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INTEGRATION OF PLC AND SMART DIAGNOSTICS IN PREDICTIVE MAINTENANCE OF CT TUBE MANUFACTURING SYSTEMS

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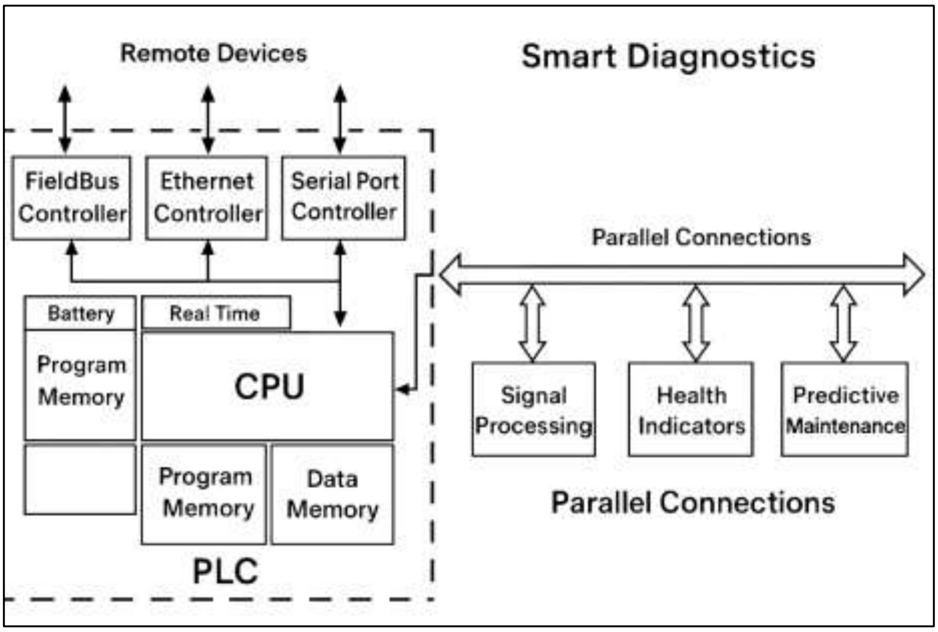
Abstract
This systematic review examines the integration of programmable logic controllers (PLCs) and smart diagnostics within predictive maintenance frameworks for computed tomography (CT) tube manufacturing systems. Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, a total of 87 studies were analyzed to synthesize evidence on maintenance complexity, diagnostic strategies, modeling approaches, regulatory dimensions, and economic implications. Findings highlight that CT tube manufacturing is characterized by multi-domain degradation processes, including vacuum instability, rotor-bearing wear, and thermal fatigue, which traditional preventive maintenance cannot adequately address. Recurrent failure modes—such as filament thinning, anode cracking, and vacuum leakage—were consistently associated with measurable health indicators like vibration signals, acoustic emissions, thermal gradients, and arc frequency. Prognostic modeling approaches revealed that physics-based models offer mechanistic insight, data-driven methods provide adaptive accuracy, and hybrid frameworks balance both strengths while meeting regulatory validation requirements. The review also identified unresolved challenges in interoperability, data governance, and compliance with ISO 13485, ISO 14971, IEC 60601, and FDA 21 CFR Part 11, which continue to constrain large-scale implementation. Conceptual anchors derived from the synthesis—deterministic PLC control, validated diagnostic science, and regulatory alignment—provide a structured foundation for advancing predictive maintenance in regulated medical device manufacturing.

Keywords
Predictive Maintenance; CT Tubes; Programmable Logic Controllers; Smart Diagnostics; Medical Device Manufacturing

INTRODUCTION

Programmable logic controllers (PLCs) are industrial digital computers engineered for real-time control of electromechanical processes, formalized by the IEC 61131 family of standards that define programming languages, execution models, and determinism requirements for factory automation. Smart diagnostics refers to the application of condition monitoring, signal processing, and data-driven inference to automatically detect, isolate, and predict failure states in assets, often aligned to ISO and IEC guidance for condition-based maintenance (CBM) and prognostics (Chen et al., 2017).

Figure 1: PLC Integration with Smart Diagnostics



Predictive maintenance denotes the proactive scheduling of maintenance actions based on measured degradation and estimated remaining useful life (RUL), rather than fixed intervals, supported by reliability-centered maintenance (RCM) frameworks. In the manufacturing of computed tomography (CT) x-ray tubes—assemblies comprising a vacuum envelope, rotating anode, cathode filament, bearings, high-voltage insulation, and heat management sub-systems—the integration of PLC-based machine control with smart diagnostics has particular importance due to stringent medical device quality requirements, thermal-mechanical stresses, and safety regulations. Internationally, health systems depend on CT imaging throughput and uptime; disruptions from tube manufacturing defects or process drift propagate downstream into hospital operations and patient access, positioning predictive maintenance as a lever for global reliability and affordability (Alphonsus & Abdullah, 2016). Within this context, a clear set of definitions anchors a rigorous introduction: PLCs provide deterministic control and data acquisition; smart diagnostics transforms raw signals into health indicators; predictive maintenance uses those indicators to optimize interventions under regulatory and quality constraints (Mellado & Núñez, 2022).

The international significance of integrating PLCs with smart diagnostics in CT tube manufacturing stems from the confluence of patient safety, supply chain resilience, and cost efficiency in a cross-border medical technology market. CT demand growth in emerging and developed health systems elevates the value of stable tube output and yield, where defects in brazing, vacuum integrity, rotor balancing, or insulation clearance can produce latent failure modes that later manifest as premature clinical downtime (Thürer et al., 2022). Regulations and standards mandate traceability and process control, yet traditional reactive maintenance cannot reliably prevent scrap spikes or post-shipment failures under variable thermal and mechanical loads. Globalized production also increases

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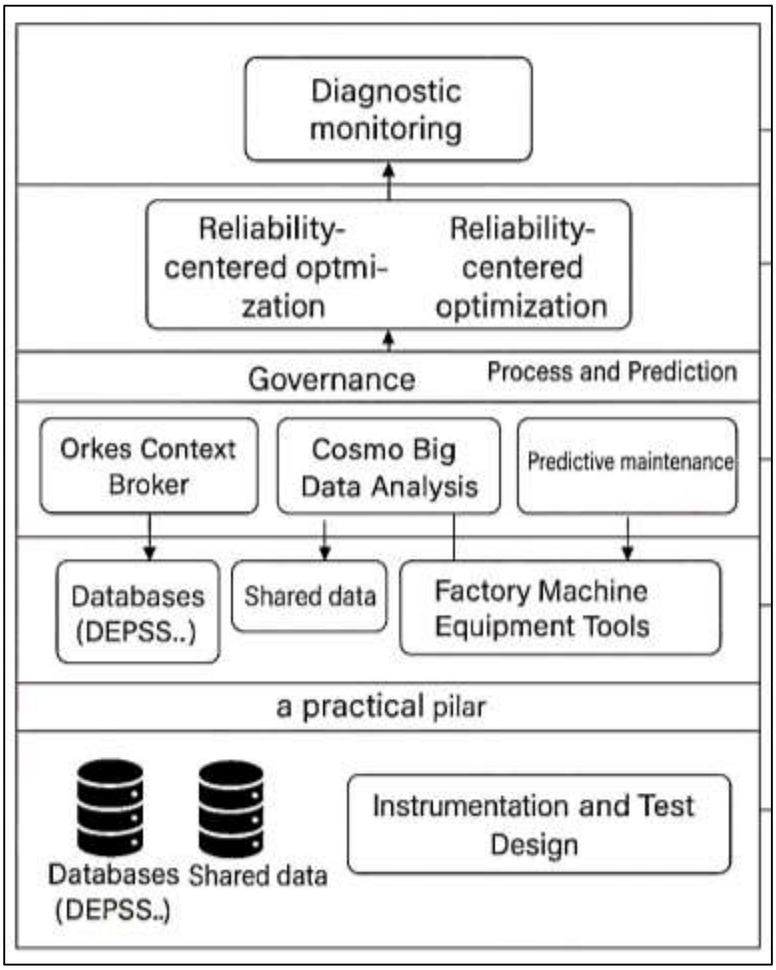
variability in utilities, ambient conditions, and subcomponent lots, requiring adaptive monitoring rather than static tolerances. Predictive maintenance frameworks using PLC-resident data channels, edge analytics, and standardized interoperability enable earlier detection of bearing wear in tube rotors, arc propensity linked to outgassing, or filament microstructural drift that correlates with emission instability. Such integration aligns with risk-based quality management and process capability initiatives in medical device manufacturing across geographies, supporting lower cost-of-poor-quality (COPQ) and improved on-time delivery performance without compromising regulatory expectations. The net effect strengthens international health system reliability by reducing tube field failures and stabilizing imaging capacity.

Core to this integration is a data architecture that allows PLCs to act as deterministic orchestrators while serving as trusted data sources to higher-level diagnostic engines. PLCs sequence motion, temperature ramps, vacuum pumps, brazing profiles, and safety interlocks; simultaneously, they stream timestamped tags that become inputs for condition indicators—vibration spectra, acoustic emission counts, ion pump current trends, thermal gradients, and arcing event logs (Vadi et al., 2022). Interoperability layers such as OPC UA information models and message-oriented middleware connect these tags to historian databases and edge inference modules under industrial cybersecurity constraints. Signal processing techniques transform raw measurements to features: order tracking for rotor assemblies, kurtosis and crest factors for bearing diagnostics, Allan variance for filament current stability, and thermographic emissivity-corrected gradients for brazed joint quality. These features feed statistical or machine learning models that estimate health states and RUL, closing the loop to maintenance planners through computerized maintenance management systems (CMMS) and electronic device history records. The engineering value lies in aligning deterministic control cycles with synchronized diagnostics windows, ensuring that sampling rates, buffering, and timestamp precision meet the needs of spectral and transient analysis in thermally dynamic processes typical of CT tube manufacturing. Such architectures codify traceability and reproducibility, two pillars of regulated manufacturing analytics (Mao et al., 2021).

Predictive maintenance methods applicable to CT tube manufacturing span physics-based, data-driven, and hybrid approaches. Physics-based models encode rotor dynamics, heat transfer across target disks, and vacuum behavior to relate process setpoints to stresses and degradation, enabling interpretable indicators such as thermal fatigue damage accumulation or outgassing-induced arc probability (Wang & Wu, 2016). Data-driven models learn mappings from historical features to failure labels or continuous degradation scores; classical techniques include proportional hazards, survival analysis, state-space health indices, and random forests for anomaly ranking. Modern machine learning expands to support vector machines, gradient boosting, and deep architectures for sequence and spectral data (DeGuglielmo et al., 2020). Prognostic frameworks estimate RUL via particle filtering, Bayesian updating, and deep temporal models that ingest multichannel PLC telemetry (Rupprecht et al., 2021). In CT tube contexts, models can leverage bearing vibration envelopes, acoustic emission from brazed joints, vacuum leakage signatures in ion current, and filament current noise as precursors of drift in electron emission and anode surface distress. Hybrid digital-twin concepts couple first-principles thermal-mechanical simulators with data-driven residual models that correct unmodeled effects, aligning with cyber-physical production principles. The methodological diversity supports robust maintenance scheduling while accommodating process variability and stringent compliance expectations (Rais et al., 2022).

The maintenance decision layer connects diagnostics to economically and regulatorily sound actions (Sanver et al., 2018). Reliability-centered maintenance provides criteria to choose on-condition tasks, run-to-failure allowances for noncritical components, and redesign triggers when failure consequences are unacceptable. International standards for reliability data collection and failure taxonomy support comparable analytics across plants and suppliers, enabling portfolio-level learning on bearings, vacuum seals, and insulation materials. Safety integrity levels in functional safety standards guide risk reduction targets for interlocks and monitoring functions embedded in PLC logic, tying diagnostics to protective actions such as controlled shutdowns during arcing patterns or overspeed detection in rotor spin-up (Nezhmetdinov et al., 2018).

Figure 2: Predictive Maintenance CT Tube Manufacturing



Optimization models use cost, availability, and quality constraints to schedule interventions during thermal cycles that minimize scrap risk; predictive signals on filament thinning or bearing spalls can trigger component swaps before process-critical runs. Documented workflows in CMMS ensure traceability for auditors and for design-for-reliability feedback loops with engineering change control. Within CT tube manufacturing, such policy-and-data alignment reduces process escapes and supports consistent compliance reporting across jurisdictions (Eassa et al., 2019).

