European Journal of Computer Science and Information Technology,13(22),68-78, 2025
Print ISSN: 2054-0957 (Print)
Online ISSN: 2054-0965 (Online)
Website: https://www.eajournals.org/
Publication of the European Centre for Research Training and Development -UK

AI-Driven Quality Assurance and Compliance Monitoring in SAP S/4HANA and Salesforce CPQ Implementations

Vijay Kumar Kola
Osmania university, India

doi: https://doi.org/10.37745/ejcsit.2013/vol13n226878 Published May 17, 2025

Citation: Kola V.K. (2025) AI-Driven Quality Assurance and Compliance Monitoring in SAP S/4HANA and Salesforce CPQ Implementations, *European Journal of Computer Science and Information Technology*,13(22),68-78

Abstract: *AI-driven quality assurance and compliance monitoring represent transformative approaches for medical device companies navigating the complex regulatory landscape of SOX and GxP requirements while utilizing SAP S/4HANA and Salesforce CPQ systems. The integration of artificial intelligence technologies across enterprise platforms addresses critical challenges in maintaining data integrity, ensuring financial controls, validating electronic signatures, and aligning quote-to-cash processes with regulatory requirements. Through strategic implementation of machine learning algorithms, natural language processing, and predictive analytics, organizations have demonstrated significant improvements in compliance effectiveness while simultaneously reducing operational burden. These technologies enable real-time anomaly detection, automated test case generation from regulatory documents, and continuous transaction monitoring that traditional manual methods cannot achieve. The shift from reactive compliance management to proactive risk prediction fundamentally changes how medical device manufacturers approach quality assurance, resulting in measurable benefits including enhanced audit outcomes, accelerated commercial operations, improved revenue recognition, and substantially lower compliance costs. The documented implementations across multiple case studies provide compelling evidence for the business case of AI-powered compliance, offering a blueprint for regulated industries seeking to transform compliance from a cost center to a strategic advantage.*

Keywords: Artificial intelligence, regulatory compliance, SAP S/4HANA, Salesforce CPQ, medical devices, GxP validation, predictive analytics

INTRODUCTION

Medical device companies operating under Sarbanes-Oxley (SOX) and Good Practice (GxP) regulations face escalating challenges in ensuring compliance across their enterprise systems. These organizations

increasingly rely on specialized ERP systems like SAP S/4HANA, which has emerged as a leading solution alongside Oracle NetSuite and Microsoft Dynamics 365 in the medical device industry [2]. The adoption of such systems is driven by the need for comprehensive quality management capabilities, with 82% of medical device manufacturers citing regulatory compliance as their primary concern when selecting an ERP system [2].

The integration of ERP platforms with commercial operations tools like Salesforce CPQ creates additional complexity. According to industry research, medical device companies implementing these interconnected systems report significant challenges in maintaining data integrity across platforms, with implementation timelines averaging 12-18 months largely due to validation requirements [2]. These extended timelines reflect the difficulty in ensuring consistent compliance across systems, particularly for companies subject to FDA regulations that require thorough documentation and testing.

Traditional manual compliance methods have proven increasingly inadequate when addressing critical requirements such as financial controls under SOX, GxP processes, and CPQ compliance alignment with billing systems. The labor-intensive nature of these processes contributes to the total cost of ownership for ERP systems in medical device companies, which typically ranges from $150,000 to $750,000 annually depending on company size [2].

Artificial Intelligence (AI) technologies have emerged as powerful tools to bridge these compliance gaps. Recent research indicates that AI implementation in industrial settings can improve process efficiency by 23-27% while reducing error rates by approximately 30% across various operational domains [1]. When applied to compliance monitoring, these technologies enable real-time anomaly detection and predictive risk assessment, transforming reactive compliance processes into proactive systems.This paper presents real-world applications of AI-powered Quality Assurance (QA) and compliance monitoring approaches that effectively address these challenges. The case studies demonstrate how machine learning (ML), natural language processing (NLP), and predictive analytics have successfully reduced audit risks, automated compliance test case generation, and enabled real-time transaction monitoring in regulated medical device environments, building on the foundational AI implementation principles documented in longitudinal industry studies [1].

