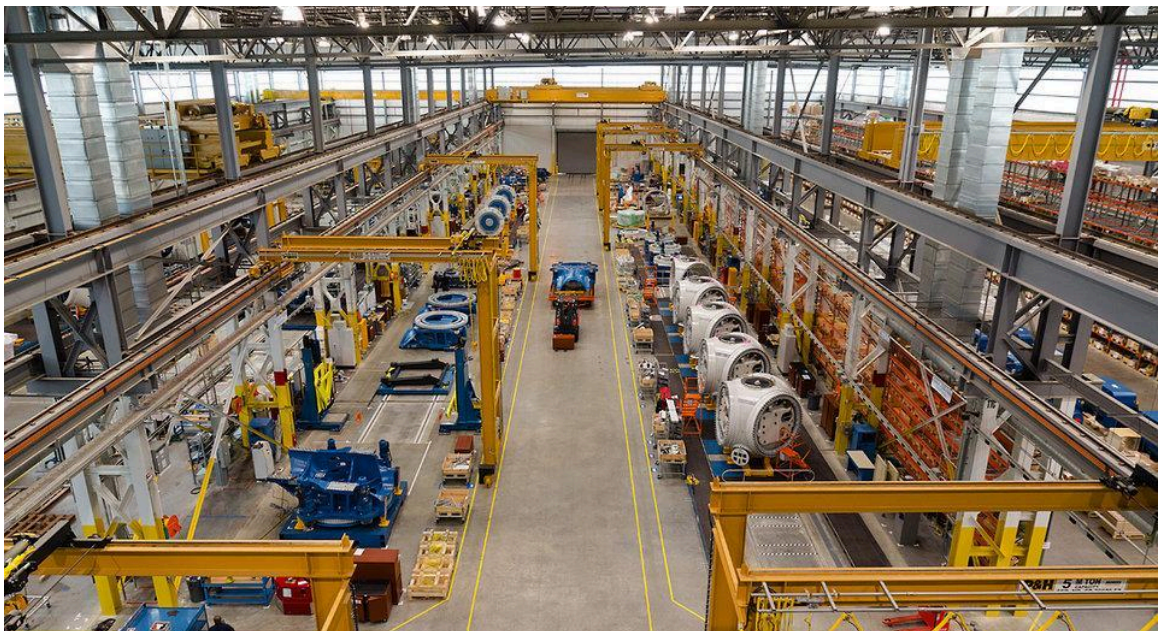
Using Ryden AI For Your Supplier Evaluations, Auditing & Monitoring



Ryden AI supplements your supplier management and audit program to maximize effectiveness and efficiency. This guide provides the best practices for using Ryden's output. This guide was written by the Ryden team; who collectively have over 100+ years of experience and 200+ internal and external QMS, technical documentation and other audits in the life science industry.

Call 1.312.219.5471 or email us at: contact@ryden.ai

Why Ryden?

AI-Driven Features: We leverage advanced AI trained for real-time regulatory gap analysis. Whether you're a startup or a global enterprise, Ryden helps you stay proactive and informed across the entire supply chain.

Scalable, Multi-Facility Architecture: Built with large organizations in mind, our platform ensures each user experiences a custom-tailored environment—perfect for multi-site and multi-country operations regardless of the languages of your supply chain.

Customizable for Global Compliance: With Ryden, you can choose laws, regulations, and industry standards to meet the needs of your compliance requirements. Our intelligent recommendations adapt to evolving global regulatory landscapes.

Benefits of A Ryden-Aided Supplier Management System

1. **Supplier Qualifications & Evaluations**
    - Customize Ryden to meet your supplier compliance checklist requirements
    - Save time from doing a supplier audit yourself
    - Save cost from requiring the supplier to complete 3rd party consultant audits or certifications for every regulatory requirement
    - See supplier's results compared to the rest of the industry

2. **Supplier Audits**
    - Maximize time spent interviewing team members and reviewing evidence records vs. procedural reviews.
    - Ryden does 100% coverage of a requirement vs. a traditional sampling-based approach.
    - Save time writing supplier audit reports with our comprehensive report.
3. **Supplier Corrective Action Request (SCAR) Effectiveness Checks**
    - Ensure prior audit findings and/or corrective actions were properly addressed.
    - If the effectiveness check is on a requirement that was already being used in the Ryden's system, then the recheck effectiveness check is no additional cost!

4. **Supplier Monitoring**
    - Quickly verify new or updated regulatory requirements with suppliers without a full fledge audit
    - Consolidate all supplier insights across the entire supply chain in one place across all laws/regulatory requirements. Even if suppliers are across the world, have internal documents in various languages or use various eQMS platforms

****Suppliers will need to agree to use Ryden****

Benefits To Supplier of Using Ryden

The supplier receives many other benefits beyond supporting your needs.

