

Digital Transformation Success: How Robling Medical Revolutionized Quality Management with IQVIA SmartSolve® eQMS



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Executive summary

Robling Medical, a leading contract manufacturer in the medical device industry, is in the process of transforming their paper-based quality management processes through strategic implementation of IQVIA's SmartSolve platform. This white paper demonstrates how a partnership-focused vendor selection approach, combined with disciplined implementation methodology, is on target to deliver quantifiable operational improvements through deploying a single, digital QMS solution while positioning the organization for future regulatory compliance and AI-enabled capabilities.

Key objectives:

- Estimated expectation of 20-30% reduction in manual processing time across all quality functions
- Estimated expectation 15-25% improvement in audit preparation efficiency with electronic record access in a single, connected digital QMS solution
- Elimination of weeks-long data retrieval cycles, reducing analysis time from weeks to minutes whilst driving enhanced regulatory compliance and audit readiness
- Streamline customer approval workflows eliminating email/scan cycles and improved customer confidence through professional electronic systems
- Foundation established for future AI and analytics capabilities through standardized data architecture in a single, digital QMS solution

Company background

Robling Medical operates as a leading contract manufacturer serving multiple Original Equipment Manufacturers (OEMs) across diverse medical device categories. The company's strategic position in the contract manufacturing ecosystem requires sophisticated quality management capabilities that



accommodate varying customer requirements while maintaining consistent internal processes and regulatory compliance standards.

The organization's client portfolio spans multiple device classifications, from Class I (low risk) devices requiring basic quality controls to Class III (high risk) devices demanding comprehensive risk management and validation protocols. Clients also include those in the pharmaceutical industry that use medical device components within kits, for example drug filled ampules and syringes. This client and product diversity creates operational complexity and associated challenges. For example, external customer approval requirements for non-conformance dispositions, multi-language workforce support needs, and regulatory responsibility sharing with OEM partners, that traditional quality management approaches struggle to address effectively, particularly when managing multiple customer approval workflows simultaneously. These factors demand a quality management solution specifically designed to accommodate contract manufacturing complexities.

Contract manufacturing industry dynamics

The contract manufacturing sector faces unique operational challenges that distinguish it from traditional OEM operations.

- **Regulatory responsibility sharing** creates complex compliance frameworks where OEMs work with Robling Medical to fulfill their global regulatory and quality compliance activities. This requires sophisticated system capabilities that can accommodate varying customer requirements while maintaining standardized internal processes throughout activities such as DHR reviews, manufacturing process reviews and QC record reviews that support OEM product and process investigations
- **Customer relationship management** in contract manufacturing involves coordinating multiple OEM partnerships simultaneously, each with distinct approval processes, quality requirements and communication preferences. Traditional quality management systems often lack the workflow flexibility needed to accommodate these varied customer interactions without extensive customization which increases both implementation complexity and ongoing maintenance burdens
- **Competitive differentiation** increasingly depends on quality system capabilities as customers evaluate contract manufacturers based on their ability to provide comprehensive quality analytics, rapid issue resolution and proactive risk management. Organizations with superior quality management capabilities can command premium pricing while building stronger customer relationships through enhanced service delivery

Regulatory environment evolution

- The global medical device regulatory landscape continues to evolve rapidly, with new requirements emerging across global markets. **EU MDR and IVDR implementation** has created significant compliance obligations for device manufacturers, while **latest QMSR requirements** in the U.S. demand enhanced quality management system capabilities. Contract manufacturers must prepare for these evolving requirements while maintaining flexibility to support customer compliance obligations in the U.S., EU and other global markets
- **ISO 13485 certification maintenance** requires continuous improvement and system effectiveness demonstration, making electronic quality management systems increasingly essential for maintaining compliance evidence and supporting certification audits. The ability to generate comprehensive audit trails and automated compliance reports becomes critical for organizations managing multiple customer relationships and regulatory obligations



The challenge: Paper-based limitations

Operational pain points

Robling Medical's paper-based quality management system is regularly audited by customers and regulatory agencies, including the U.S. FDA, and is certified to these global requirements. Maintaining this high level of compliance with paper-based activities relies on a significant amount of labor-intensive cross-referencing of quality records. The move to a single, digital QMS solution providing significant opportunities to improve the timeliness and connectivity of associated QMS processes.



