CUSTOMER CASE STUDY

TAPEMARK

Tapemark is a leading-edge contract manufacturer for the global pharmaceutical, medical device, and consumer products industries. They provide innovative converting and packaging solutions through a wide range of flexible materials, integrating coating, printing, die cutting and packaging to maximize product functionality and cost-effectiveness. Throughout its 60-year history, Tapemark has developed core competencies around web handling and understands how to work with roll materials and laminates in tight-tolerance applications. Its strong background in coating and dispensing has enabled more intricate drug delivery applications. Supported single-use drug delivery formats include active and passive transdermal patches, topical patches and pads, soluble film, hydrogel, and Tapemark's patented Snap!® packaging. Tapemark provides medical devices such as test strips, dressings, sensors, and closure and attachment devices, and multi-layer, die-cut components used in a wide range of devices and applications.

Tapemark is FDA-inspected for Drug, Device, Food, and Dietary Supplements and is DEA registered as a Schedule III - V Contract Manufacturer of Controlled Substances. Tapemark is also ISO 9001 and ISO 13485 certified, and MNSHARP-certified. All development and production is completed at its regulated, cGMP multi-building campus, which includes multiple Class 100,000 clean room suites, located in West St. Paul, Minnesota.

The Problem

As Tapemark grew its business from label printing to its global status as a preferred contract manufacturer for pharmaceutical and medical device converting and packaging, its data management system began to slow operational processing in a number of ways. The company was using a mix of computer-based systems, spreadsheets, and manual reports to track and manage its business. Some database fields were text-based and thus not conducive to searching or reporting; other information such as supplier approvals was in hard copy only. Although many of the tools were computer based, there was no integration of the systems in use, making data difficult to sort through and retrieve for production, reporting, customer or audit needs. Through a number of kaizen events focused on its business processes, it became clear to Tapemark that a more robust, consolidated system was critical to support the company's growth. In addition, Tapemark was expanding its ISO, FDA and European certifications and compliance requirements to support its pharmaceutical growth strategy.

Tapemark Goals

After establishing requirements for a solution that would manage Tapemark's increased operational processes and procedures, it was obvious their data management system was hindering operational efficiency and didn't contain the enterprise system integration, quality management capabilities, and database functionality needed. The company also wanted a system that could add value to the company in terms of continuous process improvement. "FDA regulated business itself requires you to do things that are very document-intensive," said John Mahoney, Senior Programmer Analyst, Tapemark. "If it's not properly documented, it didn't happen. The new system needed to be robust so that we could conform to the regulations and allow us the flexibility to streamline our systems and business processes. We also knew we needed a system we could grow into. The list of requirements from all the departments was huge. We required a system that allowed for future implementation of functionality."

Another goal for the new system was to be able to enter data once – and have it proliferate through the company's other systems – to reduce data entry and error, and to have quality data readily available across every department including sales, customer service, manufacturing, and accounting. "We wanted to connect our ERP, CRM and Financial solutions to leverage data across processes," said Mahoney. "This would be especially important for audits." Tapemark currently hosts as many as 25 customer and regulatory audits per year, and the data needed to reside in a system that offered flexible and readily accessible reporting capabilities.

Visit www.iqs.com for more info about software capabilities, to schedule a personalized demo, hear customer testimonials and more.

The IQS Software Solution

After vetting several quality management systems, Tapemark ultimately chose to implement IQS across its three manufacturing facilities due to its comprehensive quality management capabilities and ease of integration with the company's ERP and manufacturing systems. "IQS provided the integrated modules we required for our initial implementation, and allows us to improve our operations using additional modules that we haven't yet implemented. We are currently using about 60% of what the complete IQS system offers, and we have the flexibility to grow the solution as our requirements grow and our processes expand," said Mahoney.

"The system also has to integrate with other systems and processes; if you can't readily use the data you have collected there isn't much added value," Mahoney explains. "We integrated equipment preventive maintenance with our production schedule. Planners know when PMs are due and can plan accordingly." Tapemark also integrated documentation requirements with the production schedule. Timely, accurate access to the latest approved revision of all applicable documents is critical before production can begin. The documentation department has an integrated schedule based on a product's scheduled run date, which allows prioritization of their workload. Mahoney adds, "Most recently, we integrated IQS NCM/CAPA with our scheduling system to identify any Nonconformance's or CAPAs (Corrective Action/Preventative Action) associated with a product, allowing us to increase NCM/CAPA visibility and to reduce the instance of non-conformance in production. This gives us immediate and actionable knowledge for proactively managing production issues and greatly reduces costs associated with wasted labor and materials."