1. **Improved internal regulatory processes and internal audits**
    - Suppliers can use Ryden for any use case that you, the manufacturer, are also already using Ryden for including internal audits, regulatory monitoring, premarket submissions, global expansions, process improvements, and CAPA effectiveness checks.
2. **Use Ryden as a Portal to Select & Track Who To Share Information With**
    - Audit trail of which revisions of Ryden gap analysis reports were shared with which client customers.
    - Have control over when the reports are shared.
3. **Sales and marketing tool**
    - Ryden's gap analysis reports and compliance scores can help suppliers earn new business especially to show compliance against a requirement that they are not 3rd party certified against already.

Deep Dive

Supplier Audit Planning

Companies often have a supplier audit schedule and/or plan governing activities. These typically state who the supplier auditor is, who the supplier company auditees are, the dates of the audits, and scope/area of the audits, etc. The schedules are periodically updated; typically at least once or twice a year. Note: In this document, Ryden refers to a supplier audit schedule as a document which references which audits will be conducted over the next 12 to 24 month period. Whereas a supplier audit plan is a more detailed plan document on how a specific audit on the supplier audit schedule is to be executed.

- **Rationalize frequency of audits**: many QMS and product requirements do not change frequently and do not generate many (if any) records. If Ryden confirms those processes and documentation are compliant then rationalize auditing it less frequently and/or only using Ryden's output as the supplier audit activities without need for additional interviews. In other words, rationalize a desktop supplier audit only.
- **Assess product or regulatory requirements not historically in scope of supplier audits**: Supplier audit programs often audit the same subset of regulatory requirements that apply to a facility or product line over and over. These are often the ones that require audits against them to be performed such as ISO 13485. With the time and resources savings from using Ryden, consider doing additional Ryden-aided audits on regulatory requirements that do not get reviewed often (if ever). Examples could include HIPAA, recently released FDA guidance documents, a product-specific standard referenced in the Design History File, or corporate standards, etc. Keep in mind that ISO 13485:2016 section 4.2.1 and other regulatory requirements have catch-all needs to 'comply with any other regulatory requirement that applies to your facility or product'.
- **Rationalize duration of audits**: If the rest of this Ryden AI in Supplier Management guide is used, then it will save time to execute the audit and write its report. Calculate the expected time savings of verifying AI accuracy and doing a sampling of records and interviews outside of Ryden to put the condensed audit duration in the supplier audit schedule.
- **Reaudits:** Many companies have a requirement to reaudit a supplier with many nonconformances within a specific time period of the original audit. These reaudits are added to the supplier audit schedule as they arise. The reaudit is often dual purpose to see if there are additional nonconformances not found during the original audit and to verify effectiveness of closed corrective actions from the original audit nonconformities. Using Ryden is a fantastic way to limit time and resources on reaudits for both of those purposes.

Supplier Audit Execution

Desktop Audits:

- Ensure your company's Quality Management System (QMS) documentation including policies, procedures, objectives, work instructions, form templates, etc. are compliant to regulatory requirements such as regulations, guidance documents, and standards.
- Ensure your product design documentation contains the appropriate information such as the EU Medical Device Regulation Technical Documentation requirements or a product specific standard that is being used for conformity.
- Ensure your QMS or product documentation complies with your company's own standards. Larger enterprise companies often have a company-wide or corporate standard that all facilities must adhere to. Ryden can perform this assessment (if included in current Ryden subscription scope).

In-person Audits:

- Verify that records of conformity to company policies and procedures are being completed properly
- Verify that employee team members understand the regulatory requirements or company policy and procedure requirements. It does not perform audit interviews or execute training effectiveness check questionnaires.

Here are best practices and watchouts while using Ryden AI to execute a supplier audit.

1. **Verify Ryden AI results**
    - Ryden is only as accurate if the appropriate input documentation was used. Verify that is the case and incorrect or missing information could have led to incorrect output.
    - Skim through the Ryden gap analysis report(s) to ensure where it states conformity (no gap) that the documentation evidence source being referenced seems appropriate.
    - Skim through the Ryden opportunities list to see which are the most important. Verify in the documentation that the gap truly exists before writing a supplier audit nonconformity.

2. **Discuss any opportunities found with auditees (such as the area's subject matter experts) to see if they agree.**
    - Whether using AI-assistance for supplier audits or not, discussing any potential nonconformities with the auditee before putting it in the supplier audit report is a best practice.
3. **Do not write a supplier audit nonconformity or SCAR on every opportunity identified by Ryden AI.**
    - Ryden includes best practices and may highlight opportunities for improvement that are not mandatory per the given regulation or standard.

Supplier Audit Reports

Do's:

- Include a copy of a downloaded Ryden gap analysis report(s) in your supplier audit report; such as an appendix.
- Remove any Ryden opportunities that are false positives in the Ryden App to hide them prior to downloading the report. This is done by changing the status of that opportunity in the Ryden system.
- Reference that you used Ryden in any supplier audit report cover page(s). It is best practice to update your supplier audit QMS procedure to allow and prompt the use of Ryden during supplier audits.
- Reference that you, as the supplier auditor, reviewed the Ryden gap analysis report output with the supplier and agree with its content. This is typically done by signing the Ryden gap analysis report itself or signing a separate supplier audit report cover page which contains this verification evidence.

