What is a Cloud Serialization and Traceability Solution?

Track, trace, and serialization implementations have reached beyond the four walls of a single site. From manufacturing to dispensation, desperate trading partners and other stakeholders have an immediate need to share information at any level of the supply chain. The core principles of a Level 4 system make it uniquely positioned to deliver data sharing capability up, down, and across the supply chain.

A Best In Class Cloud Serialization and Traceability Solution should use multiple standard data exchange protocols, exchange patterns, data security, and data integrity techniques.
WHAT IS A LEVEL 4 SYSTEM?

A complete serialization solution is composed of many different software and hardware components. Each of these components focus on a single area of concern or responsibility. In the world of track, trace, and serialization each concern has been assigned to a “Level”.

According to ISA95, there are five levels when discussing Track, Trace, and Serialization. They are Levels 0-4. It is common to discuss hardware and software in terms of Level 1, Level 2, Level 3, and Level 4.

A Level 4 System (Cloud Serialization and Traceability Solution), in many ways, is the viewport into a customer’s piece of the supply chain. A Level 4 system provides various functional areas to handle an assortment of business processes, global compliance, inter and intra-organizational connectivity, reporting, identity access management, application programming interfaces, and other enterprise-level functional areas.

Perhaps the most accurate and succinct definition of the Level 4 system is that the Level 4 manages the business-focused activities of manufacturing, warehousing, and distribution operations.
FEATURES OF A LEVEL 4

This section will cover the must have features of a Level 4 System.

**User Interface**

The user interface (UI) must be clean, crisp, and modern. This cannot be understated.

The user interface should be responsive to the current viewport’s dimensions. Meaning the UI should shrink down and be 100% functional on a mobile phone and scale up to be displayed and fully functional on a large flat screen monitor.

Internationalization is another need. Not only should languages translate correctly, depending on the user’s device language settings, but care must be taken to ensure view real estate accommodates the physical area differences taken by various languages for the same words and phrases.

**Centralized Location**

A chief concern of the Level 4 is to provide functional areas to handle Business Logistics. Therefore, centralization and secure connectivity is a must. It is common for various user and system roles, within a given organization, to require access to various functional areas or APIs provided by the Level 4.

Warehouse and distribution center workers will need to perform business processes on data collected at the packaging line (Level 2) aggregated by a site level system (Level 3). Before these workers can do their jobs, the Level 3 must send relevant data to the Level 4. In this scenario, without a proper Level 4, the warehouse worker, and distribution center worker would both work on different networks and would be unable to share this same data. Therefore, the Level 4 system is centrally located and accessible by authenticated and authorized users and systems.

**Security**

Identity Access Management (IAM) plays a critical role in this requirement. Not all actors, be they human or system, will have the same access to Level 4 functionality and API operations. A secure Level 4 will use Multi-factor Authentication (MFA), Certificates, API Keys, and HTTPS, at a minimum.

**Electronic Signature**

CFR 21 part 11 clearly states that all changes within systems dealing with pharmaceutical operations must record electronic signatures for any changes made to data within that system.

**Auditing**

It is critical that all actions taken within the Level 4 by any actor, human or system, be audited. The audit should include an actor identifier, date and time, the underlying object that was changed, the value before a change, the value after a change, and the type of change that occurred. For example, deleted, created, or updated.

**Centralized Logging**

The ability to collect and centralize logging from site-wide Level 3 systems, as well as the Level 4 itself, and to provide views into that logged data is a needed feature. This feature will provide valuable, system-wide usability metrics and provide faster problem resolution.

By centrally locating logging information, a competitive point-of-difference is gained.

**Message Intermediation**

Because of the Level 4’s centralized accessibility, the Level 4 is where message interoperability, between two or more systems, occurs. Transforming AJAX into XML, XML into CSV, or one XML format into another XML format before data is moved to another system.
Global Compliance

Global Compliance, meaning adhering to various government legislation and regulations, is another functional area in which the Level 4 system is well suited.

Government laws and regulations come and go as well as change. DSCSA, SFDA, Turkey, Europe, Argentina, Brazil, South Korea, and India all have very different requirements. Therefore, a certain amount of flexibility must be factored into any system, Level 4 or otherwise, to meet these demands.

Some governments require systems to send properly formatted data directly to a central system. Others take a more manual approach such as email of (S)FTP. Whatever the case the Level 4 must be able to accommodate. In either generalized workflow category: inter-system or manual, there must be a facility within the Level 4 to record the work-flow.

Aggregation Views

The ability to inspect the aggregation of a given Batch/Lot and/or Object Identifier such as an SSCC or SGTIN is vital. It is useful for the user to view not only the identifiers and their children and parents but also to view data associated with the identifiers. A few useful data points are:

a. Disposition
b. Packaging Level (Pallet, Case, Item etc.)
c. Genealogy (Grandchildren, Children, Parent, Grandparent, Great Grandparent etc.)
d. Last Known location (GLN or LAT. LONG. Pinned on a Mapping API)
e. Current Location (GLN or LAT. LONG. Pinned on a Mapping API)

Additionally, it is useful to provide the ability to export these data to a report.

