

Go Digital. Transform.™

Ensure material validations, track ongoing quality audits, maintain regulatory compliance.

Elemica

Case Study



CLIENT PROFILE

Industry: Plastics

Employees: 500

Revenue: \$108 Million

Elemica Solution: Elemica Quality



ELEMICA QUALITY COMPONENTS

Supplier Quality Management

Traceability and Compliance

e-CoA (Electronic Certificate of Analysis)

Manufacturing Quality Management

Achieving Growth in a Competitive Global Market via Supply Chain Quality Assurance

COMPANY OVERVIEW

The Industry

For over 40 years, Handgards, a privately owned company located in El Paso, Texas, has been a North American leader for foodservice plastic disposables. Today Handgards employs around 300 people in its own 250,000 square foot facility.

The Customers

The company supplies schools, prisons, colleges, hospitals and institutional feeders. In addition, the company services a number of commercial accounts at the regional and national level, providing more than 800 products through its sales force of over 120 independent salespeople.

History

Founded in 1959 as PlasticSmith, the company changed its name to Handgards in 1966.

In the beginning, the company supplied disposable gloves for hair-care product manufacturers, department stores and mail order houses, as well as veterinary, laboratory, physicians and safety supply houses.

INNOVATION AND GROWTH

First to introduce disposable gloves

Handgards was the first company in its industry to introduce disposable polyethylene gloves to the school foodservice and food processing trades. The use of these gloves was soon adopted by the entire



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foodservice industry to prevent contamination through food contact with the hands of workers.

Innovation in saving food and time

The company developed new lines of food storage and handling bags that not only protect products but also save time, both of which are so critical in any processes that relate to food.

Expanded processes to manufacture products for specialized applications

Handgards has expanded its manufacturing processes to allow the company to develop additional products for school foodservice applications. These now include a wide variety of High Density Polyethylene (HDPE) fast-loading sandwich bags for both hot and cold applications, food storage and freezer bags, as well as aprons.

The fundamentals

The fundamental commitment of the company is to make sure that each product is top quality, protecting the health of people, as well as the reputation of the company.

Protecting customers and brands

Beyond that, Handgards is acutely aware of how important it is for their customers to protect their own customers and brands. Recent events demonstrate that when a problem occurs, the headlines invariably feature the most famous brand involved, with a less-known supplier named as a footnote. Handgards is intensely aware that their customers depend on Handgards to not only deliver a quality product, but to also make sure that their brands are not sullied by human rights abuses (such as child labor violations) anywhere in the supply chain managed by Handgards.

Quality management, the top priority, depends on data management

All these conditions, against the background of growing government as well as consumer demands, mean that quality management is key to Handgards' continued success.

To stand behind this commitment requires the ability to manage data. It is the data that not only reflects the activities assuring quality and compliance, but also allows the company to intervene in negative practices, and reward good performance. To deliver on this commitment means the data management system must be efficient, as well as cost-effective.



HANDGARDS SUPPLY QUALITY MANAGEMENT BEFORE ELEMICA QUALITY

The three areas Handgards manages in the general domain of quality include:

1. The "Quality" side of the business (manufacturing specifications).
2. The "Compliance" side of the business (meeting regulatory standards and reporting requirements)
3. Social assessments (certifying that human rights standards are not being violated, for example that no child labor is being used to manufacture their products.)

Managing quality at Handgards must address the fact that 75% of finished products sold come from overseas independent suppliers, while 25% is manufactured in El Paso.

Managing variability in processes, sizes, capabilities, languages and cultures

Although the quality processes employed across the supply chain are similar, the day-to-day management of quality is nevertheless performed locally by the quality departments of the suppliers. The suppliers themselves vary in size, with varying capabilities. This makes it important to be proactive in order to have consistency in achieving and maintaining high quality standards.

To that end, Handgards employs five China-based consultants who regularly visit their suppliers. They not only validate that the products are being made to Handgards specifications, but also make sure that products are being manufactured in clean and well-maintained facilities, consistent with food level, and in some cases, medical grade products.

How it was done

Before using Elemica Quality, Handgards would send suppliers a list of the information they needed to provide, and request they submit COAs (Certificates of Analysis) for each batch of product.

Some suppliers have the additional challenge of complying with FDA requirements for medical devices because although the products, such as gloves, were to be used for food services, some of Handgards' clients ask that products meet even higher, medical device standards. This meant that Handgards 'raised the bar' on reporting requirements for these suppliers.

