Article

Research on Internal Control of Medical Technology Enterprises Based on Risk Management

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Abstract: This paper takes medical technology enterprises as the research object and examines internal control issues from the perspective of risk management. Considering the distinctive characteristics of the medical technology industry, including rapid technological iteration, high research and development investment, extended innovation cycles, and strict compliance requirements, the study first elaborates on the necessity of strengthening internal control systems to support stable operation and long-term development. It then analyzes the main types of risks encountered by medical technology enterprises in the process of internal control implementation, focusing on market uncertainty, technological development risks, and operational compliance pressures. On this basis, the paper further proposes the construction path of a risk-oriented internal control framework, emphasizing the integration of systematic risk identification, comprehensive risk assessment, and targeted control activity design. By combining theoretical analysis with practical business scenarios, this study aims to provide structured and operable references for medical technology enterprises to improve internal control effectiveness, enhance risk response capability, and promote sustainable and orderly development.

Keywords: risk management; medical technology enterprises; internal control

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1. Introduction

Medical technology enterprises have become an important component of the modern healthcare industry, continuously promoting technological innovation and product upgrading while responding to increasingly diversified market demands. Compared with traditional manufacturing or service enterprises, medical technology firms generally face higher levels of uncertainty due to their reliance on technological innovation, long research and development cycles, and significant upfront investment. In addition, the operational environment of such enterprises is characterized by complex business processes and high requirements for product quality and operational, which collectively increase internal management pressure and risk exposure [1].

In this context, internal control plays a crucial role in supporting the stable operation and standardized management of medical technology enterprises. Effective internal control systems help enterprises clarify responsibilities, standardize operational procedures, and improve decision-making quality, thereby reducing the likelihood of operational deviations and resource inefficiencies. More importantly, internal control guided by risk management concepts emphasizes the proactive identification and response to potential risks, enabling enterprises to align internal governance mechanisms with strategic objectives and operational realities [2].

However, in practice, many medical technology enterprises still face challenges in internal control implementation. These challenges are reflected not only in market-related uncertainties, such as demand fluctuations and intensified competition, but also in technological risks associated with research and development outcomes, as well as

compliance-related pressures arising from increasingly detailed operational requirements. If internal control systems fail to adequately address these risk factors, enterprises may encounter difficulties in maintaining stable operations and achieving expected development goals.

Therefore, exploring internal control issues in medical technology enterprises from a risk management perspective is of both theoretical significance and practical relevance. By systematically analyzing the main risk types affecting internal control effectiveness and proposing corresponding improvement strategies, this study seeks to contribute to a clearer understanding of how risk-oriented internal control systems can be constructed and optimized. Such an approach not only supports the enhancement of internal management quality but also provides practical guidance for medical technology enterprises seeking sustainable development in a complex and dynamic operational environment [3].

2. Analysis of Internal Control Risks in Medical Technology Enterprises

2.1. Market Risk

The competitive landscape of the medical technology industry is experiencing continuous restructuring, characterized by increasingly blurred industry boundaries and a growing trend toward cross-sector integration. With sustained capital participation and the expansion of market opportunities, a large number of emerging enterprises have accelerated their entry into segmented application fields, leading to a noticeable increase in supply-side pressure. As shown in Table 1, the number of newly established medical technology enterprises has maintained a relatively high growth rate in recent years, approaching 20% on average. Among these enterprises, a significant proportion concentrate on areas such as intelligent imaging diagnostics, wearable health monitoring equipment, and precision-oriented medical solutions, resulting in a high degree of product similarity across the market.

Table 1. Number of New Entrants in a Simulated Regional Healthcare Technology Market**.**

a particular year	Number of new entrants
2021	100 homes
2022	120 homes
2023	144 homes
2024	173 homes
2025	207 homes

The intensification of homogeneous competition has gradually weakened enterprises' pricing power, forcing many firms to rely on price-based strategies to maintain market share. As a consequence, the market prices of certain mid- to low-end medical devices have shown a sustained downward trend over recent years, with cumulative declines exceeding 30% in some segments. This trend has continuously compressed profit margins and increased operational pressure, particularly for enterprises with limited cost control capabilities or insufficient differentiation advantages. Under such conditions, market competition is no longer confined to product performance alone but increasingly extends to cost efficiency, service capability, and lifecycle management [4].