Data retrieval and analysis constraints

- Robling Medical's paper-based system severely hindered quality management efficiency through manual processes
- Robling Medical noted that their trend analysis process required manually reviewing paper documents to gather data. This often delayed timely containment decisions and hindered early identification of systemic issues



Document management challenges

- Lost documentation posed the most serious operational risk. An example shared was with a potential CAPA investigation where missing training records could prevent demonstrating that line operators received required training
- Whilst this was remediated through manual activities, the ability to connect related quality events in a single, digital platform would reduce compliance risk and improve operational quality management oversight



Resource misallocation

- Manual data collection consumed an estimated 20-30% of high-salary engineers and quality professionals' time on administrative tasks instead of value-added, professional analysis
- This misallocation prevented qualified personnel from focusing on strategic quality improvements that would benefit both Robling Medical and their customers



Compliance risks

- Missing training records and incomplete documentation would create audit vulnerabilities and slow response times when addressing auditing-body questions, potentially weakening confidence in the organization



Customer workflow inefficiencies

- Contract manufacturing requirements demanded complex approval cycles involving scanning documents, emailing customers, waiting for responses and re-scanning approved materials — creating weeks of delays in resolution timelines



Strategic implications

The paper-based approach created multiple barriers that limited Robling Medical's competitive positioning, operational effectiveness and growth potential. In an increasingly demanding marketplace where customers expect rapid response times and comprehensive data analytics, while regulatory bodies require complete audit trails and proactive quality management. The existing paper based system, constrained the company's ability to execute efficiently.

Scalability presented a significant challenge as adding new customers or expanding existing relationships required proportional increases in administrative overhead for document management and customer communication. This inefficient scaling model created cost structure challenges that directly impacted growth potential and competitive positioning.

Modern medical device companies increasingly expect real-time visibility into quality metrics, rapid issue resolution and sophisticated analytics capabilities from their contract manufacturing partners. The paper-based system could not deliver these capabilities, creating gaps in customer expectations that potentially impacted satisfaction and retention while limiting opportunities for service differentiation.

The inability to integrate with customer systems or provide electronic data exchange capabilities also created technology integration barriers. This limitation restricted partnership opportunities with technologically advanced OEMs who required sophisticated supply chain integration and real-time quality visibility, further constraining the company's market reach and competitive advantage.

Solution selection: Partnership-driven evaluation

Comprehensive vendor assessment

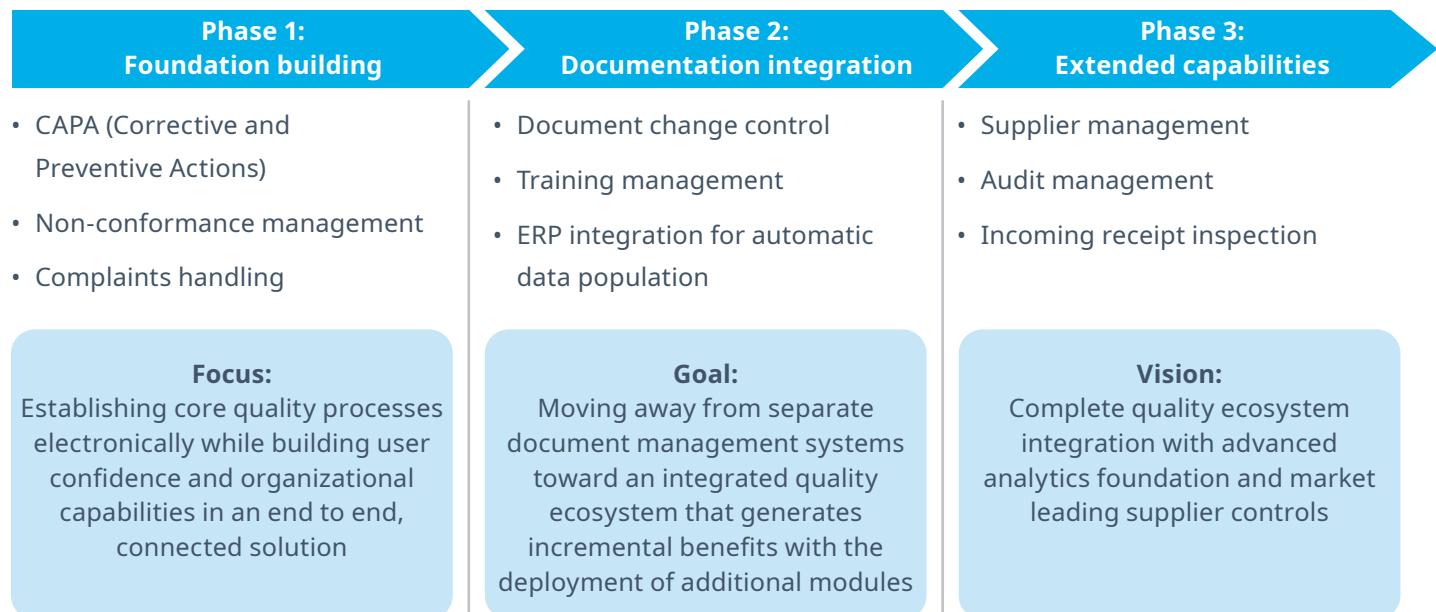
Robling Medical evaluated multiple enterprise quality management platforms, the evaluation process extending beyond traditional technical capabilities to include partnership approach, long-term relationship focus, customer service quality and regulatory support capabilities.

