



TRANSFORMING QUALITY MANAGEMENT SYSTEMS WITH ARTIFICIAL INTELLIGENCE: A STRATEGIC BLUEPRINT FOR INFOSYS



Quality Management Systems (QMS) are fundamental to ensuring compliance, product integrity, and operational excellence in Life Sciences.

However, conventional QMS frameworks often lack the agility, scalability, and predictive intelligence required to meet the demands of today's rapidly evolving regulatory and business landscape.

Artificial Intelligence (AI) is redefining quality management by introducing intelligent automation, advanced analytics, and risk-based decision-making. These capabilities enable organizations to transition from reactive quality control to proactive, data-

driven strategies—enhancing compliance, mitigating risks, and accelerating time-to-market.

Infosys is leading this transformation through strategic investments and real-world deployments of AI-powered QMS solutions.

By integrating cutting-edge technologies with industry best practices, Infosys delivers next-generation quality systems that align with global regulatory standards and ethical principles. This paper demonstrates why AI-driven QMS is not merely an innovation but a strategic imperative for sustainable quality and competitive advantage—and why Life Sciences organizations should partner with Infosys to achieve this vision.

The Problem Statement

Traditional Quality Management Systems (QMS) in regulated industries like pharmaceuticals and medical devices are outdated—siloed, manual, and reactive—causing delays, compliance risks, and poor scalability. They fail to leverage growing data volumes for predictive insights and continuous improvement.

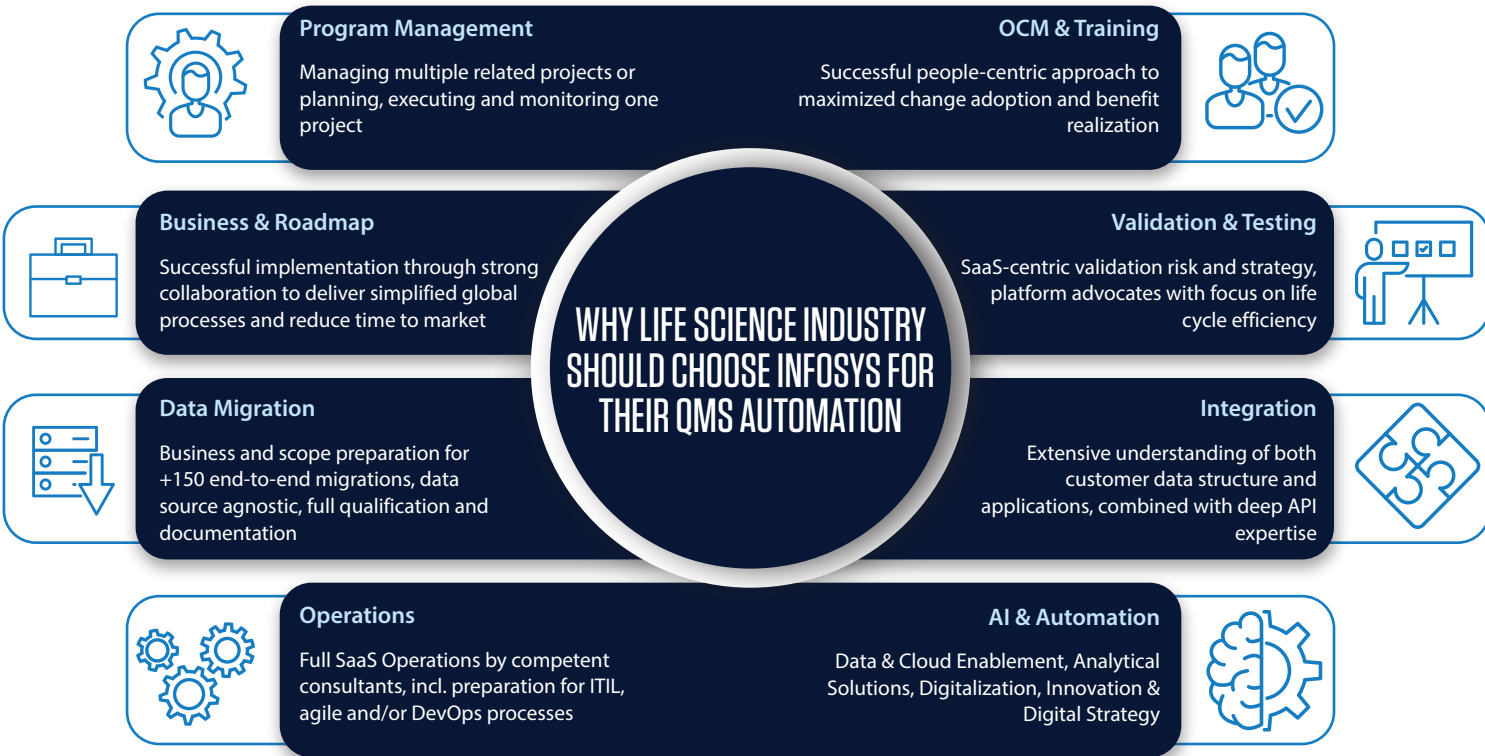
To remain competitive and compliant, organizations need an intelligent, adaptive QMS that transforms quality into a strategic enabler. Artificial Intelligence (AI) drives this evolution through automation, advanced analytics, and risk-based decision-making, creating a future-ready, sustainable quality ecosystem.

