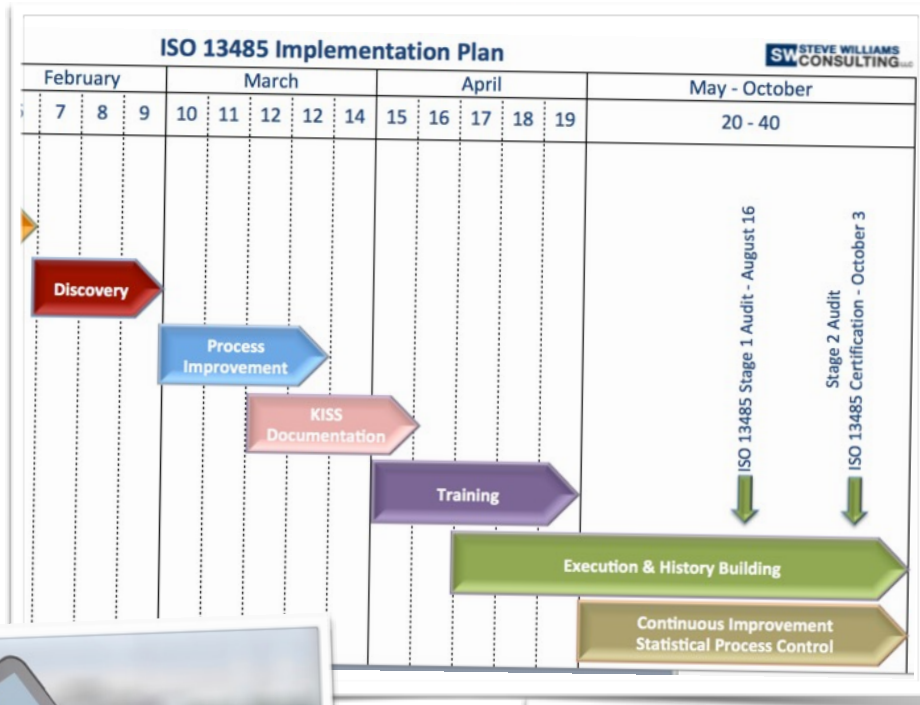


Case Study

ISO 13485 QMS

Medical Device Contract Manufacturer



- Top five ISO benefits
1. Reduced scrap and rework
 2. Improved internal communication
 3. Increased productivity
 4. Fewer customer complaints
 5. Increased top-line growth

COMPANY

Midwest Products & Engineering Inc. is a private equity-owned medical cart manufacturer with extensive internal sheet metal fabrication capability with operations in Milwaukee Wisconsin & Monterrey Mexico. The company supports a limited customer base consisting of industry leading medical device OEMs. The company has annual sales of \$42 million, employing 165 employees across both facilities. Years in business: 36.

CHALLENGE

The organization had been ISO 9001 for 12 years, but pressure from their medical OEM customers to become ISO 13485 certified was dramatically increasing. The company's current quality management system (QMS) had grown into a cumbersome, complex paper monster that was difficult to manage and maintain. The documentation system had no linkage or intelligence built into the number and naming conventions, which created problems identifying all appropriate documents during revision changes.

Every customer and ISO audit resulted in the company adding minor, discrete "bolt-on" changes to the QMS that continued to grow the system, but also made it more difficult for employees to execute with constant changes. Many ISO 13485 specific processes needed to be created from scratch, such as Regulatory Affairs, Management, Process Validation, Voice of the Customer, Risk Assessment, & Device Master Records & Device History Records.