In general, the company's requests (keeping in mind the three general areas) cover

- Product specifications
- Manufacturing methods
- Testing methods
- Labeling requirements

Suppliers were, and still are, expected to supply the documentation certifying compliance in all these areas. This resulted in a large volume of documentation requiring constant Handgards review along with meticulous data management.

MOTIVATION FOR A CHANGE IN APPROACH

Increased number of products and orders Handgards' business has continued to grow every year. The requirements continue to increase as does the sheer volume of suppliers and products the company sells.

Before changing their methodology, Handgards received COAs from every supplier as well as from an array of laboratories, using e-mails.

With hundreds of products arriving from overseas suppliers (many of them making the same items) managing the data became an overwhelming task.

"We had to work with 45 suppliers who could be making 800 products, all with different lot numbers. Volume increased.

We were getting a COA from every supplier for every product for every lot. It was very time-consuming, but suppliers knew it was necessary because of the medical level requirements."

– Ana Ramos, VP of Quality, Handgards

If the suppliers were producing vinyl gloves, they were required to list each ingredient used in their manufacture. If an item required ten ingredients to make, the suppliers needed to produce certifications for each of the ingredients, not only for the final product itself.

Multiple formats

Handgards gave suppliers a standard template, but while each of the suppliers was able to produce the documentation, they adjusted the data itself, based on their internal conventions.

In addition, suppliers sent documents in a range of formats. Some of the documents arrived as images, some came as PDF files, and some were Excel spreadsheets. In the beginning, some sent their data to Handgards in their own language, so that each document needed to be translated.

Initial approach: Excel spreadsheets

"In the beginning, we were more focused on production, rather than on the documentation that came with the level of management we were committed to having.

We began with the clearest, most basic system: the data relating to all three domains (quality, compliance, social assessments) was managed using Excel spreadsheets."

– Ana Ramos, VP of Quality, Handgards

Limitations and challenges

One of the major limitations of this system was the barrier to applying Statistical Process Control (SPC.)

In order to make trends visible, data would need to be re-typed into a format that could populate a system with SPC capabilities. There was nothing in the system that could tell Handgards management quickly if materials were in- specification or out.

The company was faced with developing specialized spreadsheets. If, for example, Handgards received 10,000 batch COAs during the year, they needed to see if they had, in fact, received 12,000 batches but had only received 10,000 COAs.

“We crashed the system”

As Handgards developed the spreadsheets, and the number of orders and items and lots grew, the data became so massive that the flow of data eventually ended up “crashing” the system. One day, the company was unable to access the quality data because they could not open the spreadsheets.

A system that had appeared to serve the company well, at little cost, was now breaking down.

Even before the “crash”, it was clear that accessing necessary data had become too slow and cumbersome. To limit the sizes of files, the data had already been broken up into several spreadsheets. Anything that required checking a complete set of data about any single item required referencing several spreadsheets.

This process was time consuming and labor- intensive.

Quality data generated at the receiving end

Before implementing Elemica Quality, every time a single batch arrived in Handgards' warehouse, the quality inspection group checked/tested the product to ensure it met specifications. As a result, this team itself was generating a volume of quality data upon arrival, matching the volume that the suppliers were sending along with their products.

“The COAs might have 10, 20 or 30 data points of information, and we validate the same data points for the 10,000 products when they arrive. We’re talking about 20,000 different documents, with many testing points in each one of them. It was a massive amount of data that takes a lot of work to summarize in a way that is meaningful to either your suppliers, or for your own company, to help decide whether something needs to be inspected tightly, or inspections could be reduced because of an outstanding quality record.”

– Ana Ramos, VP of Quality, Handgards

While Handgards was in possession of all the required data, it took the work of several people and a lot of time to make that data usable.

New compliance requirements

On the compliance side of Handgards' data management, the company was facing a growing volume of documentation requirements.

“When we started out, no one in our industry was required to submit any of it. Our approval process now requires not only information about price and specifications, but a checklist of documents attesting to the fact that they are complying with the regulatory requirements to which we are held in the United States.”

– Ana Ramos, VP of Quality, Handgards

Because some of the products Handgards produces are considered “medical equipment” Handgards requires Certificates of Guarantee from their suppliers. These Certificates declare that the suppliers' products meet FDA and other regulatory requirements. Along with these come contact lists showing employees, positions, copies of all their certifications, and copies of audits. Preferred suppliers also sign codes of conduct, and submit written acknowledgements of the specifications for every product. In addition, they submit the formulation of every product they will produce for Handgards, as well as the material safety data sheet for every ingredient they have listed in the formula.