Key Improvement Areas

Implementing IQS led to key improvements in several targeted areas:

- Significant reduction in time required to complete CAPAs, due to improved tracking of associated documentation, root cause analysis, corrective action planning and routing for approvals.
- Visibility to pending work orders with outstanding CAPAs, ensuring resources are focused on the most urgent needs.
- Reduction in CAPAs by over 50%, due to visibility and prioritization.
- Improved manufacturing efficiencies due to more efficient scheduling, a direct result of reduced approval time for CAPAs and various documents.
- Consolidation of systems into one integrated platform, eliminating discrete systems and duplication of data.
- Time to prepare management reviews reduced by over 75%, due to easy retrieval of reports and metrics.
- The ability to generate and view trends on various metrics related to equipment, people, materials, or suppliers.
- The ability to maintain and schedule equipment maintenance and device calibrations.

Immediate Benefits Realized

One immediate benefit to the IQS system includes the reduction of time and resources needed to successfully conduct regulatory and customer audits. In the past, audits took days to prepare and complete but have been reduced to hours due to IQS' ability to immediately generate informative data ranging from maintenance records, non-conformance records, and suppler information. "We leverage IQS as a dashboard for audit meetings, jumping from one module to the next so that customers or officials get a visual understanding through the entire audit session," said Mahoney. "We can also print reports based on the audit data as needed to fulfill their requirements. Our customers have been very happy with this process and impressed with the level of informative data we can produce in real-time."

An additional benefit, not originally anticipated with IQS, is that Tapemark is able to automate and record training requirements associated with the production of a product. "Training has to be proven, so every change to a process or procedure has to be rolled out to employees for training, then recorded before the revised process can be utilized on the production floor,"

Mahoney continued, "IQS easily generates reports that show the production planners which operators are trained and who requires training prior to the production run." In addition, as employees progress in their career and change positions within the company, IQS enables an easy "gap analysis" to see what training is required for their new position.

IQS also manages the audit schedule for every document, including standard operating procedures (SOPs), customer and supplier contracts, and training requirements. If a revised SOP requires retraining, the document owner can easily access the list of employees to be trained. IQS also is a repository for tests to help verify the employees' understanding of each procedure. Even when an SOP has not changed, Tapemark requires periodic retraining of all employees, which is easily recorded and managed in IQS.

Regulatory Compliance

Tapemark uses IQS to manage the following regulatory designations and audits:

- FDA audited as a Drug, Device, Food, and Dietary Supplements Contract Manufacturer
- DEA Registered as a Schedule III - V Contract Manufacturer of Controlled Substances
- ISO 9001:2008
- ISO 13485:2003
- cGMP/QSR Compliant
- Compliance Verification to EU-GMP
- Regulatory support (Master Device Records)
- Security procedures and protocols
- 21 CFR Part 11
- DOE (Design of Experiment)
- Process verification and validation

For customer and supplier contracts, the document owner appreciates receiving automatic notification from IQS of any contracts with an upcoming expiration date. The owner has time to negotiate a new contract or an addendum before any interruption in service.

Today, Tapemark employees have fully embraced IQS and all functional areas rely on the system daily. One feature of IQS, "My To-Do List" has dramatically altered employees' daily tasks. At a glance, each employee can see what needs their attention, whether it be a CAPA, approval of a Document Change Request, a document audit, or tasks from any of the other IQS modules. The prioritized "to-do" list offers easy access to open the associated documents, and supervisors are alerted if the deadline is imminent. As a result, Tapemark has seen significantly shorter approval cycles throughout all its processes.

Continuous Improvement

Tapemark is continuing to implement additional modules and expand use of IQS functionality. The Product and Collect modules are so feature-rich that a cross-functional team has been working for several months on implementation plans. Tapemark sees the Product module as the "hub" of the system, a strong tool that supports the FDA's emphasis on Quality By Design. "We've been very happy with IQS and its features and functionality," notes Marilyn Tucker, Tapemark's Vice President of Quality Assurance and Regulatory Affairs. She concludes, "Tapemark has been lauded for our strong, streamlined quality systems that support both Drug and Device regulations, and we could not have achieved such success without IQS."

IQS, Inc. Headquarters
24950 Country Club Blvd. #120
North Olmsted, OH 44070 USA
(800)635-5901
info@iqs.com
www.iqs.com