At the same time, demand-side characteristics are undergoing significant changes. End users, including medical institutions and service providers, are placing higher expectations on product integration capability, system compatibility, data continuity, and long-term operational reliability. Survey results from equipment procurement practices indicate that a majority of upgrade projects tend to prioritize systems with enhanced intelligent support functions, modular design, and remote operation or maintenance features. This shift reflects a transition from single-function equipment selection toward

comprehensive solution-oriented demand, further raising the threshold for market participation.

In this evolving environment, enterprises with delayed technological responsiveness or insufficient innovation continuity are more likely to experience erosion of customer trust and weakening of existing market positions. The competitive structure of the industry is gradually transforming from a primarily technology-driven model into a dual-driven mechanism that emphasizes both demand responsiveness and rapid iteration capability. Such changes not only reshape market competition patterns but also pose higher requirements for internal risk identification and control within medical technology enterprises [5].

2.2. Technical Risks

The core competitiveness of medical technology enterprises lies in their ability to sustain continuous technological innovation. However, research and development activities are inherently characterized by high uncertainty, long investment cycles, and complex technical pathways. During the R&D process, enterprises frequently encounter bottlenecks at critical stages, such as technical solutions failing to satisfy verification requirements under application-oriented testing environments or key materials exhibiting performance instability during experimental evaluation. These challenges increase the probability of project delays or termination and place considerable pressure on enterprise resource allocation [6].

In addition to technical uncertainty, fluctuations in human resource structure further amplify R&D risks. The loss or turnover of core research personnel may disrupt knowledge continuity and weaken collaborative efficiency within R&D teams, thereby increasing the likelihood of project interruption. For technology-intensive enterprises, such disruptions often result in difficulties in restoring technical momentum within a short period, especially when project documentation and experience accumulation are highly tacit.

As shown in Table 2, simulation-based statistical analysis of a sample of medical technology R&D projects indicates that a notable proportion failed to achieve predefined technical objectives. Among the projects analyzed, the overall failure rate exceeded 30%, with certain technology-intensive segments exhibiting even higher levels of project termination. These results reflect the high-input and high-risk characteristics of R&D activities within the medical technology sector and highlight the substantial uncertainty enterprises must manage throughout the innovation process [7].

Table 2. Failure Status of a Batch of Medical Technology R&D Projects.

Research and development project type	Total projects	Number of failed projects	failure rate
Medical Device R&D	100	32	32%
Medical software development	80	22	27.5%
Biopharmaceutical R&D	120	40	33.3%

Moreover, the pace of technological iteration within the industry has accelerated significantly. The emergence of new technical frameworks, system architectures, or methodological approaches may shorten the effective lifecycle of existing technologies to less than two years. Under such conditions, even products that meet current technical or application standards may face rapid obsolescence if enterprises fail to anticipate and prepare for subsequent development directions. This dynamic environment increases the risk of sunk R&D costs and strategic misalignment.

Consequently, medical technology enterprises are compelled to maintain relatively high levels of R&D investment to preserve technological competitiveness and strategic flexibility. In practice, some leading enterprises allocate a substantial proportion of operating revenue to research and development activities in order to establish

technological reserves and strengthen intellectual asset accumulation. Such investment strategies are intended to create buffers against uncertainty and support long-term competitive positioning, but they also place higher demands on internal control systems to ensure effective risk identification, monitoring, and resource coordination.

