MasterControl

Case Study

Flexibility and Audit-Readiness Give Compounding Companies a Competitive Advantage

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Since opening its doors in Quebec in 1989, Medisca has become a leading supplier of pharmaceutical compounding products and supplies to North American, Australian and other international markets, primarily servicing compounding pharmacies, but also hospitals, veterinary clinics and research labs. Its continually expanding product line includes high-quality active pharmaceutical ingredients (APIs); excipients such as bases, oils, colors and flavors; and medical equipment and devices.

Today, with 400 employees and multiple sites in the U.S., Canada and Australia, Medisca thrives in a constantly evolving and quickly growing compounding landscape with ease and confidence thanks to the help of its automated MasterControl solution.

Compounded Medications: The Original Pharmaceuticals

Pharmaceutical compounding is the science of combining individual ingredients in specific strengths and dosage forms according to the unique needs of an individual patient. Dating back to ancient Egypt, it is the oldest form of pharmacy. Compounded medications are essential to patients who are unable to use standard-marketed drugs due to allergies to non-essential ingredients, or those needing a unique dosage amount or alternative delivery vehicle not available in commercial drugs (e.g., a syrup or topical solution for a patient who has difficulty swallowing a capsule). They are also imperative in the event of drug shortages and discontinuations.

As recently as the early 1900s, most medications were still the result of pharmaceutical compounding, but the practice soon gave way to mass drug manufacturing. Today, as the demand for personalized medicine increases, the compounding industry is experiencing a resurgence, and with it heightened regulatory oversight. Companies involved in compounding must be able to manage the enormous opportunity, constant change and potential risk they face in order to be successful.

Commitment to Quality

In an industry where small doses of highly customized medical treatments are mixed and formulated every day – no two the same – quality is a priority but also a moving target. Managing quality and compliance at each point of the supply chain, including the ingredients and supplies that are used to create the compound, is critical to ensuring safety and efficacy.

As such, Medisca has designated quality as a cornerstone of its brand and the responsibility of each employee involved in the product lifecycle. It is also reflected in the company's vision to be the global standard bearer for quality, innovation and service in the compounding industry.

Medisca currently markets over 2,000 products in more than 65 countries and is a U.S. Food and Drug Administration (FDA)-, Therapeutic Goods Administration (TGA)-, and Health Canada-registered repackager/relabeler. The company must comply with current good manufacturing practices (CGMPs) that meet the latest United States Pharmacopeia Formulary (USP/NF), European Pharmacopeia (EP) and British Pharmacopeia (BP) standards, and is subject to many regulations and standards, including FDA, U.S. Drug Enforcement Agency (DEA), Health Canada, TGA, TÜV, VAWD, EudraLex, PIC/S, ICH Q7, ICH Q10, state Boards of Pharmacy, ISO 9001, ISO 13485 and CE requirements.

Challenges of a Manual Quality System

When Quality Project Manager Sarah Murphy joined Medisca 3 ½ years ago, the company was primarily paper based. While this is not unusual for regulated companies, Medisca was quickly outgrowing its manual processes and systems.

"Regulations are constantly changing and the company is growing rapidly," explained Murphy, whose responsibilities include audits, managing external suppliers and serving as Medisca's MasterControl system administrator. "As a result, manually processing paperwork and our previous electronic system were becoming insufficient for our growing needs."

The company also used about a dozen software solutions to manage various parts of its business. That meant data was stored and maintained in disparate systems, making it difficult to access and analyze holistically. It also meant that most employees had to log in to multiple systems on at least a weekly basis, causing inefficiencies and security concerns.

Furthermore, with locations situated globally and an expanding product portfolio, it became increasingly challenging to standardize documentation, systems and processes across the company.

Thus, Medisca began its search for an electronic quality management system that could integrate with its existing systems, and maintain its documentation in a consistent, accessible and reportable manner to improve quality, support company growth, and increase efficiency of audits and inspections.

MasterControl Solution

In 2014, Medisca implemented MasterControl All Access version 10 as a hosted solution. It has since upgraded twice and is currently moving to MasterControl v11.7. Medisca's implementation includes MasterControl Documents™, Training™, Audit™, Risk™, Process™ and Supplier™, with anywhere from 10 to all 400 of its employees using each module. The company will implement MasterControl Projects™ during its upgrade to v11.7.

