



CHALLENGE

Develop a more secure global supply chain, demonstrating continued commitment to patient safety.

SOLUTION

EMD Serono created a robust GS1 standards-based track and trace system capable of handling its entire product line for end-to-end visibility and a more secure supply chain.

BENEFITS

- Protects patients through improved product security
- Improves customer confidence: physician, pharmacist, and patient
- Helps law enforcement combat drug counterfeiting
- Prepares company to meet regulatory compliance requirements
- Helps company gain greater insight into demand patterns and inventory management.



EMD Serono Committed to Patient Safety

Pharmaceutical companies exist to improve people's lives. They not only create innovative therapies, they also have the responsibility to establish the supply chains through which these life-altering products travel to patients. The complexity of creating and securing a global supply chain requires a disciplined and committed approach – a kind of determination that stays sharply focused on the ultimate goal: uncompromised patient safety.

When it comes to demonstrating commitment to patient safety through improved supply chain security, EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, has taken a leadership role.

Getting Started

As early as 2002, EMD Serono implemented its first secure distribution program for Serostim®, a human growth hormone used in the treatment of HIV-associated wasting.

To secure the product stream from manufacturing to wholesalers, the company redefined and launched a new distribution process for Serostim, the

Serostim Secured Distribution Program (SSDP). Now, each unit of Serostim is uniquely identified with a GS1 Global Trade Item Number® (GTIN®) plus serial number to ensure reliable data exchange across supply-chain partners. It is then shipped directly to contracted specialty pharmacies that are equipped to work with the unique patient population and special handling requirements of Serostim.

At the pharmacies, each serial number must be verified then validated within the dispensing process through an adjudication network. Once dispensed, those serial numbers are "retired" from the system and any attempt to re-dispense will fail the adjudication process. The SSDP provides EMD Serono with end-to-end visibility, leading to multiple benefits.

"For us, securing our global supply chain is not simply a matter of compliance, it's our corporate responsibility. It's about doing what's right for our patients."

– Richard Feldman, Vice President of Trade and Product Security, EMD Serono, Inc.

"We get a lot of great feedback because of the amount of data we can provide to confirm, yes, this is a legitimate box of product and it should be in a specific location, so if you are finding it somewhere else, there's an issue," Feldman explains.

In addition, law enforcement agencies have lauded the program's ability to assist with counterfeit and fraud cases. EMD Serono occasionally hears about successful prosecutions that have resulted from the information provided by SSDP.

"The pharmacies have really embraced this model and we are also hearing positive feedback from physicians who feel more confident, knowing a system is in place to protect their patients."

– Richard Feldman, Vice President of Trade and Product Security, EMD Serono, Inc.

Gaining Global Visibility

With SSDP successfully in place, EMD Serono was well prepared when the California Board of Pharmacy proposed its pedigree and serialization legislation in 2004.

"This was a significant change for the organization," recalls Feldman. "All of our products are manufactured outside the U.S., so the solution had to be suitable for other countries. It quickly became a global project."

A global team representing all related functions – IT, packaging, manufacturing, quality assurance, regulatory affairs, government affairs, legal and procurement – was assembled and charged with developing an overall track and trace solution.

The project was divided into five work streams:

- development of a packaging solution to accommodate the serial number and 2D DataMatrix bar code;
- development of an event tracking system;

NEW TRACK AND TRACE PROCESS



Products Marked: Boxes are pre-printed with 2D DataMatrix bar codes containing GTINs and randomized serial numbers by the EMD Serono packaging vendor.

Data Captured: The bar codes are then scanned and logged at the end of the packaging line.

Data Verified: When a batch is completed, the GTINs with serial numbers are then uploaded into a central database where they are verified to ensure there are no duplicates.

Data Shared: The information is then shared with the third-party logistics vendor that receives the product from the manufacturing sites.

Pedigree Generated: Products are picked, packed, and shipped per orders and all information is transferred to the pedigree vendor to produce the pedigree.

Pedigree Validated: Wholesalers and/or pharmacies can then verify and validate the pedigree of the product immediately upon arrival via a Web Portal, which is managed by a third-party ePedigree vendor.

The difference between a pedigree and an advanced ship notice is the level of detail required for each document. A pedigree requires more detail, including, but not limited to, serialization. In addition, a pedigree documents each change of ownership.

- integration of the pedigree with license verification and validation;
- integration of the pedigree with third-party logistics and distribution vendors; and,
- identification of a pedigree vendor and development of the pedigree solution to tie together all other elements.

The project was officially launched in 2007, and by the following year, EMD Serono had developed a robust track and trace system capable of handling the entire product line.

With the ultimate goal of patient safety in mind, EMD Serono has effectively ensured end-to-end visibility for a more secure supply chain.

"The track and trace program basically locks our supply chain," says Sébastien Mauel, Head of Product Security, Merck Serono and project lead for the global track and trace program. "It is nearly impossible for any counterfeit drug to enter our legitimate supply chain now that we have the track and trace solution in place."

Maintaining the Momentum

Although the California deadline was pushed back to 2015, EMD Serono has not backed off its commitment to securing its global supply chain. According to Feldman, EMD Serono has adopted a patient-centric mindset with regard to product security, which makes it impossible to justify delays. *"We've always felt that if we are going to do this, let's do it right from the beginning,"* explains Feldman.

Both Feldman and Mauel say they knew the solution had to be sustainable and scalable to accommodate the company's global footprint and plans for growth.

"We are in the process of implementing a powerful solution that will increase the security of products for our patients."