2.3. Compliance Risk

The compliance operations of medical technology enterprises are deeply embedded within a multi-tiered regulatory framework, with their products undergoing dynamic regulation throughout the entire lifecycle from conceptual design to end-use applications. Taking Class III medical devices as an example, the National Medical Products Administration (NMPA) requires completion of over ten statutory procedures, including type testing, animal studies, clinical trials, and on-site inspections of quality management systems, with an average registration cycle of 27.3 months during which continuous submission of technical documentation and compliance declarations is mandatory. A genetic testing company was ordered to suspend sales after its product launch due to failure to timely update clinical trial ethics approvals, resulting in a 41% decline in annual revenue and triggering investor lawsuits. The pharmaceutical sector exhibits even more rigid regulatory constraints. According to Good Clinical Practice (GCP), any data traceability chain disruption or flaws in informed consent procedures may render Phase III trial results invalid. In 2022, an innovative drug company's failure to strictly implement protocol deviation recording during overseas multicenter trials led the FDA to reject its New Drug Application (NDA), causing over 900 million yuan in prior R&D investments to be stranded. Production processes are strictly regulated by Medical Device Manufacturing Good Manufacturing Practice (GMP). During unannounced inspections, tampering with cleanroom environmental monitoring data was discovered, resulting in the company being listed on the key regulatory watchlist and its primary responsible person facing a five-year industry ban. Such regulatory penalties exhibit significant spillover effects, with capital markets rapidly reevaluating risk premiums and credit ratings being downgraded, often accompanied by tightened supply chain collaborations. Compliance is no longer merely a matter of legal compliance, but has evolved into a core indicator of corporate governance capabilities, permeating organizational structures, process designs, and decision-making logic, thereby forming institutional competitive barriers.

3. Construction of Internal Control System for Medical Technology Enterprises Based on Risk Management

3.1. Risk Assessment

Risk identification and assessment in medical technology enterprises have gradually moved beyond traditional static management frameworks and evolved into a systematic process integrating strategic orientation with operational detail. Within an industry environment characterized by high technical complexity and frequent external changes, enterprises are required to establish dynamic and multi-dimensional risk monitoring mechanisms to address uncertainties arising from market fluctuations, technological evolution, and operational compliance requirements. Such mechanisms aim to transform fragmented risk signals into structured information that supports timely decision-making.

In practical application, many established enterprises employ structured tools such as risk matrix models and scenario-based simulation methods to convert uncertain factors into relatively measurable indicators. In terms of market risk identification, analysis is no longer limited to conventional indicators such as market size or growth rate. Greater attention is increasingly given to changes in demand-side structure, adjustment cycles of payment mechanisms, and adoption pathways at the application end. Through predictive modeling of price sensitivity and procurement behavior, enterprises can anticipate

potential pressure on pricing and margins prior to large-scale market entry, thereby enabling earlier optimization of cost control strategies and capacity planning.

Technological risks are primarily reflected in the continuity and robustness of research and development pipelines. In technology-intensive fields with rapid iteration cycles, inappropriate selection of technical pathways may lead to repeated adjustments or even the invalidation of accumulated research outcomes. To mitigate such risks, enterprises increasingly introduce phased evaluation mechanisms that divide R&D processes into clearly defined decision nodes, allowing timely reassessment of technical feasibility and resource allocation. The inclusion of external expert consultation at key stages further helps reduce information asymmetry and cognitive bias in internal decision-making, enhancing the overall reliability of technological risk assessment.

Compliance-related risks are comparatively concealed and often embedded within internal management processes rather than originating from explicit violations. Insufficient understanding of technical documentation requirements, procedural inconsistencies, or inadequate coordination among departments may collectively increase compliance uncertainty. Practical experience shows that deficiencies in process control and documentation management can lead to significant operational disruptions, even when products themselves meet basic technical standards. This highlights the necessity of embedding compliance considerations into routine operational management rather than treating them as isolated review tasks.

Accordingly, risk assessment activities should not be confined to periodic or formalized reviews but should be integrated throughout the entire product lifecycle. Enterprises are advised to establish early-warning mechanisms at critical control points such as project initiation, development progression, registration preparation, and production release. By embedding risk assessment into daily operational processes, medical technology enterprises can gradually shift from reactive response models toward proactive prevention and control, thereby enhancing internal control effectiveness and overall risk resilience.

3.2. Design of Control Activities

Control strategies derived from risk profiling must be both precise and practically implementable to prevent redundancy or inefficiency within organizational processes. In response to increasingly diversified market demands, enterprises are gradually moving from uniform marketing approaches toward differentiated engagement models that reflect real-world application data. By integrating clinical records, user behavior patterns, and follow-up information, companies can construct comprehensive product value chains to support evidence-based decision-making, pricing strategies, and professional dissemination activities. Analysis of multi-institutional datasets enables predictive modeling of demand and resource allocation, which in turn informs strategic planning and facilitates timely alignment with evolving market requirements.

