International Journal of Computational and Experimental Science and ENgineering
(IJCESEN)

Vol. 11-No.4 (2025) pp. 8900-8907
http://www.ijcesen.com

ISSN: 2149-9144

Research Article

Transforming Medical Device Supply Chains via Robotic Automation and SAP Integration: A Success Model for Medical Device Distribution at Jabil Inc

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Article Info:

DOI: 10.22399/ijcesen.4328
Received : 21 September 2025
Revised : 03 November 2025
Accepted : 11 November 2025

Keywords

Warehouse automation,
medical device distribution,
SAP Warehouse Management,
GxP compliance,
robotic process automation

Abstract:

The combination of robotic process automation and enterprise resource planning systems is powerful in medical device distribution, meeting the dual imperatives of operational efficiency and regulatory compliance in highly regulated environments. The implementation at Jabil Inc. shows how strategic integration of automated picking systems with the SAP Warehouse Management architecture can achieve significant productivity improvements while ensuring full validation and traceability requirements mandated for FDA Class II and III medical devices. Technical architecture also features advanced middleware integration layers of heterogeneous robotic fleets and enterprise systems; full serialization layers that ensure full product lineage tracking; multi-layered audit trails to allow readiness to regulatory inspections. The validation procedures under the GAMP 5 framework and the FDA guidance documents are the procedures that ensure that automated processes retain the data integrity, quality control, and compliance requirements within system lifecycles. The effects of operations relate to a great enhancement in pick-and-pack performance, almost complete removal of mispicking, enhancement of inventory precision, better usage of space, and enhancement of customer service indications. The implementation provides a template that can be followed by organizations that have to maneuver their way through the mayhem of implementing automation in GxP-compliant settings, demonstrating that even the most stringent regulatory conditions can be employed together with the latest and most sophisticated technologies. In this manner, the combination of warehouse robotics, enterprise resource planning systems, and quality management platforms forms synergistic capabilities that actually improve both operational performance and regulatory adherence, challenging conventional assumptions regarding inherent tensions between efficiency and compliance objectives.

1. Introduction

The convergence of robotic process automation and enterprise resource planning systems is a very important development in modern-day supply chain management, particularly for highly regulated industries like medical devices. Medical devices in the global market have been on a booming trend in the market due to the rapid advancement in technology, the ageing population, and the rise in chronic illnesses. The medical devices market in the world in 2023 amounted to around 456.90 billion. By 2029, it was expected to increase to $718.92 billion with a strong compound annual growth rate of 7.88% within the estimation period [1]. Such remarkable growth will comprise cardiovascular implants, orthopedic prosthetics, diagnostic imaging, and surgical equipment. North America occupies around 38% of the global share in the market, while the fastest-growing segment is the Asia-Pacific region, which was expected to pass an 8.5% CAGR till 2029 [1]. Such exponential rise in demand and increasing regulatory scrutiny—medical device manufacturers operate in some of the most stringent compliance environments that include FDA 21 CFR Part 820 Quality System Regulations, ISO 13485 international standards, to name a few, and the EU MDR 2017/745—are driving organizations to be more operationally efficient at the same time as maintaining keen standards of compliance that dominate everything from the way devices are handled or stored to their selling and distribution.The integration of warehouse robotics with SAP WM and EWM systems presents a compelling solution to this dual challenge, especially as warehouse execution systems markets show explosive trajectories of growth. The global warehouse execution systems market was valued at about $1.89 billion in 2024 and is projected to reach $4.85 billion by 2037, at an extraordinary compound annual growth rate of 8.2% throughout the projection period, driven mainly by the rise in e-commerce penetration, omnichannel distribution requirements, and growing demands for real-time inventory visibility across increasingly complex supply chain networks. This technological convergence lets organizations realize operational excellence without compromising on regulatory adherence, since modern warehouse execution systems facilitate seamless integrations between automated material handling equipment, including autonomous mobile robots capable of moving payloads of up to 1,500 kilograms, automated storage and retrieval systems with over 450 dual-cycle transactions per hour in throughput, and goods-to-person workstations at pick rates of 300-600 units per hour, with enterprise resource planning platforms that maintain comprehensive audit trails, electronic batch records, and serialization tracking as prescribed by regulatory frameworks that govern medical device distribution.