Customer requirements

Customer requirements were a significant motivation to speed up the process of upgrading their capacity to manage quality data.

“Food borne illnesses are nightmares for food producers, so they are a nightmare for us too. Many new customer-driven requirements appeared. We knew they were coming – and could not support the process. We had the data, what we were lacking were management and meaningful dashboards. Timelines were a major challenge.”

– Ana Ramos, VP of Quality, Handgards

HOW THE DECISION TO TAKE ACTION WAS MADE

Handgards, in reviewing the various ways management could respond to the new challenges, considered the following factors:

- Handgards had grown significantly, with both a bigger supplier network, and more clients.
- Handgards reiterated their commitment to quality as the bedrock of both serving their individual clients and maintaining industry leadership overall.
- The challenge of managing quality (along with quality data) was growing as fast as the company's client list and orders.
- Demands for higher quality standards were growing, both from the consumer side, and from the regulatory side.
- Both of these demand forces meant that more data was being generated for each product produced as well as for each client served, and for each regulatory requirement met.
- The method of managing the data was key, and making sure that it could be efficiently transformed into actionable knowledge through SPC was now paramount.

Handgards saw the above as the main reasons for improving their system of managing quality data that relied heavily on supplier quality assurance.

First steps

Initially, Handgards' management moved toward simply making the system in use more robust, i.e., by adding programs that would expand the capacity of individual managers to do their jobs more quickly and efficiently.

However, once the IT department was included in the process, the search moved in another direction. The IT department conducted a search to identify a comprehensive approach that would add a number of

capabilities to Handgards capacity for managing quality, the key being the capacity to quickly and effectively perform Statistical Quality Control. Another important requirement was that the system would manage all documents flowing in and out quickly enough to allow the quality professionals to intervene in a timely way when a threat was detected.

The IT department identified Elemica Quality and, after reviewing a number of other companies, selected Elemica Quality.



IMPLEMENTATION

Suppliers' and co-manufacturers' responses to implementing Elemica Quality and the process of getting them on board

The most surprising aspect of implementing the new system was that it was much easier than Handgards expected.

One of the reasons for this was that Handgards employs several China-based consultants who function as representatives of the company.

Because of the language and cultural barrier, this was an important aspect of how successful the implementation turned out to be. Handgards included the consultants in the entire process in advance. They understood all aspects of the program and were able to give valuable input to the process. In turn, they were able to help Handgards with generating realistic timelines and other kinds of input to cross any barriers based on distance. Because the consultants were able to have face-to-face conversations with Handgards suppliers, and because they fully understood the requirements, they contributed to making the process smoother than Handgards management expected.

“With that being said, it was still not easy. Some of the suppliers are larger, with more staff that included English speakers. Some are very small, and have only one English-speaking person on their staffs. The (Elemica Quality's Supplier) interface in Mandarin helped to put them at ease.”

– Ana Ramos, VP of Quality, Handgards

Handguards' suppliers were used to what they were doing; they had their own, long-established processes. In spite of that, they began to use Elemica Quality.

“They began to see that we had not asked them to change that much.”

*– Ana Ramos,
VP of Quality,
Handguards*

Handguards began to see from the data flowing in just what the effect of any lack of attention could be. This allowed the company to create additional programs. For example, IT was able to create a program so that every order was picked up and placed into Elemica Quality. This now allowed Handguards to do a nightly comparison between what had been ordered and what had been delivered. If orders were expected, then there should be COAs for review just before shipment. If COAs were not available for review, it was now possible to remind the suppliers not to ship the order until Handguards could review the COA. In addition, the system quickly allowed Handguards to sort

out the problems
related to any



inconsistency of quantities or lot characteristics, which had made it difficult to match test results with the inbound products. When the previous system was lagging due to the slowness of data entry, there had been problems in this area.



An additional effect of the implementation of Elemica Quality on functions beyond quality (to date) includes audits, which generally require everyone's participation and have become much easier. Elemica staff created questionnaire templates for Handguards, which replaced the paper forms in use before Elemica Quality implementation. Since clients require that all paperwork related to audits be stored for several years, this created a large amount of physical storage space. Since Elemica Quality is now the repository of this information, the space is no longer necessary.

“We stopped doing things in paper.”

Everyone is excited about transitioning to data management. Even the janitors are getting excited about going digital. One of the most valuable aspects has been in the domain of being members of an industry. We now have the ability to present a very good dashboard; we can show what we are doing on the scorecard that is part of the Elemica Quality program. This means we can empower suppliers by giving them feedback.”

