GS1 Australia



CASE STUDY

ASTRAZENECA TRANSFORMS TRACEABILITY FOR PATIENT SAFETY & GLOBAL COMPLIANCE

AstraZeneca, a global biopharmaceutical company, is committed to ensuring patient safety and regulatory compliance across its extensive global supply chain. With research operations and manufacturing facilities across the globe (including Australia), the company faces complex challenges in maintaining product security through the supply chain from production to the patient.

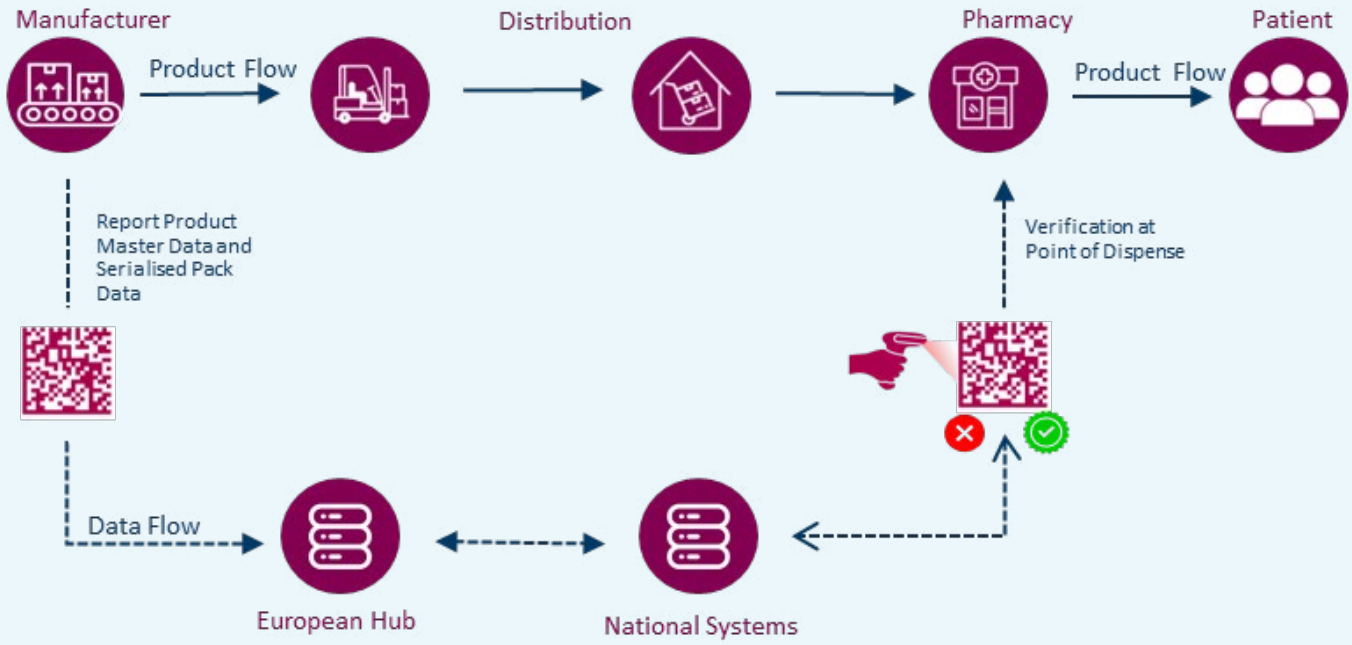
AstraZeneca

THE CHALLENGE

Ensuring the authenticity and security of pharmaceutical products is paramount in the face of growing threats such as counterfeiting, product diversion and data discrepancies. Regulatory bodies worldwide are becoming increasingly aware of these threats and, as a result, they are tightening their requirements, mandating serialisation and data reporting to enhance traceability of products as they move through the supply chain. AstraZeneca recognised that to meet evolving global standards, an integrated, standardised approach to traceability was essential to protect patients from these threats. Using GS1 global standards is key to achieving this.

> Traceability is not just about compliance—it's about ensuring that every patient receives the right product, at the right time, with absolute certainty. Implementing GS1 standards has been a game-changer for AstraZeneca in safeguarding supply chain integrity.

Richard Driscoll
Associate Director
Traceability & Product Security
AstraZeneca



Adopting GS1 standards for traceability in the pharmaceutical industry enhances supply chain transparency and efficiency by facilitating the accurate identification and tracking of products. This ensures authenticity and safety, combating counterfeit medications and ensuring patient safety. For countries looking to adopt these standards, GS1 provides a universal framework that simplifies cross-border trade and regulatory compliance, fostering trust and enabling swift recall responses, ultimately contributing to more secure healthcare systems globally.

At the packing line, there are also significant benefits associated with adopting global standards for traceability. Adopting GS1 over a bespoke traceability system reduces complexity while global standards allow new markets to be set up quickly with fewer errors.

Bespoke traceability systems (such as implementing non-GS1 solutions without industry consultation) can result in parallel processes at the packing site as well as non-conformances/further customisations when reporting the data.

With increased complexity, also comes an increased risk of data errors due to different processes, which can result in product recalls, reputational damage and can even present a risk to the patient.

Standardising our traceability processes using GS1 standards has not only increased efficiency but also strengthened our ability to respond to regulatory changes with confidence. The benefits extend beyond compliance to overall supply chain resilience.

