MASTER DATA & SERIALIZATION

Understanding the Bidirectional Impact

tracelink
Life Sciences Cloud

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With at least 75 percent of the global drug supply requiring track and trace regulation by early 2019, companies are focused on addressing the complexities of serialization. One major challenge is the maintenance and exchange of information about each product, source, and destination. Such information—known as master data—is integral to both the packaging and labeling process and the data exchange requirements involved with serialization. Understanding the impact of master data on compliance will help you determine how to plan your serialization strategy.

Every serial number must be accompanied by master data as it journeys through the supply chain. As one global serialization leader from a Top 10 manufacturer recently noted, "We're no longer just shipping product. Now we have two shipments: the actual product, and information about each individual product."

In this eBook, we look at master data definitions and types, how it impacts country compliance, and why it's critical for serialization.

PART I: MASTER DATA AND SERIALIZATION

DEFINING MASTER DATA

What is master data? Master data functions as a single source of truth to build a reliable system of record—no matter where the data is encountered in the supply chain. Master data defines the contextual attributes of a data object at a foundational level by describing elements such as product name, a price list, or a partner shipping address. It can be helpful to think of master data as the nouns in business data: company location, unit of measure, dosage form, contact email, or government drug code.

Master data interacts with transactional data, which describes what the data is doing. Think of transactional data as the set of verbs in business data: the sale, shipment, or decommissioning of a product, for example. Pairing master and transactional data streamlines the number of data elements sent to disparate compliance systems throughout the supply chain, thereby reducing the risk of data ending up in the wrong place or format. Even within the same market, different supply chain participants may require slightly different sets of master data or different formats to meet unique needs of their current systems and processes.

MASTER DATA CREATION

Master data is created and then reused repeatedly and stored in many systems, such as an ERP or government repository. It is constantly being added, removed, or edited within a dataset. Adding a new site or partner location contact requires data such as GLN or other identifiers, while a new product may require manufacturer name and packaging code type. Different companies may refer to products or partners in different ways, so efforts to synchronize such information must be made. Since it lives in multiple places, master data is at risk of becoming inaccurate, redundant, or stale if vigilance and best practices are not employed.

KEY TYPES OF MASTER DATA

Master data tends to have a single definition with a very low frequency of change versus being defined situationally. In the life sciences supply chain, there are three key subsets, each with its own fundamental attributes, dataset, and requirements:

- **Company Master Data** contains a record for each of your company's locations, including address and company identifiers such as GLN and DUNS number, country code, business logo, and business type.

- **Partner Master Data** identifies your partners and their locations using attributes describing addresses, contact information, and global identifiers, such as DEA, HIN, DUNS, or State License.

- **Product Master Data** is a list of all your products and their descriptive information. When adding a new product, you might need to include elements such as target market code, product name and description, currency code, unit price, strength, GTIN, or aggregation requirements.

Product master data is often the most difficult form of master data to manage because its information is complex, changing, and stored across multiple internal systems. Depending on country, you may need to codify elements such as the Brazil ANVISA registration number, Saudi drug code, or United States national drug code (NDC). Only after you've entered a product into your master data can you create and manage its serial numbers using your company's serialization solution.

Different countries and trade partners will want different attributes of data for different reasons. In order to share your master data across multiple complex and disparate systems as part of serialization, you will need a well-crafted management approach that addresses all government and trade partner requirements.

THE IMPORTANCE OF MASTER DATA FOR SERIALIZATION

In serialization, you are applying serial numbers to a given product, case, or other packaging unit, so you need a defined set of attributes that a track and trace system can use to manage data. Ultimately, master data is referenced during data exchange between internal and external interfaces and is used to ensure that core information gets to the right place and is aligned with the right serial number.

Master data also supports the complexities of packaging and labeling by including a product's "pack-out" configuration during serialization. To generate serial numbers for an aggregated product, for example, you'll need the ability to identify how many items are in a case and how many cases are in a pallet. Each pack-out configuration can even vary from market to market.

When companies begin thinking about serialization, they tend to focus first on just the serial number, and then on transactional data—with the foundational aspects of master data often getting overlooked. An inherent part of compliance reporting, your master data must be well-defined and clearly managed. If you focus just on the packaging line and how to get a serial number on a package, then you are likely to run into challenges later because you have not accounted for master data usage throughout the entire serialization process.

