



Seraph.

Seraph Medical Device Services

Repeatable, Flexible World-class Operating Methodology

Rapidly evaluate situations, uncover opportunities for performance enhancement, and maximize financial potential. Our experts create a strategic go-forward implementation plan designed to accelerate value creation and build lasting stability.

SERAPH ASSESMENT AND SERVICES

Comprehensive Tools & Experience

When time is critical, medical device manufacturers can't afford delays. Seraph's proprietary assessment process delivers fast, accurate insights into organizational health, helping clients solve complex operational challenges. Our hands-on experts work globally alongside manufacturers to enhance factory performance, profitability, and supply chain resilience while ensuring strict regulatory compliance. We drive alignment, develop strategic roadmaps, and execute solutions that lead to long-term operational excellence.

Industry leaders trust Seraph to stabilize operations, resolve capacity constraints, and meet stringent quality and regulatory demands. With deep expertise in QMS, M&A, turnarounds, and product launches, Seraph provides a results-driven approach tailored to the unique needs of medical device manufacturers.

Assessment & Appraisal

Seraph assesses a manufacturer's capability and performance in key business areas: Operations, Logistics, HR, and Quality Management. With over 170 standardized elements, our assessment procedure is both comprehensive and rigorous. Evaluations occur through both shop floor observations and direct discussions and reviews conducted by qualified appraisers.

We evaluate the effectiveness of the plant's production, logistics and Quality Management System (QMS) against FDA 21CFR Part 820 and/or EU MDR and ISO 13485:2016 standards, based on the plant's registration. Our assessment and appraisal is built to identify risks, create a clear understanding of priorities and to provide a recommended approach.

Assessment types

Seraph has two assessment processes:

Rapid Plant Assessment

- 1-day duration
- High-level review of risks associated with a distressed company
- Focus is people, production, quality, and logistics

Manufacturing Assessment

- 2.5-day duration
- Deep, data-driven review of risks associated with distressed company
- Focus is program management, people, production, quality, and logistics

SERAPH ASSESMENT AND SERVICES

Seraph assessments are designed for decisive action, structured as below:

1	Assessment Scope & Team
2	Executive Summary
3	Key Takeaways, Issues and Risks
4	Recommendations & Action Plan Overview
5	Situation Context & Detail
6	Next Steps

Comprehensive Services



Quality Management

Seraph preserves the health and longevity of medical device companies facing significant challenges. Our extensive playbook of strategies delivers effective solutions for issues such as Non-Conformance & CAPA Management, reducing the cost of poor quality, permanently resolving and addressing customer complaints, mitigating potential citations, and managing product recalls.



Refinement & Turnaround

When medical device operations struggle, our teams provide focused support to restore stability and profitability. We create comprehensive convergence plans that align teams and management to achieve target KPIs. Through hands-on leadership, we maximize production line performance and capacity, streamline material flow, and optimize supply chains to ensure compliance, customer satisfaction and financial sustainability.



Mergers, Acquisitions & Spinoffs

Our practitioners help clients mitigate risk and position medical device transactions for success. We create practical value-creation plans that identify clear paths to improved profitability. Our thorough analysis uncovers operational failure-points and opportunities, empowering you to negotiate with confidence and accelerate post-deal objectives. From diligence through post-merger carve-outs or integrations, we bring energy and expertise to ensure success.

SERAPH SERVICES



Relocation and Consolidation

Seraph has successfully transferred and consolidated hundreds of production lines while ensuring uninterrupted supply to our clients' customers. We establish dedicated workstreams for both products and processes, with clear management and governance steering committee. Our structured approach ensures compliance throughout the transfer, including MDR completion, equipment and process validation, Risk Management Plan updates, and supplier qualification.



Project Management

Our project-based engagements are handled by industry leaders supported by functional experts. Our dedicated project management team collaborates closely with your leadership to establish and track milestones, schedule and drive activities, and manage resources. Examples of projects we handle include IQ, OQ, and PQ equipment validation; Non-Conformance/CAPA Management; QMS Process/Procedure Development; Supply Chain Management; and Quality Assurance and Control.



Production Data Collection

Seraph's Operational software empowers your team with real-time transparency, allowing for immediate detection of downtimes or deviations from the plan, enabling early intervention or plan adjustments as needed. Achieve greater efficiency by sustainably improving manufacturing processes. Optimize resource planning by maximizing utilization, considering availability, performance, and quality (OEE).



Logistics

Our team of supply chain and logistics experts leads transformation initiatives to give your organization a competitive advantage. We use both strategic and tactical approaches to ensure sustainability across all functions, covering supplier selection and development, traceability, UDI, lean material flow, SIOP, regulatory compliance, and other critical areas.



