

CASE STUDY



Building an Enterprise  
Quality Management  
Ecosystem for the  
Long Haul



Leveraging powerful processes to build a quality management system to increase accountability, generate meaningful data, and drive continuous improvement.

Highline Warren is a leading national manufacturer and distributor of consumable and maintenance products with 27 facilities, over 1,700 employees, and revenue exceeding \$1B. The company carries over 24,000 products including exclusives such as Mag 1<sup>®</sup> oil and lubricants, Rain-X<sup>®</sup> windshield washer fluid, and Prime Guard<sup>®</sup> products. The company is headquartered in Memphis, TN.



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*Michael Hansen  
Senior Director, Quality  
Assurance and Regulatory Affairs*

### MAKING THE DECISION TO MODERNIZE QUALITY PROCESS AUTOMATION

The decision to automate quality processes often happens when staff become overwhelmed by manual processes, resulting in errors, gaps, and overall lack of control and efficiency. At Highline Warren, two foundational quality processes initially stood out as those most in need of automation: document management and corrective and preventive actions (CAPA).

**Document Management:** All documents (forms, SOPs, etc.) were managed by one person within a segregated system. Most of her time was spent sending emails, making phone calls, and searching for people to complete the review and approval process.

**Corrective Actions:** The CAPA system was paper-and-pencil, and managed within an Access database. CAPAs were printed and manually distributed. Next, the hand-written responses were entered into the database.

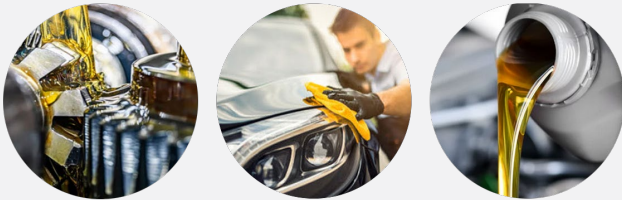
Managing these quality issues was resource intensive. Facilitating input, approvals, and changes took a disproportionate amount of time. In addition, manual processes made it hard to track accountability along the quality chain.

### CHAMPIONING FOR QUALITY

When a system is "working," albeit not as efficiently as it could, it takes a bit of perseverance to get management buy-in for a new system. However, Michael Hansen, Senior Director Quality Assurance and Regulatory Affairs at Highline Warren, recognized the efficiencies that automation would facilitate to speed product and process improvements.

"I was persistent," explained Hansen. "It's important to consider the amount of time consumed by manual tasks. Automating your processes frees up your staff's availability and allows them to focus on more value-driven activities. That's what computers are for."

Over the last 12 years, Highline Warren has leveraged AssurX to continually expand and update its quality system as guided by internal needs, industry changes, and ISO standards.



Highline Warren performs extensive analytics with quality data from the AssurX QMS. Data is utilized to spot trends, solve problems, and provide insights for continued process improvements.

## **IMPLEMENTING THE ASSURX QUALITY MANAGEMENT SYSTEM**

Once the go-ahead was given to implement the AssurX platform, Hansen and his technical team hit the ground running. The company used its own internal expertise and engaged with AssurX Professional Services to collaboratively implement the system.

Due to the nature of the industry and a wide range of product lines, Highline Warren used AssurX out-of-the-box forms as a starting point. Unique product lines required unique workflows, which were made possible by AssurX's extensive configurability. The company started by deploying document management and CAPA, and over the last 12 years has continually expanded and updated its quality system as guided by internal needs, industry changes, and ISO standards.

*AssurX is used to manage:*

### **Corrective Action Requests (CARs)**

AssurX configurability enabled Highline Warren to create a multi-layer CAPA approval process that aligns with the company's specific objectives. "For our needs, the process works, although it may not work for other customers. We put a heavy emphasis on root cause analysis and our corrective action requests," explained Hansen.

### **Document Management**

Highline Warren takes data integrity seriously. With AssurX, document revisions and changes are managed in a closed loop. The cost and time associated with manual errors, wrong document usage, and long cycle times was eliminated.

### **Manufacturing Deviations/Incident Tracking**

The CAR process is designed to successfully identify threats to quality. CARs begin by addressing deviations with a solid investigation process built around highly structured root cause analysis. Statistics are utilized to assess trends and identify areas for continual improvement.

### **Environmental and Safety Tracking**

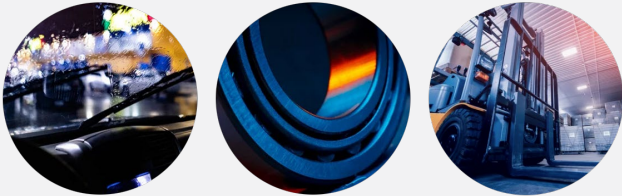
Additional configured solutions for environmental and safety occurrence management were integrated into the AssurX platform as well. Users track and manage incidents in a collaborative way that connects all required information. Consistently classified and secure processes contain all incident details with a full audit trail. All records become accessible and reportable (based on permissions) in the AssurX system.

### **Complaint Management**

In this unique configuration, complaints are considered "external CARs." Customer service has the authority to record any complaint that comes directly from a consumer or a customer. All pertinent information is gathered during the complaint intake for thorough investigation and remediation.



The implementation of AssurX for document management and corrective action requests resulted in an estimated savings of **at least 20 personnel hours per week.**



“The way AssurX assigns tasks and reminders was exactly what we needed...The automation of email reminders alone keeps the user community task-oriented and accountable.”

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Senior Director, Quality  
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## KEY BENEFITS OF THE ASSURX QUALITY MANAGEMENT PLATFORM

### Accountability

By nature, automation drives accountability for quality tasks. “The way AssurX assigns tasks and reminders was exactly what we needed,” said Hansen. The automation of email reminders alone keeps the user community task-oriented and accountable.” With automated alerts on tasks, authorizations and escalations, employees are held responsible for working in line with the QMS to achieve organizational goals.

### Efficiency

Hansen estimates that after the initial implementation and training on AssurX Document Management and CAR, time spent on manual activities was reduced by **at least 20 personnel hours per week.** With greater control over process execution, the quality team is more productive and able to focus on higher value tasks.

### Visibility into the State of Quality

For high-level insight into the state of quality issues, Highline Warren uses multiple dashboards for each unique product line. Each provides a clear snapshot of KPIs to identify any issues that may require escalation. Reports can be accessed directly from the dash at the click of a button.

Highline Warren performs extensive statistical analysis of quality data to proactively spot trends, solve problems, and provide insights for continued process improvements.

### Alignment with ISO Quality Standards

All processes are designed to meet ISO 9001 quality management system standards. In addition to employing key software functions including audit trails and electronic signatures, ISO best practices drive the focus on production quality. Everything done within the integrated system is done with purpose, from improving the customer experience, to engaging the enterprise as quality stewards, to making evidence-based decisions.

## CONCLUSION

By leveraging the benefits of an automated, configurable quality management system, Highline Warren backs up its commitment to quality with robust processes designed to promote continuous improvement. Highline Warren uses AssurX to enforce industry and organizational standards, and create opportunities to improve customer and consumer satisfaction. What started as a few much-needed process automations ultimately evolved into an integrated, collaborative quality ecosystem that will continue to scale to meet the company’s future needs.

SEE ASSURX IN ACTION.  
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