



Ryden Records Intelligence

The new standard for compliance: from checking documents to proving your Documents follow your Procedures.

Ryden is releasing a breakthrough module that finally closes the loop between what your Quality System says you *should* do-and what your teams and suppliers *actually* do.

Introducing **Records Intelligence**, an Al-driven engine that evaluates real-world records (complaints, CAPAs, DCOs/ECOs, inspections, training, validations, calibrations, and more) against your design requirements, QMS requirements such as procedures and Good Documentation Practices (GDP) - continuously, verifiably, at scale, and all in one place.



Why this changes everything

For years, compliance teams have had to choose between **sampling** and **speed**. Auditors review a tiny fraction of records; everyone else wrangles spreadsheets and spot-checks. With Records Intelligence, you can **assess 100% of applicable records** (or any sampling level you choose), unlock early issue detection, and turn record reviews into a real-time **continuous internal and supplier audit program** - ready for inspection every single day.

Even in cases where 100% of records have historically been reviewed as part of the normal QMS process, Ryden's time savings and additional **automated insights** unlock benefits never realized before.

What you'll get on Day 1

- 60%+ time saved on mandatory record reviews; freeing your experts to focus on root
 causes, process fixes, throughput, and savings from less time preparing for, traveling to
 and executing audits on these same records
- **Escalations before defects matter.** For example, receiving inspection paperwork can be reviewed *before* parts hit the dock; low-risk pathways like skip-lot or dock-to-stock become data-driven.
- Audit-ready evidence-anytime. Individual record reports and cross-record trending are generated out-of-the-box and easy to verify and archive no more messy spreadsheets.
- Faster ROI-measured in months. Automated trending, Management Review metrics, and slide outputs are produced for you-every cycle. Whether it is Mergers and Acquisitions, Pre-Submission, supplier audits, or Corporate audits, the saves will add up.

How it works

Assess against what matters. Ryden ingests your governing specifications/requirements, procedures, work instructions, form templates, and applicable regulatory requirements, then evaluates each record on four dimensions:



- Accuracy did the process outputs meet specification requirements? Did the parts pass?
- Completeness & FDA inspection readiness did the record include all required fields, approvals, data, and attachments? Were common inspection pitfalls for that specific record type addressed?
- QMS process adherence was the right work done as the procedure and/or specification requires?
- **GDP** were Good Documentation Practices followed (legible, attributable, contemporaneous, etc.)?

Each record produces a structured report with overall section compliance scores, Y/N compliance for each requirement, AI rationale, and room for your notes and overrides-all versioned and attributable. Cross-record views trend performance by record type topic (Design, Manufacturing, Quality, Regulatory), facility, regulatory requirements, and timeframe, including first-time yield calculations and improvement deltas.



Built for real-world variety

Ryden analyzes nearly any time of record from eQMS integrations or outside of integrations. Examples of accepted record formats include:

- **Electronic records** (eQMS entries with audit trails & signatures)
- Electronic Documents, PDFs, Word, Spreadsheets (with/without fixed templates)
- Scanned, handwritten forms (supported with clear performance caveats)
- Optional pre-approval checks so creators can fix issues before signing.

Where the savings stack up

The more record types that are assessed, the more ROI realized and insights generated. Real world examples include:

Receiving & Incoming Inspection

Review time drops ~60%; paperwork issues are caught pre-arrival; parts can flow to inventory without queueing inspection when appropriate.

Auto-compute FTY, CpK, and SPC drift - then recommend skip-lot or dock-to-stock with enforcement via system rules.

Complaints

60% less time validating timeliness, risk assessments, investigation links, and CAPA references.

Lower-risk complaints may no longer require dual approvers-Ryden serves as the independent second opinion.



Change Control (DCO/ECO)

Review cycles shrink dramatically; rework and ping-pong declines as completeness/GDP gaps are flagged earlier.

Quality/Compliance trending and slides generated automatically.

Across all areas, Records Intelligence *reduces internal audit time by up to 80%* because results are always on - and inspection-ready.

A dashboard executives will actually use

- Compliance Score by record type
- Trend signals (increasing, stable, decreasing) you can tune by facility/record type
- Opportunity density (avg. high/low-priority items per record) by topic and record type
- **Drill-through** from trends to affected records to the exact requirement behind a non-conformance-in one click.

Designed for your operating model

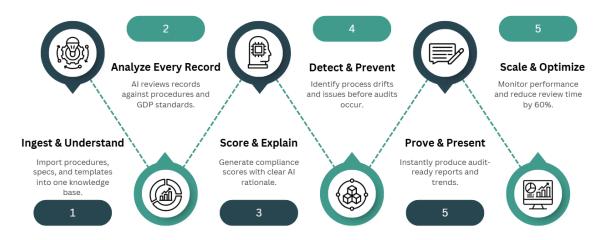
- Choose **individual**, **sampled**, **or 100**% verification by facility and record type-scale from dozens to **25,000+ records/month per facility**.
- Limit scope by topic (Design, Manufacturing, Quality, Regulatory) and by applicable **regulatory requirements** tied to the governing procedures.
- Role-appropriate access for executives, admins, and consultants with action-plan commenting.





From Records to Readiness

Al-powered compliance in six simple, audit-ready steps



Pricing that aligns to value

Simple **per-record pricing** with volume discounts. Larger, complex records are supported without forcing you into unwieldy tiers. Pre-upload or upload at assessment time; purchased vs. remaining assessments are tracked for full spend transparency.

Security & scope

- Manufacturer records are in-scope initially; supplier records follow the same approach and are available as an extension.
- Records with patient medical information are out of scope (keeps HIPAA/GDPR out of the boundary).
- No edits are made inside Ryden; if you update a record, Ryden re-assesses the new version as a fresh artifact for complete traceability.



What this means for your next audit

- From snapshots to motion pictures. Stop proving compliance once a year;
 demonstrate it every day with rolling evidence, trends, and effectiveness checks (including CAPA/SCAR).
- From opinions to measurements. Replace sampling and anecdotes with 100% data-backed conformance, trend graphs, and compliance-aware rollups.
- From firefighting to prevention. Visibility into frequent GDP errors, process drift, late sign-offs, and aging "living documents" means you can prioritize fixes before auditors-and patients-feel the impact.

Ready to change the compliance industry with us?

<u>Schedule a Demo</u> and learn how leaders are cutting review time by 60%+, trimming audit prep by up to 80%, and shifting resources from paperwork to performance in weeks, not years.