

Aspen Australia

# Global traceability requirements for medicines

The value of global standards



## Aspen Australia serialisation implementation using GS1 standards

# The company

Aspen Australia is a subsidiary of Aspen Pharmacare Holdings Limited (South Africa). They are one of the largest pharmaceutical companies in Australia and have one of the most comprehensive portfolios of medicines in the country. Aspen operates a large-scale manufacturing facility located in Melbourne producing pharmaceuticals for both local and export markets.

# The challenge

Regulatory requirements are ever-changing with an increased focus on the detection of falsified medicines and traceability. The European Commission (EU) developed the Falsified Medicines Directive (FMD) which requires serial numbers to be printed onto pharmaceutical products and for product serialisation data to be transferred from the manufacturer to the regulator. Several overseas markets have similar guidelines to verify authenticity at the point of sale.

Aspen was awarded a contract manufacturing portfolio for new Middle Eastern markets (including UAE, Bahrain, Jordan, Oman, Lebanon, Kuwait, Qatar & Saudi Arabia) adding to their South Korean and UK markets. All had existing or pending regulatory requirements for serialisation, with the common thread being the GS1 DataMatrix barcode. To meet the anti-counterfeiting requirements of their target markets, in late 2018 Aspen embarked on the journey toward implementing a serialisation system.

### The upfront challenges Aspen faced were:

- **A very low local knowledge base**
- **Sourcing equipment and solutions that did not exist in Australia**
- **Meeting customer and regulatory timelines**
- **Performing sufficient due diligence around the solution(s)**
- **Implementing solution(s) for scalability**

# The solution

The project implementation team needed to research and understand how a serialisation system works. This included reaching out to Aspen’s global network to gather information about software and equipment solutions, system hierarchy and workflow drawings, system specification documents and operating procedures. This research was supplemented by information from solution providers and market regulators. The scope was limited to Point of Dispense Authentication (PoDA – refer to Figure 1), meaning serialisation was only required at the sales unit level. This is a subset of full ‘Track and Trace’ (Aggregation) whereby higher packaging levels (shippers and pallets) are serialised to provide visibility of product movements through the supply chain. It was a critical requirement that any solution implemented could be built upon in the future for full Aggregation.

### The following selection criteria were formalised:

- Flexibility- Ability to integrate with third-party equipment/software solutions (universal interface)
- Scalability- Ability to expand/more packing lines and functionality (Aggregation)
- Ease of Use- Simple user interfaces
- Ubiquity and Innovation- Balance of well-proven solutions/new technology
- Technical Implementation and Validation- Resources support
- Customer Service – Technical support post implementation
- Cost- Capital/ongoing

