Axway Cloud Global Traceability and Compliance Service

Simple and affordable enterprise traceability in the cloud

Meet DSCSA compliance requirements with a GS1-certified affordable solution used by Life Sciences industry leaders.

To improve the safety and integrity of the global supply chain, the United States Food & Drug Administration (FDA), the EU, China, Brazil, Turkey, South Korea and other government entities around the world are instituting stringent traceability regulations for pharmaceuticals and medical devices. In the coming months and years, these anti-counterfeiting regulations will require pharmaceutical supply chain constituents to implement systems and processes to trace financial and physical chain of custodies from the pharmacy back to the manufacturer. Emerging regulatory requirements in global markets require unit-level serialization, point of sale verification, central government reporting, and manufacturer to pharmacy traceability. Rigid point solutions to meet these requirements become costly and unmanageable over time as new requirements emerge and change.

Simple and affordable deployment models

Complying with complex global regulatory requirements doesn't have to be a science project. Axway offers a simple and affordable deployment model to meet the needs of your organization, whether you have 1 million, 50 million or 100 million serialized items and whether you do business with a handful, dozens or hundreds of partners.

Hosted private cloud

Axway has 15 years' experience hosting regulatory applications for healthcare, financial services and government organizations. More and more Life Sciences enterprises — from the largest manufacturers and distributors to rapidly growing mid-sized companies — are selecting Axway's solutions deployed via a private cloud in order to save time and money.

Deploying Axway's Global Traceability and Compliance Solution via a private cloud enables your business to gain fast, economical access to Axway's enterprise-class technology, eliminate the overhead required to expand your current infrastructure, and leverage the economies of scale inherent in cloud computing — all while maintaining the highest levels of security, reliability and scalability in a single-tenant environment.

Get ready for US DSCSA compliance

Starting December 2017, manufacturers must serialize 100% of Rx products and have systems and processes in place to verify product identifiers. Rolling timelines over the next 6 years require the entire U.S. pharmaceutical supply chain to transact only serialized products.

Pharmaceutical supply chain leaders must re-evaluate their current and future traceability strategies now.

Key Considerations:

- Interoperability standards
- Trading partner infrastructure capabilities
- Support for lot-level traceability and unit-level serialization
- Product identifier verification systems and processes
- Searchable, single system of record to respond to Requests for Information
- Global strategy alignment
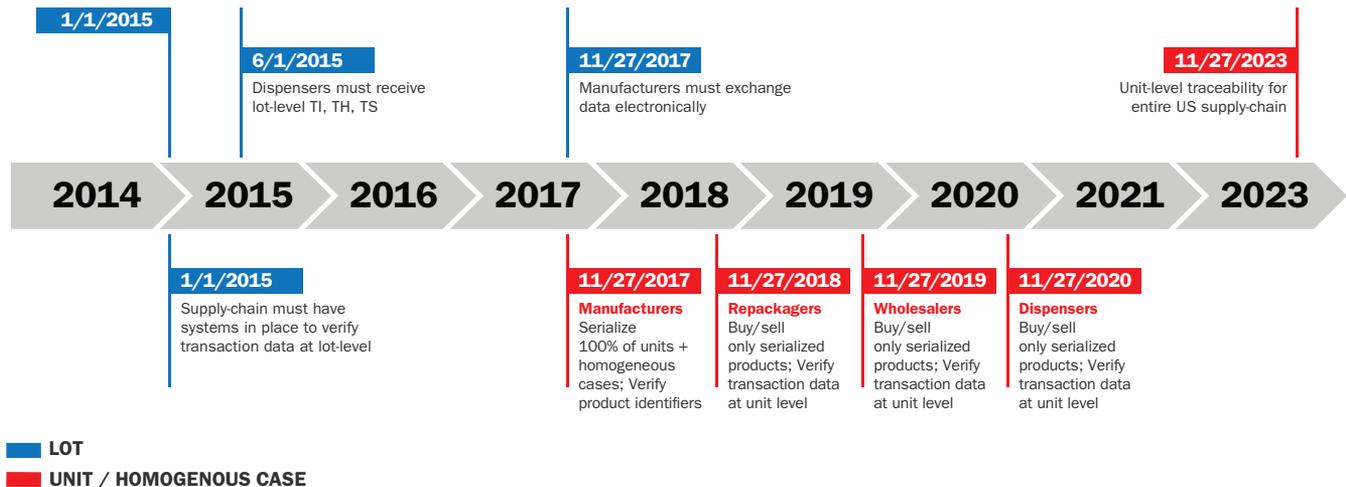
axway
business. in motion.

Virtually all data flowing throughout the Life Sciences supply chain (including interoperability with our competitors' systems) will move through an Axway infrastructure.

By allowing us to run your Axway Global Traceability and Compliance Service in a private cloud, you can:

- **Reduce costs.** Avoid capital expenditures and high up-front hardware and software costs.

- **Speed implementation and focus on your core competencies.** Free your organization from complex, time-consuming IT functions. Let the experts configure and manage the infrastructure to meet your business needs.

- **Improve reliability and performance.** Our private cloud solutions are optimized to ensure minimal latency, comply with data residency rules and meet your security and performance needs. With over 99% uptime, 24x7 global support, and real-time system monitoring, you gain the reliability you need to support your compliance initiatives.

- **Take advantage of flexible processing, storage and deployment capabilities.** You can easily scale your Axway private cloud solution to accommodate changing traffic volumes.

