



# Axway Track & Trace

GS1 EPCglobal compliant and certified

## Securing the integrity of complex healthcare supply chains and facilitating compliance with global serialization regulations

As pharmaceutical supply chains grow infinitely more complex, counterfeiting, diversion, and importation of unapproved or substandard drugs pose threats to supply chain integrity and patient safety. With countries around the world implementing and enforcing pharmaceutical product serialization and track-and-trace regulations, each with their own unique set of requirements and enforcement timelines, organizations across the pharmaceutical supply chain are re-evaluating their IT infrastructure and investing in software capabilities to address increasingly complex compliance directives.

Global traceability mandates require pharmaceutical manufacturing and distribution companies to deliver improved visibility across their global supply chain ecosystems in order to identify threats that compromise product quality and safety, such

as counterfeiting, diversion, theft, and importation of unapproved or substandard drugs. Pharmaceutical manufacturers must seamlessly integrate, connect and collaborate with supply chain partners in new ways to transform rigid supply chains into responsive and more proactive end-to-end systems.

### Business challenges

<b>Secure the integrity of complex global supply chain ecosystems</b>	<ul style="list-style-type: none"><li>• <b>Anti-counterfeiting.</b> Meet safety and quality demands and protect your brand by rapidly identifying counterfeit products</li><li>• <b>Product diversion.</b> Protect profits and brand equity by detecting potential “gray market” product diversion</li><li>• <b>End-to-end supply chain visibility.</b> Enable exception management based on event consolidation of all partners involved in various business processes, improving productivity and supply chain efficiency</li></ul>
<b>Address evolving global product serialization mandates</b>	<ul style="list-style-type: none"><li>• <b>Regulatory compliance.</b> Reduce the complexity of meeting compliance regulations across multiple countries with chain-of-custody and track-and-trace capabilities for pharmaceuticals</li></ul>
<b>Optimize operational efficiency to address rising customer demands</b>	<ul style="list-style-type: none"><li>• <b>On-shelf availability.</b> Improve on-shelf availability and reduce inventory levels so that consumers benefit from an enhanced shopping experience</li><li>• <b>Returns, recalls, reverse logistics.</b> Improve timely and efficient return and recall management</li></ul>

Axway Track & Trace helps organizations address today's challenging and evolving global serialization requirements. The solution delivers an integrated Electronic Product Code Information Systems (EPCIS) event repository for global regulatory compliance, diversion detection, product recall, and

anti-counterfeiting within complex supply chains. Axway Track & Trace manages serialized product events to allow internal and external trusted parties to access product identification, location and event data at any point in the delivery supply chain. Built on an EPCIS GS1 EPCglobal-compliant and certified,

standards-based framework, Axway Track & Trace provides the end-to-end transparency, logistics management and product ID verification services needed to optimize all of your track-and-trace initiatives.

**Key features & benefits**

**GS1 EPCglobal-compliant and certified event repository with built-in master data**

Leverage a truly open and highly scalable solution infrastructure

- Comply with changing global compliance regulations with the confidence of GS1 certifications of EPCIS compliance
- Create a highly scalable event repository to support huge volumes of serialized events
- Use built-in master data to automatically enrich events with meaningful business attributes
- Provide an EPC-certified interface with business extensibility to EPCIS-ready applications and partners (web services, AS2, JMS)
- Use the dynamic repository structure for maximum business agility and enrichment of your repository structure over time
- Connect to third-party EPCIS event repositories
- Speed integration for a lower total cost of ownership using a simplified solution architecture
- Manage queries returning large amounts of data effectively using asynchronous queries

**Multipurpose lifecycle and aggregation management**

Empower business users with direct access to your event repository

- Provide a single source of actionable intelligence for all business users including quality managers, channel managers and data managers
- Provide powerful queries to business users to search the event repository, including commissioning, aggregations, decommissioning, reaggregations and transaction events
- Easily change the aggregations hierarchy and enter ad hoc events into your repository
- Create new queries without IT support and distribute them to users with role-based security