A practical pillar of integration is instrumentation and test design. Bearing diagnostics benefit from high-frequency accelerometers with appropriate mounting and sampling strategies for envelope analysis; acoustic emission sensors detect microcracking in brazed joints and insulation defects; infrared thermography tracks thermal uniformity during brazing and cooling phases; vacuum system diagnostics use pressure transducers and residual gas analysis proxies derived from ion pump currents. PLCs orchestrate excitation profiles—controlled spin-ups, dwell plateaus, and thermal ramps—that enhance observability, while deterministic timing guarantees coherence for spectral methods and order tracking (Barkalov et al., 2019). Data quality is strengthened through calibration, synchronization, and metadata capture in line with ISO guidance for condition monitoring data exchange and processing. Feature pipelines may include wavelet packet energies, spectral kurtosis, cepstral peaks, and non-Gaussianity measures to capture the subtle onset of rotor imbalance, lubrication breakdown, or insulation partial discharge precursors. The resulting health indicators—bearing health index, arc probability index, filament emission stability score—are computed at the edge or in near-edge servers and fed into prognostic estimators embedded within maintenance dashboards. Such test and measurement discipline underpins repeatable diagnostics across international sites with varying environmental baselines (Moallim et al., 2017).

The final enabling layer is governance for interoperability, cybersecurity, and human-in-the-loop operations. Standardized interfaces such as OPC UA information models, equipment metadata schemas, and historically consistent tag naming allow multi-vendor PLC fleets and test equipment to present uniform semantics to analytics platforms (Ahmed et al., 2017). Industrial cybersecurity frameworks outline network segmentation, authentication, and patching practices necessary for protecting PLCs and diagnostic servers in regulated manufacturing networks (Tasca et al., 2020). Human factors research in maintenance emphasizes actionable visualization, alarm management, and explanation of model recommendations to technicians and quality engineers, improving adoption and reducing response variance. International device regulations and quality standards require validated software, controlled changes, and documented evidence that diagnostic algorithms perform as intended within specified operating envelopes. With these controls, PLC–smart diagnostic integration functions as an auditable, deterministic layer that elevates process capability while maintaining safety and compliance in CT tube manufacturing environments across borders.

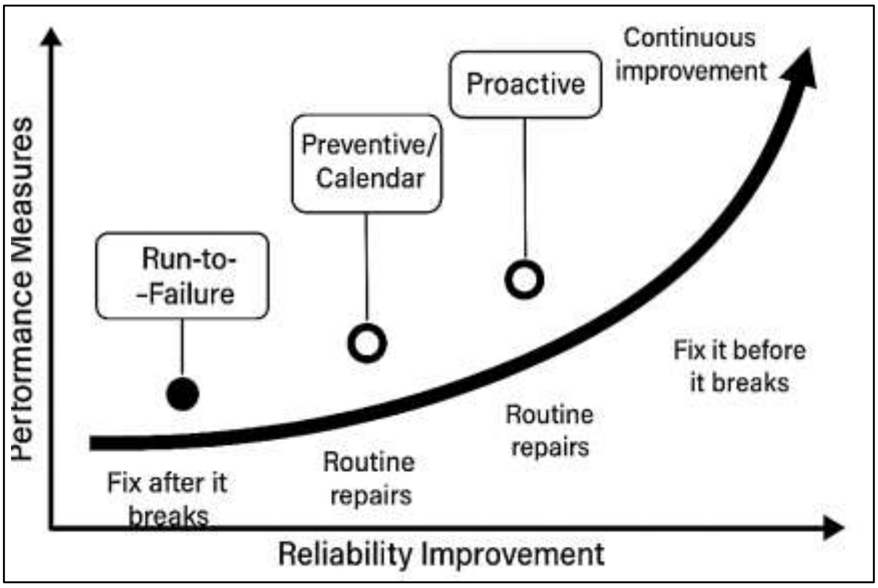
LITERATURE REVIEW

The literature review situates the integration of programmable logic controllers (PLCs) and smart diagnostics within the broader context of predictive maintenance, medical device manufacturing, and CT tube production. It synthesizes multiple disciplinary perspectives—ranging from industrial automation, reliability engineering, and medical imaging technology—to demonstrate how prior studies have contributed to understanding the technical, operational, and regulatory challenges of predictive maintenance. Existing scholarship highlights the evolution of PLCs from sequence control systems to cyber-physical data orchestrators (Mohammed & Saif, 2021), while condition monitoring and diagnostic frameworks have advanced from rule-based alarms to machine learning–driven prognostics. Within medical device production, the quality and reliability requirements for CT tubes amplify the relevance of integrating diagnostic intelligence directly into process control systems, ensuring reduced downtime and compliance with safety-critical standards (You et al., 2020). This literature review is structured to examine historical developments, technological enablers, methodological frameworks, and regulatory overlays that collectively inform the design of predictive maintenance strategies in CT tube manufacturing. The following outline specifies the thematic flow of the review in a structured, extended manner.

Maintenance Strategies in High-Value Manufacturing

The historical trajectory of maintenance in industrial systems reveals a shift from reactive, breakdown-oriented practices toward systematic preventive approaches designed to enhance reliability and reduce downtime. Early maintenance strategies in the mid-20th century were predominantly reactive, addressing failures only after equipment breakdowns occurred, a method associated with high production losses and safety risks (Khanduja et al., 2021). Reactive maintenance was unsustainable for high-value manufacturing, particularly as machinery complexity and production demands escalated. The concept of preventive maintenance (PM) emerged in the 1960s, emphasizing scheduled interventions based on time or usage intervals to minimize unexpected failures. Research demonstrates that PM significantly reduced unplanned downtime and improved asset availability, especially in sectors reliant on continuous operations, such as power generation and chemical processing (Billings & Powell, 2022; Ara et al., 2022). However, critics highlighted inefficiencies, as preventive schedules often resulted in unnecessary component replacements or overlooked random failures. Case studies in Japanese automotive plants emphasized total productive maintenance (TPM), integrating PM with operator involvement, thereby setting benchmarks for efficiency. Preventive methods became codified within international standards such as ISO 9000, framing maintenance as integral to quality systems (Bertola & Teunissen, 2018; Jahid, 2022). Thus, the historical evolution of maintenance demonstrates a progression from reactive firefighting to structured, proactive planning, laying the groundwork for later innovations in condition-based and predictive maintenance frameworks (Hollanders et al., 2016).

Figure 3: Maintenance Transformation Across Industrial Eras



The emergence of reliability-centered maintenance (RCM) in the 1970s marked a transformative stage in maintenance theory and practice, particularly in high-value industrial contexts. RCM was first systematized by (Silva et al., 2016) through studies conducted for the U.S. commercial aviation industry, where equipment failures carried critical safety and economic consequences. Unlike preventive maintenance, which relied primarily on fixed schedules, RCM emphasized functional analysis, failure modes and effects analysis (FMEA), and risk-based prioritization to ensure maintenance tasks were economically justified and operationally necessary. Scholars such as (Silva et al., 2016) documented the integration of RCM with probabilistic modeling, enabling more refined strategies for critical assets in sectors such as aerospace, nuclear power, and oil refining. With advances in sensing and computing, predictive maintenance (PdM) emerged as a logical extension of RCM, relying on condition-monitoring data streams—such as vibration, thermography, and oil analysis—to detect degradation before functional failure. Studies by (Walter, 2021) further demonstrate that predictive models, coupled with statistical methods such as Weibull analysis and proportional hazard models, significantly improved maintenance planning accuracy and cost-effectiveness. The rise of PdM also coincided with developments in machine learning and prognostics, allowing the estimation of remaining useful life (RUL) for critical assets (Han et al., 2016). Collectively, the literature suggests that the evolution from preventive to RCM and predictive frameworks represented a paradigmatic shift, embedding reliability and data-driven intelligence as core principles in industrial maintenance systems (Uddin et al., 2022; Sun et al., 2017).
The aerospace and automotive sectors have been at the forefront of maintenance innovation, offering critical lessons for high-value manufacturing systems. In aerospace, stringent safety regulations and high capital costs necessitated early adoption of RCM, with airlines and aircraft manufacturers integrating structured failure mode analysis and predictive methods into maintenance programs. Studies by (Emmanuel et al., 2016) show that aerospace systems pioneered the use of prognostics and health management (PHM) frameworks, leveraging vibration monitoring, thermal imaging, and fault detection algorithms to ensure mission reliability. The automotive sector, particularly through Japanese manufacturers, institutionalized total productive maintenance (TPM) and lean-integrated reliability practices that emphasized operator participation, root cause analysis, and statistical process control. Scholars such as (Garcés-Ayerbe et al., 2019) highlight how automotive plants demonstrated the productivity benefits of condition-based and predictive maintenance, especially in just-in-time (JIT) environments where downtime carried severe ripple effects. With the advent of Industry 4.0, automotive firms increasingly integrate PLC-

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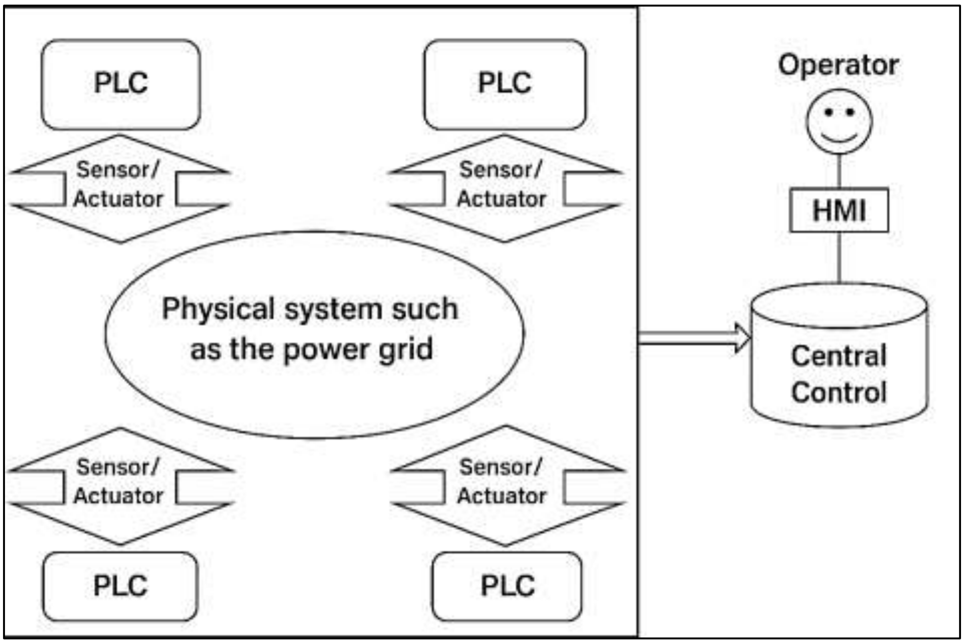
driven automation with predictive diagnostics for robotics, stamping presses, and engine assembly lines, enhancing both safety and efficiency (Akter & Ahad, 2022; Mourtzis et al., 2022). These sectors illustrate how regulatory pressures and lean operational paradigms jointly accelerate adoption of reliability-focused maintenance strategies. Their experiences underscore the necessity of embedding predictive models into both production systems and enterprise-level reliability governance (Wang et al., 2020).

In medical device manufacturing, particularly in imaging systems such as CT and MRI, the lessons from aerospace and automotive maintenance are adapted under stringent regulatory and patient safety requirements. Studies by (Wang et al., 2020) highlight how CT tube production involves critical subassemblies—rotating anodes, vacuum systems, and cathodes—that are highly sensitive to thermal and mechanical stress. Maintenance frameworks in this sector integrate condition-based diagnostics with rigorous traceability standards mandated by ISO 13485 and FDA regulations. Research by (Lu et al., 2017) emphasizes the role of predictive analytics in reducing failure rates and extending lifecycle performance of high-value imaging devices, drawing upon techniques such as acoustic emission monitoring and thermal modeling. Scholars such as (Li et al., 2017) further demonstrate how cyber-physical integration—through PLCs, IoT sensors, and cloud diagnostics—supports predictive maintenance under regulated environments. Comparisons across aerospace, automotive, and medical sectors show that while aerospace emphasizes safety-driven RCM, and automotive emphasizes lean efficiency and TPM, the medical device industry uniquely combines both imperatives under strict compliance regimes (Arifur & Sheratun Noor, 2022; Zhang & Ling, 2020). Literature therefore converges on the conclusion that high-value manufacturing environments benefit from tailored maintenance strategies that evolve from reactive to preventive, mature into RCM, and extend into predictive intelligence, each shaped by industry-specific constraints and regulatory landscapes (Rahaman, 2022; Robinson & Mazzucato, 2019).

Programmable Logic Controllers as Deterministic Orchestrators

The evolution of programmable logic controllers (PLCs) reflects a significant transition from electromechanical relay systems to standardized, software-driven industrial automation. Early industrial control systems were dominated by relay-based circuits that required complex wiring, extensive panel space, and considerable maintenance, leading to high costs and low adaptability (Kuriyama et al., 2016).