Infosys POV on the possible Solution/s- How the Solution Solves the Problem

Why Life Science Industry should choose Infosys for their QMS Automation

Infosys enables QMS automation for Life Sciences through expertise in program management, data migration, and SaaS operations. It ensures efficient validation, integration, and change management

with strong collaboration and lifecycles-focused strategies. Advanced AI, automation, and digital solutions drive innovation, cloud enablement, and faster time-to-market.



Infosys' Strategic Advantage in AI-Driven QMS Transformation

Infosys offers a unique combination of domain expertise, AI capabilities, and digital transformation frameworks:

Infosys LEAP:

Infosys Live Enterprise Automation Platform (LEAP), provides a platform-centric approach for AMS services that makes application management agile, intelligent, integrated, resilient and business

aligned, thereby enabling enterprises to realize the live enterprise vision.

Key Capabilities



Agile and Intelligent Management

LEAP enables agile application management using automation and AI to respond quickly to changing business needs.



Real-Time Insights and Predictions

The platform uses AI and analytics to process data, providing real-time insights and predictive capabilities for IT optimization.



Persona-Based Business Alignment

LEAP's persona-based approach aligns management strategies with business KPIs for measurable outcomes.

Business Impact



Optimized IT Operations

LEAP reduces downtime and prevents costly disruptions by optimizing IT operations for resilience and health.



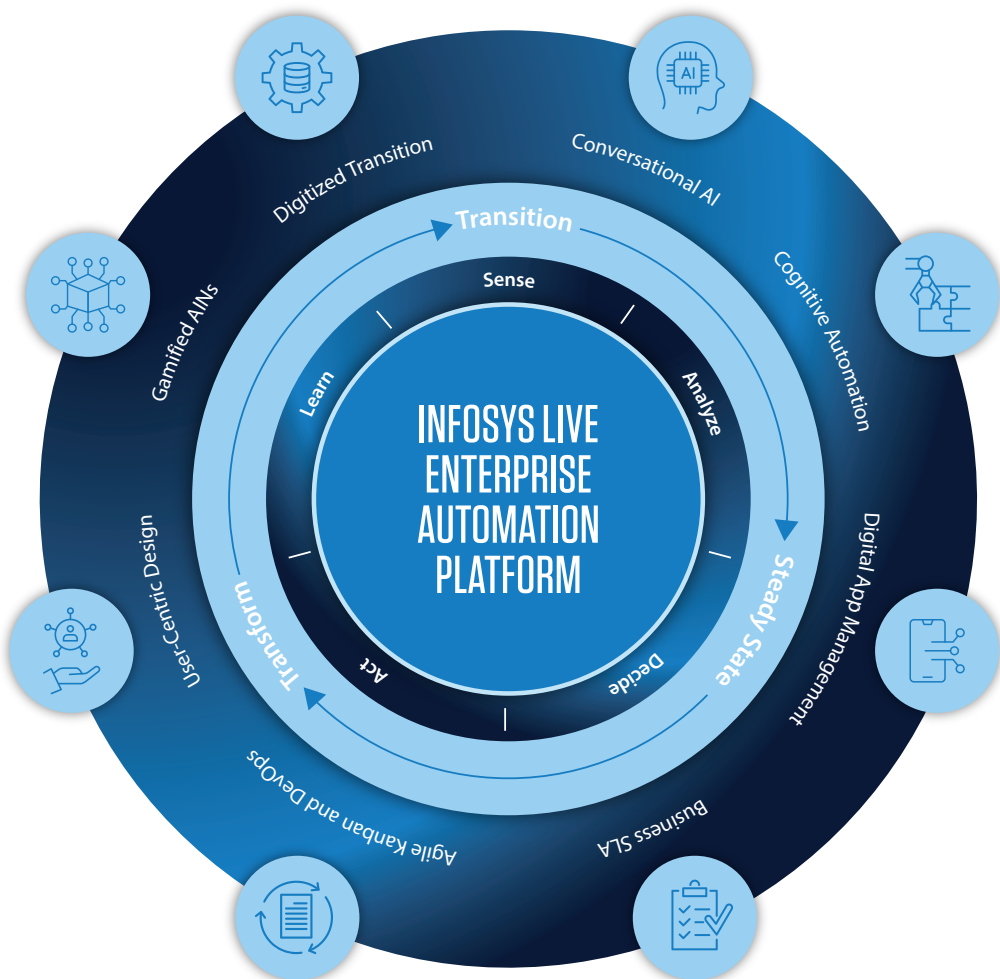
Digital Transformation Enablement

LEAP introduces automation and intelligence to application management, boosting efficiency and reducing manual tasks.