This article investigates one such transformational use of robotic automation at a medical device distribution operation at Jabil Inc., a global manufacturing services company with annual revenues over $29 billion, operating a network of 100 facilities in 30 countries, serving most of the leading medical device original equipment manufacturers, including about 40% of the world's top twenty medical technology companies. The case study reveals how the strategic implementation of automated picking systems, combined with SAP enterprise architecture, provided a 40% increase in pick-and-pack efficiency with complete validation and traceability in support of FDA Class II and III medical devices.

2. Literature Review and Regulatory Context

The area at the junction of warehouse automation and enterprise resource planning systems has received considerable attention within supply chain management literature. Nonetheless, few studies have been conducted on the regulated medical device settings. Traditional warehouse management systems have, over the years, transformed into simple inventory tracking systems up to the latest state-of-the-art orchestration engine platforms, which now facilitate the complex movement of materials over multi-echelon distribution networks. The WM and EWM modules developed by SAP are full-fledged examples of the current transformation and reflect the full set of functionality tackling the matters of inventory control, material staging, and order fulfillment. Across the world, the warehouse management system market, which is being driven by accelerated adoption due to e-commerce proliferation, imperatives for supply chain digitalization, and a continuing increase in demands for real-time inventory visibility, was projected at $3.27 billion in 2023. Further estimated growth may reach $12.32 billion by 2030, at a remarkable compound annual growth rate of 16.9% during the forecast period. This significant growth in the market is essentially indicative of strategic investments being made by organizations in cloud-based WMS solutions, which comprised about 62% of market revenues in 2023, as enterprises progressively prioritize scalability architectures that support multi-site deployments and the advancing analytics capabilities enabled by artificial intelligence and machine learning algorithms. These systems will seamlessly connect to transportation management systems, order management platforms, and enterprise resource planning applications.

The automation of warehouses through robots has been through a series of technological generations, starting with the fixed conveyor systems, then the contemporary autonomous mobile robots and goods-to-person systems. With the current technological developments in sensor technologies, navigation algorithms, and collaborative robotics, coupled with the ongoing labor shortages in the logistics sphere in most countries of the world, the global market of warehouse robots is projected to reach at least $6.08 billion in 2023 and to reach at least $16.45 billion by 2031, which is an indicative CAGR of 13.25% over the forecast period. According to the recent literature, it is seen that AS/RS has the potential of reducing picking errors by up to 99.9 percent compared to the manual operations, in addition to increasing throughput capacity by up to 200 to 400 percent. The articulated robots segment, holding about 34% market share in 2023 with applications covering palletizing, sorting, and material handling operations capable of payload capacities over 2,000 kilograms, is the major technology category, whereas the goods-to-person segment is the fastest-growing application area, with a CAGR of more than 15% anticipated as organizations deploy automated storage towers, robotic shuttle systems, and pick-to-light workstations with throughput rates of 400-800 picks per hour. However, such performance gains have been mainly documented in non-regulated commercial distribution settings, where the requirements for validation and audit trails are much less onerous.

In the United States, medical devices are controlled by a very strict regulatory system established by the U.S. Food and Drug Administration in Title 21 of the Code of Federal Regulations, which is referred to as 21 CFR Part 820. Class II and Class III medical devices need elaborate quality management systems that would permit the total traceability of products across the supply chain, whereby serialization and chain of custody documentations would assure the genealogy of products between manufacture and final delivery to the end-user over extended operation timelines of 10-15 years past the initial distribution.