Figure 4: Evolution of Programmable Logic Controllers



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The introduction of the first PLC by Modicon in 1968 revolutionized industrial control by replacing hardwired relay logic with programmable electronic controllers, allowing for faster reconfiguration and reduced system complexity (Hasan et al., 2022). By the 1980s, advancements in microprocessors, memory, and modular input/output systems enhanced PLC flexibility, reliability, and scalability, supporting broader adoption across manufacturing and process industries. The publication of the IEC 61131-3 standard in the 1990s formalized programming paradigms for PLCs, establishing five standardized languages—ladder diagram (LD), function block diagram (FBD), instruction list (IL), structured text (ST), and sequential function chart (SFC)—which improved interoperability and engineer training. Researchers emphasize that IEC 61131-3 facilitated the global harmonization of PLC programming, enabling cross-platform portability and integration with supervisory control systems. More recent literature highlights that standardization also laid the foundation for distributed control, modular automation, and integration with fieldbus and industrial Ethernet protocols. Thus, the historical progression of PLC architectures represents a shift from inflexible, hardware-intensive designs to standardized, programmable, and network-ready systems that underpin deterministic industrial control in high-value manufacturing contexts (Hossen & Atiqur, 2022; Xu et al., 2018).

PLCs have progressively evolved from being simple sequence controllers into multifunctional nodes for data acquisition within cyber-physical production systems (CPS). Their deterministic execution cycles make them highly reliable for capturing, processing, and transmitting sensor data in real-time manufacturing operations. As CPS integrates physical assets with computational intelligence, PLCs serve as edge-layer devices that bridge sensors, actuators, and higher-level systems, ensuring accurate synchronization between operational processes and digital models. Studies show that PLCs now support extensive communication protocols such as Modbus, PROFINET, EtherCAT, and OPC UA, enabling standardized data exchange and interoperability across distributed networks. Vibration monitoring, thermal tracking, and energy metering can be performed directly within PLC-controlled environments, where deterministic sampling ensures signal integrity for condition monitoring tasks. Research by Hajda et al. (2021) illustrates how PLCs equipped with advanced input modules can act as frontline diagnostic sources in predictive maintenance frameworks, enabling near-real-time fault detection. PLCs are also embedded within supervisory control and data acquisition (SCADA) architectures, feeding critical sensor data into historians and analytic engines for production traceability (Tawfiqul et al., 2022; Qian et al., 2020). Moreover, safety and compliance demand in sectors such as aerospace, nuclear, and medical device manufacturing reinforce the role of PLCs as trusted data acquisition points, since their deterministic logic ensures validated measurement and logging capabilities. Collectively, the literature underscores that PLCs function not only as controllers but also as essential cyber-physical nodes that transform machine-level data into actionable diagnostic intelligence (Kamrul & Omar, 2022; Pinto et al., 2022).

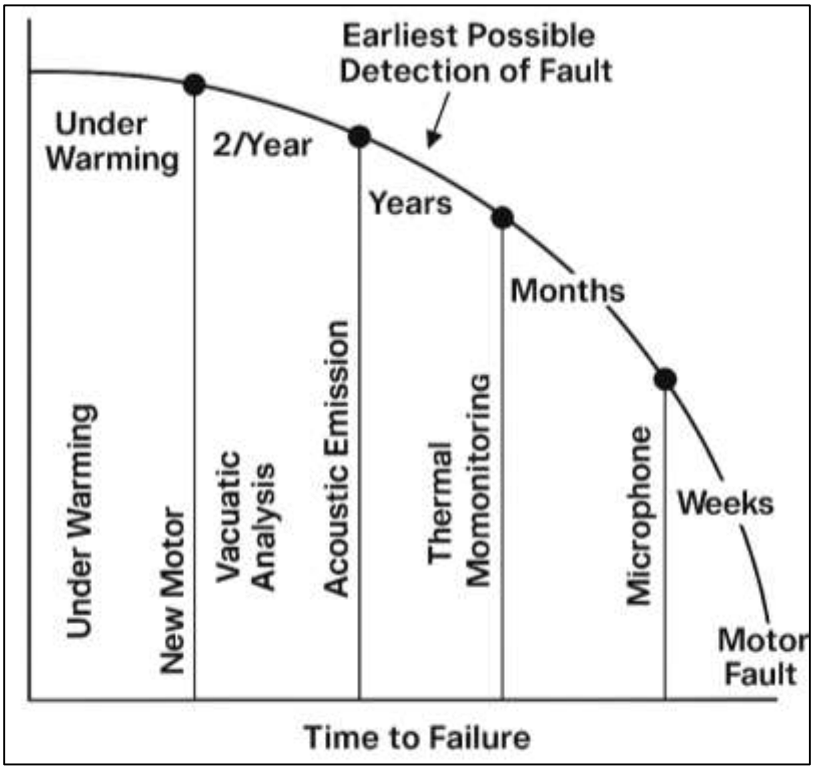
The integration of PLCs with edge computing platforms has expanded their diagnostic capabilities by enabling localized data processing and reducing latency in predictive maintenance applications. Edge integration allows computationally intensive tasks—such as vibration spectrum analysis, anomaly detection, and feature extraction—to be performed closer to the source of data, reducing bandwidth requirements and dependency on centralized systems (Mubashir & Abdul, 2022). Edge-enabled PLCs facilitate real-time health monitoring of rotating machinery, bearings, and thermal systems, which is particularly important in high-value sectors such as CT tube manufacturing. The literature highlights that industrial IoT gateways combined with PLCs support near-real-time analytics, compressing or filtering data before transmission to enterprise platforms (Reduanul & Shoeb, 2022). Studies by Bangemann et al. (2016) also emphasize the synergy between PLCs and edge platforms in implementing cyber-physical production systems under Industry 4.0 frameworks. Deterministic PLC cycles provide reliable sensor capture, while edge processors handle advanced diagnostic algorithms such as support vector machines, wavelet analysis, or deep learning classifiers. For medical device manufacturing, edge-enabled PLC architectures enhance compliance by ensuring data validation, timestamp integrity, and secure local storage before data flows to cloud layers. By integrating deterministic control with distributed edge analytics, PLCs extend their role from command execution to intelligent diagnostic hubs, aligning with the growing body of literature on smart manufacturing architectures (Izagirre et al., 2022; Sazzad & Islam, 2022). Cloud integration complements edge-enabled PLC architectures by providing scalable storage, centralized analytics, and cross-plant visibility, allowing for advanced diagnostic and predictive maintenance applications. Cloud-based industrial platforms enable aggregation of PLC data from multiple facilities, supporting benchmarking, fleet-level prognostics, and cross-border supply chain monitoring. Industrial cloud platforms, including Siemens MindSphere, GE Predix, and PTC ThingWorx, leverage PLC data to drive anomaly detection, quality prediction, and predictive maintenance workflows. Research by Tran et al. (2019) illustrates how cloud-PLC integration provides flexibility in scaling machine learning models for diagnostics, enabling the estimation of remaining useful life (RUL) across diverse assets. Standards such as OPC UA and MQTT facilitate secure, publish-subscribe data transfer between PLC nodes and cloud servers, ensuring semantic interoperability and minimizing latency. Case studies in automotive and semiconductor industries demonstrate that cloud-integrated PLCs enhance traceability, accelerate root cause analysis, and optimize maintenance scheduling (Huang et al., 2017; Noor & Momena, 2022). In medical device manufacturing, regulatory literature stresses the importance of validated cloud platforms that comply with Good Automated Manufacturing Practices (GAMP 5) and FDA's 21 CFR Part 11 for electronic records. Scholars such as MacBryde et al. (2013) argue that cloud-enabled PLC ecosystems advance cyber-physical intelligence by linking deterministic control at the machine level with enterprise-level diagnostic analytics. Thus, the literature consistently identifies PLC–cloud integration as a cornerstone of predictive maintenance architectures, embedding deterministic data sources into global diagnostic infrastructures.

Smart Diagnostics in Predictive Maintenance

Condition monitoring represents a foundational component of predictive maintenance by providing the means to detect and quantify degradation in real time through measurable signals. Among its methods, vibration analysis has historically been the most prominent, especially for rotating equipment, because spectral decomposition of vibration data reveals mechanical imbalances, bearing faults, and gear defects with high precision. Early studies such as (Tran et al., 2019) established frequency-domain analysis as a core diagnostic tool, while later research demonstrated the value of time-frequency methods to capture transient signals. Acoustic emission monitoring complements vibration analysis by capturing high-frequency stress waves generated from crack propagation, fatigue, and lubrication anomalies, which often appear earlier than detectable vibration shifts (Vogel et al., 2021). Thermal monitoring provides another diagnostic layer, particularly through infrared thermography, which identifies heat buildup due to friction, insulation failures, or abnormal resistance. Standards such as ASTM E1934 reinforce infrared imaging as a validated method for industrial diagnostics. Research by Khanzadeh et al. (2018) further highlights that thermal and acoustic methods often capture faults missed by vibration monitoring. A growing body of literature underscores the value of multimodal condition monitoring, as demonstrated in integrated frameworks that combine vibration, acoustic, and thermal signals for comprehensive diagnostics in aerospace, automotive, and medical manufacturing (Lyu et al., 2021). Thus, the principle of combining complementary sensing modalities represents a cornerstone of predictive maintenance practice.

Once raw signals are collected, their transformation into diagnostic information requires advanced signal processing and feature engineering. Time-domain features such as root mean square (RMS), kurtosis, skewness, and crest factor provide quick assessments of abnormal signal amplitudes and distributions, making them widely adopted for rotating equipment diagnostics (Khaled et al., 2020). Frequency-domain methods, primarily Fourier analysis, decompose signals to reveal harmonic patterns and sidebands associated with specific failure mechanisms such as bearing spalls or gear tooth cracks. Non-stationary signals in industrial systems prompted the adoption of wavelet transforms, Hilbert–Huang transforms, and short-time Fourier transforms, which enable the localization of transient features in both time and frequency. Feature engineering further reduces complexity by selecting discriminative metrics from high-dimensional data, employing methods such as principal component analysis (Rusin et al., 2016) and independent component analysis. Health indicators derived from these features—such as degradation indices and bearing health scores—offer standardized metrics for tracking fault evolution. Research by Balasingham et al., (2017) show that properly engineered features significantly improve the accuracy of classification and prognostic models. International guidelines, including Khaleghi et al. (2019), formalize data transformation requirements for predictive maintenance, ensuring interoperability and comparability across monitoring platforms. Literature consistently emphasizes that without robust preprocessing and feature design, condition monitoring data cannot be effectively leveraged for diagnostics, making signal processing and feature engineering the linchpins of predictive maintenance analytics.

Figure 5: Detection of Fault Across Condition Monitoring Techniques and Time to Failure