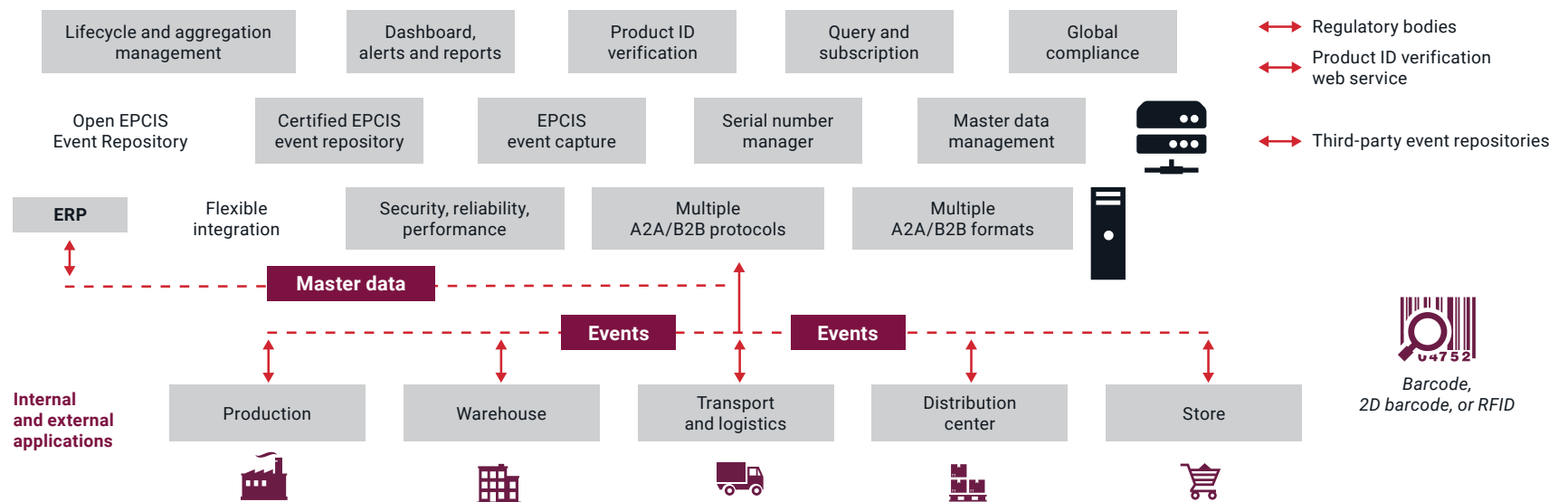
## Key features & benefits

<p><b>Product ID verification and hierarchy status</b></p> <p>Leverage product ID verification for robust anti-counterfeiting measures</p>	<ul style="list-style-type: none"><li>• Simplify product ID verification with a central database containing all serial numbers and search capabilities with key status information (valid, invalid, unknown)</li><li>• Facilitate adoption with user-friendly entry of serial number and/or GTIN</li><li>• Use the product ID verification web services to enrich existing customer-facing, internal or partner web applications</li><li>• Use a systems integration API to support warehouse operations and edge systems in real time by providing current item and hierarchy status</li></ul>
<p><b>Dashboards, alerts, and reporting</b></p> <p>Maximize the business value of your event repository</p>	<ul style="list-style-type: none"><li>• Ability to build dashboards with key indicators on visibility, security and efficiency of your supply chain events</li><li>• Build complex event-driven correlation rules to detect diversion, counterfeiting or non-compliance with business rules</li><li>• Define subscriptions to extract predefined queries at regular intervals with custom criteria and notification modes</li><li>• Generate reports on queried data in multiple formats</li></ul>
<p><b>Serial number management</b></p> <p>Manage diverse serial numbers at the enterprise level</p>	<ul style="list-style-type: none"><li>• Support randomized , list or sequential serial numbers ; randomization algorithm meets EFPIA Pack Coding Requirements</li><li>• Allocate numbers generated locally or by third party</li><li>• Support multiple serial number formats using any standard, including GTIN, NTIN and SSCC*</li><li>• Use the Serial Number Manager to define the format and allocate unique serial number ranges across multiple manufacturing lines or facilities</li><li>• Ensure the uniqueness of serial numbers at the pallet, case and/or unit level</li><li>• Integrate with multiple printing solutions by integrating Axway Track &amp; Trace with line management systems or off-line labeling systems</li></ul>
<p><b>Integrate any internal or external application (EPCIS and non-EPCIS)</b></p> <p>Manage diverse existing internal applications and external partners with maximum flexibility</p>	<ul style="list-style-type: none"><li>• Manage event and master data integration with high security, reliability and visibility</li><li>• Connect to multiple application-to-application (A2A) protocols to collect events from any existing non-EPCIS applications – such as ERP, manufacturing execution systems, warehouse management, edge system, point of sale (POS) and eCommerce portals</li><li>• Seamlessly connect your partner applications with a built-in, business-to-business (B2B) gateway providing secure and reliable communication and endpoints for your partners</li><li>• Easily transform existing application formats to EPCIS formats with a powerful Eclipse-based visual mapping tool to effectively define, maintain, simulate, print and deploy maps and integration rules</li></ul>