The ability to traverse the aggregation hierarchy, both up and down, is also required.

Serial Numbers

Although normally not the system of record for serial numbers, it is useful to have a degree of serial number management in the Level 4. The degree will depend on the system of record of the serial numbers. For example, Adents’ Supervisor manages serial numbers and would be the system of record. It is useful for the Level 4 to view serial number ranges in order to inspect and audit Supervisor’s issuance of serial numbers. It is also desirable to have the Level 4 configure serial numbers and communicate new and updated serial number information back to the Level 3 system.

Business Processes

The Level 4 must have a facility to execute business processes. A business process can be defined as any problem that a customer must solve in order to be compliant with government imposed regulations and/or to be compliant with their own SOPs.

Examples would be packing, shipping, disaggregation, global compliance reporting, printing, sending files/data to other systems, or receiving files/data from other systems.

Label Printing

In a warehouse or distribution center, it is not uncommon for labels to get destroyed or to have rework occur that requires additional label printing.

Label Printing should come in two flavors:

1. Reprinting – In the event a label is destroyed, the label would be reprinted with the same serial number.
2. Printing – If a new label, meaning a new serial number is required, the Level 4 software must facilitate obtaining a new serial number and applying that number to a new label.
**Reporting**

Reports are always a requirement in any enterprise level software system. Level 4 systems are no exception. Again, reporting can be a big point-of-difference. So far, this document has covered some reporting such as Aggregation and Global Compliance.

Reports can be thought of in two classes:

1. Industry Reports (Aggregation, Auditing, OEE, Security, Global Compliance)
2. Customer Driven Reports (Custom reports on customer defined data sets)

**Cloud Deployment**

There are many advantages to deploying any modern system into the Cloud. Many of these advantages come out-of-the-box. Features like:

1. High Availability
2. Unlimited Scaling
3. Durable Storage
4. Managed Database – SQL and NoSQL
5. Identity Access Management
6. Virtual Private Networks
7. Big Data Capabilities

All of these features and capabilities are desirable in any enterprise application. The Cloud makes these things a reality with very little, and sometimes zero, extra effort and at a tremendous cost savings when compared to on premise, physical hardware alternatives.

Data integrity, security, and resiliency benefit greatly from built-in features of the Cloud infrastructure. Data Centers that are thousands of miles apart can now be set up in minutes. Multiple Data Centers ensure data is protected from loss and that data is available to all applications dependent on that data. Backing up, restoring, and ensuring consistency among data centers is clean and concise.

Another benefit of the Cloud is the maturation of DevOps. Building, testing, and deploying software on the Cloud is able to follow predictable and repeatable processes that were not easily achievable just a few years ago. Principles and practices of solid DevOps methodologies ensure a high level of quality and dependability.

**SUMMARY**

As far as a Level 4 system goes, the aforementioned functional areas are the “Big Rocks” meaning these are the critical features outlined in this document and are by no means exhaustive. Adents is as creative as possible when adding features to Level 4 software. Like any other product, it takes constant evaluation of the market, competitors, and customers to decide what features should go into Level 4 software and in what order of priority.
Chuck Sailer

Chuck Sailer is an Adents Serialization Solutions Expert with more than 20 years of supply chain and track and trace experience.

Prior to joining Adents, Mr. Sailer served as VP of Product Development for Frequentz, a Silicon Valley track, trace and serialization company, which he helped turn from a product-centric to customer-centric company. He was also the co-founder and software architect of Apostrophe Systems, which was acquired by Systech International. At Systech, he helped to fold Apostrophe’s products and services into Systech’s portfolio and practices.

A retired Sergeant in the U.S. Army, Mr. Sailer attended Data Processing Trainers, Philadelphia for Client Server Technologies, and the University of Phoenix for Computer Science. He also has completed extensive course work in Business Financial Accounting and Marketing from the Wharton School of Business, as well as extensive course work in data science from both Johns Hopkins University and University of Illinois at Urbana-Champaign.

Christophe Devins

Christophe Devins is the CEO and Co-founder of Adents with more than 30 years of experience in coding, product identification and traceability.

Christophe was actively involved in Gencod which would later become GS1, and is recognized as one of the key architects of the global standards for barcodes.

In 2007, Christophe co-founded Adents designing one of the most powerful and visionary software solutions for unit identification and traceability capable of achieving high speed serialization and real time global unit traceability, enabling brands and manufacturers to create a more personalized connection with their markets.

Christophe is regularly approached by international institutions for discussions around product identification standards and traceability issues.
Adents is a leading software company providing solutions for unique product identification and traceability to help pharmaceutical manufacturers and contract manufacturing organizations (CMOs) adapt to market changes and comply with regulations on drug traceability. Adents Seriza, a serialization solution for manufacturing sites, has been selected as preferred solution by Siemens for its customers. Adents Prodigi, a cloud solution jointly developed with Microsoft and powered by Azure technologies, allows for secure data exchange and helps leverage the power of serialization data. Adents operates globally, with offices in Europe and in the United States and a worldwide network of solution partners. For more info, visit www.adents.com.