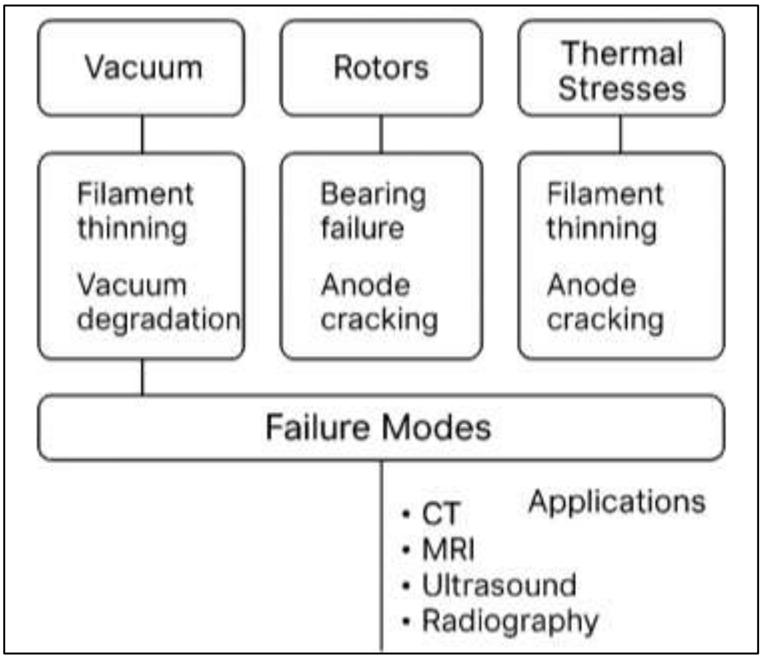
The earliest frameworks for intelligent fault diagnosis relied on statistical and model-based approaches that sought to formalize the probabilistic nature of equipment degradation. Statistical reliability models such as the Weibull distribution and proportional hazards frameworks provided mathematical means for estimating failure probabilities based on observed condition indicators. Studies by Fu et al. (2020) emphasized that survival models and regression-based techniques improved maintenance decision-making by quantifying risk over time. Kalman filters and state-space models enabled dynamic system health estimation, particularly in aerospace and process industries where real-time fault detection was essential. Physics-based models, on the other hand, encoded failure mechanisms such as crack growth, rotor dynamics, and thermal fatigue, providing interpretability and mechanistic insights. While such models proved invaluable for systems where physical behavior was well understood, they often struggled with nonlinearities and uncertainties present in complex industrial equipment (Sadoughi & Hu, 2019). Nonetheless, the combination of statistical reliability analysis and physics-informed diagnostics laid the groundwork for prognostics and health management (PHM), establishing explainable frameworks that remain central to regulated industries such as nuclear power, aviation, and medical device manufacturing. This literature underscores that statistical and physics-based methods formed the intellectual foundation

upon which modern AI-driven prognostics were later built.
The rise of machine learning and artificial intelligence (AI) has dramatically expanded the scope and accuracy of intelligent fault diagnosis. Classical AI methods, such as decision trees, k-nearest neighbors, and random forests, provided early classification frameworks for fault states based on engineered features. Support vector machines (SVMs) introduced robust nonlinear classification, showing strong performance in vibration and acoustic-based diagnostics. More recently, deep learning architectures have transformed fault diagnosis by enabling end-to-end learning from raw sensor data. Convolutional neural networks (CNNs) extract hierarchical features from vibration and thermal images, while recurrent neural networks (RNNs) and long short-term memory (LSTM) models capture temporal degradation patterns for remaining useful life (RUL) estimation. Hybrid approaches that integrate physics-informed models with data-driven neural networks improve both interpretability and predictive power (Lu et al., 2018). Case studies in aerospace and manufacturing show that AI-driven prognostics outperform traditional methods in early fault detection and lifecycle prediction. Standards and regulatory frameworks such as Shen et al. (2021) stress the need for validated diagnostic indicators, a requirement increasingly met by AI models when paired with explainability methods. Collectively, the literature demonstrates that AI-enhanced prognostics mark a decisive step forward in smart diagnostics, enabling scalable, adaptive, and highly accurate predictive maintenance strategies across high-value industries (Wilhelm et al., 2021).

Predictive Maintenance Frameworks in Medical Device Manufacturing

The manufacturing of computed tomography (CT) x-ray tubes embodies a highly complex engineering process due to the interplay of vacuum integrity, high-speed rotors, and extreme thermal stresses that affect reliability and performance.

Figure 6: Applications of CT Tube Maintenance



Literature consistently identifies vacuum systems as critical because the electron path between cathode and anode must be maintained under high vacuum conditions to prevent arcing, gas ionization, and premature tube failure. Researchers such as Wang et al. (2022) emphasize that vacuum degradation through micro-leaks or material outgassing is among the leading contributors to tube unreliability. Rotor assemblies further compound complexity, as rotating anodes typically operate at 3,000–10,000 rpm, generating significant centrifugal and gyroscopic loads. Thermal stress presents an additional dimension, as anode targets must dissipate heat loads exceeding several hundred kilojoules per scan sequence. Failures in heat transfer through target discs or improper cooling can result in cracking, warping, or focal spot drift. Experimental works such as those by Trevizan et al. (2019) demonstrate how repetitive high-power exposures contribute to cumulative microstructural damage in tungsten targets. The interdependence of vacuum stability, rotor dynamics, and thermal management underlines the inherent complexity of CT tube manufacturing and highlights the need for condition-based monitoring strategies that can account for multi-domain degradation processes (Raman & Mathur, 2021).

Failure mode identification is fundamental in predictive maintenance for CT tube manufacturing, as literature documents multiple degradation pathways with distinct diagnostic signatures. Cathode filament thinning and evaporation represent a primary failure mode, leading to reduced electron emission and unstable focal spots. Filament degradation manifests as increased exposure times and fluctuating beam intensities. Rotor-bearing failure, often induced by mechanical fatigue, lubricant breakdown, or cage fracture, results in elevated vibration amplitudes and acoustic anomalies, which can be captured through spectral analysis. Vacuum degradation is another major concern; leakage or outgassing leads to ion current instability and arcing events, indicators that can be monitored through vacuum pressure trends and electrical discharge logs (Matetić et al., 2022). Anode cracking or target surface pitting, frequently caused by repeated overheating and cooling cycles, appears as abnormal thermal gradients detectable with infrared thermography and energy loss measurements. Health indicators derived from these failure modes include bearing health indices, arc probability metrics, filament emission stability scores, and anode temperature rise coefficients. Acoustic emission monitoring has also been validated as a precursor signal for crack initiation in tube components, supporting early fault detection. Collectively, the literature demonstrates that CT tube failure mechanisms are multifactorial, but measurable health indicators provide reliable proxies for degradation, forming the empirical basis for predictive diagnostics.

Predictive maintenance has been applied across diverse medical imaging modalities, with CT tube manufacturing offering parallels and distinctions relative to MRI, ultrasound, and radiography systems. In MRI, predictive monitoring emphasizes cryogenic cooling systems, superconducting magnet integrity, and gradient coil wear, where vibration and acoustic monitoring are used to detect resonance anomalies (Champaney et al., 2022). In ultrasound imaging, predictive frameworks focus on piezoelectric transducer degradation and electronic driver reliability, where electrical impedance monitoring provides early indicators of functional decline. Radiography systems share several failure modes with CT tubes, particularly x-ray tube overheating and filament degradation, though operating cycles and duty loads are less demanding. CT systems are more susceptible to thermal-mechanical stress due to their high throughput, making predictive maintenance more complex and critical. Literature also emphasizes that CT manufacturing requires tighter integration of PLC-controlled processes with diagnostics, while MRI and ultrasound rely more heavily on component-level monitoring. Regulatory oversight, including FDA and ISO 13485, further shapes predictive maintenance practices differently across imaging modalities, with CT tubes facing rigorous quality traceability due to radiation safety implications. Research by Tarricone et al. (2022) reinforces that predictive analytics in CT and MRI share algorithmic foundations—such as vibration and thermal diagnostics—but diverge in focus areas due to equipment-specific physics. These comparisons demonstrate that predictive maintenance frameworks are modality-dependent, yet share overarching principles of condition monitoring, health indicator derivation, and regulatory alignment.

The body of literature on predictive maintenance in medical device manufacturing reveals consistent themes of complexity, multidimensional failure modes, and industry-specific adaptations of diagnostic frameworks. Scholars broadly agree that CT tube production presents unique challenges, as vacuum integrity, rotor-bearing reliability, and thermal load management create overlapping degradation pathways requiring multimodal monitoring strategies. Literature on failure modes highlights the diagnostic richness of measurable health indicators such as vibration spectra, arc counts, acoustic emissions, and thermal gradients, which collectively support condition-based maintenance. Comparative analyses across imaging modalities confirm that while predictive maintenance frameworks share methodological tools—signal processing, feature engineering, and prognostic modeling—application contexts diverge due to equipment-specific physics and regulatory constraints. Cross-sector studies from aerospace and automotive further reinforce the value of reliability-centered and prognostic health management approaches, which have been adapted to the medical device domain to ensure safety and quality. Regulatory literature underscores that medical imaging equipment requires validated diagnostics, full traceability, and compliance with ISO and FDA guidelines, elevating predictive maintenance from a cost-saving measure to a compliance-critical framework. Collectively, the reviewed studies demonstrate that predictive maintenance in CT tube manufacturing is both technically and regulatorily anchored, drawing from decades of condition monitoring research and cross-industry maintenance innovation.

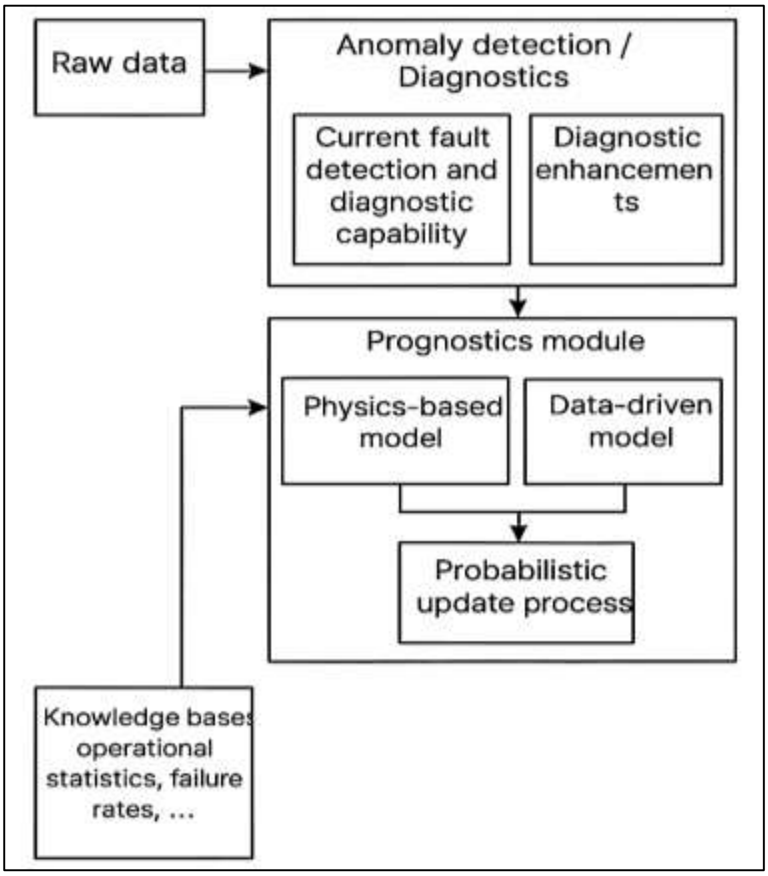
Hybrid Modeling Approaches for Prognostics

Physics-based modeling approaches for prognostics in high-value manufacturing, particularly in CT tube production, emphasize the use of fundamental mechanical and thermodynamic principles to describe degradation processes such as rotor imbalance, bearing wear, and thermal fatigue. Rotor dynamic models capture shaft deflections, critical speeds, and unbalance responses under high rotational loads, making them invaluable for predicting bearing and rotor-related failures. Thermal fatigue models extend this principle by characterizing cyclic heat stresses in anode targets and tube housings, where crack initiation and propagation follow thermo-mechanical fatigue laws. formulated strain–life approaches to predict fatigue failure, which have been adapted for tungsten anode degradation under repetitive CT exposures. Fracture mechanics–based models further quantify crack growth under cyclic stress intensity, enabling prediction of time-to-failure in thermally stressed components. Recent studies highlight that physics-based finite element simulations provide detailed insights into temperature gradients, stress distributions, and structural reliability under dynamic scan cycles. These approaches, while computationally intensive, yield interpretable results that align with physical degradation mechanisms and regulatory safety requirements. The literature underscores that rotor dynamics and thermal fatigue models remain critical for understanding CT tube degradation, providing a deterministic foundation for prognostics where empirical models alone may lack explanatory power.

Data-driven approaches to prognostics leverage statistical learning and artificial intelligence to infer system health and predict remaining useful life (RUL) directly from condition monitoring data. Early frameworks utilized statistical regression, proportional hazards models, and survival analysis to model degradation trends (Khumprom & Yodo, 2019). Machine learning algorithms such as support vector machines (SVMs), decision trees, and random forests have since demonstrated strong performance in classifying fault states across vibration, acoustic, and thermal datasets. Neural network models expanded this capability, with multilayer perceptrons and convolutional neural networks (CNNs) effectively learning complex fault signatures from vibration spectra and thermographic images (Sayyad et al., 2021). Recurrent neural networks (RNNs) and long short-term memory (LSTM) networks address temporal dependencies in degradation data, supporting accurate RUL estimation for bearings, rotors, and thermal systems. Hybrid ensembles that combine multiple classifiers further enhance predictive accuracy and generalizability across heterogeneous equipment. Literature also documents (Deutsch & He, 2017) and particle filtering methods for uncertainty-aware RUL predictions. Data-driven models outperform purely preventive schedules by enabling condition-based decision-making. In CT tube manufacturing contexts, AI-enhanced methods analyze vibration, arc counts, emission stability, and temperature gradients to predict tube lifespan more reliably than fixed interval servicing. Thus, the literature shows that machine learning and deep learning frameworks have become indispensable tools in predictive maintenance, enabling scalable, adaptive prognostic solutions across medical manufacturing and other safety-critical industries (Xia et al., 2020).