IQVIA SmartSolve: The strategic choice

Robling Medical selected IQVIA SmartSolve based on several compelling factors:

- **Partnership-driven support:** The selection decision reflected Robling's philosophy that relationship quality is key to determining long-term implementation success. IQVIA's accessible team structure of dedicated professionals ensures consistent implementation support; their advisory board model allows customer input on development priorities while keeping the platform current with industry evolution. Robling Medical characterized the vendor relationship as "like an enduring partnership," emphasizing the importance of long-term commitment and mutual success, with a joint focus on a collaborative approach to product development which creates confidence in ongoing mutually beneficial value
- **Contract manufacturing specialization:** IQVIA SmartSolve's specific capabilities for contract manufacturing operations, particularly native support for external customer approval workflows and the ability to configure solutions critical to contract manufacturing customers. Along with regulatory responsibility management, SmartSolve is distinguished from general-purpose quality management platforms that would require extensive customization to accommodate these requirements. Direct customer portal access eliminates email bottlenecks while maintaining complete electronic audit trails
- **Regulatory intelligence:** Built-in compliance monitoring and proactive regulatory updates ensure platform evolution with changing requirements. Global regulatory capabilities prove invaluable as medical device companies expand into diverse international markets
- **Proven track record:** Robling's 8-10-year relationship with key IQVIA personnel has demonstrated reliable execution. The seamless transition from customized on-premise systems to cloud-based solutions highlighted both technical expertise and partnership commitment. Previous successful implementations reinforced trust in the vendor team, and proven cloud-based platform capabilities reduced implementation risk while providing confidence in execution capabilities and timeline adherence
- **Total cost of ownership optimization:** The out-of-the-box configuration approach, cloud-based infrastructure and comprehensive module integration capabilities provided favorable total cost of ownership compared to alternatives requiring extensive customization, infrastructure investment or ongoing integration maintenance

Implementation strategy: Phased approach for success



Critical success factors



Data standardization priority

Recognizing the “garbage in, garbage out” principle, Robling Medical invested heavily in data clean-up before implementation. This strategic focus on data quality created a solid foundation, as standardized failure modes, root causes and product data would enable future AI capabilities and ensure reliable system performance



Configuration over customization

Learning from previous experience, the team made a deliberate choice to prioritize out-of-the-box configuration rather than pursuing extensive customization. This approach delivered significant benefits by ensuring faster implementation timelines and reducing long-term maintenance complexity