– Ana Ramos, VP of Quality, Handguards

CONCLUSION

The Handguards implementation of Elemica Quality has enabled them to save time, reduce costs and provide better quality assurance than ever.

They are in the process of expanding Elemica Quality use to domestic manufacturing. An updated version of this case study will be issued to reflect the comprehensive results of the implementation of Elemica Quality.

About Elemica

Elemica is the leading Digital Supply Network for the process manufacturing industries. Elemica accelerates digital transformation by connecting, automating, anticipating, and then transforming inter-business supply chain processes for the products they buy, sell, move, and comply. Launched in 2000, customers process over \$500B in commerce annually on the network. For more information, visit www.elemica.com.

How Elemica Quality Works....

Elemica Quality fills the void left by most enterprise applications. Elemica Quality collects, stores and analyzes material parameters and production settings to improve manufacturing yield. Elemica Quality's knowledgebase of raw material characteristics and process variables allows manufacturers to correlate input cause to output effect. This correlation allows manufacturers to proactively prevent disruptions, resulting in improved yield by reducing waste.

At the same time, Elemica Quality improves the relationship between the licensing company and its supply base. The supply base is managed via easy-to-access web-based portal technology for regulatory and industry certifications. Procurement professionals gain data-driven insights into supplier performance for more effective sourcing. Plant operations management exerts more control over material variability, increasing yields and return on assets.

Research and Development personnel gain visibility to supply chain compliance with material specifications (raw, WIP, finished products) and can adjust interactively as internal or market conditions dictate. Instead of focusing on interruptive issues that reduce supply chain effectiveness and profitability, quality professionals using Elemica Quality have a system resource for proactively driving process improvement that supports operational excellence.



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A System of Savings

PLANT-LEVEL SAVINGS

Reduced Testing - Reduced costs associated with testing of incoming raw materials based on supplier confidence from online Elemica Quality compliance knowledge with automatic SPC and time trends analysis. Includes reduction in test equipment and consumable savings.

Reduced Non-Conforming Material - Online shipment validation of material specification prior to materials being shipped by the supplier reduces wasted time and money dealing with out-of-spec materials.

Reduced Waste - Reduced manufacturing waste caused by supplier material quality variability. Automatic SPC, PPK and time trends analysis on incoming materials reduce unexpected results in the manufacturing process reducing defects, unusable lots and wasted materials and associated disposal and reclamation costs.

Reduced Regulatory Documentation - On-Line CAR/CAP, Supplier Development, Audit, and Statistical Analysis data reduce the manual generation, tracking, management, storage and archival of quality records required for Regulatory Compliance. Also realize a reduction in CAR/CAP, audit and quality record storage and archival.

Simplified Cost Recovery - Online Cost Recovery automation simplifies the ability to track and analyze the costs incurred due to a supplier's non-conformance and quality issues. These charges may be passed back to the supplier.

Simplified Recordkeeping - On-Line supplier-entered COA data eliminates a plant's need to manually enter, file and store COA data. Simplified record keeping and accessibility supports supplier shipment tracking and material traceability. Also realize a reduction in COA storage and archival costs.

Efficient Inventory Management - On-Line Advance Shipment Notification with On-The-Way, Shipment Received or Released Status with date produced supports first-in first-out material management increasing production efficiency.

Efficient Production Scheduling - On-Line Advance Shipment Notification provides material delivery dates supporting more accurate production scheduling; reducing line down time waiting on needed materials, providing increased production efficiency.

Reduced Specification Costs - On-Line management of supplier viewable material specifications and test procedures reduces costs associated with supplier communications and specification management.

CORPORATE QUALITY-LEVEL SAVINGS

Reduced Supplier Oversight - Corporate-wide, on-line, real time view of all suppliers, CAR/CAP summaries, supplier performance reports and audit status simplify the management of suppliers worldwide. Also results in a reduction in documentation storage and archival costs.

Simplified Supplier Ratings - Simplified supplier rating and ranking through on-line supplier quality performance summaries.

Reduced Manual Entry - On-line management of CAR/CAP, Supplier Development, Audit, and Statistical Analysis data reduce the manual generation, tracking, management, reporting, storage and archival of quality records required for ISO/QS/AS and TS-16949 compliance. Also results in a reduction in documentation storage and archival costs.

Simplified Vendor Communications - On-line message of the day and automated supplier notification of CAR, Audit and Quality Manual events reduces mailings, faxes and e-mail to suppliers.

Elemica Quality saves the Goodyear Tire and Rubber Company \$26 Million (USD) annually across 80 plants with an average of \$325K per plant