AI-Powered SOX Compliance in SAP S/4HANA

A global medical device manufacturer faced significant challenges with manual SOX controls that repeatedly led to audit failures and unauthorized financial postings. According to Protiviti's 2023 SOX Compliance Survey, organizations spend an average of $1,133,000 annually on SOX compliance, with 53% reporting increases in compliance hours and 51% experiencing higher external audit fees [4]. The survey further reveals that companies leveraging technology enablement achieve 30-50% more efficiency in their compliance processes compared to those relying on manual efforts [4].

To address these issues, the company deployed an integrated solution combining SAP Process Control with AI Core to monitor more than 50,000 monthly transactions. This approach aligns with industry trends, as 47% of organizations now utilize automation tools for SOX compliance, with 72% of chief audit executives planning to increase their technology and automation investments [4]. The implementation was supplemented with process mining technology to detect duplicate vendor payments, a strategy that typically delivers 30-45% process cost reduction according to established AI ROI metrics [3].

The solution implemented self-healing controls that automatically remediated 95% of Segregation of Duties (SoD) violations, eliminating the need for manual intervention in most cases. This automation addressed a critical pain point identified in the Protiviti survey, where 69% of organizations reported increasing or significantly increasing their focus on IT general controls, including access and SoD management [4]. The impact of such automation goes beyond compliance, as AI-powered process improvements typically reduce task completion time by 40-75% while increasing accuracy by 50-65% across various business functions [3].

This comprehensive approach to AI-powered SOX compliance delivered remarkable results: the company reported zero SOX findings in its 2024 audit and achieved an 80% faster month-end close process. These outcomes reflect the upper tier of AI implementation success, where top-performing organizations achieve ROI of 134% on average within 14 months of deployment [3]. The survey data supports these findings, as companies with advanced automation initiatives report 38% lower compliance costs on average and complete their SOX testing 45 days earlier than organizations with minimal automation [4].

The success of this implementation demonstrates how AI can transform financial compliance from a reactive, labor-intensive process to a proactive, efficient system that provides greater assurance with less manual effort. This transformation is increasingly important as 65% of organizations report that SOX compliance demands continue to increase year over year, creating a compelling case for AI-powered solutions [4].

Table 1: Impact of AI Implementation on SOX Compliance Metrics [3, 4]

Metric	Before AI Implementation	After AI Implementation
SOX Compliance Cost ($)	11,33,000	7,02,460
Month-End Close Time (Days)	12	2.4
SoD Violation Auto-Remediation (%)	5	95
Transaction Coverage (%)	12	98.7

Salesforce CPQ GxP Compliance with AI

An FDA-regulated medical technology firm faced significant delays due to manual validation of CPQ-generated quotes. According to industry assessments, life sciences organizations spend approximately 40% of their operational resources on compliance-related activities, with validation processes representing a

major bottleneck in commercial operations [5]. The manual review of pricing configurations against regulatory requirements not only extended sales cycles but also introduced inconsistency, with studies showing that human reviewers achieve only 60-70% consistency when applying complex regulatory requirements across different product configurations [6].

The company implemented Salesforce Shield integrated with Einstein AI to automatically validate quotes against FDA 21 CFR Part 11 compliance templates. This approach aligns with digital transformation trends in life sciences, where 64% of organizations have prioritized automation of compliance-intensive processes to accelerate time-to-market while maintaining regulatory adherence [5]. Machine learning algorithms demonstrated particular effectiveness in compliance applications, with supervised learning models showing 83.7% accuracy in identifying non-compliant patterns based on historical regulatory decisions [6].

The system was configured to flag non-compliant discounts (those exceeding 20%) in real-time, enabling immediate corrective action before quotes reached customers. This capability addressed a significant pain point, as approximately 35% of compliance errors in life sciences occur during the pricing and contracting phase of product commercialization [5]. The solution integrated natural language processing to interpret regulatory guidelines and translate them into executable rules, a methodology that reduced interpretation variation by 74.2% compared to manual compliance processes [6].

Additionally, the company integrated MuleSoft to synchronize data between Salesforce CPQ and SAP systems, ensuring accurate revenue recognition across platforms. This integration strategy reflects best practices identified in digital transformation initiatives, where 72% of successful implementations in life sciences prioritize system interoperability to maintain data integrity across compliance boundaries [5]. The automated synchronization eliminated manual reconciliation processes that typically consume 15-20% of financial closing cycles in regulated industries [6].The implementation produced significant operational improvements, reducing quote approval time by 70% while successfully passing FDA audits with no observations. This outcome is consistent with research findings that organizations implementing AI-augmented compliance systems experience a 47.3% reduction in audit findings on average and achieve 31.5% faster response times during regulatory inspections [6]. This case demonstrates how AI can transform commercial operations in highly regulated environments while maintaining strict adherence to GxP requirements, delivering both efficiency and compliance improvements simultaneously.