## Serialisation: Point of Dispense Authentication (PoDA) model

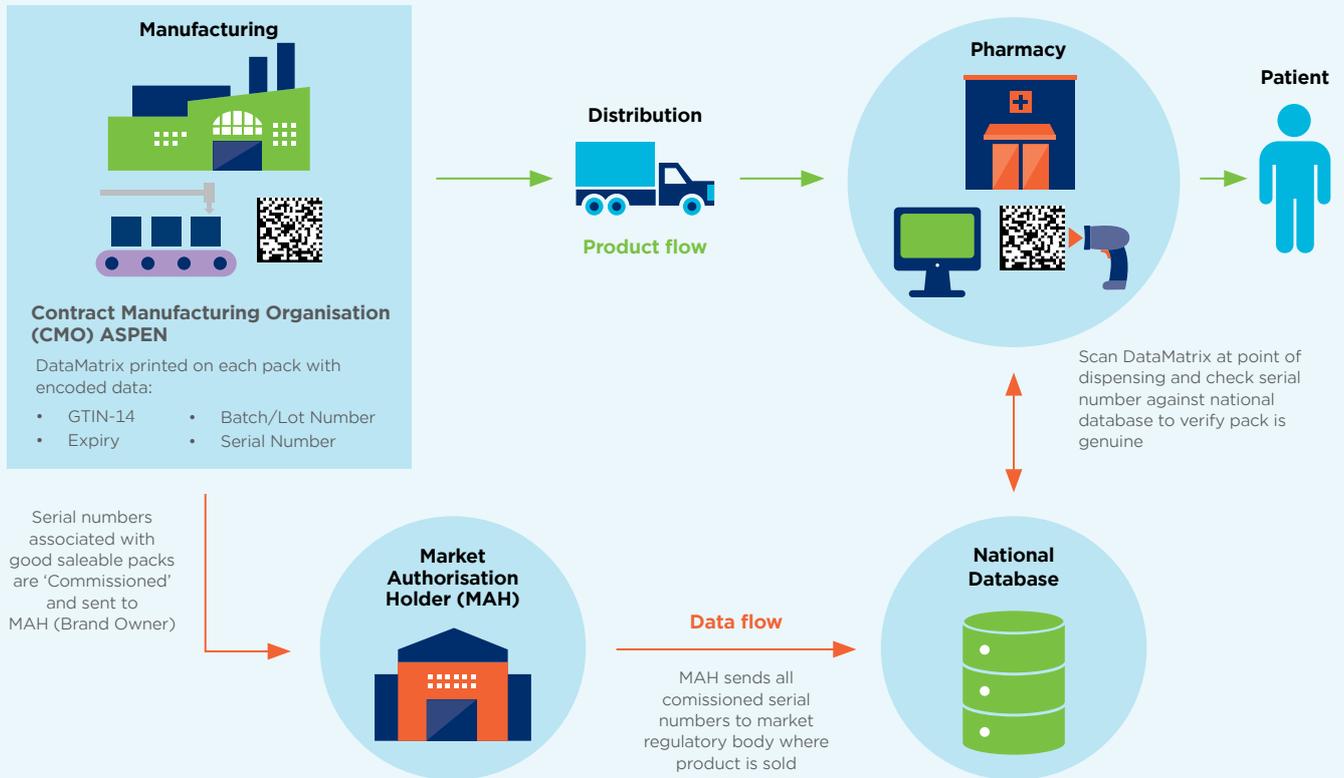


Figure 1

## The implementation

Aspen implemented a traditional serialisation model of **Level 4**, **Level 3** and **Level 2** systems (Refer to Figure 2).

### Aspen Serialisation System Infrastructure

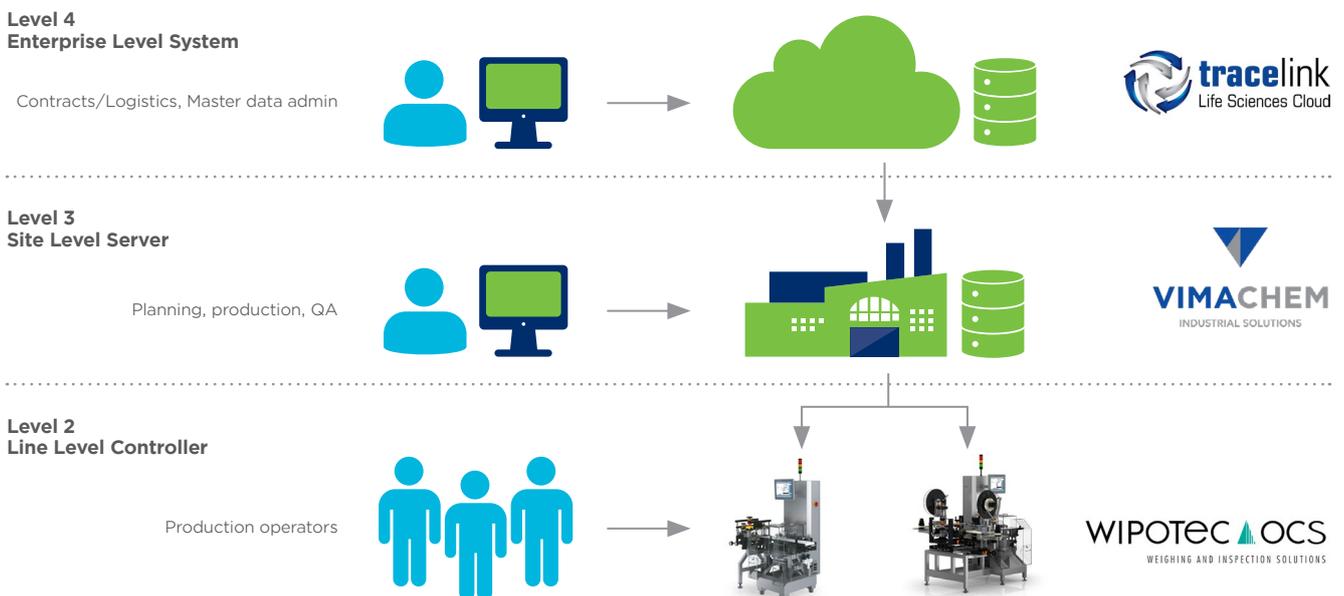


Figure 2

## Level 4 Enterprise Level System - Tracelink

This is the 'brains' of serialisation containing:

- All master data
- Management of serial number pools, Business to Business (B2B) interface, and data repository to meet regulatory obligations.