DevOps and Continuous Delivery

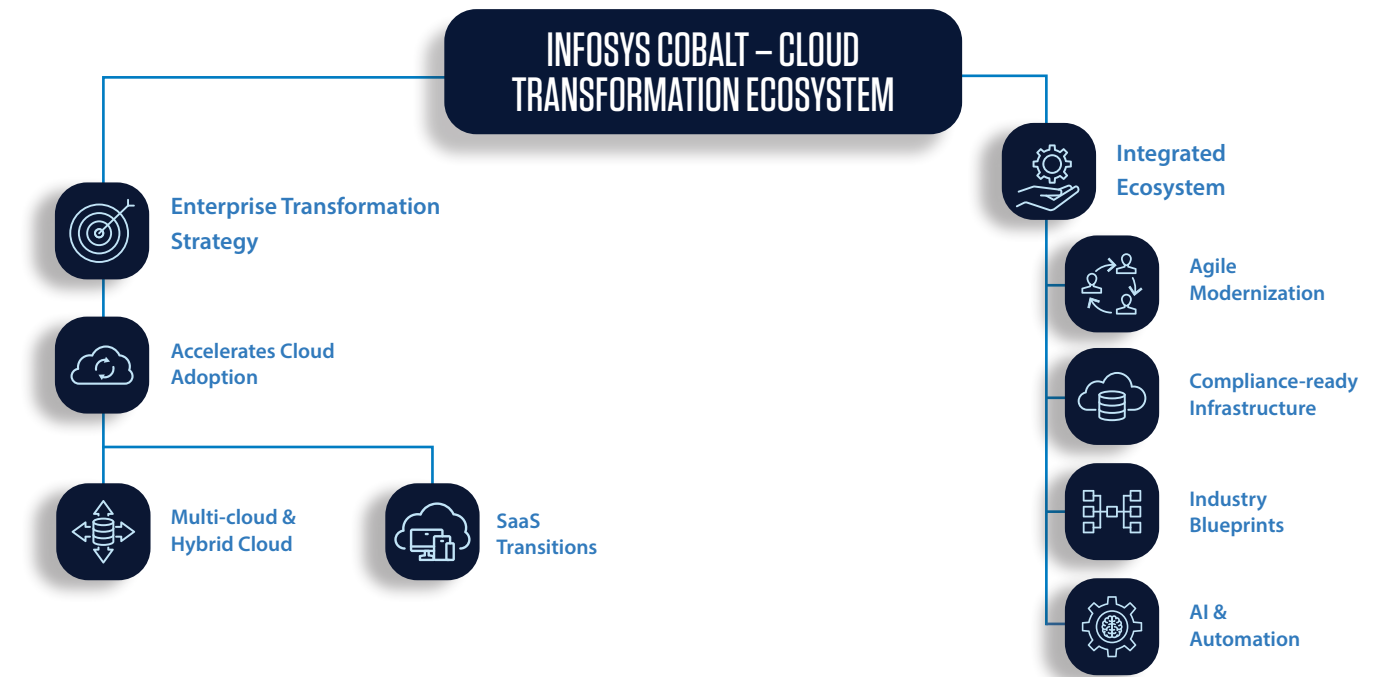
LEAP supports DevOps practices, fostering continuous integration and rapid delivery of new features.



Infosys Cobalt:

Infosys Cobalt is an integrated cloud ecosystem that accelerates enterprise transformation through agile modernization,

compliance-ready infrastructure, and AI-driven innovation across multi-cloud environments.



Infosys Topaz Fabric:

Infosys Topaz Fabric is an AI-powered, composable platform that unifies IT service delivery across enterprises. It offers modular, interoperable layers of data infrastructure, models, agents, workflows, and AI apps, enabling services-as-software through a single, integrated ecosystem.

By leveraging existing IT investments and AI-led automation with humans in the loop, it accelerates processes, eliminates repetitive tasks, and avoids vendor lock-in—unlocking enterprise value at scale.

INFOSYS TOPAZ FABRIC CORE AREAS



Operations

Run super-intelligent operations that learn, predict, and self-heal.



Transformation

Accelerate engineering and brownfield transformation through AI-first modernization.



Quality Engineering

Fast-track quality engineering services with AI-driven validation and testing.



CyberSecurity

Embed secure and responsible AI by design across the enterprise.