– Sébastien Mauel, Head of Product Security, Merck Serono

PEDIGREE COMPLIANCE AND ADOPTION

A pedigree is a certified record that shows the chain of custody (physical movement) and legal ownership of a product along the entire supply chain. Current FDA regulations define pedigree as beginning with the first wholesaler in the chain and ending at the pharmacy. The California law begins at the manufacturer and ends at the pharmacy. Although pedigree requirements currently vary by state in the U.S., and authentication and serialization requirements are emerging throughout the world, industry experts all agree that global track and trace standards are needed for harmonized supply-chain solutions.

They also knew it had to be flexible enough to meet the needs of trading partners. *“That was another reason it was so important to start early and not wait for legislation,”* explains Feldman. *“We wanted to ensure that when requirements were finalized and mandated, we had a validated and tested system in place with established communication lines with our trading partners.”*

Feldman and others on the team say it’s a matter of ‘when’ not ‘if’ pedigrees will be a universal requirement, so there’s simply no good reason to postpone implementation. Feldman also notes that to delay could ultimately compromise patient care. *“If they flip the switch with the legislation, we are prepared with a solution, which will help to ensure patient access,”* Feldman explains. *“With our track and trace system in place, we can get patients the drugs they need, when they need them. Our focus is always on the end patient.”*

In addition to the success of the track and trace programs, Feldman notes a cultural change in the organization that he feels is vital to their ongoing success. *“I believe that, as a company, we’re now ahead of the curve in keeping our product lines as safe as possible,”* says Feldman. *“Nothing is foolproof, but there’s an energy across the company that is focused on anti-counterfeiting. Much of it has stemmed from the global teamwork that we achieved with this project and it’s become a way of life for EMD Serono.”*

GS1 Standards for a Harmonized Solution

EMD Serono says a key element in the success of the program has been the use of unified global standards from GS1®. *“The reason why we chose to follow GS1 standards was because of the ongoing global activities around track and trace,”* says Feldman.

Mauel points to the critical need for standards when implementing efficient and effective track and trace systems. In his work with the European Federation of Pharmaceutical Industries and Associations (EFPIA), he has found that colleagues throughout the EU are pushing for GS1 standards. *“If we do not come up with one standard solution, it will be a nightmare for the industry and the pharmacists who are on the front lines when it comes to patient safety,”* says Mauel. *“If the pharmacist has to deal with ten different track and trace systems it will create the opportunity for a serious breach in the security process.”*

Best Practices for Success

The EMD Serono global team acknowledges the challenges they faced and overcame when planning and implementing their track and trace system. Following are best practices for others considering a track and trace solution:

1 Get leadership buy-in early. Work in advance to communicate the critical nature of track and trace and pedigree to your leadership. Make a business case that identifies the investments and resources needed along with the targeted benefits.

2 Create a vision that goes beyond compliance. Make a commitment to secure your supply chain for the benefit of the patient and the business – not just to meet a new regulatory requirement. When California delayed its compliance deadline, the EMD Serono team remained committed to the outcome and continued to inform internal stakeholders that the program should maintain its original timeline and trajectory.

3 Leverage global standards. Standards help ensure all participants in the supply chain – manufacturers, wholesalers, pharmacies – are speaking the same language. The EMD Serono team notes that adopting global standards also helped “sway naysayers” who believed the challenge of implementing a global track and trace program was simply too complex and ultimately unachievable.

4 Partner with government. Legislators, regulators and manufacturers have the same goal: ensuring that products are delivered to patients safely. Proactively, work with government to help ground the understanding around what industry needs for the supply chain to produce safe products within compliance.

5 Communicate internally. Since product security efforts may be global, communication and collaboration can present challenges to geographically dispersed teams. Do not underestimate the importance of regular team conference calls and updates to be sure everyone is involved and informed.

SUCCESS STORY: EMD Serono



"Working with GS1 standards was the best approach to creating a harmonized, global solution."

– Richard Feldman, Vice President of Trade and Product Security, EMD Serono, Inc.

ABOUT EMD SERONO, INC.

EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, is a leader in the US biopharmaceutical arena, integrating cutting-edge science with unparalleled patient support systems to improve people's lives. The company has strong market positions in neurodegenerative diseases, with Rebif® (interferon beta-1a), as well as in endocrinology, with Saizen® (somatropin (rDNA origin) for injection) and Serostim® (somatropin (rDNA origin) for injection). EMD Serono is a leader in reproductive health, with Gonal-f® (follitropin alfa for injection), Luveris® (lutropin alfa for injection) and Ovidrel® Prefilled Syringe (choriogonadotropin alfa injection). With a clear focus on the patient and a leadership presence in the biopharmaceutical industry, EMD Serono's US footprint continues to grow, with more than 1000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts. For more information, please visit www.emdserono.com.

GS1 STANDARDS USED

The EMD Serono track and trace program uses GS1 standards including:

- **Global Trade Item Number (GTIN):** Identifies a product such as Serostim.
- **Serial Number:** Used in conjunction with a GTIN, identifies a unique instance of a product.
- **GS1 2D DataMatrix Bar Code:** Carries data in a small footprint.
- **GS1 Linear Bar Code:** Meets current FDA regulations.
- **EPCglobal Drug Pedigree Messaging Standard (DPMS):** Meets regulatory pedigree requirements.
- **Electronic Product Code Information Services (EPCIS):** Shares serialized data between supply chain partners.

ABOUT GS1 HEALTHCARE US™

GS1 Healthcare US is an industry group that focuses on driving the adoption and implementation of GS1 standards in the U.S. healthcare industry to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States.

CONTACT US

GS1 Healthcare US™ provides expertise, tools, and resources to help you implement GS1 standards to improve patient safety and supply chain efficiency. To learn more, contact GS1 Healthcare US at gs1healthcareus@gs1us.org or visit our Website at www.gs1us.org/healthcare.



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