Using Ryden AI In Your Internal Audit Program

Ryden's AI supplements your internal 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.

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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.

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.

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 Internal Audit

1. **Audit Duration and Scope Justifications**
    - Rationalize having a reduced frequency of audits for areas Ryden confirms are in compliance.
    - Reduce the time needed for external and internal audits.
    - Increase the scope of your audits, without adding to your cost.
2. **Gap Analyses vs. Regulatory Requirements**
    - 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 internal audit reports with our comprehensive audit report.
3. **Effectiveness Checks**
    - Ensure prior audit findings were properly addressed.
    - Collaborate across departments and regions to maintain alignment.

Internal Audit Planning

Companies often have an internal audit schedule and/or plan governing activities. These typically state who the internal auditor is, who the 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 an internal audit schedule as a document which references which audits will be conducted over the next 12 to 24 month period. Whereas an internal audit plan is a more detailed plan document on how a specific audit on the internal 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 internal audit activities without need for additional interviews. In other words, rationalize a desktop audit only.
- **Assess regulatory requirements not historically in scope of internal audits**: Internal 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 internal 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 HIsotry 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 Internal Audits 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 internal audit schedule.
- **Re-audits:** Many companies have a requirement to re-audit an area with many nonconformances within a specific time period of the original audit. These reaudits are added to the internal 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.

Internal Audit Execution

Ryden AI currently can:

- 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).

Ryden AI currently does not:

- 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 an internal audit.

1. **Verify Ryden AI results**
    - Ryden is only as accurate if the appropriate input documentation was used. Verify that is the case as incorrect or missing information could lead to incorrect output.
    - Read through the Ryden gap analysis report(s) to ensure where it states conformity (no gap) that the documentation evidence source being referenced seems appropriate.
    - Reading through the Ryden opportunities list to see which are the most important. Verify in the documentation that the gap truly exists before writing an internal 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 internal audits or not, discussing any potential nonconformities with the auditee before putting it in the internal audit report is a best practice.

3. **Do not write an internal audit nonconformity or CAPA 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.

4. **Use Ryden AI's output to tailor where to dig deeper**

Internal Audit Reports

Do's:

- Include a copy of a downloaded Ryden gap analysis report(s) in your internal 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 internal audit report cover page(s). It is best practice to update your internal audit QMS procedure to allow and prompt the use of Ryden during internal audits.
- Reference that you, as the internal auditor, reviewed the Ryden gap analysis report output and agree with its content. This is typically done by signing the Ryden gap analysis report itself or signing a separate internal audit report cover page which contains this verification evidence.
- It is best practice to add Ryden on your approved supplier list (ASL) if it is not already there

Dont's:

- Use Ryden's gap analysis report as your sole internal audit evidence record. Follow your internal audit's procedure. The Ryden analysis report out-of-the-box does not contain typically required internal audit report information such as name of internal 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 internal audit nonconformities and/or require corrective action of some kind. Include in the internal 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 internal audit nonconformity severity. Do a more tailored product and process risk assessment and assign an internal 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 an internal audit nonconformity, then you can copy and paste the gap text found as the nonconformity text.
- **Work with Ryden** to create a custom internal audit report cover page that seamlessly uses Ryden's output while ensuring all internal audit report content requirements from your company's procedures are covered.

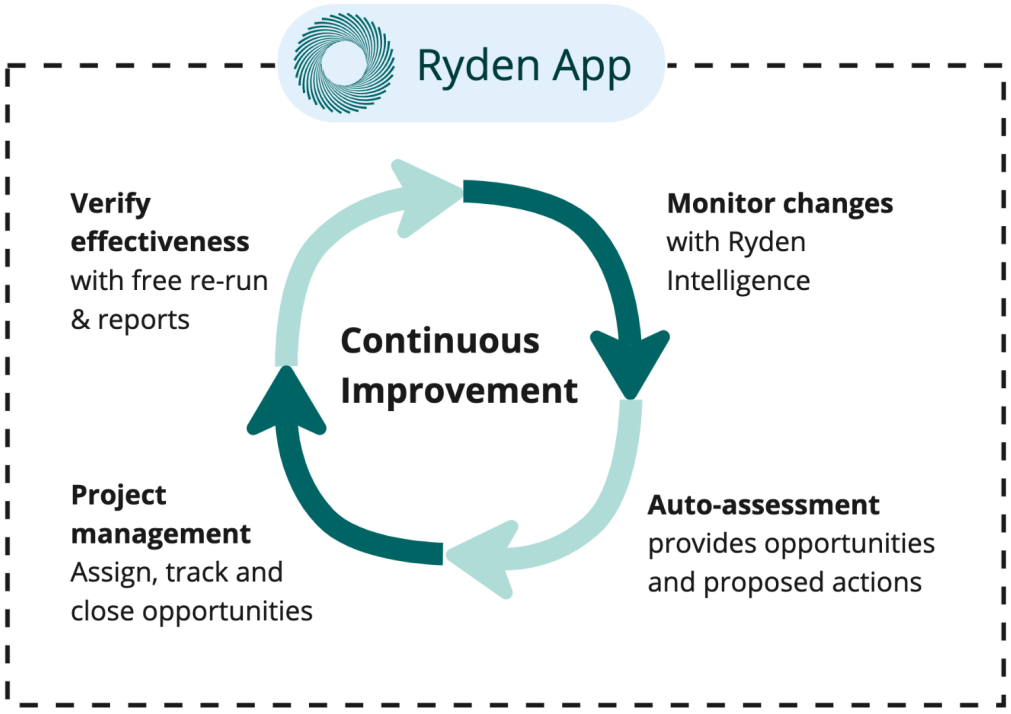
Internal Audit Nonconformity Followup and Effectiveness Checks

Internal 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 CAPAs 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 essential documentation to keep teams synchronized and compliant. It enables internal audit to be the continuous improvement tool it is intended to be.

1. **Prep** – Rationalize less frequent and/or smaller in scope audits knowing Ryden is continuously auditing.
2. **Execution** – Use Ryden's gap analysis reports and opportunities identified along with a quick cover page you author covering additional audit activities you performed and verification notes of which Ryden results are nonconformities. Focus on what matters.

The next internal audit you participate in, revisit Ryden's latest features and functionality. There is likely to be new regulatory requirements you can do an auto-audit against. There may also be other features available since the last time; such as records reviews, teammate knowledge assessments, or supplier audit results.