INFOSYS TOPAZ FABRIC FEATURES



Integrated Automation and AI

Combines automation-led processes with AI-powered capabilities for enhanced service delivery and operational efficiency.



Composable and Scalable Ecosystem

Emphasizes composability and scalability for quick adaptation to market changes and customer needs.



Holistic Security and Compliance

Integrates cybersecurity and compliance to maintain operational excellence and protect enterprise data.



Business Benefits

Improved agility, faster time-to-market, enhanced customer experience, and cost optimization via intelligent automation.

Infosys Domain Expertise:

Infosys provides comprehensive Life Sciences solutions spanning three key areas. Digital & Technology Solutions include platforms for digital health, multichannel analytics, AI-driven scientific writing, drug discovery, and data integration.

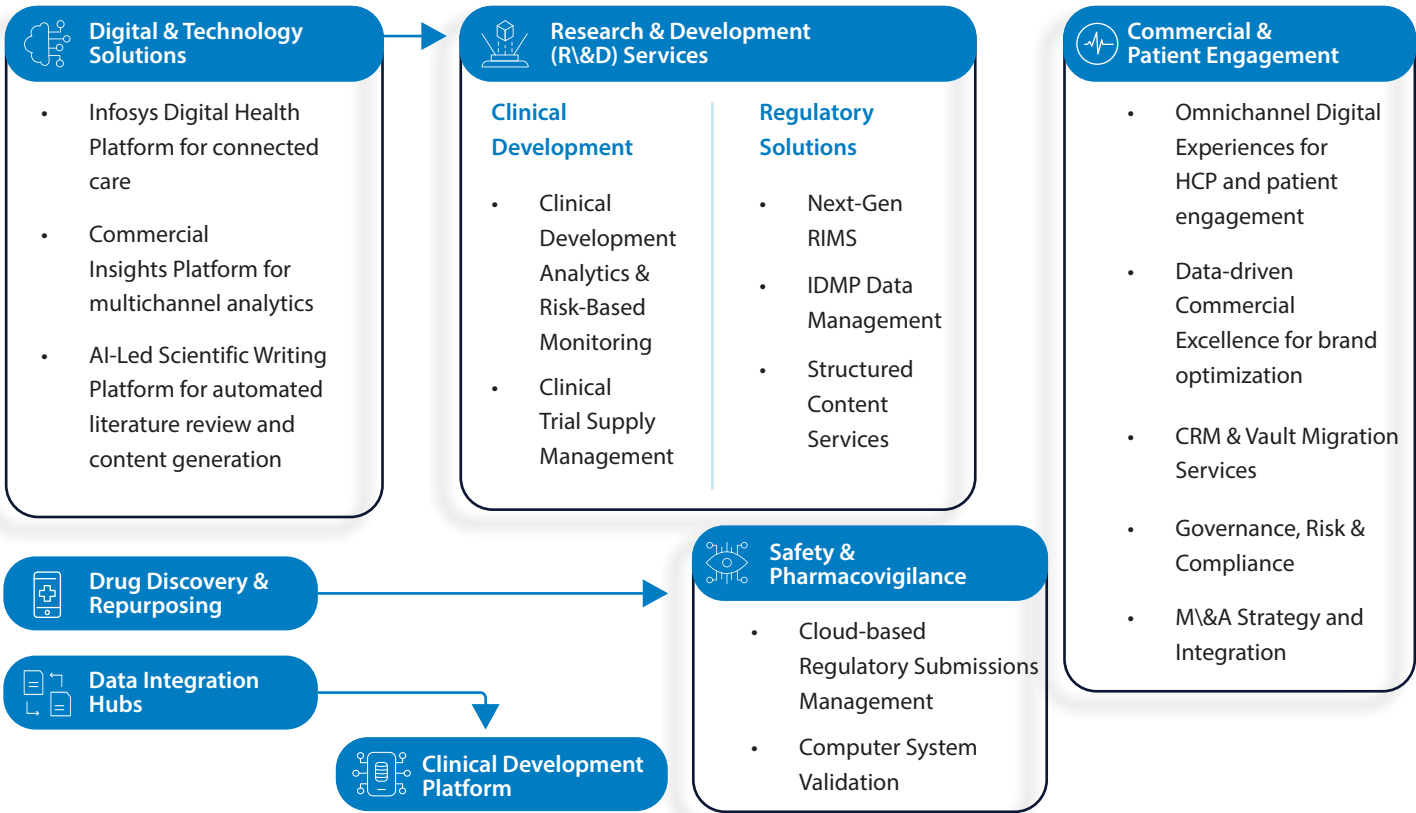
Research & Development Services cover quality management systems, clinical development, regulatory solutions such as RIMS

and IDMP data management, safety and pharmacovigilance, along with a clinical development platform.