For example, reporting the exchange of serial numbers and other data often involves integrating with government systems. One drug may actually have dozens of representations based on varying country requirements, such as:

- India – Whether or not it is a scheduled drug.
- South Korea – The current supply price.
- European Union – May be available over-the-counter in one country and by prescription-only in another.

In the United States, master data is required in both lot-level and serialized exchange of data. If your partner master data contains inaccurate information for contract packagers or wholesalers, it is very difficult for partner systems to manage your products effectively in their operations. If contract packager or internal packaging sites don't have the proper master data, serialization processes can run into problems. By understanding data requirements and addressing master data challenges from project inception, you are positioning your business to scale more quickly and efficiently.

Many large organizations begin serialization projects believing they have good master data, only to discover that many of their identifiers—such as those associated with their trade partners—are no longer valid or are rarely found in the same system. It's crucial that you are using the right data to serialize your products, associating this data with each serial number in your enterprise repository, and sending the right data with your products to the right partners. Fulfilling this objective begins with managing and integrating your master data in the serialization and track and trace process. Unless you address master data as a fundamental component of your serialization and regulatory reporting project, compliance may be at risk.

WHAT IS MASTER DATA MANAGEMENT?

Master data management (MDM) concerns the technology and processes used for the ongoing maintenance of master data. To protect the health of your master data, you need a comprehensive program that can measure and deliver on four key objectives:

- Accuracy—Give operators the chance to enter data correctly.
- Availability—Optimize search features and minimize interruptions.
- Quality—Minimize errors and protect your brand.
- Integrity—Protect your systems and your patients.

The best MDM program requires efficiency and accuracy to improve system performance and trade partner satisfaction. Your success hinges on forward-thinking leadership that advocates the grooming of consistent, accurate master data. Your data modeling process must include participation by business users in your organization. Their knowledge of business processes is crucial in determining how your master data will evolve and adapt to the ever-changing business requirements.

The more you prepare up front and incrementally, the greater opportunity you will have to provide, receive, and verify good, clean data during data exchange instances. Ultimately, you want your MDM approach to address regulatory complexity, trade partner diversity, and operational efficiency in such a way that you can spend more time serving customers and less time managing systems.

PART II: THE IMPACT OF MASTER DATA FOR YOUR COMPANY

Good management practice is about maintaining master data throughout its lifecycle. While the level of effort may seem high, be aware of the risks you are taking when you choose a "business as usual" approach to MDM in the age of serialization.

THE RISKS: THE IMPACT OF MASTER DATA ERRORS

Having incorrect or incomplete master data can result in compliance reporting errors throughout all segments of the supply chain. In a typical CMO integration, for example, serial number structure and forms are validated against the CMO partner master data and the product master data attributes that an authorized CMO will produce. The validation and acceptance of serial numbers relies on the serial number flow. This flow can be disrupted, and cause system errors, when a piece of master data is incorrect.

Organizations that must integrate various enterprise resource planning (ERP) systems introduce risk because each system may contain conflicting or incomplete master data attributes. Storing the wrong unit price in one place may have a tremendous impact on the financial outcome of a product. Listing the wrong strength or shipping address can lead to fines, recalls, and a public health risk.

In the United States, for example, you are legally required to send T3 (transaction history, information, and statement) containing master data to your wholesalers. If your partner master data does not contain accurate information for those wholesalers, then it is very difficult for your compliance solution to send data to partners when it cannot recognize them.

If you're a manufacturer and your compliance data is wrong, your drug products can end up quarantined, costing you money, holding up your downstream partners, and causing drug supply shortages for patients. Incomplete or erroneous master data may result in additional significant risks, including:

- Patient safety data.
- Compliance costs for corrections and development of more efficient processes.
- Risk to the rest of supply chain.
- Trade partner satisfaction.
- Heavy fines.
- Legal exposure.
- Risk to company image and investor perception.

But even smaller inconsistencies in your master data can cost you in terms of labor and system resources. In some cases, you may need to track down required data provided in a transaction history to ensure that it meets a certain format for compliance. Or an inspector may ask you to describe the processes you have in place to meet certain requirements, such as the archiving and retrieval of your documentation. In the United States, this can include a spot-check request to see all the archived T3 for a product that meets given criteria, such as a specific NDC. If there is a discrepancy in how your business categorizes that specific type of NDC, you may find yourself spending crucial hours investigating how that master data was created and how it may have been corrupted.