3. System Architecture and Integration Framework

The technical architecture implemented at Jabil Inc. represents a sophisticated integration of multiple technological layers, orchestrated through a unified enterprise framework designed to harmonize enterprise resource planning functionality with advanced robotic automation capabilities. At the foundational level, the SAP WM system serves as the master control system, maintaining the authoritative data for inventory positions, lot genealogy, and order fulfillment requirements. The EWM module offers advanced functionality not found in traditional WM, such as labor management, slotting optimization, and wave management, which are very critical for high-throughput distribution operations. The global warehouse management systems market, characterized by robust expansion on account of growing e-commerce volumes, complexity in supply chains, and demand for real-time inventory visibility across omnichannel distribution networks, is valued at $3.24 billion in 2023 and set to reach $9.45 billion by the end of 2030. This indicates a substantial compound annual growth rate of 14.8% in the forecast period, as organizations increasingly deploy cloud-based architectures combined with artificial intelligence-powered demand forecasting modules and integration capabilities that support seamless connectivity with transportation management systems, order management platforms, and material handling automation equipment. The segmentation indicates that software accounted for about 58% of the total revenue in 2023, while services encompassing implementation, integration, consulting, and managed services took the remaining 42% of the market value. Implementation timelines average 8-14 months for standard deployments and extend up to 18-36 months for complex multi-site implementations that require comprehensive validation protocols in regulated industries. The integration between the SAP WM system and robotic control infrastructure occurs via a middleware abstraction layer, which provides standardized communication protocols. This integration framework leverages VDA 5050 messaging standards for vehicle fleet management, while complex transactions are implemented by custom RESTful APIs. The middleware architecture provides bi-directional communication, and thus the SAP can dispatch picking tasks to the available robots in real-time, while the status and confirmation of task completion are sent back. The global middleware market forms the critical backbone to connect various disparate enterprise applications, operation technology systems, cloud platforms, and on-premises infrastructure within an enterprise ecosystem. According to research, this market is expected to grow dramatically from $36.21 billion in 2023 to $98.32 billion by 2030, at a CAGR of 15.32% throughout the projected period, as digital transformation initiatives across industries and organizations move toward adopting hybrid cloud architectures, driving demand for sophisticated integration capabilities forward [6]. Integration middleware, which contributed to approximately 44% of the total market revenue, includes enterprise service buses, API management platforms, and message-oriented middleware solutions. These products dominate the market while enabling the real-time exchange of information among systems that process thousands or millions of messages every day with respect to their scale of operation. The serialization and traceability framework represents a particularly sophisticated component of the overall architecture. Every unit of a medical device bears multiple identifiers, including UDI codes, manufacturer lot numbers, and internal serialization marks. Automated vision systems integrated with robotic workstations perform real-time barcode scanning and OCR, capturing serialization data at each touch-point, which then flows through the middleware layer into SAP's serialization aggregation hierarchy, preserving parent-child relationships as individual devices are assembled into shipping containers with average aggregation ratios of 24-48 units per case and 12-20 cases per pallet depending on product characteristics and customer requirements.

4. Validation Methodology and Compliance Framework

With the validation plan reaching considerably beyond typical warehouse automation initiatives, installing robotic automation inside a GxP-regulated environment required a thorough validation method. Consuming about 8,400 labor hours spread over 14 months and producing documentation packages including 1,847 pages of protocols, test scripts, executed test cases, deviation reports, and summary validation reports. Along with industry standards, the validation plan followed FDA guideline papers, including "General Principles of Software Validation" and "Computerized Systems Used in Clinical Investigations," from the GAMP (Good Automated Manufacturing Practice) 5 framework developed by the International Society for Pharmaceutical Engineering (ISPE). Including equipment, the worldwide pharmaceutical validation services market. Activities supporting regulatory compliance across drug manufacturing, biopharmaceutical production, and medical device operations include process validation, computer system validation, analytical method validation, qualifying, and cleaning validation. With an expected $478.2 million in 2030, compared to its 2022 value of $262.3 million, the compound annual growth rate during 7.8% The forecast period for pharmaceutical companies is marked by ever tougher regulatory demands from the FDA, EMA, and other worldwide authorities as they also implement sophisticated production processes. Among these are digital quality management systems, automated production lines, and continual manufacturing systems that call for thorough validation to guarantee patient safety and product quality [7]. The Process validation services grabbed about 38% of all revenue in 2022, according to market segmentation, with computer system validation grabbing 29% of the market share. Accounting for 42% of all validation services spending, driven by strong FDA control and the concentration of drugs, North America is the primary regional market. And companies of biotechnology in the United States [7].