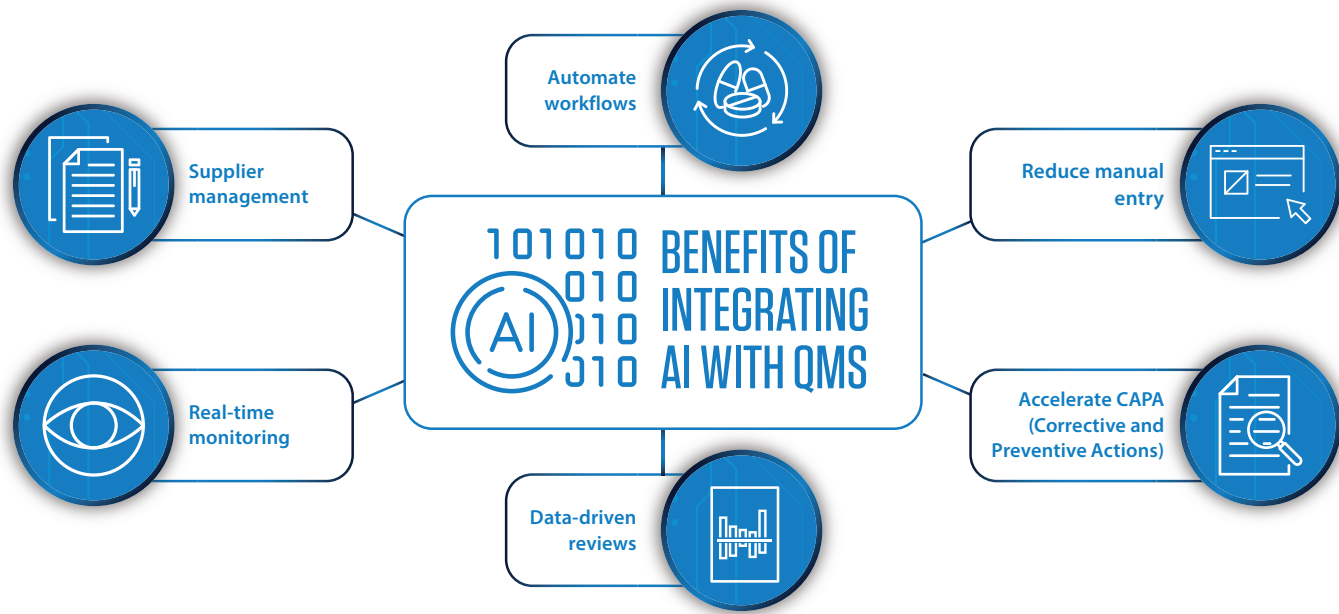
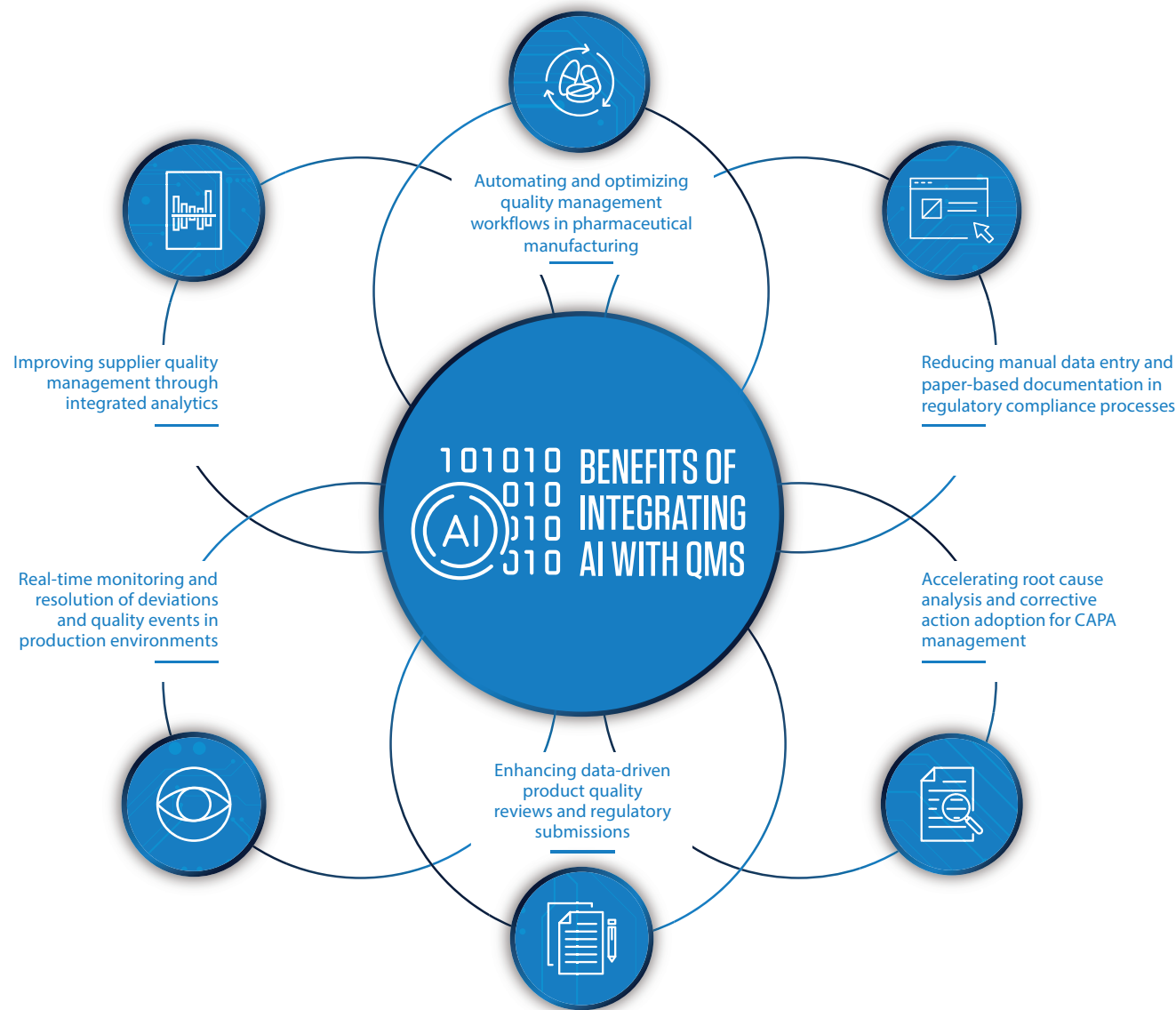
Commercial & Patient Engagement focuses on omnichannel digital experiences, data-driven commercial optimization, CRM and vault migration, governance, risk and compliance, and M&A strategy. These offerings enable end-to-end support across the life sciences value chain.