Table 2: AI Impact on Salesforce CPQ Compliance Performance [5, 6]

Metric	Manual Process	AI-Enabled Process
Reviewer Consistency (%)	65	83.7
Quote Approval Time (Days)	18.3	5.5
Compliance Error Rate (%)	35	9
Interpretation Variation (%)	100	25.8

European Journal of Computer Science and Information Technology,13(22),68-78, 2025
Print ISSN: 2054-0957 (Print)
Online ISSN: 2054-0965 (Online)
Website: https://www.eajournals.org/
Publication of the European Centre for Research Training and Development -UK

End-to-End AI Monitoring Across SAP and Salesforce Platforms

A Fortune 500 pharmaceutical leader faced revenue leakage challenges stemming from disconnected ERP and CPQ systems. According to industry analysis, compliance issues typically consume 30-50% of senior management time in pharmaceutical companies, with disconnected systems being a primary driver of inefficiencies [7]. The lack of integration between front-end sales systems and back-end ERP platforms creates particular challenges during regulatory inspections, with 63% of compliance officers reporting difficulty providing consistent documentation across systems [7].

The company implemented IBM OpenPages with Watson to correlate Salesforce CPQ discounts with SAP Sales and Distribution (SD) billing anomalies, creating a comprehensive view of the quote-to-cash process. This approach addressed a key challenge in the regulatory landscape, as inconsistent data between systems creates opportunities for both revenue leakage and compliance failures. Life sciences organizations implementing AI-driven monitoring typically achieve a 42% reduction in manual monitoring efforts while increasing data coverage from partial sampling to near-continuous oversight [7].

This cross-platform monitoring approach was enhanced with Darktrace AI to detect potential insider data exports that could compromise compliance or intellectual property. The security integration component proves particularly important in pharmaceutical environments, where the risk of data exfiltration carries both intellectual property and regulatory compliance implications. Organizations implementing cross-platform security monitoring report reducing mean-time-to-detection for anomalous behaviors by 71% compared to traditional security approaches [7].

The company automated pre-audit reporting using ServiceNow Governance, Risk, and Compliance (GRC), creating a streamlined process for audit preparation. This integration builds on industry best practices, where standardized validation procedures reduce preparation time while improving documentation quality [8]. Automated compliance frameworks have demonstrated effectiveness across pharmaceutical environments, with implementation studies showing up to 60% reduction in audit preparation time and significant improvements in first-time-right documentation [8].

The results were substantial: the system identified $5 million per year in revenue discrepancies that had previously gone undetected and reduced audit preparation time by 60%. These outcomes align with industry benchmarks for AI-augmented compliance processes, where organizations typically recover 2-4% of previously unidentified revenue while reducing compliance-related costs by 25-40% [7]. The efficiency gains extend beyond direct cost savings, as streamlined compliance processes enable faster responses to regulatory inquiries, reducing uncertainty periods by an average of 47% according to industry metrics [8].

European Journal of Computer Science and Information Technology,13(22),68-78, 2025
Print ISSN: 2054-0957 (Print)
Online ISSN: 2054-0965 (Online)
Website: https://www.eajournals.org/
Publication of the European Centre for Research Training and Development -UK

Table 3: Integration Impact on Pharmaceutical Compliance Management [7, 8]

Metric	Before Integration	After Integration
Senior Management Time on Compliance (%)	45	21
Documentation Consistency Issues (%)	63	17
Manual Monitoring Effort (Hours/Quarter)	840	487
Revenue Discrepancy Detection ($ Millions)	0.8	5
Audit Preparation Time (Days)	45	18

Advanced AI Applications: Test Generation and Predictive Compliance

Two additional case studies demonstrate more advanced applications of AI in medical device compliance, operating within the FDA's evolving regulatory framework for artificial intelligence and machine learning technologies. As the FDA notes in its approach to AI/ML-based Software as a Medical Device (SaMD), these technologies have the unique capability to learn from real-world feedback and improve functionality, creating both opportunities and regulatory challenges in ensuring device safety and effectiveness [9].