Dont's:

- Use Ryden's gap analysis report as your sole supplier audit evidence record. Follow your supplier audit's procedure. The Ryden analysis report out-of-the-box does not contain typically required supplier audit report information such as name of the supplier auditor, anyone interviewed, records reviewed outside of the Ryden system, etc.
- Leave it up for interpretation of which Ryden AI opportunity findings are being considered supplier audit nonconformities and/or require corrective action of some kind. Include in the supplier audit report cover sheet what the nonconformities are.
- If Ryden's outputs (in the software or the downloaded reports) indicate a potential prioritization or severity of the opportunities found, then do not automatically accept that as your own supplier audit nonconformity severity. Do a more

tailored product and process risk assessment with the supplier and assign a supplier audit nonconformity that aligns with your company's nonconformity severity definitions.

Save Time By:

- Quickly copy and merge the documentation reviewed list at the end of the Ryden report template with your list of records reviewed outside of Ryden to generate
- Not retyping the traceability link of QMS documentation to the regulatory requirements section but use Ryden's report to do it for you.
- If you agree that a Ryden-identified opportunity is a supplier audit nonconformity, then you can copy and paste the gap text found as the nonconformity text.
- **Work with Ryden** to create a custom supplier audit report cover page that seamlessly uses Ryden's output while ensuring all supplier audit report content requirements from your company's procedures are covered.

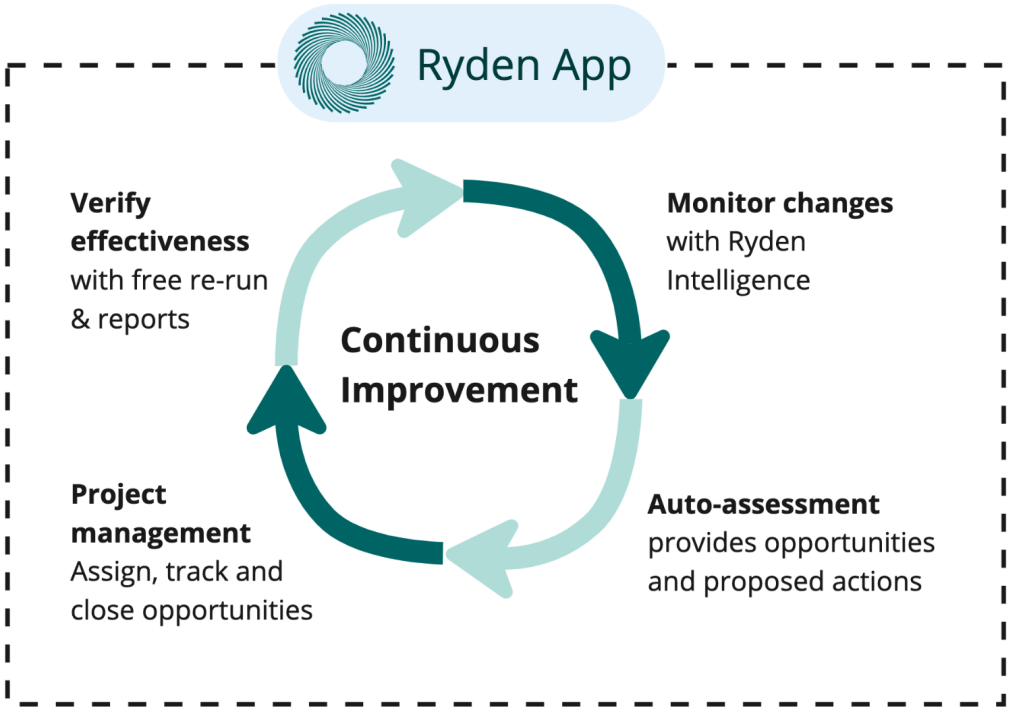
SCAR Effectiveness Checks

Supplier audits often include a verification that prior audit nonconformities from the same area were properly addressed and closed. Similarly, typically recently closed and currently opened SCARs from that area being audited are reviewed.

- **Prior audit nonconformity closures**: if a prior nonconformity was on the QMS or product documentation that is in Ryden's capabilities to check, then run the assessment to see. If you are auditing a section of ISO 13485 (such as design controls), then run the ISO 13485 assessment, go to the design control section and see if the same gap remains.

- **CAPA effectiveness checks**: The same process applies for verifying if effectiveness checks that closed out CAPAs in the area you are auditing were executed properly. Follow the same process as described in the 'Prior audit nonconformity closures' above.

  Note: Ryden does not currently have the capability to run an assessment on only one regulatory requirement clause.



Conclusion

Ryden works with your supplier's essential documentation to keep teams synchronized and compliant:

1. **Prep** – Rationalize less frequent and/or smaller in scope audits knowing Ryden is supplementing your activities.
2. **Execution** – Use Ryden's gap analysis reports and opportunities identified allow the supplier and you to focus on what matters. The system promotes the supplier to take action and close their opportunities in the Ryden system as well as in their own processes and documentation.

Contact Ryden on how to best use Ryden to support your supplier management program.