Tracelink was selected for its cloud-based platform and established network of B2B connections, including many of Aspen's customers. Their automated internal validation program ensures that monthly updates do not impact the validated state of the application, and much of the complexity of maintaining the system is outsourced.

The implementation was led by a small project team with the involvement of Aspen's stakeholders to agree on the workflow. The team then configured the master data and tested the connections with Aspen's partners, first in the Test environment and then subsequently in the Production environment.

## Level 3 Site Level Server System - Vimachem Site Serialisation Manager (SSM)

This is used for batch management at the manufacturing facility. In this system serialised orders are created, assigned to lines, monitored for status and finally quality released. This system is accessed by day-to-day operations so must have a user-friendly interface while still being customisable. Vimachem SSM was best aligned with Aspen's selection criteria, as it seamlessly integrates with Tracelink while having a universal (non-proprietary) interface with the serialisation equipment.

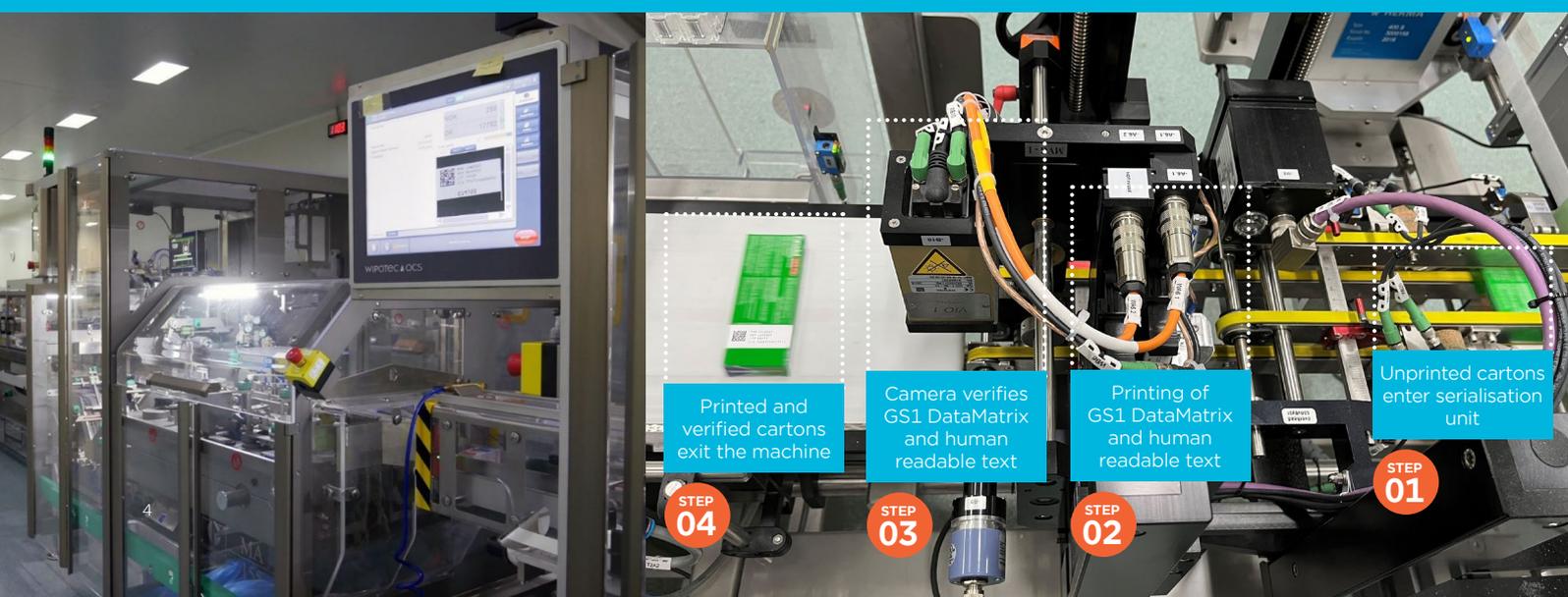
The implementation was led by a small project team who remotely managed the application connections, developed all specification documents and executed a validation package across both Test and Production environments.

## Level 2 Line Level Controller System - Wipotec OCS (Germany)

This is at the 'coal face' of serialisation. It receives the serial numbers, prints the numbers onto packs, verifies the data and the barcode quality, performs other functions (applies tamper-evident labels and check-weighing), accepts/rejects packs, and commissions/deactivates serial numbers. Because the launch was across five packaging lines, the Level 2 systems took up a majority of the project budget and presented the highest level of risk to timelines, functionality and flexibility. Aspen initiated a large tender to eight vendors of serialisation equipment to have the utmost confidence in their chosen solution.