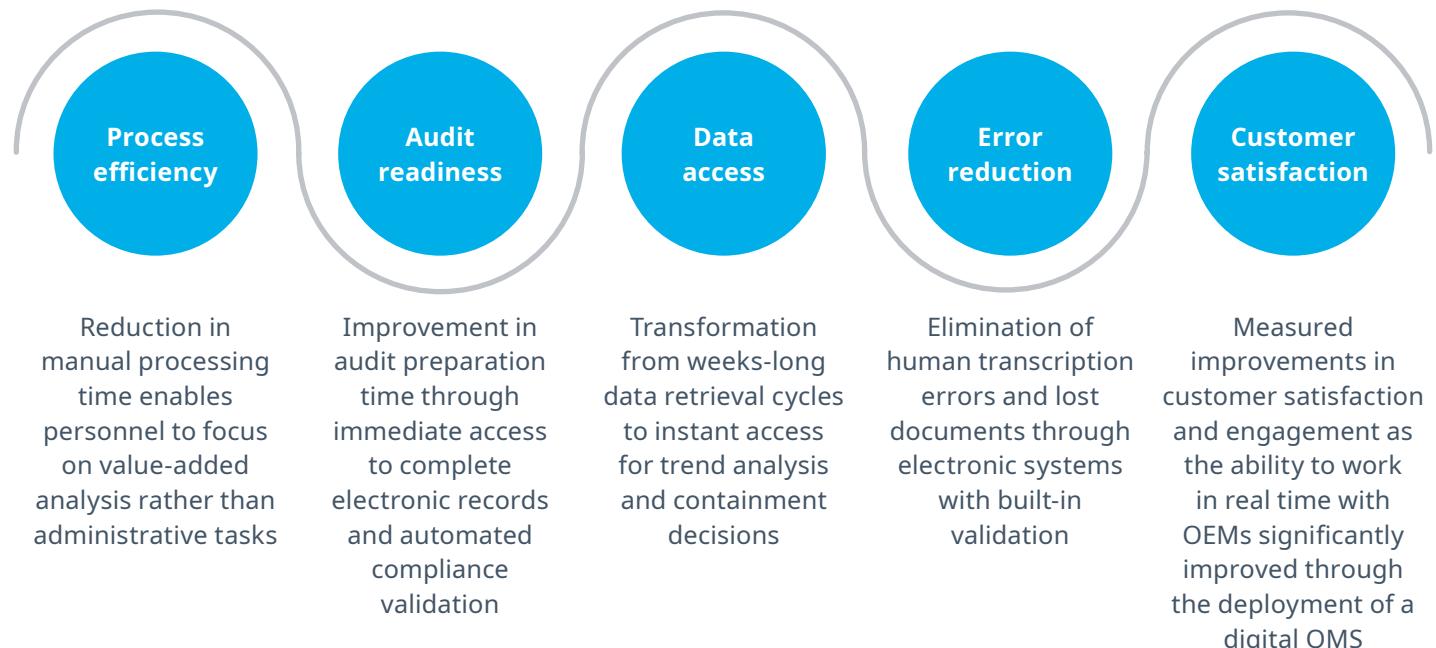


Change management focus

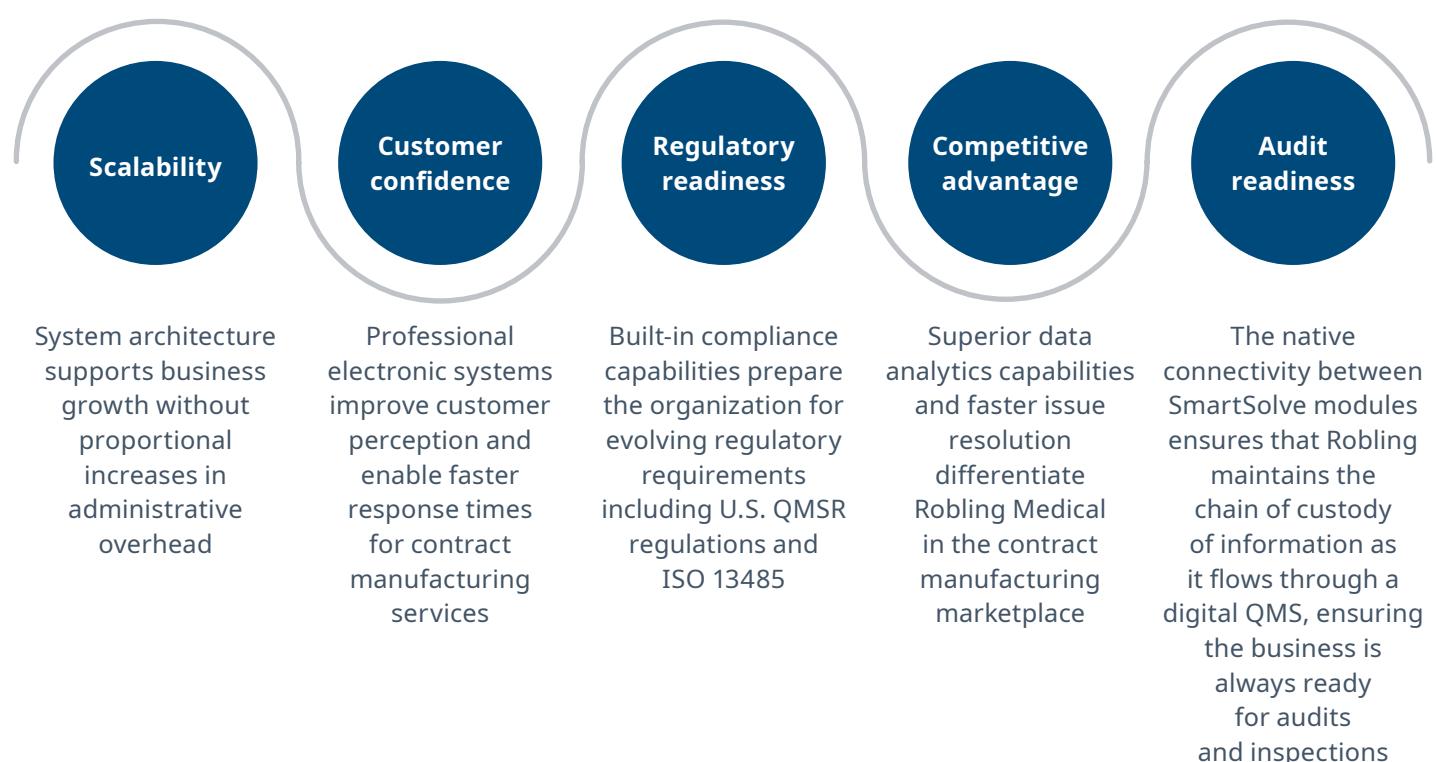
The organization is committed to offering comprehensive training programs and adopted a phased rollout strategy. By demonstrating incremental value at each stage, they successfully built organizational momentum and fostered user adoption throughout the transition process

