 titles of the CFR addresses a different regulated area.

Subsequent FDA CFR Title 21 regulates food and drugs manufactured or consumed in the United States, under the jurisdiction of the Food and Drug Administration (FDA), the Drug Enforcement Administration, and the Office of National Drug Control Policy. The regulations outlined in CFR Title 21 Part 11 set the ground rules for the technology systems that manage information used by organizations subject to FDA oversight. Any technology system that governs such GxP processes as Good Laboratory Practices (GLP), Good Clinical Practices (GCP), and Good Manufacturing Practices (GMP) also requires validation of its adherence to GxP.

CFR Title 21 Part 11 sets requirements to ensure that electronic records and signatures are trustworthy, reliable, and generally equivalent substitutes for paper records and handwritten signatures. It also offers guidelines to improve the security of computer systems in FDA-regulated industries. Subject companies must prove that their processes and products work as designed, and if these change, they must revalidate that proof. Best practices guidelines cover:

- Standard operating procedures and controls that support electronic records and signatures such as data backup, security, and computer system validation.
- Features that ensure that the computer system is secure, contains audit trails for data values, and ensures the integrity of electronic signatures.
- Validation and documentation that supply evidence that the system does what is intended, and that users can detect when the system is not working as designed.

## Frequently asked questions

**To whom does the standard apply?**

FDA CFR Title 21 Part 11 applies to organizations with products and services that deal in FDA-regulated aspects of the research, clinical study, maintenance, manufacturing, and distribution of life science products.

**How do Microsoft enterprise cloud services demonstrate compliance with FDA CFR Title 21 Part 11?**

Using the formal audits prepared by third parties for SOC 1 Type 2, SOC 2 Type 2, ISO/IEC 27001, and ISO/IEC 27018, Microsoft is able to show how relevant controls noted within these reports address the requirements.

Audited controls implemented by Microsoft help ensure the confidentiality, integrity, and availability of data, and correspond to the applicable regulatory requirements defined in Title 21 Part 11 that have been identified as the responsibility of Microsoft. The qualification guidelines for Azure and Office 365 detail how Microsoft audit controls correspond to those requirements.

**Can I use Microsoft compliance in the certification process for my organization?**

Yes. The independent third-party compliance reports of the IEC/ISO 27001, ISO/IEC 27018, SOC 1, and SOC 2 standards attest to the effectiveness of Microsoft controls. Microsoft enterprise cloud customers may leverage the audited controls described in these related reports as part of their own CFR Title 21 Part 11 risk analysis and qualification efforts. Customers who build and deploy applications subject to FDA regulation are responsible for ensuring that their applications meet FDA requirements.

**What are Microsoft responsibilities for maintaining compliance with this standard?**

Microsoft ensures that its enterprise cloud services meet the terms defined within the governing Online Services Terms and applicable Service Level Agreements (SLAs). These define our responsibility for implementing and maintaining controls adequate to secure and monitor the system.

## Additional resources

- Strategies for Life Sciences Companies using Microsoft Azure with GxP Systems
- FDA guidance for industry Part 11: Electronic records and signatures
- Microsoft and GxP
- Microsoft Government Cloud