PERSONNEL: WHO SHOULD BE INVOLVED?

Your IT and business strategies are what support the quality of your master data. A robust and scalable master data management approach works best when the business and IT personnel are harmonized and working closely on data definitions and processes.

When considering the best approach, evaluate the upstream and downstream impacts of how your trade partners will engage with the data. Giving equal attention to processes, the organization, and the technology—with a focus on how data will be consumed—will ensure the most responsive MDM processes and systems in which continuous improvement is achieved and celebrated.

Working with IT and business personnel early on can help you prioritize the most pressing requirements, scope of the project, available resources, and project milestones. You can work with these resources to start small and allow you to scale your MDM efforts as you are ready to add new master data streams.

GETTING STARTED

Engage with internal and external stakeholders to better understand master data design and structures as early as possible. By starting the review of data as soon as the project begins, you will develop a collaborative system with data modeling that supports both the sending and receiving parties.

Here are several key areas to consider as you formalize your project:

- Define the roles and responsibilities.
- Get engagement and agreement from all stakeholders.
- Define holistic business policies and processes across the organization.
- Identify and capture standard operating procedures (SOPs).
- Identify core entities that need to be identified by your master data.
- Design applications to avoid unnecessary need for master data creation.

The importance of developing a company master data policy cannot be overstated. By formally identifying and defining your required process of setting up one product, you are positioning yourself to scale your business in order to successfully capture the master data of your next product. Investigate and monitor the complexities of compliance requirements for other countries. Do you know how many potential market codes you will have to prepare? Your current master data may have only 10 attributes required for a certain product in one country, but how will your system handle a very complex market such as China?

TARGET MARKETS: WHAT VARIATIONS ARE THERE BY COUNTRY?

Regulatory variances in product and packaging requirements between countries are nothing new for the pharma industry. But the new world of global serialization, the scale of master data nuances, and system customization requirements demand a new level of MDM sophistication. For example, one serialized product may have 100 data elements that inform a pack-out configuration, determining how many units go into a bundle, case, and pallet.

The same product is going to have different identifiers by country, such as NDC (United States), PZ (Germany), and ANVISA Registry Number (Brazil). And the supply quantity may range from a 7-day to a 60-day supply. If one of those data elements contains stale or inaccurate information, errors can occur and you may be prevented from importing your drug product into another country.

Let's look at a few examples of regional requirements that may inform your need to plan for future master data challenges.

United States

By law, you are required in the United States to send compliance documentation containing master data to your wholesalers or other trade partners. If your system cannot identify those entities, then the data cannot be shared with them. Your compliance system also needs access to the correct NDC for each drug product being sold to address the issue in which the NDC's 10-digit form at point of manufacture may not match the 11-digit form used by a wholesaler for the exact same drug.

China

Under the current system in China, serial numbers are issued by the Chinese government and then obtained after manually uploading the master data for all products that you sell in-country. The company then runs a query on the China Food and Drug Administration (CFDA) system. Reporting data is manually uploaded to the CFDA before shipment, with a file-size limit of four megabytes. Given the complexity of these requirements, master data is critical here. You need to be sure that the right data is being channeled; if not, your compliance report can fail by not using the same point of truth for your master data.

European Union

European Union (EU) regulations have a significant impact on the reporting requirements of your system. Since the EU isn't a homogeneous market for Falsified Medicines Directive (FMD) compliance, you'll need to know the correct drug product code for each of your target markets. But the volume of serialization in the EU is significantly higher than in the United States because the actual packaging is at the level of the patient-use drug form.

For every drug product you produce for the EU, you must let the European hub know which countries or target market that product is intended for so that the hub can determine to which national system it should supply product pack data. What if your drug product requires a prescription in one country but is available over the counter in another? A manufacturer or parallel distributor is required to report such product master data, plus any subsequent product updates, to the central European hub. From there, the product pack data is then distributed to the appropriate national systems serving the identified target markets. Your system must account for these variations so that you can appropriately inform the European hub and ensure supply across the diverse EU market.

