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Whitepaper

Reimagining Audits in the Pharmaceutical Industry—A Tech-enabled Approach

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Content

Executive Summary

Since the pharmaceutical industry has a direct impact on human life, every manufacturing site must comply with the standards and regulations established by global regulatory agencies. As a result, the industry invests significant time and effort in auditing manufacturing sites. Hence, organizations need to adopt a technology-driven approach to auditing processes to ensure patient safety and standardized operations, thereby improving efficiency and effectiveness.

This whitepaper explains the current challenges in pharmaceutical auditing processes and highlights how Tech Mahindra's digital audit transformation solutions help global pharmaceutical leaders achieve standardized, efficient, and resilient compliance.

Introduction

Audits are the backbone of quality assurance and regulatory compliance in the pharmaceutical industry. They safeguard patient safety, protect public trust, and ensure adherence to global standards, including Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), and Good Laboratory Practice (GLP). However, as the industry undergoes rapid transformation with cloud-native manufacturing, AI-driven drug discovery, decentralized clinical trials, and globally distributed supply chains, traditional audit methods are increasingly insufficient.

Manual, paper-based, and resource-intensive audit processes create bottlenecks at a time when agility, accuracy, and real-time compliance are critical. Regulatory requirements continue to evolve at a global scale, and the complexity of monitoring diverse geographies, suppliers, and partners has made conventional audit models unsustainable.

This shift demands a reimagined approach where audits should be proactive and embed technology-enabled safeguards into business operations. By integrating digital tools, automation, and AI, organizations can significantly enhance audit readiness, reduce compliance risk, and improve efficiency across the audit lifecycle.

This whitepaper explores the current compliance landscape and why audits are indispensable to the pharmaceutical ecosystem. It addresses key challenges and inefficiencies in traditional audit processes, as well as emerging technologies, including digital audit management systems, RPA, cloud-based quality platforms, digital twins, blockchain, and GenAI, to play a crucial role in transforming the audit process. The whitepaper also highlights Tech Mahindra's capabilities in driving digital audit transformation, including a case study of a global pharmaceutical client.

By adopting an "Audit Ready by Design" framework, pharmaceutical enterprises can not only meet regulatory expectations but also build sustainable, resilient, and future-ready operations.

Regulatory Landscape at a Glance

Pharma is a highly regulated industry, given the critical impact its products have on human lives.

There are multiple regulatory bodies worldwide that oversee compliance in the industry. For instance, the US FDA (Food and Drug Administration) oversees drug development and manufacturing through laws such as the Federal Food, Drug, & Cosmetic Act and regulations like 21 CFR Parts 210-211 (Current Good Manufacturing Practices for drugs).

Regulators worldwide place great emphasis on data integrity, requiring all manufacturing and testing-related data to be complete, accurate, and reliable. Pharmaceutical companies are also expected to implement modern quality management principles, such as the ICH Q10. There are specific regulations that govern areas of drug development, for example, GCP for clinical trials.

This means that companies must comply with multiple sets of regulations to sell their products in the global market. Failure to comply can lead to warning letters, import bans, or factory shutdowns.

Between 2005 and 2021, the FDA issued 1,569 warning letters to various pharmaceutical organizations worldwide. The annual number of warning letters increased significantly from an average of 17 in the early 2000s to 304 in 2020. Quality system issues were the most common violation, accounting for 34% of all citations from 2014 to 2016. Data integrity breaches emerged as a significant concern, rising from negligible levels before 2014 to 24% of violations by 2016. The proportion of warning letters issued to foreign manufacturers increased from 22.9% in 2019 to 33% in 2020 [1].

Hope your organization didn’t receive any warning letters in recent times.

The Critical Need for Audits in The Pharmaceutical Industry

Audits serve as essential checkpoints within the pharmaceutical ecosystem, helping to verify that companies' processes and products meet regulatory standards.
They help ensure patient safety by assuring that every batch of drug released into the market has been adequately tested and developed, in full compliance with the standards.

Audits serve as a compass guiding pharmaceutical companies through the complex terrain of GMP, GCP, and GLP. The purpose is to ensure that every drug product and medication meets the gold standard set by global bodies such as the FDA, EMA, and WHO.

In an industry where even the slightest oversight can have the most severe consequences, audits are indispensable.

Audits also have business implications. Every company invests heavily in R&D; any compliance issue can trigger product recalls, resulting in significant financial losses and eroding consumer trust. Audits help avoid the costs of non-compliance, which include legal fees, regulatory fines, and loss of market share.