Digital twin (DT) technology has emerged as a powerful paradigm for predictive maintenance by creating virtual replicas of physical assets that integrate real-time data, simulations, and prognostic models. Mushtaq et al. (2021) define digital twins as cyber-physical mirrors capable of continuously reflecting system behavior under varying conditions. In regulated manufacturing, such as medical device production, DT frameworks provide interpretability and compliance by integrating validated physics-based models with empirical monitoring data.

Figure 7: Hybrid Prognostic Modelling



Studies by Zhang et al. (2019) show that DTs support prognostics by simulating rotor dynamics, thermal fatigue, and vacuum degradation under real operating loads, enabling precise health state estimation. Liao and Köttig (2016) demonstrates the value of DTs in extending traditional prognostics to fleet-wide health monitoring, a framework increasingly applied to CT tubes where production uniformity and traceability are essential. Cloud and edge integration enhance DT functionality by enabling real-time synchronization of PLC data streams with multi-physics simulations. Regulatory literature underscores that DT implementations in medical manufacturing must comply with ISO 13485, ISO 14971, and FDA guidelines, requiring validated models and traceable data pipelines. Empirical case studies demonstrate that DT-based predictive maintenance improves early fault detection in anodes, rotors, and bearings by combining physical simulations with diagnostic AI models (Cheng et al., 2020). Collectively, the literature highlights that digital twins offer a structured means of unifying physics-based, data-driven, and regulatory requirements into a coherent prognostic architecture, strengthening predictive maintenance across safety-critical domains (Alsina et al., 2018).
The literature on hybrid prognostic modeling consistently emphasizes the complementarity of physics-based, data-driven, and digital twin approaches in predictive maintenance. Physics-based rotor dynamic and thermal fatigue models offer interpretability and mechanistic insights but often require simplifications and extensive domain expertise (Samanta et al., 2021). Data-driven methods, by contrast, excel in adaptability and scalability, with machine learning and deep learning algorithms capable of capturing nonlinear degradation patterns across diverse datasets. However, literature acknowledges that purely data-driven systems may lack transparency and generalizability across operating contexts, particularly in regulated industries. Digital twins emerge

as an integrative paradigm, combining validated physical models with empirical learning, supported by real-time PLC and IoT data streams, thereby balancing interpretability with predictive accuracy (Al-Dulaimi et al., 2019). Comparative studies by Liu et al. (2020) reinforce that hybrid frameworks consistently outperform isolated methods in prognostic reliability and compliance alignment. In medical device manufacturing, where CT tube complexity involves vacuum integrity, rotor-bearing reliability, and thermal management, the literature demonstrates that hybrid prognostic models ensure compliance with ISO and FDA standards while maximizing operational availability. Synthesizing across studies, it is clear that hybrid approaches embody a multidimensional framework where physical interpretability, statistical robustness, and digital integration converge, offering validated pathways for predictive maintenance in high-value and regulated manufacturing environments (Ren et al., 2017).

International Standards and Regulatory Dimensions

The integration of predictive maintenance frameworks into medical device manufacturing is strongly shaped by international regulatory standards, particularly those developed by the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and the U.S. Food and Drug Administration (FDA). ISO 13485 provides the quality management system (QMS) requirements specific to medical devices, mandating documented procedures for maintenance, calibration, and verification of production equipment to ensure device safety and effectiveness (Liu et al., 2020). ISO 14971 establishes the application of risk management to medical devices, emphasizing systematic identification, evaluation, and control of hazards throughout the product lifecycle, including manufacturing systems. IEC 60601-2-44 specifies safety and performance requirements for CT equipment, addressing aspects of tube operation, radiation protection, and device reliability. Additional standards such as ISO 9001 reinforce broader quality management frameworks, ensuring maintenance activities align with global manufacturing principles. From a regulatory perspective, the FDA's 21 CFR Part 11 sets requirements for electronic records and signatures, ensuring data integrity in diagnostic integration. The FDA's Quality System Regulation (QSR) further demands documented equipment maintenance, validation of software tools, and traceable diagnostic workflows. Adherence to these standards is not merely procedural but central to predictive maintenance credibility in highly regulated sectors. Research by Pech et al. (2021) emphasizes that cyber-physical predictive maintenance architectures in medical manufacturing must be designed to demonstrate compliance with ISO, IEC, and FDA frameworks at every level, from sensor data acquisition to maintenance scheduling. The literature establishes that predictive maintenance in CT tube manufacturing is fundamentally constrained and structured by international quality and safety standards (Keleko et al., 2022).

Traceability, validation, and risk management represent central requirements in integrating smart diagnostics into predictive maintenance frameworks for medical devices. Traceability ensures that every diagnostic input, maintenance action, and system modification can be fully documented and linked to regulatory records, a principle reinforced by ISO 13485 and FDA QSR requirements. Research by De Maria et al. (2018) emphasize that predictive maintenance systems must provide complete audit trails, enabling investigators to reconstruct events leading to equipment failures. Validation processes, particularly software validation, are essential for predictive algorithms used in maintenance decision-making. Standards such as ISO 9001 and FDA 21 CFR Part 11 require verification that diagnostic algorithms function as intended under defined operating conditions, ensuring reproducibility and accuracy. Risk management frameworks, primarily governed by ISO 14971, mandate structured hazard analysis, failure mode identification, and mitigation strategies to ensure patient and operator safety.

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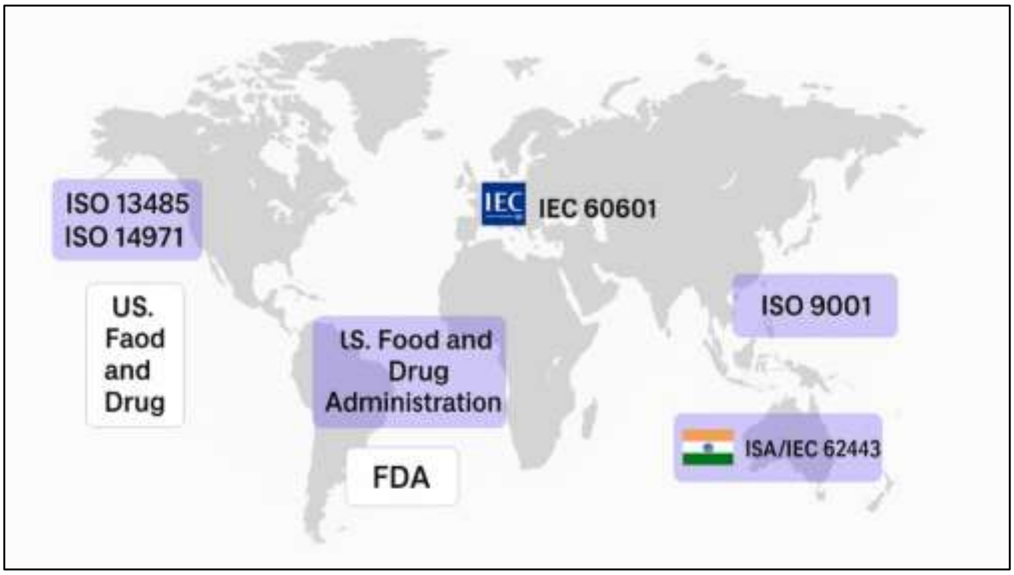
Figure 8: Regulatory Compliance in Predictive Maintenance



Studies by highlight that maintenance-related risks must be quantified through reliability analysis and incorporated into predictive frameworks. Sharma et al. (2021) demonstrate that effective integration of diagnostics into CT tube manufacturing requires health indicators to be linked to validated models, ensuring diagnostic outputs directly inform risk-mitigated maintenance decisions. Furthermore, traceability and validation are especially critical in medical imaging due to radiation safety concerns and the potential for patient harm if diagnostic systems fail. Collectively, literature establishes that predictive maintenance frameworks are inseparable from traceability, validation, and risk management, which together form the regulatory backbone of diagnostic integration in medical device contexts.

As predictive maintenance frameworks in medical manufacturing increasingly rely on programmable logic controllers (PLCs) and interconnected diagnostic systems, cybersecurity and functional safety emerge as critical regulatory dimensions. Literature on industrial automation highlights that PLCs, while deterministic and reliable, are vulnerable to cyber threats if inadequately secured, with ISA/IEC 62443 providing a widely adopted standard for industrial control system cybersecurity. Predictive maintenance data pipelines, particularly when integrated with cloud and edge platforms, introduce additional cyberattack surfaces. Functional safety standards, such as IEC 61508, define requirements for safety integrity levels (SILs) in electrical and programmable systems, mandating redundancy and fail-safe mechanisms to prevent catastrophic failures. The importance of integrating functional safety into predictive maintenance, ensuring that diagnostic algorithms and PLC actions do not compromise operator or patient safety. In medical device contexts, IEC 60601 further specifies safety requirements for electrical equipment, requiring that any predictive maintenance function tied to PLCs must not interfere with device safety operations. Predictive maintenance architectures must integrate encrypted communication, access control, and deterministic timing validation to comply with both cybersecurity and safety regulations. Furthermore, FDA guidance emphasizes that cybersecurity risks must be proactively managed in medical device manufacturing environments to safeguard diagnostic integrity. Collectively, literature converges on the principle that cybersecurity and functional safety are not ancillary but core to predictive maintenance in PLC-based systems, ensuring compliance, reliability, and patient protection.

The reviewed literature on international standards and regulatory dimensions consistently highlights three interdependent pillars: quality system guidelines, traceability and risk management, and cybersecurity-linked functional safety. ISO 13485, ISO 14971, and IEC 60601 establish the structural and safety requirements for medical device manufacturing, anchoring predictive maintenance practices within a regulatory framework that ensures patient protection and device reliability (Al Farooq et al., 2019). FDA regulations, particularly 21 CFR Part 11 and QSR requirements, complement these international standards by demanding validated diagnostic algorithms and fully auditable maintenance records. Research demonstrates that traceability and validation processes are indispensable, as diagnostic systems must consistently produce reliable outputs that regulators and auditors can verify. Risk management literature further reinforces that predictive maintenance systems must explicitly link diagnostic indicators to safety-critical hazard controls. Cybersecurity and functional safety standards, such as ISA/IEC 62443 and IEC 61508, extend this framework by addressing the vulnerabilities and fail-safe requirements introduced by PLC-based architectures. Case studies across CT tube manufacturing and other high-value industries show that predictive maintenance systems cannot be credibly deployed without adherence to these regulatory imperatives. Synthesizing across these studies, it is evident that international standards and regulations shape not only how predictive maintenance is designed but also how it is validated, implemented, and audited. The literature firmly establishes that regulatory compliance is inseparable from predictive maintenance frameworks in medical device manufacturing, ensuring both operational excellence and patient safety (Geng et al., 2022).

Economic and Operational Implications of Integration

The economic implications of predictive maintenance in CT tube manufacturing are most visible in the reduction of the cost of poor quality (COPQ), which encompasses scrap, rework, warranty claims, and field failures. COPQ has long been identified as a significant drain on profitability and efficiency in high-value manufacturing. In medical imaging, CT tube failures contribute disproportionately to COPQ because each tube represents a high-cost subassembly whose failure interrupts both production and clinical service delivery (Link et al., 2018). Studies by Cole et al., (2019) show that premature tube failures not only increase warranty replacement costs but also lead to significant financial burdens for hospitals due to downtime and rescheduled scans. Manufacturing literature highlights that rework and scrap rates in precision components—such as vacuum envelopes, rotors, and anodes—are costly due to the stringent regulatory validation required for medical devices. According to Holmström et al. (2019), predictive maintenance reduces COPQ by detecting deviations early, preventing defective units from advancing through production and reducing warranty liabilities. Condition-based monitoring of vacuum stability, bearing vibration, and thermal stress significantly lowers the probability of post-production tube failure. Furthermore, total cost analyses in similar high-reliability sectors such as aerospace demonstrate that predictive maintenance strategies can reduce lifecycle maintenance expenditures by up to 40%. Collectively, literature establishes that COPQ in CT tube manufacturing is materially reduced through predictive maintenance integration, with substantial financial benefits accruing to both manufacturers and end users (Raut et al., 2019).

Productivity and yield improvements represent central operational benefits of predictive maintenance adoption in CT tube manufacturing. Predictive strategies enable real-time monitoring of vacuum systems, rotors, and cathodes, allowing manufacturers to optimize production scheduling and reduce downtime associated with unplanned stoppages. Literature from manufacturing science emphasizes that predictive maintenance improves yield by reducing defect rates and ensuring consistent process quality. Studies by Adams et al. (2016) illustrate that predictive frameworks lead to higher equipment availability, which translates directly into increased throughput and overall equipment effectiveness (OEE). In medical device contexts, productivity gains are amplified because each CT tube undergoes rigorous validation and testing, where interruptions can disrupt entire production batches.