Medisca relies heavily on MasterControl Documents and Process to collect, store and organize its critical data and documents. To accommodate its unique processes and global requirements, Medisca also uses numerous custom forms, including customer complaints, change control, CAPA, deviations, nonconformance and supplier management.

Anxiety-Free Audits and Inspections

Audits are particularly complex for a company like Medisca, whose product line and global presence is growing in an industry receiving more regulatory scrutiny. And as Medisca expands, the complexity of its audit process only increases.

"Our R&D team has almost doubled in size over the past year. We also have many more proprietary products that are coming out," Murphy said. "As a result, we're looking at different types of submissions, whether it's a device, a new equipment, a chemical or a new face cream, for example. All of these things have different regulations, and keeping track of which regulations go with what and all of the different paperwork that needs to be part of submissions, is definitely a challenge."

But when asked what MasterControl has made easier for Medisca on a day-to-day basis, Murphy's response came without hesitation: "Audits and inspections. That's absolutely an easy answer."

Medisca's audit efficiency has improved since implementing MasterControl, thanks to the immediate accessibility and reporting provided by the system, and the subsequent reduction in time to retrieve required documentation.

Flexibility in the Face of Rapid Change

"Compounding is very much an evolving industry, particularly in North America. We see drastic changes in regulations that can sometimes impact very huge portions of our sales, so we need to be very flexible," Murphy explained.

Medisca works within a broad supplier ecosystem bound by a common standard of quality and compliance. The company, along with many of its suppliers and manufacturers, must be able to adapt to rapid changes when, for example, products become reclassified, which sometimes entails building new facilities, hiring new staff, and training the entire workforce on new requirements and regulations.

However, not all suppliers are created equal. Potential suppliers must maintain the same high level of quality as Medisca, including compliant documentation and validation. As part of its thorough vetting process, one of the first things Medisca considers is how well a potential supplier manages its documentation.

"If they don't have their paperwork straight, we can't import product from them," Murphy stated. On a few occasions, Medisca has required suppliers to implement MasterControl as a means of ensuring their documentation was in order. The suppliers obliged.

Medisca recognizes that returning to a standardized state as quickly as possible after change occurs is just as important as adapting to it in the first place. And in a regulated environment, at the heart of any change is a solid change control process, and at the heart of a solid change control process is proper documentation.

"MasterControl really does help us keep track of that paperwork," Murphy said.

Consolidated and Connected Enterprise Systems

Ultimately, Medisca selected MasterControl because of the breadth of its solutions, which proved second to none.

"The main reason we chose MasterControl was the diversity of systems that we could put in one software," Murphy said. "There are a lot of programs out there that do a really great job of document management, they even do a pretty good job of risk management and sometimes change control. But MasterControl does all of these things and more, from traceability to reporting and so forth."

In addition to wearing many hats, MasterControl also complements Medisca's existing systems. For example, by integrating MasterControl with its inventory management system, Medisca can directly relate change controls, complaints, etc. to the exact specifications in that system.

Moreover, Medisca has seen companywide improvements in consistency and efficiency, which is key to its continued growth and expansion.

"We consider Medisca to be one company, so we maintain consistent processes across all of our facilities," Murphy said. "Being able to transfer [documents] electronically in a way that can be communicated and easily added on to a new facility is a huge help."

The Future Is Bright

Medisca is a growing compounding company that continues to expand its product portfolio and enter new global markets. As it prepares to open a new distribution facility in the U.K. in late 2018, Medisca looks forward to the continued benefits and support of its MasterControl solution.

"MasterControl has the most options, the most flexibility. It really is the best thing out there for us."

Learn more about Medisca.

About MasterControl Inc.

MasterControl Inc. creates software solutions that enable life science and other regulated companies to deliver life-improving products to more people sooner. MasterControl's integrated solutions accelerate ROI and increase efficiencies by automating and securely managing critical business processes throughout the entire product lifecycle. More than 1,000 companies worldwide, ranging in size from five employees to tens of thousands, rely on MasterControl cloud solutions to automate processes for new product development, clinical, regulatory, quality management, supplier management, manufacturing and postmarket surveillance. MasterControl solutions are well-known for being scalable, easy to implement, easy to validate and easy to use. For more information, visit www.mastercontrol.com.

Contact information and addresses for other regional MasterControl offices and MasterControl partner offices are listed on the MasterControl website at www.mastercontrol.com.

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