In 2022, an Indian pharmaceutical company received inspectional observations from the FDA for not achieving the necessary compliance with laboratory records [2]. Such non-compliance can lead to regulatory sanctions, product recalls, reputational damage, and legal consequences.

Between 2019 and 2023, the FDA documented 31,125 recalls, of which 6,217 involved drug products from 593 different companies. These recalls are frequently initiated by the companies themselves, with primary causes including sterility assurance failures, contamination, and improper storage conditions [3].

Audit			
Help organizations to ensure products and processes meet regulatory standards.	Identifies hidden cracks in clinical trial documentation, missing logs, mislabeled products and potential threats to the safety efficacy, and quality of the products.	Avoids the cost of non-compliance, which includes legal fees, regulatory fines and loss of market access.	Guides pharmaceutical companies to meet the gold standard set by global bodies such as FDA, EMA and WHO to ensure patient safety.

Internal vs External Audit Stakeholders

Internal Audits

Internal audits, often referred to as self-inspections or internal compliance audits, are conducted by the organization's employees or contracted auditors to evaluate its operations and systems, identify non-compliance issues, and implement corrective actions.

The primary stakeholders are the company's Quality Assurance (QA) or the compliance department, which appoints trained internal auditors to conduct audits. These auditors are independent of the areas that they review.

On the auditee's side, the stakeholders include department managers and staff, who must provide the necessary documentation to ensure a smooth audit process. Senior management is also a stakeholder as they review and act on audit reports. In some cases, internal audits extend to suppliers, including raw material providers, contract manufacturers, and service providers, to ensure compliance across the entire value chain.

External Audits

External audits are usually conducted by independent parties outside the organization to assess a company's compliance with the most critical, which are those led by regulatory bodies such as the FDA, EMA, and WHO.

In these audits, regulatory inspectors act as the auditors while the QA/compliance department typically serves as the Point of Contact (POC) for the inspectors. Subject matter experts from different functions may be called upon to address specific questions, and senior management participates in the opening and closing meetings.

While both internal and external audits demand full cooperation and transparency from auditees, their dynamics differ. Internal audits are generally more collaborative, whereas external audits tend to take a stricter, enforcement-driven approach.

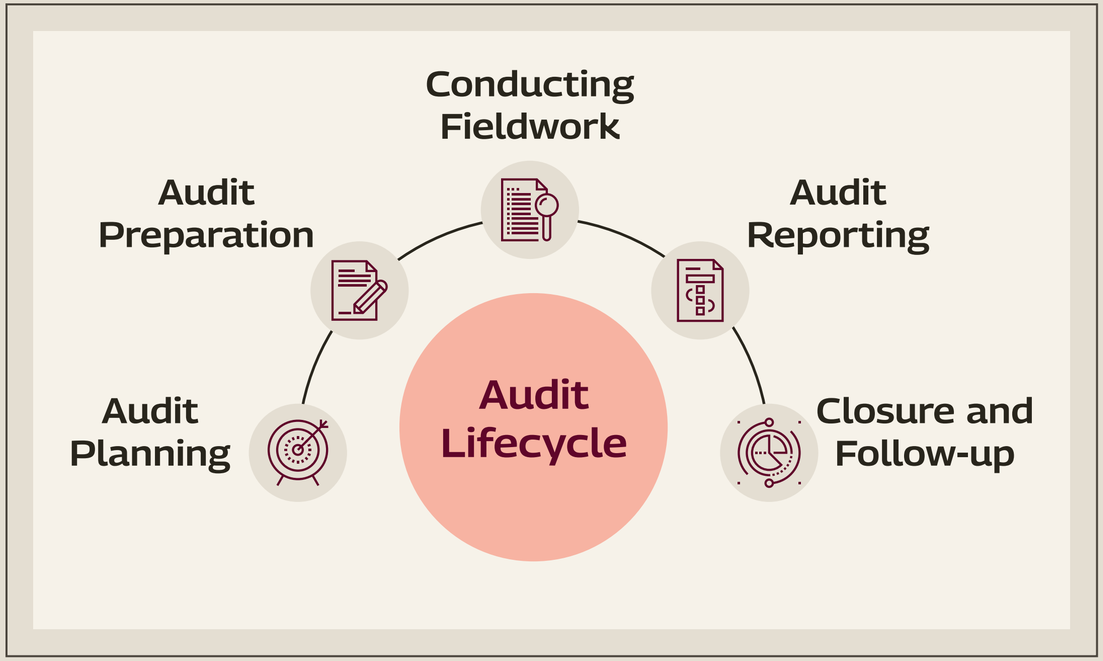
Understanding the Audit Lifecycle in the Pharmaceutical Industry

Audit Planning

Auditors begin by requesting comprehensive data from the auditee to gain an understanding of the organization's operations, processes, policies, and regulatory compliance. They review prior audits and relevant industry literature, as well as key documents such as SOPs, batch records, and QC data. For internal audits, auditors are expected to have thorough knowledge of the organization's policies and procedures.