Wipotec OCS provided the best overall fit and offered a highly integrated solution with simple setup and operational procedures, a universal (non-proprietary) interface for flexibility, and can be extended if full Aggregation is required.

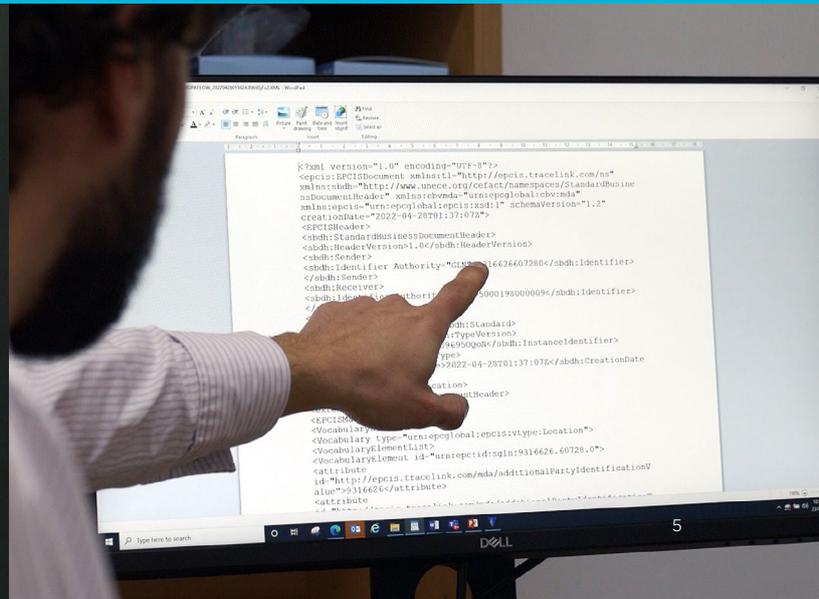
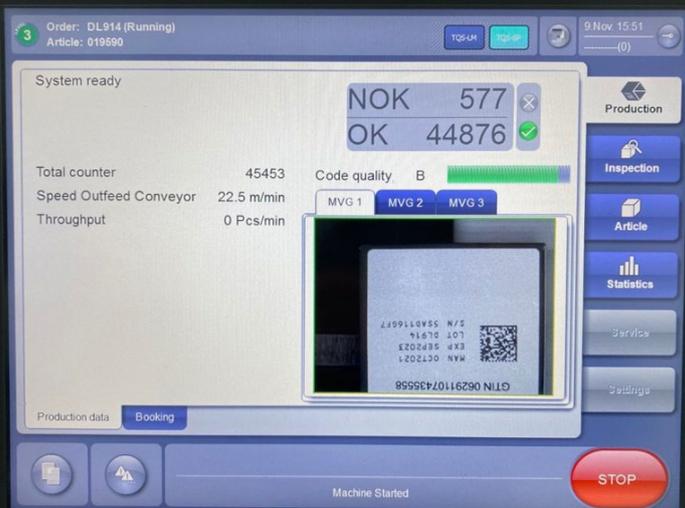
The implementation included a Factory Acceptance Test (FAT) in Germany and installation, qualification and Site Acceptance Testing (SAT) on Aspen's premises.



# How the system works

- As a Contract Manufacturing Organisation (CMO) Aspen's serialisation workflow begins with the automatic replenishment of product-specific serial number pools in the Enterprise level system (Tracelink), with serial numbers externally sourced from the Market Authorisation Holder's (MAH) Enterprise level system.
- When a serialised order is created in the Site level server system (Vimachem SSM) the required quantity of serial numbers is requested and downloaded from Tracelink. These serial numbers are removed from the available pool and now exist in a Reserved state.
- When the order is due to be packed, a user in Vimachem SSM will assign it to the corresponding Line level controller system (Wipotec OCS) and the serial numbers will be downloaded.
- Each pack processed by the Wipotec OCS unit will be assigned a unique serial number. The machine prints a unique GS1 Datamatrix barcode with GTIN-14, Expiry, Batch/Lot, and Serial Number and inspects it by taking a photo of the barcode and human-readable text elements. Acceptable packs will be classified as 'OK' and unacceptable packs will be classified as 'NOK' and automatically rejected.
- For every pack, production data is linked to each serial number. This includes the OK/NOK, Expiry, Lot, Date/Time, GS1 Datamatrix quality, the reason for rejection (if NOK) and pack weight.
- After the order is packed, it is ended on the Wipotec OCS unit and the data is updated in Vimachem SSM.
- During the final stage of Quality Release, a user will approve the commissioning in Vimachem SSM to allow the transfer of data to the Enterprise level system (Tracelink).
- All corresponding serial numbers in Tracelink (which are still in a Reserved state) are updated with their final disposition. The serial numbers for good saleable packs are Commissioned and the lot-specific information is linked. The serial numbers for rejected packs are Deactivated and can no longer be used. Any unused serial numbers are returned to the number pool and changed to Unreserved.
- Coinciding with the shipment of stock a Shipment Transfer is performed in Tracelink. This sends the serialisation data for all Commissioned packs to the Market Authorisation Holder, with Global Location Numbers (GLNs) for the source and destination of the goods. This is in an Electronic Product Code Information Services (EPCIS) XML file which is a GS1 standard for sharing event data. [Find out more](#)
- This is the final stage of the serialisation process for Aspen. The Market Authorisation Holder (MAH) will report the commissioned serial numbers to the regulatory database of the target market, which enables the authenticity of pharmaceutical products to be verified at the point of sale.