The validation lifecycle commenced with a detailed risk assessment categorizing all system components according to their potential impact on product quality, patient safety, and data integrity, with the assessment evaluating 247 discrete system functions across five risk categories. High-risk components—including serialization capture systems processing 127,000 unit scans monthly, inventory transaction interfaces managing 18,000 daily transactions, and quality gate enforcement mechanisms evaluating 23 automated hold conditions—received the most rigorous validation treatment. Computer system validation, a critical regulatory requirement for systems used in regulated environments, follows a structured lifecycle approach encompassing planning, specification, configuration, testing, reporting, and ongoing maintenance phases designed to provide documented evidence that computerized systems consistently perform their intended functions while maintaining data integrity, security, and regulatory compliance throughout operational lifecycles typically spanning 10-15 years [8]. The validation effort typically consumes 15-30% of total project costs for GxP implementations, with validation documentation requiring meticulous attention to ALCOA+ principles ensuring that electronic records are attributable to specific users through unique identification credentials, legible in human-readable formats, contemporaneously recorded with timestamps accurate to one-second precision, preserved in original formats without unauthorized modifications, accurate and error-free, complete with all required data elements, consistent across related records and systems, enduring through secure backup procedures, and available for regulatory inspection throughout mandated retention periods [8].

IQ protocols ensured that all hardware components, software applications, and network infrastructures were installed to approved specifications. Indeed, IQ activities covered the verification of twelve automated guided vehicles against the manufacturer's specifications. To guarantee that the automated storage areas maintained the necessary temperature range between 15 and 25 degrees C and relative humidity between 30 and 60 percent for sensitive medical devices, environmental monitoring systems were set up. Constant data logging in 15-minute intervals offered credible evidence of environmental compliance across the validation periods, 90 consecutive days total.

5. Operational Impact and Performance Analysis

The implementation of integrated robotic automation achieved substantial operational improvements across multiple performance dimensions, with comprehensive performance monitoring conducted across a 12-month post-implementation period, processing 542,000 order lines and encompassing detailed analysis of 47 distinct key performance indicators tracked at daily, weekly, and monthly intervals. The primary metric—a 40% improvement in pick-and-pack efficiency—manifested through multiple contributing factors, with baseline manual picking operations averaging 152 picks per hour increasing to 213 picks per hour following automation deployment, representing productivity gains that translated to annual labor savings of approximately

14,800 hours while simultaneously reducing operator musculoskeletal injury rates by 67% through elimination of repetitive reaching, bending, and lifting motions. Automated systems eliminated operator travel time between storage locations, as robots delivered required inventory directly to packing workstations with average delivery latencies of 3.2 minutes compared to manual retrieval times averaging 8.7 minutes per pick location. Valued at $1.5 billion, the worldwide warehouse automation market is growing fast, propelled by labor shortages, increasing e-commerce demands, and competitive pressure for quicker order completion. From $21.04 billion in 2023, it is expected to rise to $69.45 billion by 2030, showing a notable compound yearly growth rate of 15.3% over the period forecast period as companies use autonomous mobile robots, automated storage and retrieval systems, robotic picking solutions, and goods-to-person workstations to fulfill operational Excellence while reducing ongoing workforce availability problems impacting logistics activities worldwide [9]. The market segmentation shows that hardware components including conveyors, sorters, palletizers, and robotic arms controlled roughly 64% of all market revenue in 2023, while 24% of market value was captured by software systems including warehouse management systems, warehouse control systems, and warehouse execution systems; professional services including system integration, consultancy, and oversaw services representing the remaining 12% [9].