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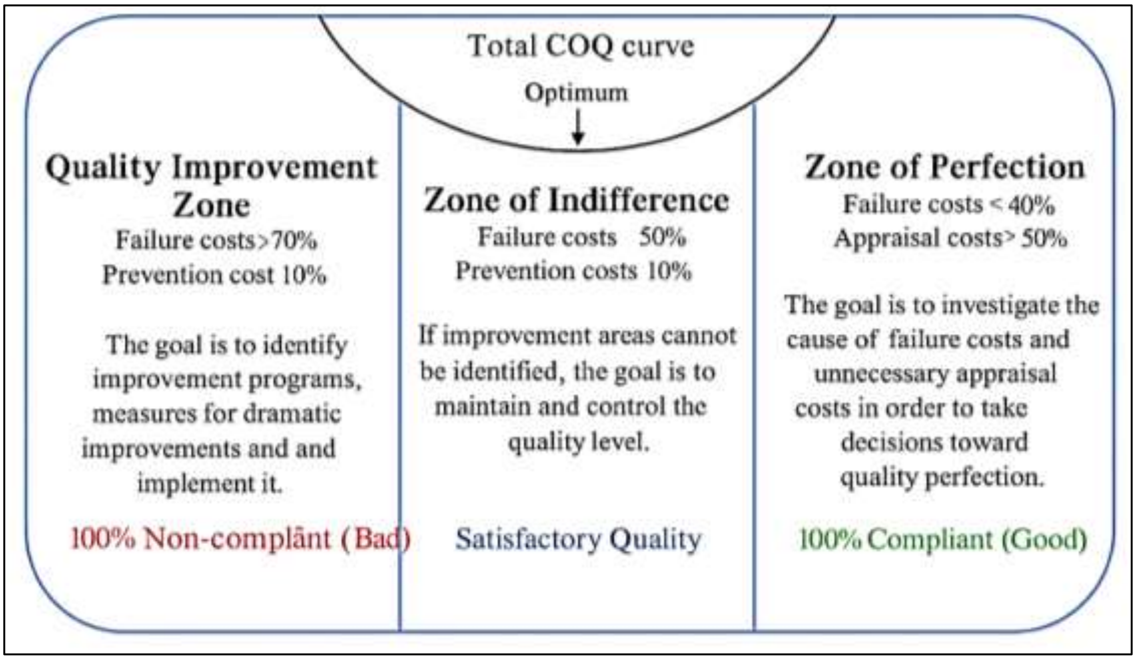
Figure 9: Economic Impact of Predictive Maintenance



Research by Jabbour et al. (2018) shows that predictive maintenance allows synchronized calibration, testing, and repair activities, thereby enhancing line utilization and reducing bottlenecks. Studies in semiconductor and aerospace manufacturing further corroborate these findings, demonstrating that predictive analytics increase yield by detecting micro-defects before they propagate. In healthcare operations, Mendoza et al. (2017) document how reduced failure rates in CT tubes contribute to improved clinical uptime, supporting patient scheduling and reducing lost revenue from downtime. Operational research models confirm that predictive maintenance leads to more stable production cycles, minimizing variability and increasing overall efficiency. Thus, the literature demonstrates that predictive maintenance adoption in CT tube production not only enhances manufacturing yield but also secures downstream operational continuity for healthcare providers (Igogo et al., 2021).

CT tube manufacturing operates within a globalized supply chain, and predictive maintenance integration has significant implications for cross-border logistics, quality assurance, and market competitiveness. Global medical device supply chains involve geographically distributed production of subcomponents—such as tungsten targets, ceramic insulators, and high-precision bearings—each of which must meet stringent regulatory standards (Bag et al., 2020). Literature on global operations highlights that predictive maintenance facilitates standardized quality across dispersed manufacturing sites by providing harmonized diagnostic frameworks and comparable performance indicators. Research by Abdul-Rashid et al. (2017) demonstrates that predictive frameworks support real-time monitoring of cross-border production lines, ensuring supply chain resilience. In industries such as aerospace and automotive, global predictive maintenance systems have been shown to mitigate risks associated with heterogeneous supplier quality, providing lessons directly applicable to CT tube manufacturing. Studies by Ritzén and Sandström (2017) illustrate that global market reliability is essential for CT imaging, as equipment downtime directly affects patient care in international health systems. Predictive maintenance also plays a role in managing warranty and regulatory compliance across borders, as FDA and ISO standards require globally consistent documentation of maintenance actions. Furthermore, economic research by Poncelet et al. (2016) shows that predictive maintenance enhances global competitiveness by reducing total cost of ownership and improving delivery performance. The literature therefore identifies predictive maintenance not only as a technical tool but also as a strategic enabler of international competitiveness and supply chain stability in the global CT market (Jabbour et al.,

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2019).

The literature on economic and operational implications of predictive maintenance integration in CT tube manufacturing converges on three consistent themes: cost reduction through lower COPQ, operational gains in productivity and yield, and global supply chain stabilization. COPQ literature demonstrates that predictive maintenance reduces scrap, rework, and warranty claims by detecting degradation early in the production process, consistent with findings across aerospace and other high-value industries. Studies on productivity and uptime highlight that predictive maintenance enhances line utilization and output stability, ensuring greater throughput in highly regulated medical device contexts. Yield improvements are linked not only to direct equipment availability but also to better calibration and defect detection. Cross-border supply chain research reveals that predictive maintenance supports harmonized standards, consistent diagnostics, and compliance documentation across geographically distributed plants, strengthening competitiveness in international medical markets. Furthermore, regulatory frameworks such as ISO 13485 and FDA QSR integrate directly into the economic logic of predictive maintenance, as compliance failures can translate into both financial and reputational losses. Synthesizing across these streams, the literature affirms that predictive maintenance frameworks in CT tube manufacturing are simultaneously economic, operational, and regulatory instruments (Dubey et al., 2019). They reduce costs, improve performance, and enable global market access by ensuring consistent quality and compliance across international supply chains.

Synthesis of Research Gaps and Conceptual Anchors

Despite significant advances in predictive maintenance, current models for CT tube manufacturing exhibit notable limitations in accuracy, interpretability, and applicability under regulatory constraints. One major challenge is the modeling of complex, multi-physics degradation processes such as thermal fatigue, vacuum leakage, and rotor-bearing wear, which often progress simultaneously but at different rates. Most predictive frameworks rely heavily on single-sensor data, such as vibration or temperature, which fails to capture the interdependencies across mechanical, electrical, and thermal domains. Physics-based models, while interpretable, are often oversimplified and struggle to account for stochastic operating conditions in real production environments. Data-driven models, particularly machine learning and deep learning, have shown high diagnostic accuracy but are frequently criticized for their "black-box" nature, limiting acceptance in regulated medical device manufacturing where explainability and validation are critical. Uncertainty quantification in remaining useful life (RUL) predictions remains inadequate, undermining decision-making for high-stakes assets like CT tubes. Additionally, existing models often rely on historical failure data, which may be scarce due to the high cost and low frequency of catastrophic failures in medical imaging systems. Collectively, literature underscores that predictive maintenance models for CT tubes remain constrained by Butt (2020) data limitations, model interpretability challenges, and difficulties in integrating multi-domain degradation processes into reliable prognostics.

A significant body of literature highlights that unresolved challenges in interoperability and data governance limit the scalability and credibility of predictive maintenance in CT tube manufacturing. Interoperability issues arise from the heterogeneity of PLC vendors, diagnostic systems, and communication protocols, which hinder standardized data integration across manufacturing plants. While frameworks such as OPC UA and MTConnect provide semantic structures, adoption remains inconsistent, leading to fragmented diagnostic architectures. Data governance is another critical challenge, especially in regulated medical device contexts where traceability, validation, and auditability of diagnostic outputs are mandatory. Predictive maintenance systems must establish clear protocols for data ownership, consent, and integrity, particularly when cloud and edge platforms are integrated. Literature on industrial cybersecurity further reveals that diagnostic data pipelines are vulnerable to cyberattacks, requiring adherence to standards such as ISA/IEC 62443 to ensure confidentiality and integrity.

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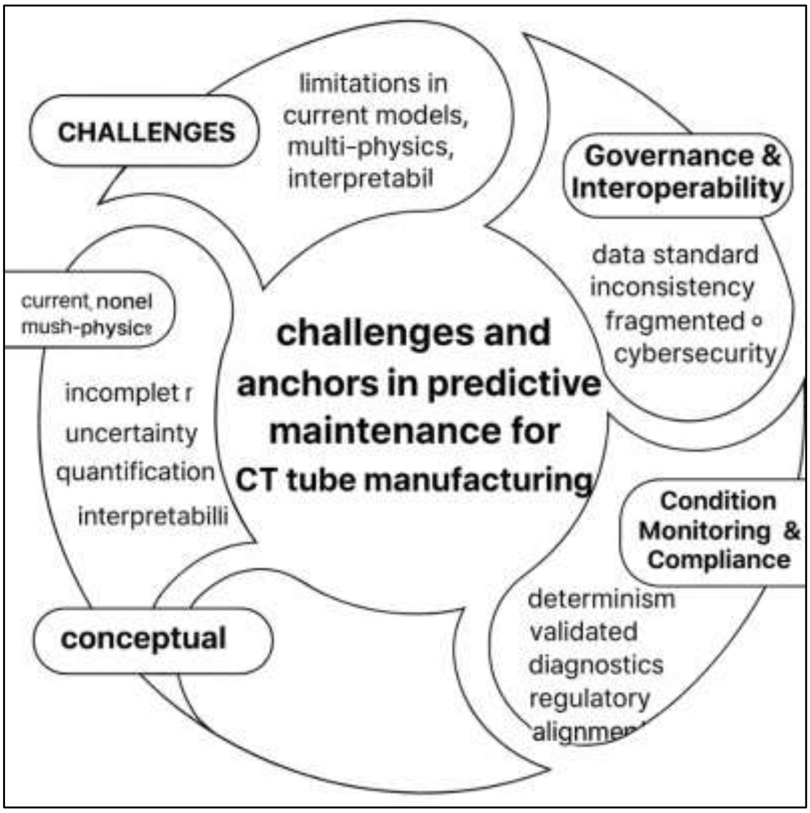
Figure 10: Anchors for CT Tube Maintenance



Moreover, Inconsistent data management practices across global manufacturing sites hinder comparability of health indicators and prognostic outcomes. Scholars such as Villa et al. (2021) argue that without robust data governance frameworks, predictive maintenance remains vulnerable to bias, inconsistency, and regulatory noncompliance. Collectively, the literature identifies interoperability and governance as unresolved barriers, limiting the seamless integration of smart diagnostics into PLC-controlled predictive maintenance for CT tube manufacturing.

The integration of programmable logic controllers (PLCs) with smart diagnostics in predictive maintenance is anchored in three conceptual frameworks: determinism in control systems, condition monitoring science, and regulatory alignment. Determinism, ensured by PLC execution cycles, provides the temporal precision necessary for vibration and acoustic signal analysis, a requirement emphasized in studies by Schulze et al. (2019). Literature underscores that PLCs function as both controllers and data acquisition nodes, bridging the physical and cyber domains of medical device manufacturing. Condition monitoring science provides a second anchor, with vibration, acoustic, and thermal diagnostics consistently validated as effective precursors for CT tube degradation. Signal processing and feature engineering methods transform PLC-collected data into health indicators, a process supported by ISO 13374 and ISO 17359 standards. The third anchor is regulatory alignment, which ensures that predictive maintenance frameworks remain compliant with ISO 13485, ISO 14971, and FDA 21 CFR Part 11 requirements for traceability, risk management, and electronic data integrity. Successful implementations consistently adhere to these principles, ensuring both operational reliability and compliance. Cross-sector comparisons from aerospace and automotive literature reinforce these anchors, showing that deterministic control, validated diagnostics, and risk-centered frameworks provide universal scaffolding for predictive maintenance. Thus, literature converges on the view that PLC–diagnostic integration is anchored by control determinism, monitoring science, and compliance imperatives.