A cardiac device manufacturer implemented large language model technology to analyze over 10,000 Standard Operating Procedures (SOPs) and Functional Design Documents (FDDs) to automatically generate GxP test cases. This approach aligns with the FDA's guidance on computer software assurance for manufacturing, operations, and quality system software, which emphasizes risk-based approaches to validation based on intended use and potential impact on product quality, safety, and data integrity [10]. The manufacturer implemented a test strategy that prioritized high-risk elements affecting patient safety, following the FDA's recommendation that "testing activities should be commensurate with risk" [10].

Using Tricentis Tosca to execute these risk-based tests with priority on batch records, the company achieved 90% test coverage in half the time previously required and encountered zero deviations during FDA inspection. This outcome reflects the benefit of implementing the FDA's suggested "critical thinking approach" to testing, which focuses validation efforts on features that directly impact product quality rather than exhaustive testing of all software aspects [10]. The FDA guidance explicitly notes that "focusing on high-risk elements can improve both product quality and the efficiency of the quality system" [10].

In a parallel innovation, an In-Vitro Diagnostics (IVD) provider implemented AWS SageMaker to predict batch failures using historical SAP Quality Management (QM) data combined with environmental sensor inputs. This implementation addressed the FDA's acknowledgment that AI/ML systems can be designed to continuously learn and adapt from new user data, potentially improving the evaluation of manufacturing processes and product quality [9]. The system was designed in accordance with the FDA's framework for modifications to AI/ML-based SaMD, which requires appropriate controls for continuously learning systems [9].

The system integrated with SAP Digital Signatures to ensure proper audit trails, maintaining compliance with 21 CFR Part 11 requirements for electronic records as referenced in the FDA's software assurance guidance [10]. This predictive compliance solution reduced deviations by 50% and enabled the company to achieve ISO 13485 certification seamlessly. The implementation exemplifies the FDA's recognition that "automated tools, when appropriately used, can improve the consistency and effectiveness of testing activities" [10].

Together, these cases demonstrate how advanced AI technologies implemented within appropriate regulatory frameworks can transform compliance processes through predictive capabilities and intelligent test generation.

Table 4: Advanced AI Applications Outcomes [9, 10]

Metric	Traditional Approach	AI-Powered Approach
Test Coverage (%)	71	90
Test Development Time (Hours)	3240	780
Batch Failure Prediction Accuracy (%)	42	88
Deviation Rate (%)	100	50

AI-Powered Automation Frameworks

The implementation of comprehensive automation frameworks represents a crucial evolution in compliance strategies, extending beyond isolated AI applications to establish systematic approaches for ensuring regulatory adherence throughout enterprise systems. These frameworks leverage machine learning to optimize test workflows, reduce manual effort, and maintain continuous compliance across connected platforms.

The orchestration of test automation represents a cornerstone of these frameworks. A multinational medical technology company implemented Tricentis qTest with custom ML algorithms to analyze historical test execution data and dynamically prioritize validation scripts based on risk patterns. This approach reduced test execution time by 73% while increasing defect detection rates by 38% compared to traditional methodologies [6]. The system employed reinforcement learning principles to continuously refine test prioritization, creating a "self-optimizing" validation framework that directed testing resources to areas demonstrating higher historic vulnerability to compliance issues [6].

These frameworks extend beyond test execution to encompass test design and maintenance. According to industry benchmark studies, 42% of validation effort in regulated environments is consumed by test script maintenance as system configurations evolve [5]. Organizations implementing AI-augmented test design frameworks report 67% reductions in maintenance effort through automated impact analysis and selective test regeneration [5]. These systems scan regulatory document updates and automatically modify affected test cases, maintaining validation alignment with evolving requirements.

The integration of low-code test automation platforms with ML capabilities has proven particularly effective. Companies utilizing tools like UiPath Test Manager with ML-based object recognition report 82% reductions in test breakage during system updates compared to traditional automation approaches [7]. These platforms enable non-specialist users to maintain compliance test suites, democratizing validation activities that previously required specialized programming expertise and reducing dependence on scarce technical resources.

Process documentation automation represents another critical framework component. A prominent implantable device manufacturer implemented an AI system to automatically generate compliance evidence from test execution data, reducing documentation effort by 84% while improving traceability between requirements and validation evidence [8]. This system employed natural language generation to create human-readable documentation that met FDA submission standards without manual intervention, addressing a critical bottleneck in the validation process [8].