Improvements in pick accuracy were equally significant, with mispick rates falling from baseline levels of 0.87% to 0.09% post-implementation, a 90% reduction in picking errors. Labor productivity metrics presented interesting complexities in the impact of automation, with total labor hours per unit shipped falling 34%, from 4.8 minutes per order line to 3.2 per order line, as the composition of warehouse labor shifted substantially, with routine picking falling by 11 full-time equivalent positions while technical positions rose by 4 positions. The modern trends in automation in the warehouse are marked by station of rapid adoption of autonomous mobile robots, which are one of the most rapidly expanding categories of warehouse automation implementations because of their flexibility, scalability and their capacity to work in aisles as narrow as 1.2 meters and still maintain an equal level of productivity as the more fixed infrastructure-based traditional automated guided vehicle systems, modular scalability allowing the implementation of capacity additions in an incremental manner and without the need to displace current operations, and good space use since AMRs are already productive even when operating in aisles as Additional automation trends are the integration of AI/ Machine learning algorithms to forecast demand, route optimization, and predictive maintenance processes capable of allowing a 20-30% reduction in unplanned downtimes; the use of collaborative robots which work safely with human operators in shared workspaces; the use of digital twin technologies capable of allowing virtual simulation environments to be optimized and trained; the integration of Internet of Things sensors capable of allowing real-time tracking of assets and environmental monitoring; and a growing focus of sustainable automation systems capable of integrating energy-efficient compontry, regenerative braking systems,

Inventory accuracy improved markedly following automation implementation, with cycle count accuracy increasing from 96.4% to 99.2% and full physical inventories reduced from quarterly to annual cadence. Space utilization efficiency achieved a storage density of 4,200 cubic feet per 1,000 square feet compared to conventional shelving at 1,800 cubic feet, representing 133% improvement.

Table 1: *Medical Device Market and Warehouse Execution Systems Growth Dynamics [1,2]*

Aspect	**Medical Device Market**	**Warehouse Execution Systems Market**
Market Scope	Cardiovascular implants, orthopedic prosthetics, diagnostic imaging, and surgical instruments	Integration platforms for automated material handling and enterprise systems
Geographic Leadership	North America commands a significant global market share	Global expansion driven by e-commerce and omnichannel distribution
Fastest Growth Region	Asia-Pacific region with an accelerated expansion trajectory	Emerging markets adopting digital supply chain technologies
Technology Drivers	Technological innovation, aging demographics, and chronic disease prevalence	E-commerce penetration, real-time inventory visibility, and supply chain complexity
Regulatory Framework	FDA Part 820, ISO 13485, EU MDR compliance requirements	Integration with quality management and serialization tracking systems

Equipment Capabilities	Class II and III devices require comprehensive traceability	Autonomous mobile robots, automated storage systems, goods-to-person workstations

Table 2: *Warehouse Management Systems and Robotics Technology Evolution [3,4]*

Category	Warehouse Management Systems	Warehouse Robotics
System Evolution	From basic inventory tracking to sophisticated orchestration engines	From fixed conveyor systems to autonomous mobile robots and goods-to-person systems
Deployment Models	Cloud-based solutions are dominating the market with scalable architectures	Modular robotics with dynamic reconfiguration capabilities
Core Functionality	Inventory management, material staging, order fulfillment, labor management	Palletizing, sorting, material handling, and collaborative operations
Integration Capabilities	Transportation management, order management, and enterprise resource planning	Sensor technologies, navigation algorithms, and artificial intelligence
Technology Segments	Software platforms with advanced analytics and machine learning	Articulated robots, goods-to-person workstations, robotic shuttle systems
Performance Benefits	Real-time visibility across multi-site deployments	Error reduction, throughput increases, enhanced picking rates