## Optional Compliance Modules

<p><b>US DSCSA Compliance Module</b></p> <p>Enables pharmaceutical manufacturers to comply with current Drug Supply Chain Security Act (DSCSA) requirements.</p>	<ul style="list-style-type: none"> <li>• Captures aggregations, change-of-ownership and decommissioning events to provide a complete picture of the product lifecycle</li> <li>• Accelerates CMO integration with embedded integration technology that supports diverse message format transformation and connectivity needs</li> <li>• Associates and manages product master data, serialized events and distribution channel events</li> <li>• Provides full visibility of serialized product lifecycle</li> </ul>
<p><b>EU FMD Compliance Module</b></p> <p>Enables pharmaceutical companies to comply with EU Falsified Medicines Directive (FMD)</p>	<ul style="list-style-type: none"> <li>• Provides an end-to-end solution for unique serialization with random numbers at the product pack level, upload serialization data to the European Medicines Verification System (EMVS), and product verification</li> <li>• Generates serial numbers that meet EFPIA pack coding requirements</li> <li>• Submits product code data targeted for EU member states to the European Medicines Verification System (EMVS)</li> <li>• Manages serialized product pack data, and status changes for prescription drugs targeted for European supply chain</li> <li>• Triggers compliance reporting to EMVS based on customer configured operational processes and event data attributes</li> </ul>

## Compliance, anti-counterfeiting, diversion detection, product recalls and more





### **Specifications**

Cloud service or on-premise deployment

### **Operating Systems**

Windows 2008 R2

Windows Server 2012 R2

Windows 2012

Oracle Linux 7

Red Hat Enterprise Linux 7.x

SUSE Linux Enterprise 11 Sp3

SUSE Linux Enterprise 12

### **Databases**

Oracle Enterprise Edition 11gR2

Oracle Standard Edition 11gR2

Oracle Enterprise Edition RAC 11gR2

Oracle Standard Edition RAC 11gR2

Oracle Enterprise Edition 12c

Oracle Standard Edition 12c

Oracle Enterprise Edition RAC 12c

Oracle Standard Edition RAC 12c

### **Additional B2B Protocols**

HTTPS and JMS (based on ActiveMQ)

EDIINT AS1, AS2, AS3

SFTP, FTP/S, File System

Web Services

EDIINT and ebXML are certified by the Drummond Group annually

### **Data Format Support**

Additional message formats can be supported with Axway B2Bi

EPCIS

ANSI X12

XML



[axway.com/track-and-trace](http://axway.com/track-and-trace)