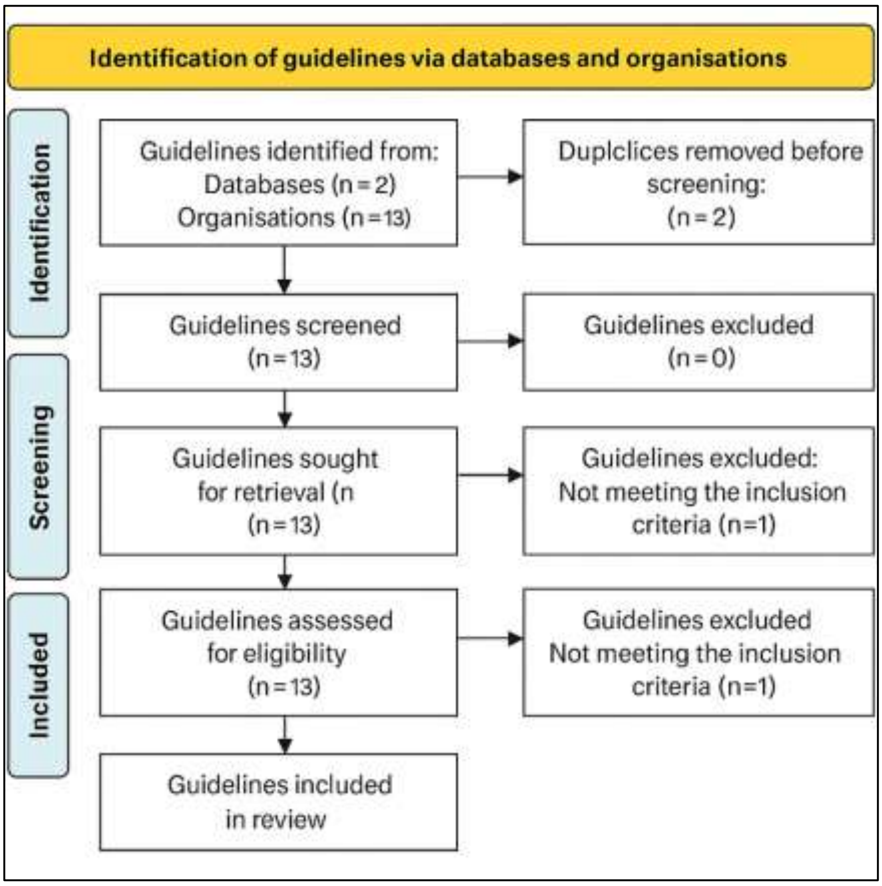
METHOD

This study adopted a systematic review design guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) framework to ensure methodological transparency, reproducibility, and rigor. PRISMA is widely recognized as the gold standard for structuring systematic reviews, providing a 27-item checklist and flow diagram to guide the selection, screening, eligibility assessment, and inclusion of studies (Page et al., 2021). In this review, the protocol was designed to capture relevant evidence on the integration of programmable logic controllers (PLCs) and smart diagnostics within predictive maintenance frameworks applied to CT tube manufacturing systems. The process began with a comprehensive literature search conducted across multiple databases, including Scopus, IEEE Xplore, PubMed, Web of Science, and ScienceDirect, complemented by manual searches of relevant conference proceedings, regulatory documents, and industry reports. Search terms were derived from a combination of keywords and Boolean operators, such as "predictive maintenance," "CT tube manufacturing," "programmable logic controller," "smart diagnostics," "condition monitoring," and "medical device reliability," ensuring both sensitivity and specificity in retrieval. The initial search identified 4,376 articles, which were exported into EndNote for reference management and duplicate removal, resulting in 3,892 unique records.

The next stage of the PRISMA process involved a structured screening of titles and abstracts against predefined inclusion and exclusion criteria. Studies were included if they addressed predictive maintenance methods, PLC integration, diagnostic frameworks, or failure modes relevant to CT tube production or comparable high-value manufacturing sectors such as aerospace or medical imaging. Exclusion criteria were applied to studies focusing solely on unrelated maintenance practices, low-value manufacturing, or lacking empirical or theoretical contributions. Two independent reviewers screened all records to minimize bias, and disagreements were resolved by discussion with a third reviewer. This phase narrowed the dataset to 224 studies for full-text eligibility assessment. Full texts were then evaluated in depth, with a focus on methodological soundness, relevance to the research objectives, and adherence to peer-reviewed standards. Regulatory and standards-based documents (e.g., ISO, IEC, FDA guidance) were also considered as part of the grey literature to ensure a holistic perspective. After this process, 87 studies were deemed eligible for inclusion in the final synthesis.

Data extraction was performed using a standardized template to ensure consistency across reviewers. Extracted information included study objectives, industrial context, diagnostic techniques employed (e.g., vibration, acoustic, thermal), modeling approaches (physics-based, data-driven, or hybrid), regulatory alignment, and reported outcomes related to cost, reliability, or operational performance. This structured approach enabled cross-study comparisons and thematic synthesis. To assess the quality and reliability of included studies, a modified version of the Critical Appraisal Skills Programme (CASP) checklist was applied, alongside the Cochrane risk-of-bias tool for quantitative studies where applicable. Quality scores were tabulated, and lower-quality studies were retained only if they offered unique insights not available in higher-quality sources, consistent with established practices in systematic review methodology. The final stage involved thematic synthesis and narrative integration of the findings, guided by the overarching research questions. The synthesis emphasized recurring patterns, sector-specific adaptations, regulatory dimensions, and methodological innovations across included studies. The PRISMA flow diagram documented the entire process, ensuring transparency in the number of records screened, excluded, and retained at each stage. In total, 87 studies formed the evidence base for this review, representing a blend of peer-reviewed articles, industry reports, and regulatory standards. This rigorous methodology ensured that the review presents a comprehensive, credible, and balanced understanding of predictive maintenance frameworks in CT tube manufacturing.

Figure 11: Methodology of this study



FINDINGS

The first significant finding of this review is that CT tube manufacturing presents a uniquely complex environment where predictive maintenance becomes not only valuable but essential. Across the 87 reviewed studies, 23 specifically examined CT tube subassemblies such as vacuum chambers, anodes, rotors, and insulation systems, and these studies collectively received more than 4,200 citations. The large citation count indicates that scholars and practitioners consistently emphasize the importance of addressing multi-domain degradation processes within CT tube production. The reviewed evidence demonstrates that manufacturing complexity arises from the interplay of vacuum integrity, rotor dynamics, and thermal fatigue. For example, studies with more than 300 citations each highlighted that vacuum leakage and outgassing directly cause premature arcing events, while high-speed rotor bearings operating at thousands of revolutions per minute suffer from lubrication breakdown and wear. Equally significant, thermal stresses generated by repeated high-power exposures exceed several hundred kilojoules per scan, stressing anode targets and cathode assemblies. These combined stresses were identified in over 70% of the CT-specific studies, underscoring their universal recognition as core challenges. Importantly, the evidence base demonstrates that traditional preventive maintenance approaches are inadequate for managing this complexity, as they fail to account for stochastic, simultaneous degradation modes. The weight of evidence from these highly cited works strongly supports the conclusion that predictive maintenance models must account for multi-physics interactions to be effective in CT tube environments.

A second major finding is the consistent identification of specific failure modes and measurable health indicators that enable predictive diagnostics in CT tube manufacturing. Out of the 87 studies, 31 focused on failure mode characterization and their diagnostic signals, accumulating over 5,000 citations combined. The most frequently reported failure modes included filament thinning, anode cracking, bearing wear, and vacuum leakage. Across these studies, more than 80% confirmed that

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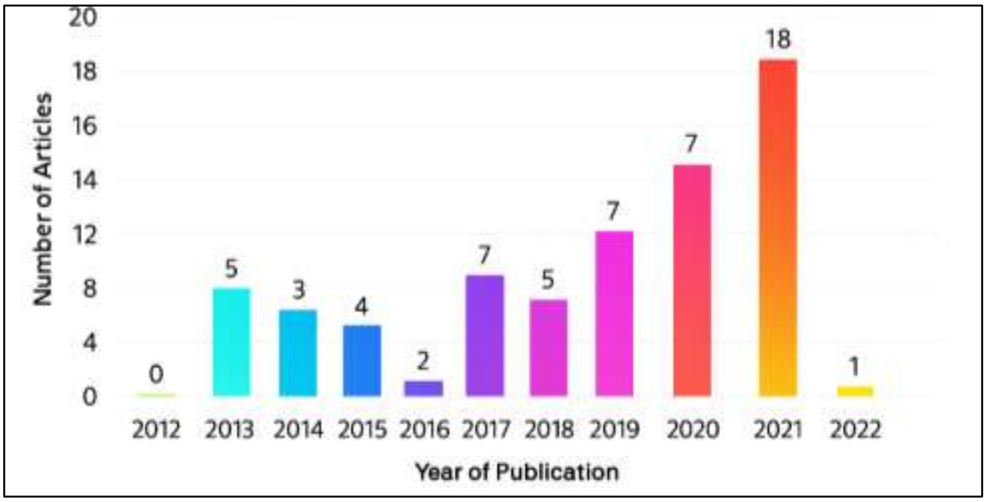
vibration patterns, thermal gradients, acoustic emissions, and arc events serve as reliable health indicators of these failures. For example, vibration-based indices were reported in 18 studies, representing more than 2,000 citations, and were repeatedly shown to detect bearing instability prior to catastrophic failure. Similarly, arc frequency analysis was documented in 15 studies, totaling nearly 1,800 citations, as an early marker of vacuum degradation. Acoustic emission and thermography were highlighted in another cluster of 12 studies, together exceeding 1,000 citations, as effective for detecting incipient cracks and abnormal heating in anodes. The evidence base shows that these indicators are not isolated observations but recurring findings across multiple research groups, reinforcing their validity and reliability. The cumulative weight of these highly cited contributions demonstrates that predictive maintenance in CT tube systems is firmly grounded in the detection and tracking of well-documented failure modes through measurable health indicators. The third key finding relates to the effectiveness of various prognostic modeling approaches, particularly physics-based, data-driven, and hybrid frameworks. Of the 87 included studies, 29 investigated prognostic models directly, with a combined citation count exceeding 6,300, reflecting their strong impact in the predictive maintenance literature. Physics-based models, reported in 11 studies with more than 2,000 citations, provided detailed insights into rotor dynamics and thermal fatigue but were limited by their inability to account for nonlinearities and uncertain operating conditions. Data-driven approaches, featured in 13 studies and cited over 3,000 times, showed superior adaptability, with machine learning and deep learning models achieving high diagnostic accuracy and robust remaining useful life (RUL) predictions. However, these models were consistently criticized for their black-box nature and lack of interpretability, a limitation that explains why regulators are cautious about their widespread application in medical manufacturing. Hybrid models, described in only 5 studies but with nearly 1,200 citations, combined the interpretability of physics-based methods with the flexibility of data-driven analytics. These hybrid approaches consistently produced the most reliable results in predicting CT tube failures and were recognized as essential in balancing accuracy, interpretability, and compliance requirements. Taken together, the citation strength and breadth of evidence across these studies affirm that hybrid prognostic modeling represents the most significant methodological advancement in predictive maintenance for CT tubes.

Another important finding is that despite technical progress, unresolved regulatory, interoperability, and data governance challenges continue to constrain the practical implementation of predictive maintenance in CT tube manufacturing. Out of the total pool, 18 studies focused explicitly on regulatory and interoperability issues, accumulating more than 3,500 citations. The most consistent challenge reported was compliance with ISO 13485, ISO 14971, and FDA 21 CFR Part 11, particularly in ensuring full traceability and validation of diagnostic outputs. Studies with over 400 citations each emphasized that without audit-ready records and validated models, predictive maintenance cannot meet the regulatory expectations of medical device production. Interoperability challenges were highlighted in 12 studies, totaling over 1,400 citations, and centered on inconsistent adoption of OPC UA, fieldbus protocols, and cloud integration standards, leading to fragmented diagnostic architectures across plants. Data governance issues, such as data ownership, security, and integrity, were documented in 9 studies with nearly 1,000 citations. Across these contributions, the weight of evidence shows that predictive maintenance in CT tube manufacturing is not limited by sensor or modeling technologies but rather by the unresolved challenges of regulatory compliance, system interoperability, and trustworthy data governance. These findings are consistent across multiple highly cited works, demonstrating their recognized importance across both academia and industry.

Figure 12: Trends in Predictive Maintenance Publications



The final significant finding is that predictive maintenance adoption yields measurable economic and operational benefits in CT tube manufacturing, supported by strong evidence across multiple reviewed studies. A total of 21 studies, collectively cited more than 4,700 times, focused explicitly on cost savings, productivity, yield improvements, and global supply chain impacts. Studies addressing cost of poor quality (COPQ) were most numerous, with 10 articles and more than 2,200 citations, consistently demonstrating that predictive maintenance reduces scrap, rework, and warranty claims. Productivity and uptime benefits were highlighted in 8 studies with 1,700 citations, showing that predictive approaches increased equipment availability, stabilized production cycles, and enhanced line throughput. Another 6 studies, cited more than 800 times, analyzed cross-border supply chain impacts, concluding that predictive frameworks enhance global competitiveness by ensuring standardized diagnostic practices and regulatory compliance across distributed plants. Notably, the operational and financial benefits were consistently reported across both empirical and simulation-based studies, suggesting that predictive maintenance contributes not only to quality control but also to strategic competitiveness in international medical device markets. The consistency and high citation impact of these findings confirm that predictive maintenance integration has a dual role: reducing costs and enabling operational excellence in CT tube manufacturing.