Components of audit planning:

- Determining the goals and objectives of the audit
- Determining the time periods for audits
- Assign roles to audit team members
- Identify management representatives to review the reports
- Establishing the criteria for evaluation and GMP checklists
- Set up rating criteria for audit observations (qualitative/quantitative)



The pharmaceutical audit process follows a well-defined *five-phase cycle* to ensure thoroughness and compliance.

Audit Preparation

The lead auditor guides the team, maintains communication, develops the audit agenda, and prepares the audit checklist. It is the responsibility of the lead auditor to communicate with the auditee to establish the format, objective, and initiate the agenda. The proposed agenda should be communicated and reviewed, and working documents prepared. For internal audits, the GMP audit checklist should include:

- Quality Management
- Personnel
- Facility and Equipment System
- Documentation
- Production System
- Packaging and Labelling System
- Storage System
- Laboratory Control System

Audit Reporting

Based on their findings, auditors draft the audit report, which should include the following:

- Objective of the audit
- Scope of audit (areas covered)
- A thorough explanation of all the findings, which include both areas that are up to mark, as well as those that need further improvement
- If any compliance-related rules are broken, then a reference to the pertinent regulations or policies must be provided
- Corrective and Preventive Actions (CAPA) are recommended for process improvements or enhanced compliance.
- Any further recommendations
- A conclusion, which contains a summary of the overall audit

A draft of this report must be sent to the management of the audited area for their review and response.

Conducting Fieldwork

The auditors review all documents related to the company's operations to verify legal compliance and assess the effectiveness of quality systems. They conduct physical inspection of equipment and facilities, including laboratories, production areas, and storage areas, to evaluate adherence to GxP regulations as well as process audits. Auditors must ensure that the inspection does not disturb regular operations. All observations are documented for reporting purposes, followed by a meeting with key stakeholders, including auditors and the auditee management, to communicate and discuss findings and conclusions.

Closure and Follow-Up

A closing meeting is held with the auditee to communicate the results, address any questions, and provide recommendations for improvement. The final audit report is distributed to all stakeholders involved, including those in outsourcing and supplier management. Auditors may conduct follow-up reviews to verify implementation of corrective actions. For instance, in response to an FDA warning letter, companies must submit an action plan for FDA review within 15 business days.

Challenges in the current process

Increasing Regulatory Complexity

Auditors face challenges in keeping up with constantly evolving regulations and guidelines, which are frequently updated to reflect new technologies across multiple regions. With over 70% of pharmaceutical ingredients sourced internationally, ensuring compliance becomes even more complicated[4].

Adhering to the Latest Guidelines

Ensuring adherence to the latest revisions of compliance documents is challenging. Frequent regulatory changes create a need for solutions that can monitor and track updates. For example, in 2024, the FDA reviewed and released updates to the Current Good Manufacturing Practice (CGMP) regulations [5].

Inefficiencies in Manual Auditing

Traditional audits rely heavily on manual processes, such as completing checklists, collecting data, and generating audit trails, which increases the risk of errors. Auditors spend considerable time reviewing records, paperwork, and spreadsheets to identify discrepancies or irregularities, which slows the process and increases the likelihood of missing critical issues. Manual methods also make it difficult for auditors to keep up with real-time changes.

Time-Consuming Nature

Manual audits are time-consuming, often taking days or even weeks to complete. Over 83% of internal audit practitioners spend more than eight hours on internal audits that are not fully comprehensive, excluding mandatory accounting documentation [6]. Additionally, 77% of respondents report needing an average of three days to prepare the internal audit report. Such delay can be costly, especially in an industry where downtime affects supply chain continuity and slow access to documentation hinders quick inspection.

High Costs of Traditional Audits

Conducting frequent audits can be a costly affair, requiring highly trained professionals to perform the inspections, analyze the findings, and issue CAPA.

