From Reactive Compliance to Predictive Resilience: An Auditable AI Framework for Regulatory and Supply Chain Optimization in Class II Medical Devices

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Abstract:

Small and mid-sized medical device manufacturers face a growing operational challenge. Regulatory requirements are becoming more complex, global supply chains are becoming less predictable, and product life cycles are becoming shorter. At the same time, many firms do not have the headcount, capital, or system maturity of large multinational manufacturers. This creates a structural gap between market demand and organizational capacity.

This study examines that gap in Class II diabetes medical devices, including insulin pumps, continuous glucose monitoring systems, and blood glucose monitoring systems. These products require strong quality systems, controlled documentation, supplier oversight, and clear regulatory evidence. They are complex enough to create serious regulatory and supply chain pressure, but structured enough for AI based evidence retrieval, documentation support, supplier risk scoring, and scenario modeling to be tested in practice.

The study develops and evaluates an auditable AI operating framework that connects regulatory readiness with supply chain resilience. The framework uses two linked loops. The Regulatory Readiness Loop supports evidence retrieval, predicate comparison, documentation drafting, GSPR mapping, and submission quality checks. The Supply Adaptation Loop supports supplier early warning, alternate source readiness, change impact assessment, and total landed cost modeling. Both loops are governed by human review, quality controls, and audit ready documentation.

The framework was tested through a six-month pilot at New Horizon Biotech, a small Class II diabetes device manufacturer. The pilot used a five person AI Business Unit, and a hybrid build and buy technology model. Results showed measurable improvement. Regulatory drafting cycle time decreased from 6.5 weeks to 4.4 weeks. Evidence retrieval time decreased from 12.5 hours to 1.5 hours. First pass GSPR linkage completeness improved from 65 percent to 95 percent. Supply lead time recovery improved from 8.5 weeks to 5.2 weeks. Critical stockouts were avoided during the pilot period. The pilot also generated positive financial returns.

The findings suggest that small and mid-sized regulated manufacturers can use AI to improve both compliance and supply chain performance. The value does not come from replacing expert judgment. It comes from better data access, earlier risk detection, stronger cross functional coordination, and disciplined human oversight.

Keywords:
Artificial intelligence, supply chain resilience, medical devices, Class II devices, FDA 510(k), EU MDR, regulatory affairs, quality management systems, predictive analytics, medtech operations.