India

India has many unique requirements for serialization, including:

- Generating compliant, digital XML reports for company and product master data to be transmitted to the India Drug Authentication and Verification Application (DAVA) portal. You must prepare and report the company, product, and partner master data initially, as well as update the data in DAVA when it changes. The company master data includes a company prefix assigned by GS1 India as part of the initial registration process and you have to coordinate with GS1 India, which is the responsible party for providing it to the DAVA portal.

- Requiring unique product master data, such as the need for companies to include a flag that identifies scheduled drugs. You are required to include a product image as well, introducing further complexities: you must ensure that product images are available for all product configurations, that the images fit tight file-size limitations, and that the images can be made available to your compliance system for reporting purposes.

- Exporting goods from India. The Directorate General of Foreign Trade (DGFT) is currently working to identify the precise data attributes needed for partner master data. Once that dataset is identified, there will be partner master data to work with when exporting goods from India to be distributed to another trade partner.

PART III: HOW THE TRACELINK SOLUTION CAN HELP

Preparing for compliance is about much more than just collecting your master data and getting it into a system. You may need to manage master data based on serialization requirements that didn't exist before. This information then needs to flow in from different parts of your organization so it can be shared with governments, trade partners, or other organizations when needed.

Serialization is much more than affixing a number to the side of a package. Companies must support trade partner choreography by generating, tracking, exchanging, and storing serialized information. If you are preparing a comprehensive manufacturing integration, it is important that your serialization provider validates information that CMOs provide to you to make sure the data is clean. Your trade partner should also validate the information you give to them in order to establish a clean integration. A CMO, for example, typically receives serial numbers from their pharmaceutical customers and then communicates when a serial number for a drug is reserved, commissioned, shipped, decommissioned, or destroyed at their facility.

This choreography requires electronic integration with each trade partner. When working with multiple partners, you likely don't have enough time to tackle each individual connection on a point-to-point basis. A better solution is to find a network approach that supports a single set of formats, workflows, and file taxonomy in order to simplify data exchange with multiple partners.

THE TRACELINK ADVANTAGE

Master data coordination is an integral part of the TraceLink solution. There is built-in intelligence throughout the platform to create checks and balances, and ensure that the correct master data is routed to and used in each trade partner and government authority data exchange. TraceLink acts as a central master data exchange for company and location data for you and your trade partners, while streamlining your ability to share product master data with packaging lines, distribution centers, and 3PLs to ensure optimal serial number management.

Integrate

TraceLink provides a single, flexible platform that supports data exchange throughout the entire supply network. Being able to integrate with various middleware, ERP, and WMS systems ensures that the necessary master data is received, analyzed, processed, and transmitted in order to enable virtual team collaboration on supply planning and execution.

Synchronize

TraceLink synchronizes master data for company, partner, and product information by allowing you to choose among several options for how you exchange master data from your internal master data management system to any and all supply or trade partners, including:

- Manual entry through the TraceLink user interface.
- File upload (such as CSV).
- Automated XML interface for updates on a period- or change-triggered basis.
- Push master data to other subscribing systems to coordinate serialization data exchange.

And with comprehensive and continually updated master data support, TraceLink works with your MDM system across a broad range of regions, including the United States, EU, Brazil, China, South Korea, and Turkey.

Accelerate

Integrating TraceLink with your master data has other distinct advantages including a reduction in implementation time and expense. When a request is sent to the TraceLink network, it passes in key identifiers for companies, locations, and products, with TraceLink performing the necessary lookups against the master data and populating the additional required data elements for the transaction before delivering the data outbound. That means your company will need to use fewer data elements in your transactional data, simplifying your transaction integration when country-specific master data isn't readily available in the transactional systems.

NEXT STEPS

Serialization brings a greater level of security to the life sciences supply chain, a benefit ultimately passed on to patients. Most companies have not taken the time to address the master data complexities they'll be managing, but that is an essential step.

Here are some key questions you and your company should be able to answer as you conquer the master data management peak on your way to serialization compliance:

- Are we giving enough attention to master data during projects?
- Where does master data live in my company and how do we access it?
- Do we have a comprehensive MDM program and/or roadmap?
- What do our partners need in order to consume our master data?
- Do we have a master data policy for maintaining and adding products?
- What general master data fields do we need?
- Will my solution have a full-featured master data exchange capability?
- How will my solution enable me to verify that the product I'm shipping out of a packaging site is properly serialized?
- How will my solution address global export requirements?