Lack of Proper Documentation

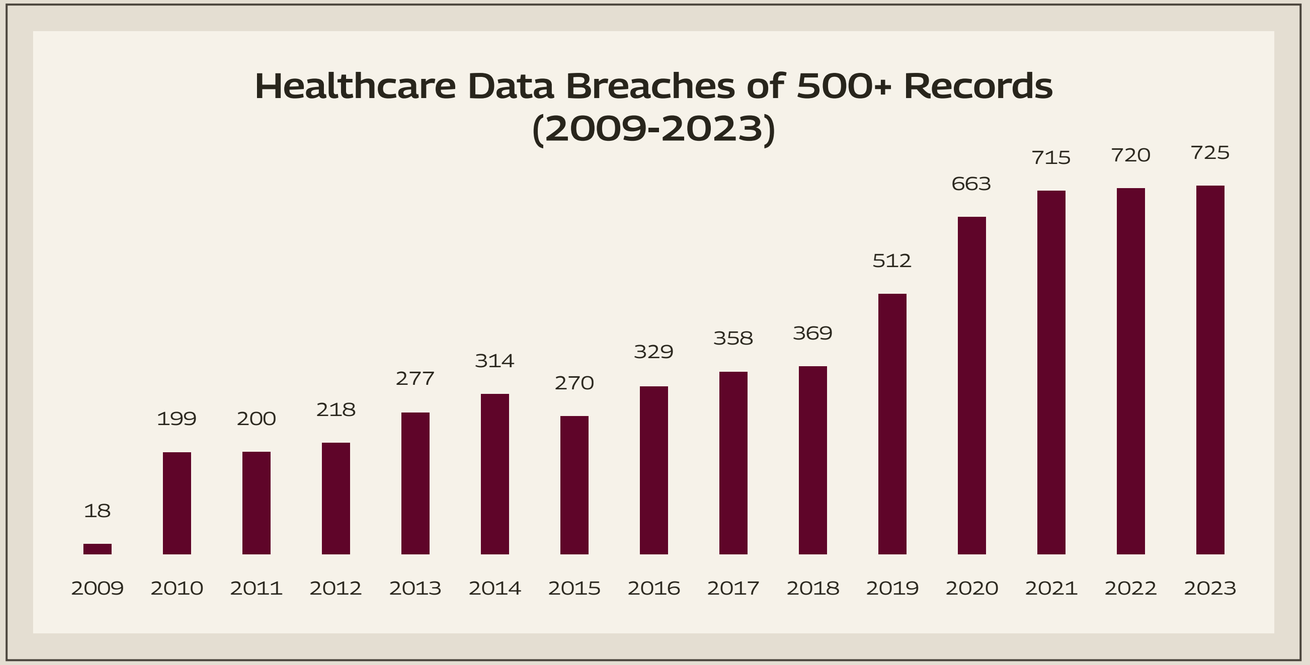
Proper record-keeping is crucial for ensuring regulatory compliance and facilitating a seamless audit process. However, managing large volumes of documentation while maintaining accuracy is highly challenging and can hinder the audit process.

Data Integrity and Traceability Gaps

Maintaining the integrity and security of data presented to auditors is essential throughout the audit process. However, auditors often encounter issues such as data fabrication or incomplete information, which can hinder the audit. In 2023, the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) reported 725 data security breaches in healthcare. [7]

Audit Challenges

- Ensuring data integrity and accuracy.
- Detecting non-obvious issues through time-consuming walk-throughs.
- Recording observations accurately with supporting evidence.
- Drafting clear, guideline-compliant reports.
- Extensive planning and documentation divert resources, impacting productivity.
- Pharmacovigilance:
- Monitoring drug safety and reporting ADRs.
- Establishing robust systems for collection, analysis, and reporting.
- Maintaining timely communication with regulators.
- Rapid identification and reporting of safety concerns to protect public health.



Technology Interventions

Tech Mahindra believes that ‘Audit-Ready by Design’ is essential to address the challenges faced by stakeholders throughout the audit lifecycle. Digital technology interventions play a key role in enabling this, offering levers such as cloud enablement, AI-driven frameworks and models, and generative AI solutions.

Existing Tech Interventions

Audit Stage	Technology Interventions	Features	Value Additions
Entire Audit Life Cycle	Digital Audit Management System	Comprehensive digital audit management suites (often part of digital QMS) are software platforms that centralize and automate the entire audit workflow, from scheduling and planning to execution, reporting, and follow-up. These cloud-native suites facilitate automated audit scheduling, create checklists, record audit findings, assign corrective and preventive actions, and track those actions. Some key features of this software include centralized audit calendar and forms, electronic findings capture, automated workflows and dependencies, search/retrieval of evidence, and integration with CAPA and change control.	Because all documentation is stored in a single repository, it is easier to access and generate an audit report from all findings. The data is kept up to date, allowing auditors to monitor all events in real time. It makes it much easier for auditors to access past audit records in the planning process. It eliminates repetitive, time-consuming manual tasks in the audit process.