DIGITAL & TECHNOLOGY SOLUTIONS AND R\&D SERVICES



Benefits of integrating AI with QMS



GEN AI Enabled QMS Approach using Infosys - LEAP (Live Enterprise Automation Platform)

Evolution of QMS: From Legacy Systems to Intelligent Platforms

Quality Management Systems have rapidly evolved from manual, paper-based processes to sophisticated, AI-driven platforms:



LEGACY QMS

- Paper-based systems, manual workflows, isolated data repositories
- Documentation and audits managed through physical records (slow, error-prone, hard to scale)
- Limited visibility across departments, delayed issue detection



DIGITAL QMS

- Platforms like Veeva Vault, MasterControl, TrackWise
- Electronic records, centralized data, automated workflows
- Cloud-based architectures for real-time access and collaboration



AI-ENABLED QMS

- Harnesses AI capabilities: machine learning, NLP, predictive analytics



Industry Use Cases



AI-Augmented Decision-Making

AI, ML, and NLP analyze structured and unstructured quality data to detect patterns and predict issues. LEAP uses AI, ML, and analytics to sense, analyze, and decide in real time, enabling **proactive interventions**. Predicts failures and anomalies by correlating logs, metrics, and events across IT and operational systems.



Risk Management

Integrated risk assessment modules, aligned with ICH Q9 and ISO 14971, enable **systematic evaluation** and **mitigation of risks** across processes, suppliers, and products. For example, risk scoring for new suppliers based on audit history and material quality ensures consistent, compliant strategies that enhance product safety and build regulatory trust.



Paperless Documentation

Paperless documentation leverages digital workflows to replace manual processes for SOPs, training records, change controls, and audit trails. By **incorporating electronic signatures** and **automated version control**, organizations achieve improved traceability, reduced human error, and streamlined regulatory audits, ensuring compliance and operational efficiency.



Automated Analytics

Real-time dashboards integrate data from LIMS, MES, and ERP systems to deliver actionable insights on critical quality metrics such as OOS trends, CAPA effectiveness, and audit readiness. By **visualizing deviation patterns** across manufacturing sites, organizations can accelerate **decision-making**, **enhance root cause analysis**, and **reduce downtime**—ultimately minimizing product recalls and ensuring compliance.



Trend Analysis & Benchmarking

Trend analysis and benchmarking are essential for continuous improvement within QMS. By systematically **reviewing audit outcomes** and **supplier performance**, organizations can uncover recurring issues, monitor compliance, and set realistic performance standards. Benchmarking against internal and industry best practices **ensures data-driven decision-making** and **operational excellence**.

