CASE STUDY:

Finding the Right Quality Fit

medi Manufacturing is one of the world's leading manufacturers of medical compression products, orthopedics, prosthetics and compression sportswear. Headquartered in Bayreuth, Germany, medi applies 60 years of German design, research and manufacturing to garments for people who suffer from venous disease, lymphedema, swelling and varicose veins. medi's products are available through distributors, pharmacies, retailers and hospitals in more than 125 countries.

Quality Focus & Challenge

As a medical device manufacturing company, medi is committed to delivering quality garments that consumers feel safe and confident wearing. At its Whitsett, North Carolina, facility, medi was using its own proprietary software for data collection and quality monitoring in its manufacturing processes. However, error codes in the software produced a large amount of paperwork because operators could not make changes to incorrectly entered information. Making corrections often took as long as an hour and a half, and duplicate data entry created variations in reporting.

Also, in order to maintain compliance with medical safety regulations on technology used in manufacturing, medi needed to validate its software to demonstrate its reliability and effectiveness. The homegrown system was outdated and medi was uncertain if it could satisfy the strict validation requirements. Rather than continue with its homegrown software, medi sought a new solution that could drive quality improvements and increase efficiency, while at the same time facilitating the validation process.

Solution

medi found its answer in InfinityQS ProFicient, an enterprise quality hub powered by a Statistical Process Control (SPC) analysis engine. medi installed ProFicient on its Whitsett facility's terminal server and purchased licenses for 30 users. To provide medi's shop-floor operators with a more intuitive experience, InfinityQS customised and configured ProFicient's graphical user interface. Prior to the "go-live," an InfinityQS third-party affiliate validated the software to ensure compliance with industry regulations. Previously, validation would have taken six months (with medi's own staff), whereas it took only a week due to InfinityQS' thorough template and work instructions to guide the process.

With InfinityQS' Dynamic Scheduler, medi's operators obtain a shop-floor checklist for scheduled quality checks and receive notifications when data collection is needed. Dynamic Scheduler automatically notifies key personnel if data collection is not performed, ensuring quality checks are completed in a timely manner.

To reduce the amount of manual input and ultimately save over 500 labor hours per year, medi integrated a number of its machines with ProFicient, to collect data across its departments, including knitting, dyeing, sewing, finishing, returns and final inspection. medi even integrated some machines to feed measurements directly into the database. A key integration is with the CMD-100 machine, which checks stockings' compression. medi's stockings have multiple levels of compression tolerance that are dependent upon the severity of affliction—it is important to make sure there is not too much compression, which can be harmful.

Solution cont.

In the returns department, quality assurance managers are using ProFicient to track returns and customer complaints, such as whether stockings are too tight or too long, are susceptible to holes, or if they have inaccurate product measurements. medi can then export this information into a graph, like a Pareto chart, to identify patterns and pinpoint which items are producing a high number of returns or complaints. From there, medi can make corrections to the processes involving the products in question.

medi also uses ProFicient in its final inspection department where the company requires 100 percent inspection of its stockings. Inspectors can now easily scan a barcode that pulls a stocking's measurements from the database, which allows them to quickly determine if it passes or fails the inspection.

"InfinityQS ProFicient was an ideal fit for replacing our homegrown quality system. It not only met our initial requirements for software validation and ease of use, but has also extended our data collection and reporting capabilities to support our continuous improvement efforts."

— Sedrick Bigelow, Quality Assurance Manager, medi Manufacturing

Results

In addition to streamlining compliance with industry regulations, InfinityQS ProFicient has helped medi gain control over product quality and safety with a systematic approach to data collection. With this information and advanced reporting capabilities, quality assurance managers are better able to make data-based, informed decisions that drive continuous improvement.

The software has also enabled medi to instill a more preventative—rather than responsive—approach to maintaining its equipment and processes by monitoring error codes and addressing them with Assignable Cause and Corrective Action. Errors codes can help to indicate if a machine requires maintenance or if it is about to break down. If a specific machine is repeatedly producing errors, a report is issued and quality assurance managers can notify mechanics to address the problem before the machine fails. Previously, it took four hours to generate a report, whereas it now takes between five and 10 minutes.

Also, ProFicient has helped medi minimise errors and paperwork by increasing the accuracy and efficiency of data collection. Without the need to correct errors or enter duplicate data, medi estimates that it is saving 300-350 man-hours per year. Moreover, the company achieved a return on investment (ROI) within 10 months of implementing the software.

Looking ahead, medi plans to introduce ProFicient's Data Management System to gather and compare quality-related data from multiple departments for real-time insight into its manufacturing processes. medi also hopes to implement lot genealogy to trace the root causes of quality issues back to suppliers and vendors.

Sedrick Bigelow, quality assurance manager, medi Manufacturing, said, "InfinityQS ProFicient was an ideal fit for replacing our homegrown quality system. It not only met our initial requirements for software validation and ease of use, but has also extended our data collection and reporting capabilities to support our continuous improvement efforts. We are able to use the insight, or Manufacturing Intelligence, acquired from the data we collect to continue ensuring customer satisfaction and safety."

- **Completed software validation in just a week, a task that otherwise would have taken medi's staff six months.**
- **Minimised errors and paperwork by increasing the accuracy and efficiency of data collection.**
- **Enabled continuous improvement through advanced reporting and charts.**
- **Saved the 100-person manufacturing staff approximately 300-350 man-hours a year in data corrections and accuracy.**
- **Eliminated over 500 labor hours per year by integrating many of its machines with ProFicient.**
- **Achieved ROI within 10 months of implementing the software.**