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Existing Tech Interventions

Audit Stage	Technology Interventions	Features	Value Additions
Planning and Execution, Closure	Robotic Process Automation (RPA) and Workflow Automation	RPA is used to automate specific, repetitive, and rule-based tasks within audit processes, such as data entry, where bots mimic human actions. Workflow automation tools, on the other hand, complement RPA by coordinating tasks across different systems. Bots and process management tools automate manual, repetitive, rule-based tasks like data collection, report generation, and the enforcement of predefined workflows (approvals, notifications).	In audits, these bots can collect data from different systems, populate audit reports and checklists, thus eliminating the need for tedious manual entry tasks. Improved compliance is achieved by reducing the chances of error, as RPA bots can perform repetitive actions without fatigue. Workflow automation ensures that every step in the audit process is executed in a timely and consistent manner.
Planning and Closure	Robotic Process Automation (RPA) and Workflow Automation	A cloud eQMS provides a single platform for all quality documents and records. Built on public cloud services like Azure or AWS, it includes electronic batch logbooks, device history management, document repositories, automated validation, and data analytics.	A cloud eQMS provides a single platform for all quality documents and records. The centralized data storage and retrieval capabilities enhance audit readiness, improve response times during inspections, and enable the automated generation of compliance reports.

Emerging Interventions

Audit Stage	Technology Interventions	Features	Value Additions
Documentation and Closure	Blockchain for Audit Trails	In a blockchain network, each record is cryptographically time-stamped and stored across multiple nodes. Once entered, data cannot be altered. Every step in the process, starting from raw material receipt to product release, can be logged on-chain in a tamper-proof manner. Since regulators and partners access the same real-time ledger, blockchain naturally provides clear visibility into the origin and custody of pharmaceutical products.	Ensures data integrity by preventing forgery. Provides a clear audit trail, thus simplifying regulatory compliance for traceability requirements.
Planning and Execution	Predictive Compliance with Digital Twins	Digital twins are virtual, data-driven replicas of physical processes or facilities, which can be used to simulate an organization's processes and controls in real-time.	The live compliance dashboard helps identify gaps and trends, making compliance predictive.

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Emerging Interventions

Audit Stage	Technology Interventions	Features	Value Additions
Documentation and Closure	Blockchain for Audit Trails	This system features dynamic mapping of the current risk and compliance state, scenario simulation (What-if analysis), cross-system integration, and real-time dashboards.	Simulating regulatory changes (which are so frequent in nature within the pharma industry) and supply shocks helps the organizations gain strategic resilience. Digital twins enable proactive audit-readiness.

Tech Interventions in the AI and GenAI space

Audit Stage	Challenges	Latest Interventions
Planning	Changing global regulations, scattered data sources, and inconsistent risk scoring	**GenAI audit planners** draft audit scopes from global guidelines. **Knowledge graphs** link past findings, SOPs, and risks. **AI copilots** guide scoping and team setup.

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Tech Interventions in the AI and GenAI space

Audit Stage	Challenges	Latest Interventions
Preparation	• Manual checklist building • Complex region/product mapping • Redundant info gathering	**GenAI audit planners** draft audit scopes from global guidelines **Knowledge graphs** link past findings, SOPs, and risks **AI copilots** guide scoping and team setup
Fieldwork	• Overload of unstructured data • Interview fatigue • Missed observations	**GenAI assistants** help with live transcription and questions **Multimodal AI** analyses docs, speech, and visuals together **Smart wearables** collect on-site data and display it in dashboards
Reporting	• Time-consuming report writing • CAPA logic isn't always aligned • Inconsistent narratives	**GenAI tools** write summaries, deviations, and insights **AI CAPA engines** suggest fixes based on benchmarks **LLM copilots** refine reports and flag regulatory gaps
Follow-up	• CAPA tracking delays • Missed trends • Slow alerts and feedback	**Predictive tools** flag CAPA delays early **AI nudges** send timely reminders to the right people **GenAI reviewers** summarize lessons learned from outcomes