Artificial Intelligence (AI) enhances these processes by **automating pattern recognition**, **predicting compliance risks**, and **delivering real-time analytics**, enabling faster, more accurate **quality improvements** and **proactive risk mitigation**.





Training Content Creation

AI can automate the creation of SOP-based training modules and translate them into multiple languages, ensuring global compliance and workforce readiness. This approach **streamlines content development**, **maintains consistency with regulatory standards**, and **integrates seamlessly with QMS platforms** for **tracking** and **audit** readiness.



CAPA Recommendation

The system analyzes historical data and similar cases to suggest effective corrective and preventive actions. It prioritizes these actions based on **risk severity** and **business impact**, ensuring **critical issues are addressed first** and reducing the likelihood of recurrence.



Audit Management

AI can transform audit management into Quality Management Systems by automating **routine tasks**, **improving accuracy**, and enabling **predictive insights**. It streamlines audit planning through **risk-based scheduling**, uses **NLP to review documents** for compliance, and supports real-time audits with **smart checklists** and **anomaly detection**.

AI-driven analytics predict potential **non-conformities**, **generate instant reports**, and suggest root causes for recurring issues. By leveraging these capabilities, organizations can **enhance compliance**, **reduce manual effort**, and **drive continuous improvement** in quality processes.



Improving Duplication in QMS

Artificial Intelligence (AI) offers a robust solution for mitigating duplication within Quality Management Systems (QMS). By employing advanced techniques such as **Natural Language Processing (NLP)** and **Machine Learning (ML)**, organizations can identify semantically similar documents and predict duplicate records with high accuracy.

AI-driven data integration frameworks enable the consolidation of information across disparate systems, while **intelligent automation** ensures consistency during data entry and process execution. These capabilities collectively enhance **data integrity**, **reduce compliance risks**, and **improve operational efficiency**, thereby strengthening the overall effectiveness of QMS.



Bot Assistant

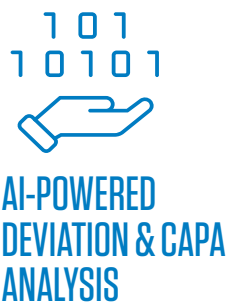
The bot assistant enhances compliance within the Quality Management System by guiding users through Standard Operating Procedures (SOPs) with step-by-step instructions and contextual support, including definitions and multimedia resources. All interactions are logged to maintain audit trails, support regulatory requirements, and enable training analytics. For routine inquiries, such as document approval workflows, the bot provides responses aligned with organizational policies and QMS standards. Complex or specialized queries are escalated to the appropriate subject matter experts or designated departments, **ensuring accuracy**, **operational efficiency**, and **adherence to quality and compliance frameworks**.



Five AI-driven capabilities for Quality Management Systems (QMS)

Quality Management Systems are evolving from reactive compliance to predictive, data-driven quality. Five AI-enabled capabilities—Deviation & CAPA Analysis, Audit Readiness & Risk Assessment, QMS Chatbots, Change Impact Analysis, and Training

Recommendations—enhance traditional workflows to cut cycle times, boost compliance, and improve product quality. This section outlines each capability, its architecture, regulatory validation, KPIs, and a GxP-aligned deployment roadmap.



Machine Learning and NLP Integration

AI uses machine learning and natural language processing to analyze deviation narratives and structured data effectively.



Holistic Quality Issue View

Integrates multiple data sources for a comprehensive understanding of deviations and quality problems.



Proactive Corrective Actions

Predicts root causes and recommends proactive CAPAs to prevent deviation recurrence and improve product quality.



Business Impact and KPIs

Accelerates investigations, reduces repeat deviations, improves CAPA success, and enhances regulatory compliance.



Continuous Compliance Monitoring

AI systems continuously track QMS workflows to identify compliance gaps like missing signatures and overdue tasks.



Intelligent Workflow Routing

AI applies intelligent routing to minimize bottlenecks and ensure timely approvals across processes.



Business Impact and KPIs

AI reduces audit preparation time, lowers regulatory risks, and improves approval cycles and compliance scores.



Transformation to Continuous Process

The AI-driven approach shifts audit readiness from periodic efforts to a seamless ongoing automated process.



Contextual Answers with LLMs

The chatbot leverages large language models to deliver precise answers from SOPs and workflows, enhancing document navigation.



Data Sources Utilized

It utilizes diverse data sources like controlled SOPs, work instructions, templates, quality manuals, and training guides.



Business Impact and KPIs

The chatbot accelerates information retrieval, improves SOP consistency, reduces training time, and boosts user satisfaction.



Operational Efficiency

Instant access to accurate information reduces errors, improves compliance, and enhances overall operational efficiency.



AUTOMATED CHANGE-IMPACT ANALYSIS



Dependency Mapping

Automated mapping links SOPs, equipment, and systems to identify change dependencies proactively.