Strategy

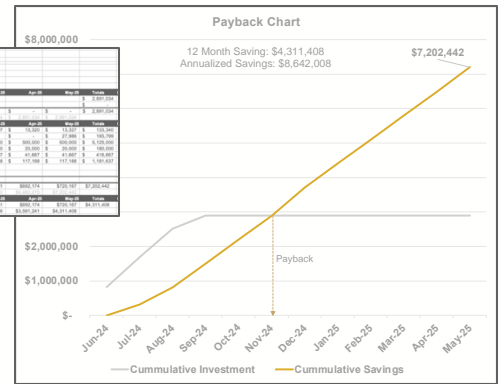
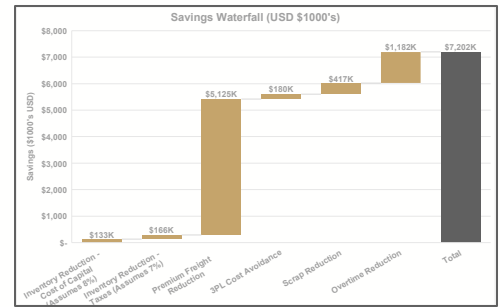
Whether tasked with developing a comprehensive strategy or enhancing an existing strategy, we address the unique complexities of the medical device industry. Our expertise lies in transforming challenges such as stabilizing growth, optimizing resource allocation, improving profitability and cash flow, and ensuring supply chain resilience into clear, actionable steps.

SERAPH ASSESSMENTS

ROI vs Cost

Our team proactively identifies potential savings during the assessment and compiles them into a structured list. Once the project cost is determined, we update the ROI table with the cost to implement and projected monthly savings. The Savings Waterfall and ROI vs. Cost charts are generated to provide an overview of the investment opportunity.

Item	Current Observation	Estimated Annual Cost Savings	Estimated Cost Flow Impact	Estimated Cost Avoidance	Comments
Facility Overview					
Est. Annual Revenue					
Estimated Total Sq. Ft.					
Total Headcount (Direct and Indirect)					
Facility Performance (OEE)					
How much downtime is in experience					Number One cause of downtime: Accounted for in the OEE reduction
Logistics IT?					
Management: Storage IT?					
How much is the Quality Loss in OEE					
Material: Storage IT?					
Return %					
Performance Loss					
Labor Cost Estimate					
What is the RTM - Direct Labor					
Current HC - Direct Labor					
What is the RTM - Indirect Labor					
Current HC - Indirect Labor					
How much Overtime is being worked					Overtime Reduction: Sunday
Inventory					
What is the Target Inventory					
Current Inventory					
Obsolete Inventory					
What was the last Physical Inv. White-off					
Cost Savings for Sq. Ft. if appropriate					
Extended/Segmented Cost					
Premium Freight					
Customer Charge Back - Mixed Delivery					
Customer Charge Back - Quality Issue					
3rd Party Quality Cost (Quality Walls, Stock walls, etc.)					
External Warehouse Cost (for trailers)					
Additional External Warehouse Cost					
Additional Capex Avoidance (Equipment, Plant Expansion, etc.)					



Final Client Package: Rapid Insights

Assessment Report

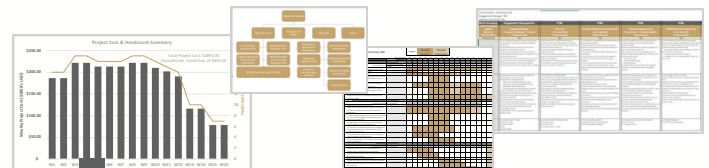
Target 24-48 Hours after assessment



Assessment Questionnaire

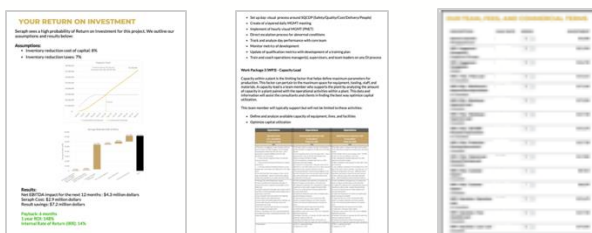


Work Packages and Timeline



Proposal

Target 72 Hours after assessment



ROI vs Cost



SERAPH'S FOUR-PHASED APPROACH

Seraph leverages a four-phased approach to enhance manufacturing operations. We implement a plan with clear deliverables, escalation, and goals to drive the project, enabling your management team to concentrate on effectively running your business without distraction.

1

UNDERSTAND

- Rapid assessment
- Detailed capacity analysis
- Evaluation of organizational structure, planning and material tracking processes
- Evaluation of production, logistics, and quality processes

2

STABILIZE

- Implement key KPIs with clear visual management
- Isolate and address key problems
- Create a detailed recovery action plan and cadence
- Secure on-time customer delivery

3

SUSTAIN

- Set management cadence and install key fundamental lean elements & tools
- Coach and build client management team
- Focus on profitability improvement
- Establish standard work and Leader Standard Work

4

TRANSITION

- Capture and communicate lessons learned
- Create and execute transition plan
- Hand off improvement program to client team

A plan with **clear deliverables, escalation and goals** drives the project while your management team focuses on running the business.

CONTACT US

**Navigate your challenges and market with a tailored plan
— connect with our experts today.**

Partner with Seraph to develop strategic action plans, streamline operations, optimize resources, and drive scalable growth while maximizing efficiency and compliance.

Discover how Seraph's manufacturing expertise can be your strategic partner in optimizing operations, maximizing value, and driving profitable growth.

Visit our website for more information.
www.seraph.com



Learn more about Seraph's research, insights, projects and the companies that trust us to drive their success.

Follow us on LinkedIn to stay updated on how we're transforming industries.

www.linkedin.com/company/seraph-consulting-inc/

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