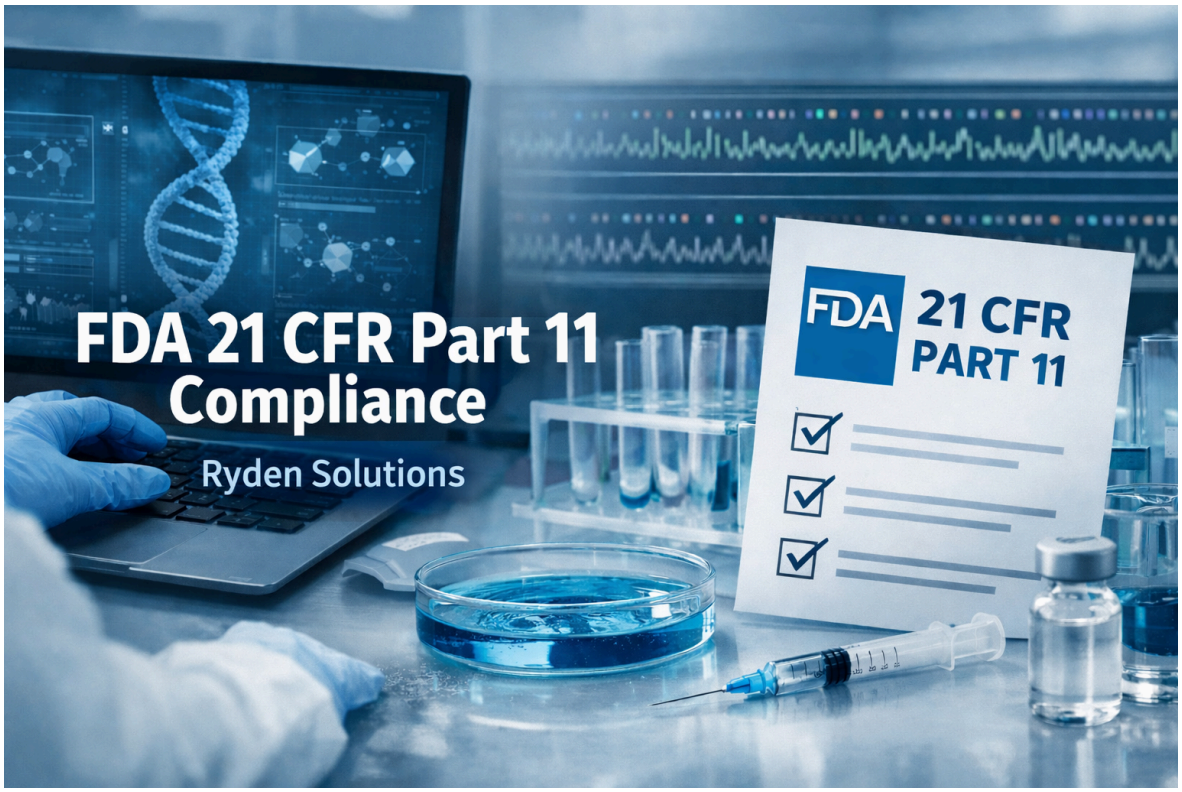

21 CFR Part 11 and Ryden AI

At Ryden AI, our goal is to deliver innovative technology solutions while helping you navigate the complex landscape of regulatory compliance. We understand that 21 CFR Part 11 is a familiar part in regulated industries, and we want to be clear about how this regulation is used for the platform; we also follow its core principles as industry best practices where applicable.

What Is 21 CFR Part 11?

21 CFR Part 11 is a set of guidelines established by the FDA to govern electronic records and electronic signatures. Its primary purpose is to ensure that digital documents used in generating records required by the regulation, regulated submissions, and other relevant communications with the agency meet rigorous standards for reliability, authenticity, and integrity. For organizations that use electronic systems to directly manage or submit data for regulatory approval, Part 11 compliance is essential.

How Ryden AI Differs in Scope and Function

Ryden AI is designed primarily as an intelligent analytics, workflow, and data processing platform that serves as a decision-support tool. Rather than functioning as the system of record for electronic submissions, QMS record retention or clinical data reporting, our solution provides insights and supports quality and operational decisions. Because of this distinct role, 21 CFR applies to two of our three modules.

When Part 11 Applies to Ryden AI

1. **Records Module:** Ryden AI's Records Module, has the ability to not only check compliance against all of your record types (DHR, Batch Records, etc), but it also has the ability to have those records signed off, to approve verification of the record.
2. **Supplier Module:** The Supplier module allows a client to view the current compliance level of each supplier. It uses both the Regulations and Records modules; but only the Records module needs to be 21 CFR compliant. Since records can be pushed to a supplier, and require that supplier to sign off on those records; we support 21 CFR Part 11.

When Part 11 Does Not Apply to Ryden AI

1. **Requirements Module:** The Requirements module in Ryden does not have any sign off process, and does not edit documents, and is not 21 CFR required.
2. **Intended Use:** Ryden AI is not used to create or manage regulatory documents. Instead, it offers analytical support and process optimization that benefits your operational or quality systems without acting as the definitive record storage location.
3. **System Architecture:** Our platform is built to prioritize information processing and decision-making rather than to serve as a validated system for electronic records. This means that while data integrity, security, and traceability are always maintained, they do not require the complete framework outlined by Part 11.
3. **Complementary Nature:** Many of our customers have systems that directly handle electronic records or submissions that are subject to Part 11; such as an eQMS platform. Ryden AI is designed to work alongside these systems, enhancing overall operational efficiency without duplicating regulatory responsibilities or processes. In fact, Ryden has some of the most recognizable eQMS company partners.

21 CFR Part 11 Requirements we cover include but are not limited to:

- System Validation
- Audit Trails
- Data Security & Access Controls
- Electronic Signatures
- Record Retention & Accessibility
- Personnel Training

Commitment to Quality, Security, and Compliance

While Ryden AI is subject to 21 CFR Part 11 in the Records Module, we remain steadfast in our commitment to building secure, reliable, and high-quality technology; for all parts of our solution.. We integrate industry-standard security measures, robust auditing functions, and data governance practices so that our platform meets the expectations of modern quality and regulatory requirements. Our customers can leverage Ryden AI with complete confidence, knowing that while the specific scope of Part 11 may not apply, quality and compliance remain at the heart of our design.

Examples of security controls referenced in 21 CFR Part 11 that Ryden also implements include encryption, individual login credentials with password complexity requirements, audit trails, and separation of data access based on user roles.

The Ryden AI platform does contain a 21 CFR Part 11 assessment which can quickly identify if you are compliant and specific improvement areas against 21 CFR Part 11 for systems that require it. The Ryden team is aware of the 21 CFR Part 11 requirements and has implemented many validations of software programs against it.

As Ryden's functionalities and intended uses continue to expand, the applicability of 21 CFR Part 11 and applicable record and security requirements will be reassessed. We are always adding and improving the Ryden AI system.