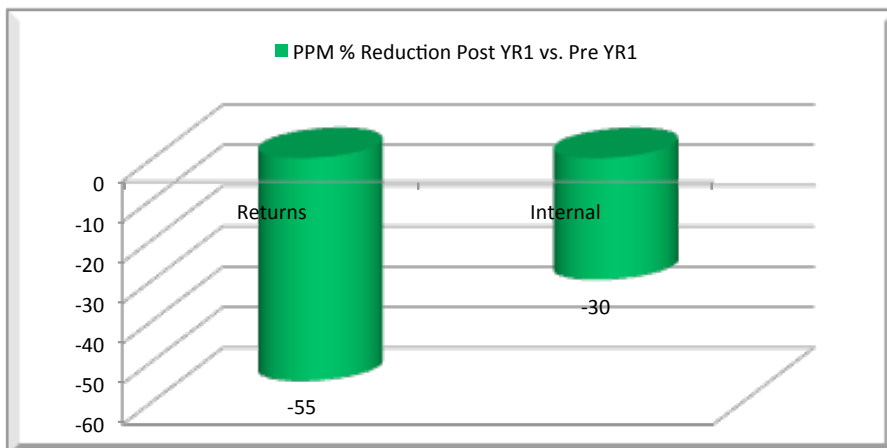
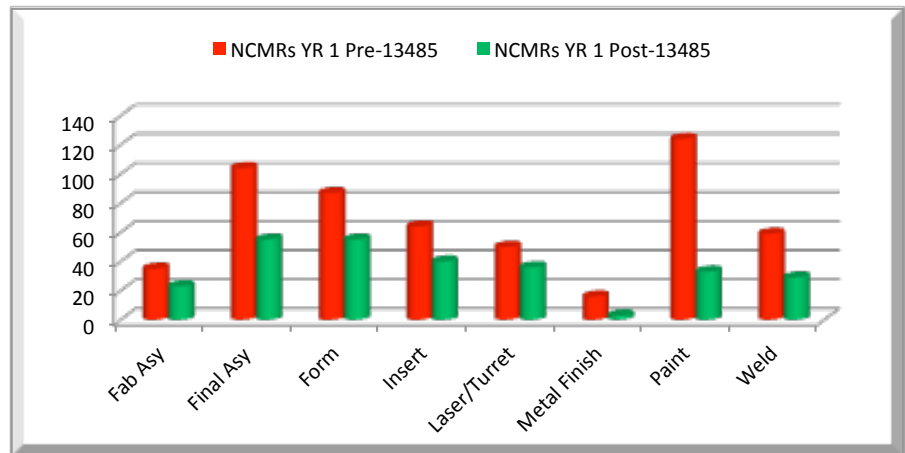
The first step was to perform a thorough QMS & business process assessment. The key to an efficient & effective QMS is to develop one that exceeds ISO & customer expectations so that it does not need constant changes to react to unfavorable audit feedback. Minor continuous improvement is expected and encouraged, but ongoing fundamental changes are not.

Through facilitation, coaching and education of the company's existing workforce, the following seven steps were implemented. During transition of the company's QMS from 9001 to 13485, improvement was realized across all business processes.

1	Created OpX Teams Crews (departmental Operational eXcellence Teams)
2	Discovery Process (capturing existing documentation, processes, tribal knowledge)
3	Process Improvement through facilitation of the OpX Teams
4	KISS Documentation to simplify, streamline & intelligently organize all documentation
5	Development of Certified Operator Program, workforce training and execution to the new QMS
6	Execution to new QMS including multi-faceted Early Warning Feedback System
7	Sustain through robust Internal Auditing Program & Continuous Improvement Program

From a system standpoint, the QMS was greatly simplified, going from over 380 documents (procedures, forms, checklists, etc.) to 150. Visual & naming linkage was implemented during the KISS Documentation transition and a defined document control & management process was implemented. The internal auditing program is driving continuous improvement in the system, and the VoC feedback has focused the organization on what really matters, the customer.

From an organization performance standpoint, dramatic improvements have been recognized across all functions of the operation.



TESTIMONIAL

“Steve Williams has been instrumental to MPE in many ways. Steve used his experience and expertise to implement a comprehensive Quality Management System that has made a very positive impact throughout our organization ... and for our valued customers. He engaged everyone in the company in a positive manner and asked for their input and buy-in. Secondly, he led the process to achieve ISO 13485 Certification, which is the implementation of processes to design and manufacture medical devices. Finally, he created the development of Operational Excellence Teams (OpX) throughout our manufacturing facilities.

Under his guidance, these Teams drove improvements in productivity and helped reduce costs and scrap. Steve is a very strong leader with excellent communication skills and process improvement expertise. He is a well-recognized speaker and writer on business topics. He has written very practical articles and books on lean, quality, continuous improvement, and operational excellence. I rely heavily on Steve for insights, advice, and best practices to improve our operation and our service to customers globally.”

*— Gary R. Les - CEO / President, MPE Inc.
Milwaukee WI, Monterrey Mexico*