Daniel Perala
Enterprise Process Lead - Traceability
AstraZeneca

THE SOLUTION

AstraZeneca has adopted GS1 global standards to create streamlined, secure, and fully automated traceability packaging and reporting systems across its global network. The end-to-end process is fully automated and integrated with global corporate ERP systems.

- Standardising manufacturing with four key data elements in a 2D GS1 DataMatrix: Global Trade Item Number (GTIN), Serial Number, Expiry Date and Batch Number. This has been developed as a global industry standard for pharmaceuticals.
- Aggregating products to the pallet level for enhanced supply chain visibility, where system maturity allows.
- Aligning with regulatory requirements, including the European Union Falsified Medicines Directive (EUFMD), Drug Supply Chain Security Act in the United States (DSCSA), and individual country requirements.
- Integrating serialisation and end-to-end automation to ensure data and product alignment.
- Working with regulators and other manufacturers to ensure that emerging markets are aware of industry standards and to share best practices.

Serialisation at the point of manufacturing enables unique identification for seamless tracking of pharmaceutical products down to the pack level, significantly reducing data discrepancies and compliance risks. AstraZeneca considers serialisation data to be as important as the physical product, so any data discrepancy is handled in the same way as a physical product quality issue. Aggregation of the product to the pallet level also ensures that the data is 100% accurate every time.

THE RESULTS

Adopting the four data elements within a GS1 DataMatrix 2D barcode simplifies dramatically what is already a complex process. If a new market is introduced to a manufacturer that complies with this standard 'out of the box', it can considerably reduce the time taken to configure and test this product at the packing line. A real reduction in labour from weeks to days. Future system development with fully integrated ERP systems will further reduce this effort to literally hours.

A recent example in Australia involved adding a new non-GS1 compliant product, which had not been implemented at the site before. The time taken for system development, configuration, documentation, testing and training took nine months. Another product was introduced at a later stage that was fully GS1 compliant and was completed in one month.

Using GS1 standards makes traceability throughout the supply chain easier and faster and enables both the country's health authority and manufacturer to be able to identify a counterfeit or diverted product in real time. Serialisation in manufacturing means you can even identify a product at any point in the supply chain to the minute it is produced on the line. Essentially, it connects the value chain from manufacturing lines right through to the patient/ consumer.



THE BENEFITS

The adoption of GS1 global standards in an industry standard and advanced automation has delivered:

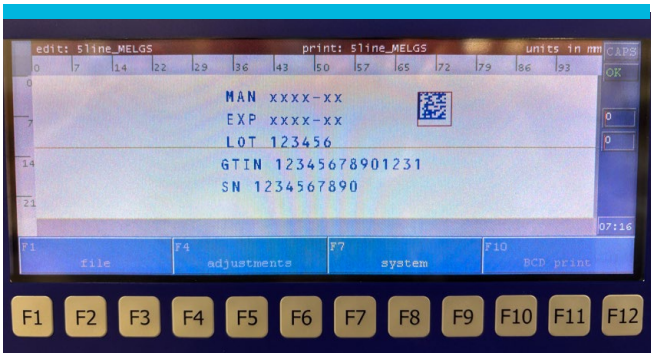
- Enhanced patient safety by reducing counterfeiting and assuring product authentication.
- Improved regulatory compliance with global and regional traceability requirements.
- Streamlined global supply chain with reduced costs and faster product distribution.
- Lower operational risk by eliminating data discrepancies and minimising process deviations.

THE FUTURE

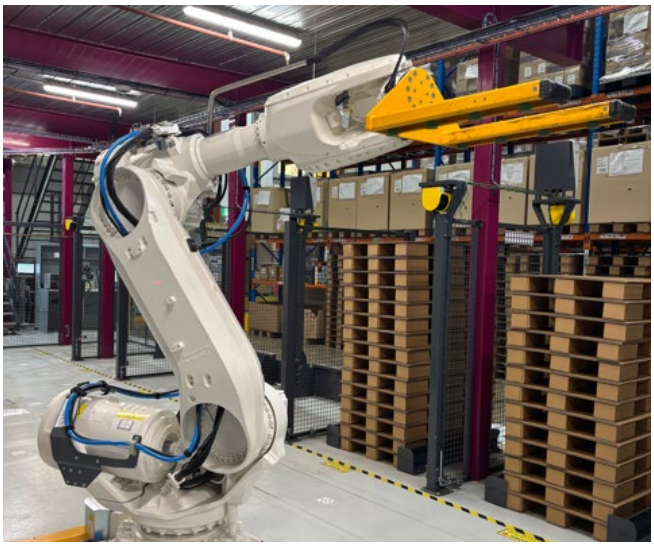
- Standardising traceability processes across all manufacturing sites to ensure consistency and regulatory compliance.
- Integrating its solution provider's system into the enterprise ERP for real-time master data updates, eliminating manual data entry at the line and reducing errors.
- Advancing straight to pallet aggregation to improve data accuracy and streamline operations.

CALL TO ACTION

AstraZeneca's commitment to GS1 standards and digital traceability is setting a benchmark for pharmaceutical supply chain security. To explore how implementing global standards can transform your organisation's traceability and learn more **contact GS1 Australia** today.









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