Getting master data right at the onset of your serialization program is difficult because it continually evolves and requires constant maintenance. That's why it's important to find a solution that addresses your master data holistically.
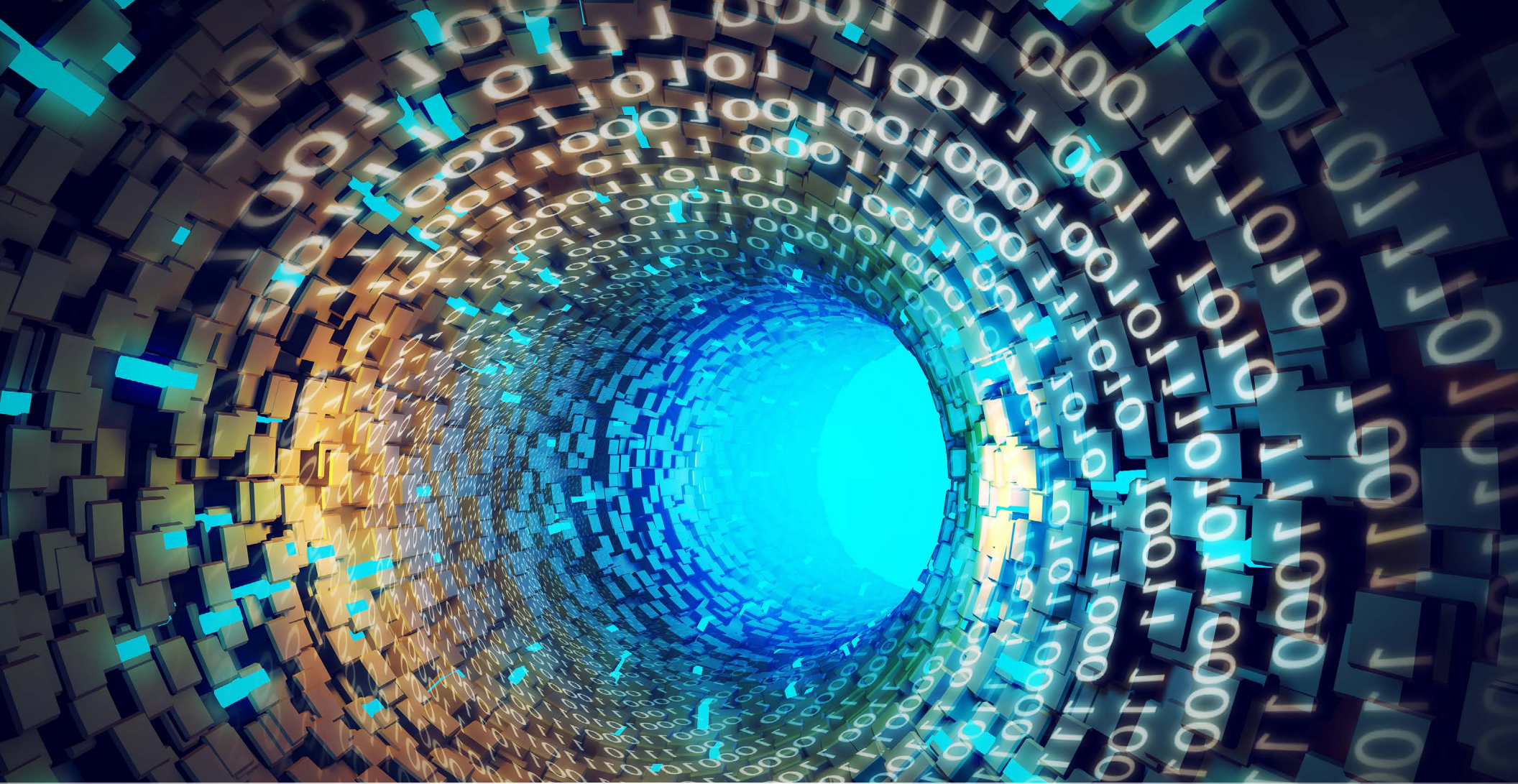
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