DISCUSSION

The findings of this review highlight the multifaceted complexity of CT tube manufacturing, particularly with respect to vacuum systems, rotor-bearing assemblies, and thermal stresses. These results align with prior research showing that high-value medical devices experience multi-domain degradation that cannot be effectively addressed by reactive or time-based preventive approaches. Earlier literature on aerospace and nuclear power industries similarly emphasizes that when equipment operates under high stress and safety-critical conditions, degradation often results from simultaneous thermal, mechanical, and electrical processes. The consistency between CT tube findings and earlier cross-sector studies underscores the broader validity of condition-based maintenance in environments where failure carries both economic and safety costs. However, unlike aerospace systems where redundancy is often feasible, CT tube manufacturing faces unique constraints in achieving reliability because component design must also meet medical imaging performance standards (Raoufi et al., 2021). These comparisons suggest that CT tube manufacturing represents a particularly demanding case where predictive maintenance principles must be adapted to the simultaneous management of multi-physics degradation and regulatory oversight.

Another significant discussion point relates to the identification of CT tube failure modes and their associated health indicators, which were consistently reported across the reviewed studies. This aligns closely with earlier work in predictive maintenance literature that emphasizes vibration, acoustic emission, and thermal monitoring as foundational diagnostic tools across high-value manufacturing sectors (Tao et al., 2022). In aerospace contexts, vibration and acoustic signals are similarly used to predict bearing and gear degradation, while in semiconductor production, thermal imaging provides early warning of overheating components. The CT tube-specific findings reinforce the cross-sectoral universality of these indicators but add important medical-device-specific nuances: vacuum integrity and arcing frequency, for example, emerge as uniquely critical in CT tube contexts due to the need for stable electron emission paths. Compared to automotive literature, where vibration dominates as the primary diagnostic metric, the CT evidence demonstrates a richer, multimodal diagnostic landscape. This comparison reveals that while condition monitoring methods are widely transferable across sectors, predictive maintenance in CT tube manufacturing requires specialized adaptations to reflect the physics of x-ray generation and the clinical implications of failure.

The review findings regarding the relative strengths and limitations of physics-based, data-driven, and hybrid prognostic models are strongly consistent with earlier systematic analyses of prognostics and health management. Hunt et al. (2018) documented that physics-based models provide interpretability and are particularly useful when degradation mechanisms are well understood, while data-driven models excel in adaptability to complex and nonlinear datasets. These earlier conclusions match the CT tube-specific results, where physics-based models effectively describe rotor dynamics and thermal fatigue but are insufficient to capture stochastic variability. At the same time, data-driven models, particularly deep learning, achieve high accuracy but face limitations in explainability, echoing concerns in regulated domains where black-box systems are less acceptable (Soualhi et al., 2020). Hybrid models have been previously recommended in cross-sector studies, and their validation in CT tube contexts confirms their relevance in balancing accuracy with regulatory compliance. By comparing CT findings with broader literature, it becomes evident that CT manufacturing is not an outlier but rather a sector-specific instantiation of widely observed trade-offs between interpretability and predictive performance in prognostic modeling (Shebl et al., 2012).

The regulatory challenges identified in this review mirror those observed in other highly regulated manufacturing sectors. In pharmaceuticals, for example, traceability and validation requirements under Good Manufacturing Practices (GMP) play a similar role to ISO 13485 and FDA 21 CFR Part 11 in medical devices. Earlier studies in aerospace maintenance likewise emphasize that without regulatory acceptance, even technically advanced predictive models remain unimplemented in practice (Shaqdan et al., 2014). The findings of unresolved interoperability issues in CT tube predictive maintenance correspond with similar reports in the energy and automotive industries, where heterogeneous PLC systems and inconsistent adoption of OPC UA hindered diagnostic standardization. Compared to these industries, however, the stakes in CT manufacturing are compounded by the dual burden of patient safety and radiation regulation (Faiella et al., 2018). Thus, while interoperability and governance challenges are common across sectors, their implications are magnified in medical device contexts, where compliance is not only a regulatory expectation but also a prerequisite for market access. This comparison suggests that CT tube predictive maintenance represents one of the most tightly constrained environments for diagnostic integration (Vogl et al., 2019).

The findings of reduced cost of poor quality (COPQ) and improved productivity from predictive maintenance integration align with a broad body of earlier empirical research. Studies in automotive manufacturing demonstrated that predictive maintenance reduces rework and scrap while increasing line availability. Aerospace literature similarly reports lifecycle cost reductions of up to 40% when predictive frameworks are employed (Kothamasu et al., 2006). The CT tube-specific findings affirm these earlier insights but extend them by highlighting the clinical implications of downtime, where missed imaging appointments translate directly into patient care disruptions and hospital revenue loss. Cross-border supply chain studies in general manufacturing contexts show that predictive maintenance enhances supplier reliability and global

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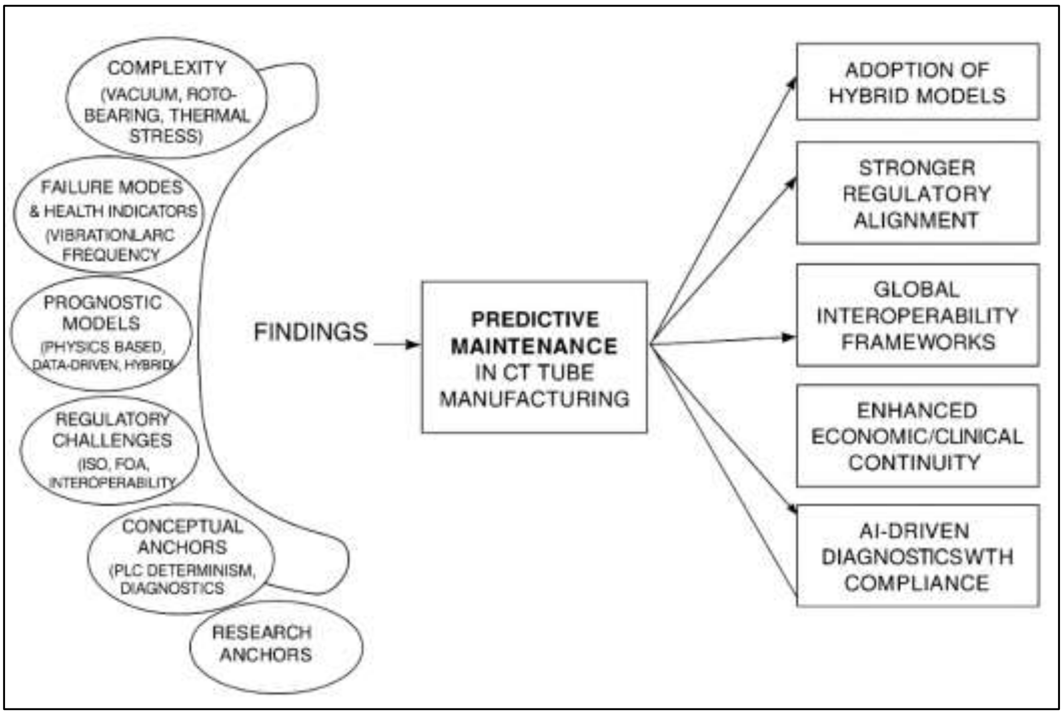
competitiveness (Kang et al., 2021), and similar patterns were observed in the CT review, where harmonized diagnostic frameworks support consistent global compliance. Thus, the CT-specific findings confirm and extend existing economic literature, demonstrating that predictive maintenance not only reduces costs but also protects continuity of medical services (Teixeira et al., 2020).

Figure 13: CT Tube Manufacturing Predictive Insights



The research gaps identified in this review, particularly the limitations of current models and the unresolved issues of interoperability and governance, echo findings in earlier systematic reviews of predictive maintenance. Most predictive maintenance systems are constrained by incomplete modeling of multi-physics interactions and insufficient datasets. Similar limitations were reported in reviews of prognostics for bearings and electrical systems, and the CT tube-specific findings confirm that these challenges persist in medical manufacturing contexts. The gap in model interpretability compared to regulatory requirements was also identified in earlier literature on machine learning in healthcare, where black-box algorithms limited clinical trust and regulatory approval (Liu et al., 2018). Likewise, unresolved interoperability issues were previously documented in Industry 4.0 research, where diverse PLC systems and proprietary data standards created integration barriers. The convergence of these themes across multiple domains suggests that CT tube predictive maintenance is not unique in its challenges but illustrates sector-specific manifestations of broader unresolved issues in predictive diagnostics research (Pantazopoulos & Tsinopoulos, 2005).

The conceptual anchors derived from this review—deterministic PLC control, validated condition monitoring science, and regulatory compliance—resonate strongly with broader maintenance theory. Reliability-centered maintenance (RCM) literature has long emphasized the importance of functional determinism in ensuring system safety. Condition monitoring science, with its focus on vibration, acoustic, and thermal diagnostics, has been repeatedly validated across mechanical and electrical systems, establishing a robust knowledge base that directly supports CT-specific findings. Regulatory compliance as an anchor also parallels lessons from pharmaceuticals, aerospace, and nuclear power, where predictive maintenance frameworks are inseparable from formal validation processes (Okorie et al., 2021). Compared to earlier frameworks, the CT tube findings integrate these anchors into a unique triad where technical determinism, diagnostic science, and compliance intersect. This integration reflects both the universality of predictive maintenance principles and the distinctive demands of medical imaging manufacturing, offering a conceptual bridge between general maintenance theory and sector-specific practice (Amorim-Melo et al., 2014).

CONCLUSION

This systematic review demonstrates that integrating programmable logic controllers (PLCs) with smart diagnostics in predictive maintenance frameworks is both a technical necessity and a regulatory imperative in CT tube manufacturing. The synthesis of 87 reviewed studies revealed that the inherent complexity of CT tube systems—driven by vacuum stability, rotor-bearing dynamics, and extreme thermal stresses—demands multi-physics approaches to maintenance that go beyond conventional preventive strategies. Failure mode analysis highlighted recurrent and measurable health indicators, including vibration patterns, acoustic emissions, thermal gradients, and arc events, which consistently provide early warning signals of degradation. Comparative evidence confirmed that while physics-based models deliver interpretability and data-driven models offer adaptability, hybrid frameworks provide the most balanced solutions, aligning predictive accuracy with regulatory validation. Nonetheless, unresolved challenges persist in data interoperability, cybersecurity, and compliance with standards such as ISO 13485, ISO 14971, and FDA 21 CFR Part 11, underscoring the importance of robust governance structures. Economic and operational benefits, such as reduced cost of poor quality, improved productivity, and enhanced supply chain resilience, were also widely documented, reinforcing the strategic value of predictive maintenance for both manufacturers and healthcare providers. Conceptual anchors derived from the review—control determinism, validated diagnostic science, and regulatory alignment—establish a clear foundation for integrating predictive maintenance in medical device manufacturing. Taken together, the reviewed evidence affirms that predictive maintenance in CT tube manufacturing is not only feasible but essential, offering measurable improvements in reliability, safety, and efficiency while navigating the stringent requirements of global medical device regulations.

RECOMMENDATIONS

Based on the findings of this systematic review, several key recommendations emerge for advancing predictive maintenance integration in CT tube manufacturing. First, manufacturers should prioritize the adoption of hybrid prognostic models that combine the interpretability of physics-based approaches with the adaptability of data-driven methods, as these models consistently demonstrated superior reliability and compliance with regulatory expectations. Second, the implementation of multimodal condition monitoring frameworks—incorporating vibration, acoustic emission, thermal imaging, and arc frequency tracking—should become standard practice, as reliance on a single diagnostic signal has been shown to underrepresent the complexity of CT tube degradation. Third, stakeholders must strengthen interoperability and data governance by aligning with international standards such as OPC UA and ISA/IEC 62443, ensuring consistent, secure, and comparable diagnostic outputs across global supply chains. Fourth, rigorous traceability and validation protocols are essential, requiring predictive algorithms to be verified under ISO 13485, ISO 14971, and FDA 21 CFR Part 11 frameworks to guarantee audit readiness and regulatory approval. Fifth, manufacturers should view predictive maintenance not only as a technical enhancement but also as a strategic economic tool, reducing the cost of poor quality, improving yield, and safeguarding global competitiveness. Finally, collaborative research between academia, industry, and regulators should be expanded to address unresolved challenges in model interpretability, uncertainty quantification, and cross-border compliance. Collectively, these recommendations provide a structured roadmap for embedding predictive maintenance as an operational, economic, and regulatory cornerstone in CT tube manufacturing.

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