Predictive Impact Analysis

Historical change data is analyzed to predict downstream impacts and compliance risks effectively.



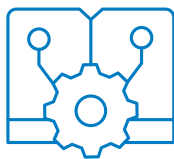
Business Benefits

Improved safety, fewer missed updates, and better compliance alignment enhance operational efficiency.



Key Performance Indicators

Reduced lead times, fewer reworks, and lower risk scores measure success of change management.



AI-DRIVEN TRAINING RECOMMENDATIONS



Personalized Learning Paths

AI creates customized training paths based on SOP changes, audit findings, and CAPA reviews to align workforce skills.



Relevant Data Sources

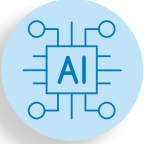
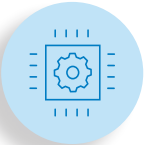
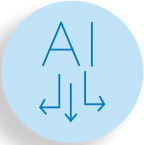
Training recommendations utilize LMS profiles, training history, SOP versions, CAPA outcomes, and deviation trends for accuracy.



Business Impact and KPIs

Improved compliance, targeted reskilling, higher on-time completion, better assessments, fewer errors, and increased engagement.



Capability	Detailed Description	Key Data Sources	Business Impact	KPIs
 AI POWERED DEVIATION & CAPA ANALYSIS	Uses ML and NLP to analyze deviation narratives and structured data, predict root causes, and recommend proactive CAPAs to prevent recurrence.	Deviation records, CAPA logs, MES/EBR data, LIMS results, equipment maintenance logs, supplier quality reports.	Accelerates investigations, improves CAPA effectiveness, reduces repeat deviations, and enhances overall product quality.	- Investigation cycle time ↓ - Repeat deviation rate ↓ - CAPA success rate ↑ - Reviewer agreement % ↑
 AI DRIVEN AUDIT READINESS & RISK ASSESSMENT	Continuously monitors QMS workflows for compliance gaps such as missing signatures, overdue tasks, and outdated SOPs; applies intelligent routing to reduce bottlenecks.	QMS workflows, document management system, training records, audit history, approval logs.	Reduces audit preparation time, minimizes regulatory risk exposure, and ensures timely approvals for critical processes.	- Time-to-readiness ↓ - Audit findings per audit ↓ - Approval cycle time ↓ - Compliance score ↑
 QMS CHATBOT (LLM ON SOPs & WORKFLOWS)	Provides contextual answers from SOPs and workflows using LLMs; assists in document navigation and reduces training effort for QA/RA teams.	Controlled SOPs, work instructions, templates, quality manuals, training guides.	Speeds up information retrieval, ensures consistent SOP interpretation, and lowers training burden across teams.	- Chatbot resolution rate ↑ - Citation accuracy ↑ - User satisfaction ↑ - Training query turnaround ↓
 AUTOMATED CHANGE IMPACT ANALYSIS	Maps dependencies between SOPs, equipment, and systems; compares historical changes to predict downstream impacts and compliance risks.	SOP library, equipment registry, system inventory, training curricula, change control tickets.	Improves change control safety, reduces missed updates, and strengthens compliance alignment across departments.	- Missed impact items ↓ - Change lead time ↓ - Approval rework ↓ - Compliance risk score ↓
 AI DRIVEN TRAINING RECOMMENDATIONS	Generates personalized learning paths triggered by SOP/system changes, audit findings, or CAPA reviews; ensures workforce alignment with current procedures.	LMS profiles, training history, SOP versions, CAPA outcomes, deviation trends.	Boosts training compliance, targets reskilling for high-risk areas, and improves audit outcomes through demonstrable competence.	- On-time training completion ↑ - Assessment scores ↑ - Observations due to procedural error ↓ - Engagement rate ↑



Challenges and Considerations

Change Management: Organizations must invest in upskilling and cultural transformation to adopt AI-enabled QMS.

Integration Complexity: Seamless integration with existing QMS platforms and enterprise systems is critical.

Regulatory Acceptance: AI output must be validated, documented, and audit-ready to meet global compliance standards.



Future Outlook

AI + IoT: Real-time quality monitoring from shop floor to cloud.

Blockchain Integration: Immutable quality records and enhanced traceability.

Autonomous QMS: Self-learning systems that continuously optimize quality processes.



Infosys Vision

To be the strategic partner of choice for AI-powered quality transformation, delivering intelligent, compliant, and scalable solutions across industries.



Conclusion

Artificial Intelligence is redefining the future of Quality Management Systems. By enabling predictive, intelligent, and adaptive quality processes, AI transforms QMS from a compliance mechanism into a strategic enabler of operational excellence. Infosys, with its robust AI frameworks and deep domain expertise, is uniquely positioned to lead this transformation and deliver measurable value to global clients.

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