Values/Benefits

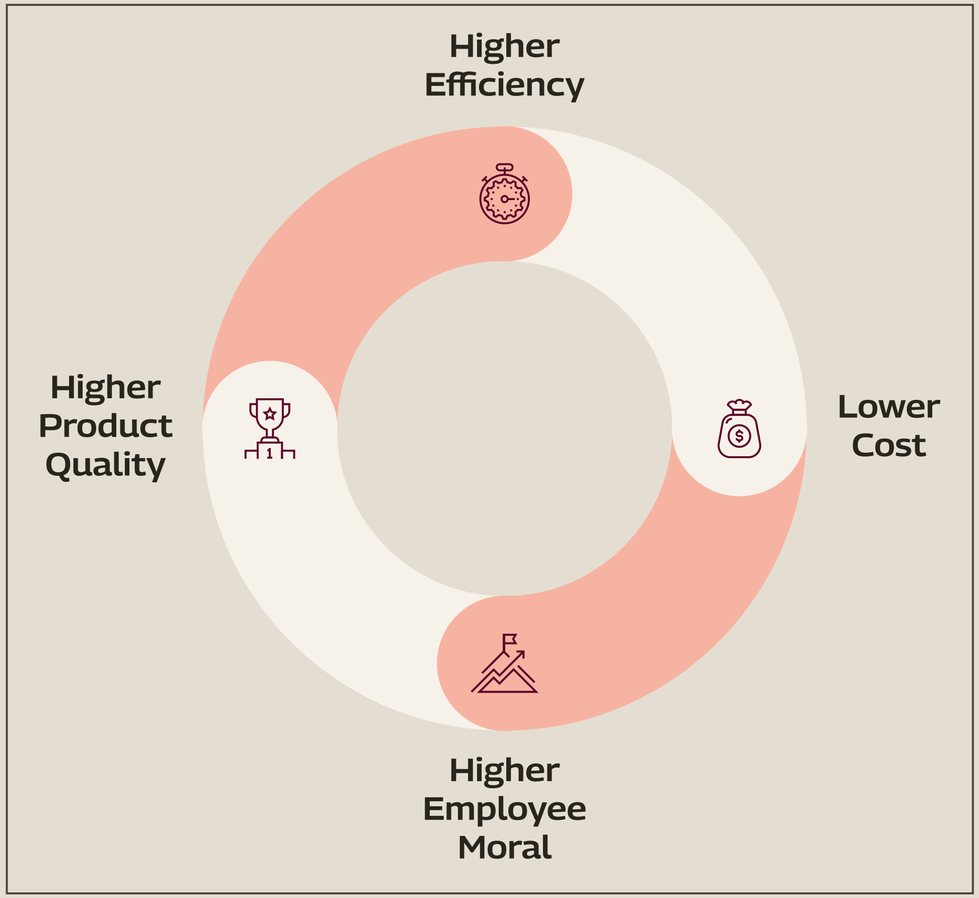
Reduced Costs

Digital tools streamline audit processes, enhance efficiency, reduce the time spent on manual tasks, and eliminate the need for paper-based documentation, thus cutting printing and storage costs. Improve efficiency and reduce the costs associated with human errors. These tools also eliminate repetitive manual tasks. According to a 2023 report, the adoption of AI has resulted in a 30-50% reduction in audit costs. Companies that perform regular audits lessen the likelihood of non-compliance penalties by 92% [8].

Increased Efficiency

Automated tools reduce audit preparation time and execution speed. They automate tasks like scheduling and reporting, freeing audit teams to focus on more strategic activities. Automating data analysis and reporting speeds up the audit process.

Benefits



Improved Employee Efficiency and Morale

Highly skilled professionals can focus on tasks that require their active involvement, rather than rule-based, repetitive tasks, which reduces staff burnout and turnover.

Improved Product Quality

Real-time monitoring and prompt corrective actions, along with comprehensive reporting, enhance audit quality and ensure they effectively mitigate risks within an organization, ultimately improving operations and product quality. Supplier audits are also streamlined, which can potentially reduce supply chain risks. CAPAs become more effective with improved root cause identification, resulting in fewer recurring problems.

