

Kiteworks Empowers GxP Compliance in Regulated Industries

Ensure Data Integrity and Security

GxP refers to a set of quality guidelines and regulations designed to ensure safety and efficacy in various regulated industries. GxP, or “Good x Practice,” encompasses quality guidelines established by regulatory bodies like the FDA to ensure safety, efficacy, and quality in regulated industries such as pharmaceuticals, biotechnology, medical devices, food and beverage, and cosmetics. The Code of Federal Regulations (CFR) Title 21, Part 11 addresses electronic records and signatures, and subpart B outlines controls for electronic records in closed and open systems, emphasizing the need for system validation, audit logs, and access controls to ensure record authenticity and integrity. This regulation aims to make electronic records as trustworthy and reliable as their paper counterparts, facilitating the transition to digital processes while maintaining compliance and data integrity in GxP-regulated industries. Kiteworks supports compliance with GxP CFR Title 21, Part 11 to address the electronic records. Here’s how:

Guard the Authenticity of Records With Access Controls and Encryption

Subpart B of CFR Title 21, Part 11 outlines compliance requirements for electronic records. It mandates the implementation of controls to ensure authenticity, integrity, and confidentiality of records in both closed and open systems. Key requirements include system validation, ability to generate accurate copies, access limitation, secure audit logs, authority checks, and proper documentation control. These measures aim to make electronic records as reliable and trustworthy as paper records. The Kiteworks platform employs advanced system validation techniques, including intrusion and anomaly detection integrated with SIEM systems, allowing for real-time threat analysis and response. Kiteworks’ ability to generate accurate and complete copies of records is supported by its extensive audit logging capabilities, which capture all user activities and system changes without throttling, ensuring no data is lost even during high-volume periods. These logs are immutable, time-stamped, and easily integrated with external SIEM tools, facilitating thorough inspections and reviews.

Access limitation and authority checks are enforced through Kiteworks’ robust role-based access controls and least-privilege principles. The platform supports multiple authentication methods, including multi-factor authentication, ensuring that only authorized individuals can access, modify, or delete records.

Solution Highlights



Multi-factor authentication



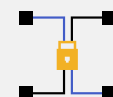
Role-based access controls



Least-privilege principles



Immutable audit logs



Strong encryption

Secure audit logs are maintained through computer-generated, time-stamped logs that integrate with NTP servers for accuracy. Kiteworks also implements strong encryption measures, including AES-256 bit, TLS 1.3 and 1.2 support, along with a dual-layer encryption approach that protects data even if the operating system is compromised. These features, combined with the platform's ability to enforce permitted sequencing of steps and events through content-based risk policies, ensure that electronic records managed by Kiteworks meet or exceed the reliability and trustworthiness standards set for paper records.

Kiteworks delivers robust support for organizations striving to achieve and maintain compliance with GxP regulations, specifically CFR Title 21, Part 11. By addressing the critical requirements for electronic records and signatures, Kiteworks enables regulated industries to confidently embrace digital transformation without compromising data integrity or security. The platform's robust features, including advanced authentication methods, role-based access controls, immutable audit logs, and encryption, directly align with the stringent demands of regulatory bodies. This compliance is crucial for pharmaceutical, biotechnology, medical device, food and beverage, and cosmetic industries, as it ensures product safety, efficacy, and quality throughout the development and manufacturing processes. By implementing Kiteworks, organizations not only meet regulatory requirements but also enhance their operational efficiency, reduce risks associated with noncompliance, and build trust with consumers and regulatory agencies. Ultimately, Kiteworks plays a vital role in safeguarding public health and safety by supporting the integrity of electronic records and signatures in GxP-regulated environments.