The maturity of these automation frameworks can be measured across several dimensions, including test coverage automation, risk-based prioritization, documentation generation, and continuous monitoring. Organizations achieving high maturity across these dimensions report 40-60% overall reduction in compliance costs while simultaneously achieving higher quality outcomes [5]. This multidimensional approach transforms compliance from a reactive, resource-intensive burden into a proactive, efficient system that provides greater assurance with substantially lower effort.

AI-Driven Compliance Monitoring Details

The implementation of real-time compliance monitoring represents a fundamental shift from periodic assessment to continuous assurance. This approach incorporates several critical capabilities that enable organizations to maintain compliance posture without traditional manual oversight.Real-time transaction evaluation utilizes machine learning to monitor system activities continuously rather than through periodic sampling. A leading cardiac device manufacturer deployed Celonis Process Mining integrated with custom ML algorithms to establish continuous monitoring across 100% of SAP transactions, achieving complete visibility compared to the 3-5% transaction review typical in traditional audit sampling [7]. The system established baseline patterns for normal operational behavior across procurement, manufacturing, and distribution processes, then flagged deviations from expected patterns for immediate review [7]. This pattern recognition capability proved particularly valuable in identifying subtle configuration changes that would have bypassed traditional controls but could have resulted in compliance vulnerabilities.

Comprehensive audit trails provide another essential component of effective monitoring systems. Organizations implementing blockchain-based audit trail technologies report 100% non-repudiation of system actions and 99.997% data integrity compared to traditional logging approaches [8]. These systems automatically record critical system events in immutable distributed ledgers, creating tamper-proof documentation that satisfies regulatory requirements for electronic records under 21 CFR Part 11 [10]. The

integration of these systems with identity management platforms ensures that appropriate authentication and authorization rules are maintained across all transactions.

Proactive risk detection represents a significant advancement over traditional compliance approaches. A multinational biotech company implemented IBM Maximo with custom ML risk prediction algorithms to analyze patterns across procurement, manufacturing, and quality management processes [5]. The system identified seven critical compliance risks that had not been detected by traditional audit methods, including subtle parameter deviations in manufacturing processes that could have impacted product quality and regulatory standing [5]. The early identification of these issues allowed for corrective action before product quality was affected, demonstrating the value of predictive compliance models over reactive approaches. Cross-system monitoring integration addresses the compliance gaps that frequently occur at system boundaries. A major surgical instrument manufacturer implemented ServiceNow GRC with custom integration to synchronize compliance monitoring across SAP, Salesforce, and specialized manufacturing execution systems (MES) [8]. This integration provided end-to-end visibility throughout the product lifecycle, from design to commercialization, enabling complete traceability and eliminating the monitoring gaps that typically occur between departmental systems [8].

The real-world impact of these monitoring capabilities is demonstrated through tangible metrics. Organizations implementing comprehensive AI-driven monitoring report average reductions of 76% in audit findings, 82% in compliance-related defects, and 68% in the time required to prepare for regulatory inspections [6]. These statistics highlight how continuous monitoring transforms compliance from a periodic, resource-intensive activity to an ongoing operational capability that provides higher assurance with significantly lower effort.

Challenges and Limitations of AI-Driven Compliance

Despite the documented successes, organizations implementing AI-driven compliance solutions face several critical challenges. Data integration complexity remains a significant hurdle, with 67% of companies reporting difficulties in establishing reliable data pipelines between legacy systems and modern AI platforms [7]. The synchronization of transactional data between Salesforce CPQ and SAP S/4HANA frequently requires custom middleware development, with implementation timelines extending 30-45% beyond initial projections when integration points exceed 15 distinct connections [5].

AI model accuracy presents another challenge, particularly in regulatory environments where false negatives could result in compliance violations. A comprehensive analysis of machine learning implementations in pharmaceutical compliance revealed that while precision reaches 92% for well-defined compliance patterns, accuracy drops to 76% when confronted with novel regulatory scenarios or unusual transaction patterns [6]. This limitation necessitates ongoing human oversight, with approximately 22% of AI-flagged anomalies requiring expert review to determine actual compliance implications [6].

Regulatory alignment presents perhaps the most nuanced challenge, as AI systems must continuously adapt to evolving requirements. The FDA's framework for AI/ML modifications acknowledges this dynamic environment, requiring manufacturers to establish predetermined change control plans that anticipate how their AI systems will learn and change over time [9]. Organizations implementing AI compliance tools report spending 16-20% of their total project budgets on validation protocols that demonstrate that algorithm adaptations remain within approved regulatory boundaries [9].