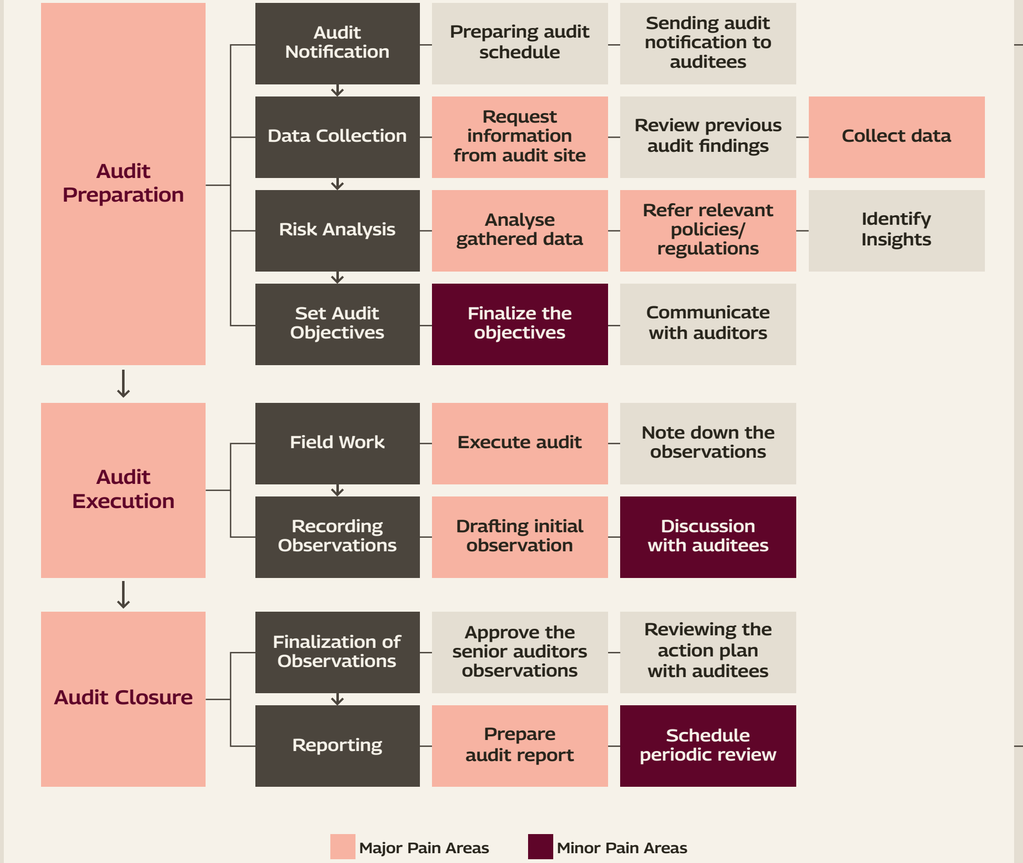
The following case study illustrates how Tech Mahindra served as a co-innovator by collaborating with a pharmaceutical healthcare giant to co-create a solution for reimagining audits through technology-led interventions.

Case Study: TechM's Audit Transformation with Risk Assessment and Standards Manager Tools

The Challenge

A global pharmaceutical company struggled with fragmented audit operations. Data was scattered across multiple systems—emails, SAP modules, dashboards, and document repositories—making risk analysis slow and inconsistent. With varied audit types and evolving global regulations, auditors found it difficult to link findings to the right standards, identify recurring risks, and maintain consistency in reporting.

Current States-Process Steps and Areas of Improvement



Current States Pain Points

- Collection of Data is manual and time consuming
- Risk analysis is not standardized, and no tools are available
- Difficult to keep track of teh main point identified during the risk analysis and audit agenda
- Capturing and managing notes during field work in challenging
- Writing findngs is time consuming and difficult.
- Coordination with auditee on CAPAs takes a lot of time in external audits.
- Narrative report preparation is manual process. Collection of audit metrics requires sifting through multiple reports.
- Establishing continuity of data and information across different phases of audit and managing multiple templates is challenging

The Solution

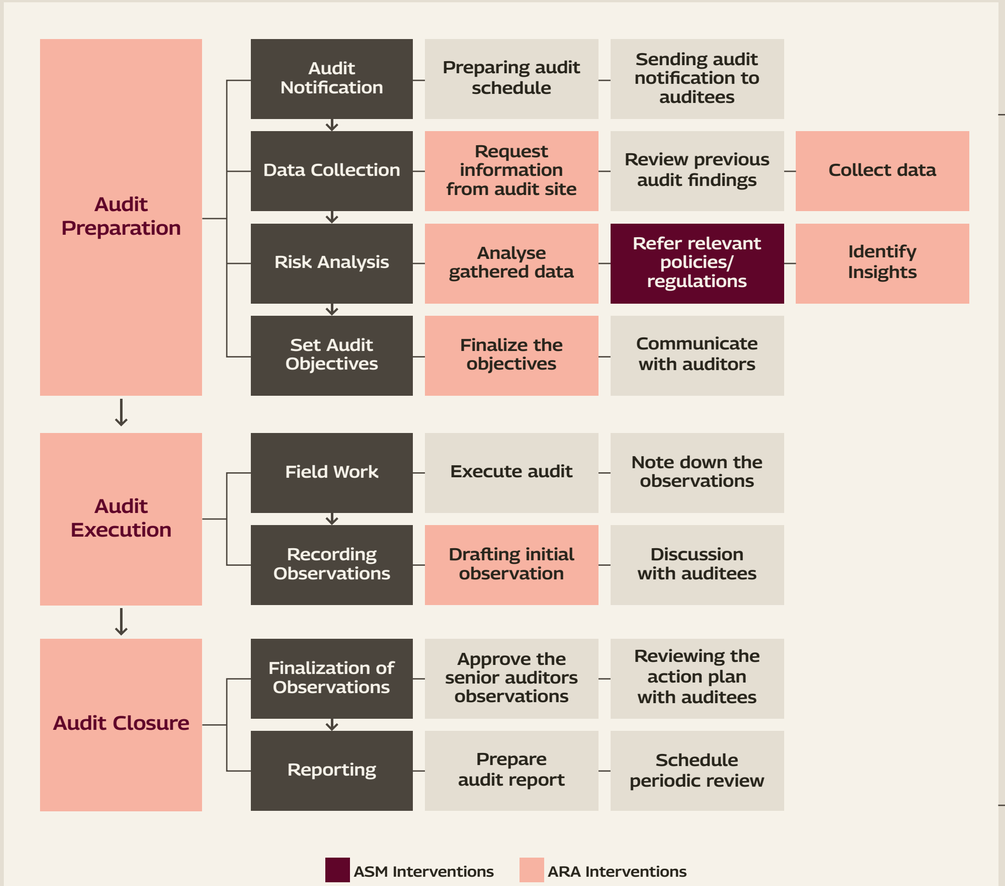
Tech Mahindra developed an integrated, AI-enabled platform combining two core tools—Audit Risk Assessment and Audit Standards Manager—to standardize and simplify the audit lifecycle.