## WIPOTEC OCS



## The challenges

It took Aspen two years to implement their solution, of which the first nine months were research, pre-tender and tender phases before the final solutions were nominated. The biggest challenge was the validation of three layers of networked infrastructure, (cloud-based, Aspen server-based and factory floor-based) to meet pharmaceutical regulatory standards.

The single most valuable document was the Project Validation Plan. This set out the roadmap of milestones across the three layers of infrastructure in both test and production environments, culminating in Performance Qualification (PQ) exercises to rigorously test the system end-to-end.

### The key advice from Aspen is:

- Invest adequate resourcing into the validation process.
- Stakeholder management is extensive and will typically be across several time zones.
- Provide dedicated resources for the generation of Standard Operating Procedures and Operating Manuals.
- Allow sufficient time for user training and embedding of the new workflows.

## The results

Since the commercial launch of the serialisation system (July 2020), the implementation has successfully enabled Aspen to supply serialised products into export markets, fully compliant with their regulatory requirements using GS1 DataMatrix and EPCIS standards. Using global standards for serialisation tackles the issue of falsified medicines in global markets, whilst enabling traceability.

## What's Next?

Aspen is currently in the process of adding three more serialised lines over the next twelve months. This is to increase the flexibility of their solid dose blister packing operation to meet the growing demand for export (serialised) products.

## Benefits

- One serialisation process for all markets
- Fully compliant and meets regulations
- Implementing global standards enables traceability
- Combats counterfeit product





It was fortunate for Aspen that the ten different target markets adopted a standardised method for encoding the unique serial number and other critical information onto their packaging, and that method was the GS1 DataMatrix. Furthermore, the means of sharing serialisation event data between us (the Contract Manufacturing Organisation) and all our customers (the Market Authorisation Holders) is via an Electronic Product Code Information Services file (or EPCIS file for short) which is also a global GS1 standard. Hence what made this complex project more manageable and allowed us to implement a single ‘catch-all’ solution was the widespread adoption of GS1 standards.

**Michael Hadjion**  
Engineering Manager  
Aspen Australia



**Michael Hadjion** is Engineering Manager at the Aspen Australia manufacturing facility located in Dandenong South, Melbourne. With eighteen years of experience in the pharmaceutical industry, he first specialised in equipment and facilities validation before heading into project engineering and maintenance roles. Joining Aspen as Project Manager in 2012, Michael has delivered a diverse range of projects including major capital works, contract manufacturing tender submissions, and the transfer of a large portfolio of Consumer and Over the Counter products into the Aspen facility. Between 2018 and 2020, Michael managed Aspen Australia’s serialisation system implementation.



**Aspen Australia**  
Case Study Video  
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## About GS1 Healthcare

GS1 Australia works in Healthcare to support adoption and implementation of interoperable GS1 standards within the Australian healthcare industry to enhance patient safety, and operational and supply chain efficiencies.

Our global community brings together healthcare stakeholders and experts to lead the successful development and implementation of global GS1 standards and guidelines. Evidence available from healthcare industry implementations shows that GS1 identification, data capture and data sharing standards deliver tangible benefit to all stakeholders - pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, trade associations and most importantly patients and consumers of healthcare.

For more information about GS1 standards in Australian healthcare, visit the GS1 Australia website [www.gs1au.org/healthcare](http://www.gs1au.org/healthcare) or follow us on Twitter [gs1au\\_health](https://twitter.com/gs1au_health) and LinkedIn [gs1-australia](https://www.linkedin.com/company/gs1-australia)

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