Furthermore, the explainability of AI decisions remains problematic in audit contexts, with regulatory bodies increasingly requiring transparent documentation of how algorithmic conclusions are reached. According to industry surveys, 58% of quality assurance professionals cite "black box" decision-making as their primary concern when implementing AI systems in regulated environments [8]. This challenge has prompted the development of explainable AI frameworks specifically designed for compliance applications, though these typically require computational trade-offs that may impact system performance [8].

CONCLUSION

AI-driven quality assurance and compliance monitoring have demonstrated transformative potential for medical device companies implementing SAP S/4HANA and Salesforce CPQ systems. Throughout the examined case studies, artificial intelligence applications consistently delivered dual benefits of strengthened regulatory adherence and operational efficiency across diverse compliance domains. The integration of SAP Process Control with AI Core for financial compliance, Einstein AI for CPQ validation, IBM OpenPages with Watson for cross-platform monitoring, and advanced applications like GPT-4 for test generation and AWS SageMaker for predictive quality management collectively form a comprehensive framework for modernizing regulatory approaches. These technologies have shifted compliance from reactive verification to proactive risk management by automating repetitive tasks, predicting potential issues before they manifest, and providing comprehensive visibility across previously siloed systems. The unified approach resolves fundamental challenges in maintaining data integrity between commercial and financial systems while ensuring auditability for regulators. Looking forward, the continued evolution of AI capabilities, particularly in explainability and adaptability to regulatory changes, presents opportunities for further advancements. Medical device companies seeking to implement similar solutions should prioritize foundational controls, cross-platform integration, and validation aligned with FDA 21 CFR Part 11 and ISO 13485 requirements. The documented outcomes across case studies provide compelling evidence that AI-powered quality assurance delivers tangible business value beyond mere compliance, positioning these technologies as strategic investments rather than cost centers.

REFERENCES

[1] Valeriya G. et al.(2024) , "Evaluating the Impact of AI-Based Sustainability Measures in Industry 5.0: A Longitudinal Study," Researchgate,. Available: https://www.researchgate.net/publication/377359801_Evaluating_the_Impact_of_AI-Based_Sustainability_Measures_in_Industry_50_A_Longitudinal_Study

[2] Gupta S., "Top Medical Device ERP Systems in 2024: A Comprehensive Guide," ElevatiQ Blog, May 2025. Available: https://www.elevatiq.com/post/top-medical-device-erp-systems/

[3] Ivanchenko A. (2024) , "Measuring the ROI of AI: Key Metrics and Strategies," Tech-Stack Blog, Available: https://tech-stack.com/blog/roi-of-ai/

[4] Protiviti, "The Evolution of SOX: Tech Adoption and Cost Focus Amid Business Changes, Cyber and ESG Mandates," Protiviti Inc., 2023. Available: https://www.protiviti.com/sites/default/files/2023-09/2023-sox-compliance-survey-protiviti.pdf

[5] BioBostonConsulting, "Digital Transformation in Life Sciences," LinkedIn, 2025. Available: https://www.linkedin.com/pulse/digital-transformation-life-sciences-biobostonconsulting-5yjnc

[6] Ayodeji A. (2024) , "Artificial Intelligence in Enhancing Regulatory Compliance and Risk Management," Researchgate, Available: https://www.researchgate.net/publication/381045225_Artificial_Intelligence_in_Enhancing_Regulatory_Compliance_and_Risk_Management

[7] Aggarwal A. et al. (2024), "How AI is Shaking Up Compliance in the Life Sciences Industry," IQVIA Blog, 2025. Available: https://www.iqvia.com/locations/emea/blogs/2025/02/how-ai-is-shaking-up-compliance-in-the-life-sciences-industry

[8] KanboApp, "Unlocking Compliance and Efficiency: How the Medicaid Enterprise Certification Toolkit Transforms the Pharmaceutical Industry," Kanbo. Available: https://kanboapp.com/en/industries/pharmaceutical/unlocking-compliance-and-efficiency-how-the-medicaid-enterprise-certification-toolkit-transforms-the-pharmaceutical-industry/

[9] FDA, "Artificial Intelligence and Machine Learning in Software as a Medical Device," U.S. Food and Drug Administration, 2025. Available: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device

[10] FDA, "Artificial Intelligence in Drug Manufacturing," U.S. Food and Drug Administration, Available: https://www.fda.gov/media/165743/download