Results and expected benefits

Quantified operational improvements



Strategic benefits



Lessons learned and best practices

Vendor selection insights

 Partnership over features	 Industry expertise	 Reference relationships
<p>Technical capabilities matter, but a long-term partnership approach often determines implementation success. Vendor cultural alignment and customer success orientation proved more valuable than feature checklists</p>	<p>Understanding contract manufacturing specific requirements distinguished winning vendors from general solutions that could not accommodate unique operational needs</p>	<p>Long-term professional relationships and proven track records provided confidence that technical capabilities would translate to implementation success</p>

Implementation best practices

 Data quality foundation	 Phased approach	 Change management Priority
<p>Investing in data standardization before system implementation creates the foundation for meaningful analytics and future AI capabilities</p>	<p>Gradual rollout manages risk while demonstrating value, building organizational confidence and user adoption momentum</p>	<p>Comprehensive training and change management strategies address the human factors that often determine technology implementation success or failure</p>

Future outlook: AI and advanced analytics

Current positioning

The standardized data foundation and integrated platform architecture position Robling Medical for advanced analytics and potentially AI capabilities in the future as these technologies mature and gain regulatory acceptance.

Potential applications

- **Automated Processing:** Complaint categorization, the identification of similar records and initial assessment through AI-powered analysis

- **Pattern Recognition:** Identification of trending issues across large datasets to enable proactive quality management
- **Regulatory Intelligence:** Automated monitoring of global regulatory changes with impact assessment for contract manufacturing operations
- **Predictive Capabilities:** Data-driven risk assessment and resource allocation based on historical patterns and emerging trends

Risk management approach

Robling Medical plans cautious adoption with appropriate validation requirements, human oversight maintenance and regulatory compliance assurance as AI capabilities evolve and gain the regulated industry's acceptance.

Elements for success

Strategic considerations



Partnership philosophy

Vendor relationships spanning 5 to 10+ years require engaged partnership commitment and mutual success orientation rather than transactional approaches



Standardization benefits

Out-of-the-box solutions often provide better outcomes than heavily customized systems, enabling faster implementation and easier maintenance



Data quality priority

Clean, standardized data from implementation start creates the foundation for all future analytics and potential AI capabilities



Phased implementation

Gradual rollout manages risk while demonstrating value and building organizational capabilities

Operational insights



Contract manufacturing specifics

Unique operational requirements demand specialized platform capabilities that general solutions may not adequately address



Change management critical

Technology success depends as much on user adoption and organizational change as on technical capabilities



Regulatory readiness

Proactive compliance capabilities enable faster adaptation to evolving regulatory requirements



Resource optimization

Electronic systems enable high-value personnel to focus on analysis rather than administrative tasks



Conclusion

Robling Medical's ongoing digital transformation demonstrates that strategic vendor selection, disciplined implementation methodology and partnership-focused relationships enable significant operational improvements while positioning organizations for future capabilities. The combination of immediate efficiency gains and long-term strategic positioning validates investment in comprehensive quality management platforms.

The white paper reveals that success factors extend beyond technical capabilities to include vendor

partnership approach, implementation methodology, change management strategies, and data quality foundations. Organizations considering similar transformations can leverage these insights to improve their own implementation success while avoiding common pitfalls.

Most importantly, this transformation positions Robling Medical as a leader in contract manufacturing quality management, providing competitive advantages through superior operational efficiency, customer service capabilities, and regulatory readiness in an increasingly demanding marketplace.

This white paper is based on comprehensive interviews conducted in May 2025 as part of IQVIA's customer success documentation initiative. Robling Medical's experience provides valuable insights for medical device companies considering digital transformation of their quality management processes.

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