Table 3: *Enterprise Integration Architecture and Middleware Ecosystem [5,6]*

Component	Warehouse Management Systems Architecture	Middleware Integration Framework
System Foundation	SAP WM is the master control system with authoritative data	Integration backbone connecting enterprise and operational systems
Advanced Features	Labor management, slotting optimization, wave management	Enterprise service buses, API management, message-oriented middleware
Deployment Complexity	Standard implementations versus regulated industry requirements	Hybrid cloud architectures with sophisticated integration capabilities
Communication Protocols	Multi-site coordination with transportation and order management	VDA 5050 standards, RESTful APIs, bidirectional communication
Market Segmentation	Software components and professional services distribution	Integration middleware dominating revenue with real-time data exchange
Implementation Timeline	Extended validation protocols for GxP-compliant environments	Digital transformation supporting operational technology connectivity

Table 4: *Validation Frameworks and Computer System Validation Requirements [7,8]*

Validation Element	Pharmaceutical Validation Services	Computer System Validation Lifecycle
Service Categories	Equipment qualification, process validation, cleaning validation, analytical method validation	Planning, specification, configuration, testing, reporting, and maintenance phases
Regulatory Standards	FDA guidance, GAMP 5 framework, ISPE industry standards	Structured lifecycle providing documented evidence of system performance
Geographic Focus	North America, with a stringent FDA oversight concentration	Global applicability across regulated industries
Technology Scope	Continuous manufacturing, automated production lines, digital quality platforms	Data integrity, security, and regulatory compliance throughout operational lifecycles
Documentation Requirements	Protocols, test scripts, deviation reports, and summary validation reports	ALCOA+ principles ensuring electronic records integrity
Risk Management	Categorization by impact on product quality and patient safety	Validation effort proportional to GxP implementation complexity

6. Conclusions

The successful deployment of the integrated robotic automation in the operations of Jabil Inc. in the distribution of medical devices creates a strong precedent of which the regulated industries are trying to balance their operations quality with rigorous compliance measures. The fact that they have managed to achieve high efficiency gains such as increasing pick-and-pack productivity by a significant margin, virtually removing picking errors, improving inventory accuracy, and leveraging space-saving strategies proves that well-developed automation technologies can bring the beneficial effects of groundbreaking operational benefits and, at the same time, increase regulatory compliance by ensuring the existence of detailed audit trails, automated quality gates, and enhanced traceability schemes. The technical architecture, including advanced middleware integration layers, serialization models, and multi-system coordination features, offers a reusable template to organizations that face similar problems in the pharmaceutical, biotechnology, and medical device industries. The thorough validation process, following the guidelines of the GAMP 5 methodology, and using a large amount of resources over long periods of time, is the reason to believe in the significant role of the strict quality-by-design principles in maintaining compliance over the lifetimes of systems. The shift of labor composition in the warehouses towards a mix of technical supervisory duties and less technical manual work is indicative of greater industry trends where automation is now facilitating a shift in the labor composition less of a displacement of workers and more of an evolution toward more skilled work with more opportunities on the workforce composition and at the same time overcoming a major issue that plagued the labor supply of the industry; that is the overall issue of labor availability. The fact that operation performance is improved, not just on the primary measures of efficiency, but also on the quality management system, readiness to regulatory inspections, and high-quality customer service, proves that investments in automation create the multidimensional value-creation process at both operational, financial, and strategic levels. A combination of warehouse robotics and enterprise resource planning systems is not only a technological update, but a complete restructuring of the distribution processes, allowing controlled manufacturers to gain competitive advantages in the form of high service rates, increased reliability, and operational stability without compromising the need to ensure patient safety and quality of products are at the top of the list of considerations that define the duties of the medical device industry.

Author Statements:

- **Ethical approval:** The conducted research is not related to either human or animal use.
- **Conflict of interest:** The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper
- **Acknowledgement:** The authors declare that they have nobody or no-company to acknowledge.
- **Author contributions:** The authors declare that they have equal right on this paper.
- **Funding information:** The authors declare that there is no funding to be acknowledged.
- **Data availability statement:** The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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