- **Easily expand your trading community.** Add Axway's community management solution to manage your growing community, add new partners and better enable small partners.

- **Get immediate access to innovation.** Centralized updates mean you always have access to the very latest features, patches and upgrades.

DSCSA Timelines

Manufacturers, repackagers and wholesalers must exchange lot-level TI, TH, TS for 100% of shipments

1/1/2015

6/1/2015
Dispensers must receive lot-level TI, TH, TS

11/27/2017
Manufacturers must exchange data electronically

11/27/2023
Unit-level traceability for entire US supply-chain

| 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2023 |

1/1/2015
Supply-chain must have systems in place to verify transaction data at lot-level

11/27/2017
Manufacturers
Serialize 100% of units + homogeneous cases; Verify product identifiers

11/27/2018
Repackagers
Buy/sell only serialized products; Verify transaction data at unit level

11/27/2019
Wholesalers
Buy/sell only serialized products; Verify transaction data at unit level

11/27/2020
Dispensers
Buy/sell only serialized products; Verify transaction data at unit level

■ **LOT**
■ **UNIT / HOMOGENOUS CASE**

Axway Cloud Global Traceability and Compliance Service is a DSCSA ready, GS1-certified serialization solution that centrally manages regulatory requirements to reduce the cost and complexity of compliance with traceability laws.

Axway SaaS on a private cloud offering is simple and affordable, with no need for high cost consultants or extensive IT resources. Smaller organizations can choose affordable subscription-based pricing to leverage our staff and infrastructure. The software is already up and running, so you can deploy it in your enterprise immediately. Customer design and data flows leverage Axway's best practices and management expertise.

If your needs or capabilities change, you can easily switch to an on-premise deployment model for closer integration with other enterprise applications, or create a hybrid solution that perfectly suits your business and technical requirements.

Fully Validated Systems, Processes, and Technology
Axway has extensive experience working in highly validated environments including those governed by 21 CFR Part 11 and Annex 11. The Axway Global Traceability and Compliance Service is a pre-validated solution which comes with Installation Qualification (IQ) scripts, substantially reducing the time to move into production. Axway's software development practices are governed by a complete quality management system which has been extensively audited by independent consultants to verify alignment with 21 CFR Part 11. Other companies provide multi-vendor solutions built on top of 3rd party networks which introduce audit risk associated with non-compliance.

Collaborative network, company stability and market experience
In business for 25 years, Axway is a diverse, profitable, publicly traded company with 1,800 employees. We have been working collaboratively with industries and our customers to deliver traceability solutions since 2005, when the first ePedigree regulations were issued in the United States.

Because we work closely with our customers to fine-tune solutions that work in the real world, we have the largest number of successful enterprise traceability implementations, in companies of all sizes. Industry leaders using Axway systems to govern the flow of data include Amerisource Bergen, McKesson, Cardinal and many more.

In addition, Axway connects to major ERP and edge systems, and we have community connections to the main distributors you need to get started.

Pre-configured reports and self-service interfaces
Axway Cloud Global Traceability and Compliance Service reports and interfaces are packaged up front, speeding compliance with downstream partners and regulatory agencies, and making it easy for users to access information and functions. Upgrades to reports and interfaces are smooth and included — with no requirement for ongoing consulting — which keeps TCO low and eliminates "hidden costs."

Axway customers include:

4 of the top 5 worldwide logistics providers

The top 3 worldwide regulators

Top payers, retailers, 3PLs, reverse logistics providers, contract manufacturers, providers, pharmacies and HIEs

Security and scalability

Axway Cloud Global Traceability and Compliance Service	
Standards and Compliance	**Fully certified by GS1 to be EPCIS compliant** — both in its repository and its query interfaces, so it enables California e-pedigree compliance today **The only vendor that is both EPCIS and DPMS certified** — holding certification for ebXML, Rosettanet, EDI-INT and other standards **A winner of multiple iBusiness awards from HDMA** **Axway solution is 21 CFR Part 11**
Low Risk	**Financial stability and diversity** — Axway is best positioned to support your long-term regulatory compliance needs, covering this as part of our warranty and indemnification **Commitment and staying power** — Axway is the only company offering continuous support since 2005 when - regulations began; other companies, large and small, have abandoned and re-entered the market **Life Sciences industry validation** — GSK, Vertex, Covidian, Hi-Tech, Rising Pharma and Noven have chosen Axway Track & Trace after detailed vendor evaluations **Supports global product security initiatives** — BioGen, Genzyme, Merck-Schering-Plough, Allergan and Bristol Myers Squibb selected Axway's Global Traceability and Compliance to address challenges such as diversion, parallel trade monitoring, anti-counterfeiting, returns/recalls and global compliance
Global Presence	**A true global presence** — Serialization is a world-wide initiative and with a presence on every continent Axway is able to partner with local authorities for each global regulation **Global growth support** — U.S.-centric competitors do not have the size, experience or sustainability that Axway offers in support of the global growth of its customers

With Axway Cloud Global Traceability and Compliance Service, you get a dedicated environment that ensures maximum security and scalability. Other vendors use a shared infrastructure that co-mingles data, and suffers performance degradation as multiple customers increase volumes. Axway solutions run some of the largest exchanges in the world and the repository is optimized for large record volumes.

Call 1-877-564-7700 to learn more about how Axway's Global Traceability and Compliance Service can help you meet global regulatory compliance requirements using a high performance and reliable deployment model that fits your needs, regardless of the number of SKUs or the complexity of your partner network.

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