- Audit Risk Assessment: Aggregates structured and unstructured data from multiple systems into a unified risk profile. It applies business rules and machine learning to highlight focus areas, reduce subjectivity, and recommend corrective actions.

- Audit Standards Manager: Acts as a dynamic regulatory library and intelligent search engine. It enables auditors to instantly locate, tag, and reference relevant regulations and policies, with automated updates, multi-language support, and spelling corrections to minimize oversight.

  Together, these tools provide auditors with a single source of truth, reduce manual effort, and ensure consistent alignment with evolving compliance standards.

To be State - Process Steps with Solution Interventions



Audit Preparation & Risk Analysis

Audit Preparation and Risk Analysis (ARA) supports the entire audit preparation process from audit information collection, stakeholder interactions, risk analysis, priotization of risk and audit objectives finalization. Audit scope, auditee information and audit schedule would feed into the solution.

Audit Standard Manager

Audit Standards Manager(ASM) application is a harmonized repository of different Standards (GMP/Non-GMP)-jurisdictional, industry, corporate and local level, which would allow Auditors to choose applicable standards during Audit planning based on Auditee profile and scope of Audit. Different standards will be aligned on Quality topics. Based on chosen Audit Standard for a particular audit, ASM would provide inputs to Risk Analysis, Audit Script and Questions and Findings.

Implementation and Impact

The solution was rolled out in phases, starting with the creation of a central repository of global audit standards, followed by the AI-powered automation of audit preparation and risk assessment. Role-based access controls, intuitive dashboards, and SSO integration ensured seamless adoption across teams.

As a result, the company achieved:

- Standardized risk profiling and reduced audit subjectivity
- Faster preparation and reporting through automated data collection and referencing
- Simplified access to evolving regulations and audit trails
- Significant time savings in compiling and validating audit reports

Conclusion

As the pharmaceutical industry accelerates its digital transformation, the audit function must shift from a periodic compliance exercise to a continuous, intelligence-driven capability. Traditional, paper-based methods can no longer keep pace with the increasing complexity and precision required by today's regulatory and operational demands. By integrating AI, automation, and cloud-native platforms into the audit process, organizations can gain real-time visibility, ensure data integrity, and enable proactive compliance. Tech Mahindra's technology-enabled approach helps pharmaceutical companies make audits digital by design and intelligent by default, turning them into engines of trust, transparency, and resilience.

In this new approach, audits go beyond identifying gaps; they aim to build trust among regulators, partners, and patients, establishing a new benchmark for operational excellence within the pharmaceutical ecosystem.

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Rohit is Senior Consultant at Tech Mahindra, with over 9 years of experience in customer-facing roles, specializing in the healthcare and life sciences industry. He is skilled in design thinking consulting, with a strong track record of identifying process bottlenecks and delivering strategic, actionable recommendations. Rohit's expertise lies in engaging stakeholders, understanding complex business challenges, and co-creating innovative solutions that drive operational excellence.

About TechM Consulting

At TechM Consulting, we empower clients to turn disruption into opportunity by building future-ready capabilities. Our unique value velocity V Factor methodology, rooted in co-creation deep listening agile execution and seamless collaboration, enables enterprises to deliver greater stakeholder value with greater speed and agility.

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