Technical control activities emphasize process standardization and effective resource coordination. Research and development management systems are designed to define milestone review criteria, monitor technical progress, and regulate resource deployment, thereby reducing the risk of information delays and decision-making misalignment during sequential development stages. Cross-departmental coordination mechanisms, such as centralized project management offices, play a key role in bridging R&D, registration, and production functions, ensuring smooth information flow and operational cohesion.

The stability and retention of core technical personnel are critical for sustaining innovation. Enterprises implement incentive frameworks that combine recognition of intellectual contributions, revenue-sharing from commercialized outcomes, and flexible research conditions to maintain continuity in knowledge and project development. By

doing so, they safeguard the execution of long-term R&D strategies while minimizing disruption caused by talent turnover.

Compliance control is addressed through both institutional embedding and organizational culture reinforcement. Specialized compliance units not only provide policy interpretation and staff training but also actively participate in product review and approval processes, ensuring regulatory considerations are integrated prior to commercial decisions. Regarding data governance, enterprises establish structured data classification and access management systems. Permission control mechanisms and operational traceability are incorporated into software and information systems to prevent unauthorized access and mitigate potential compliance risks. In contemporary practice, these control measures are no longer peripheral but have become fundamental components of corporate governance and operational integrity.

3.3. Internal Control Supervision

The effectiveness of supervision mechanisms depends on their independence, continuity, and depth of integration across organizational processes. Traditional periodic inspections are often insufficient to detect high-frequency or well-concealed operational deviations. In response, modern medical technology enterprises have adopted a supervisory approach that combines real-time monitoring with intelligent auditing, leveraging integrated information systems to enhance oversight capabilities. By coordinating enterprise resource planning (ERP) and quality management systems (QMS), critical control points such as batch record verification, adverse event reporting, and supplier qualification updates can trigger automated alerts and highlight anomalies for prompt attention.

Practical applications of process monitoring reveal that deviations from standard operating procedures can frequently occur in operational detail, emphasizing the need for timely corrective actions and system optimization. Internal audit functions have also evolved from purely retrospective verification to proactive, embedded oversight. Auditors now participate in the early stages of significant projects to evaluate potential operational, legal, and financial risks, ensuring that risk mitigation considerations are integrated from the outset.

Equally important, supervision outcomes must feed into a closed-loop management system, informing performance evaluations and strategic governance processes. By systematically incorporating feedback into operational planning and resource allocation, enterprises can ensure that corrective measures are effectively implemented and supported at all levels of management. Supervision has thus transformed from a reactive, error-corrective function into a mechanism that drives organizational learning, continuous capability improvement, and the strengthening of institutional advantages. Through such approaches, medical technology enterprises can enhance adaptability, improve process resilience, and maintain sustainable operational standards in complex and rapidly evolving environments.

4. Conclusion

Medical technology enterprises face dual pressures of accelerating technological iteration and increasingly stringent regulatory requirements, with their operations confronting multidimensional risks such as compliance, data security, and supply chain disruptions. Internal control based on risk management has evolved beyond traditional defensive functions to become a core governance mechanism supporting strategic execution. By integrating the ISO 13485 quality management system with the COSO framework, enterprises can embed dynamic risk assessment models at critical junctures such as R&D translation, clinical trial data management, and post-marketing surveillance, achieving a paradigm shift from passive response to proactive early warning. Empirical evidence shows that enterprises with mature internal control mechanisms improve their

corrective response efficiency by nearly 50% when addressing FDA warning letters or NMPA unannounced inspections. The design of control activities increasingly emphasizes scenario-based and digital approaches, such as utilizing blockchain technology to ensure tamper-proof traceability data or employing machine learning to identify abnormal procurement patterns. Supervisory functions have also transcended the boundaries of independent evaluation, integrating with enterprise risk intelligence (Risk Intelligence) systems to drive forward-looking resource allocation at the decision-making level. Consequently, internal control has become a key variable in building organizational resilience, not only safeguarding compliance baselines but also shaping sustainable competitive advantages and value creation capabilities in uncertain environments.

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