PRODUCT TRACEABILITY IMPLEMENTATION GUIDELINE

WeDigit

Author

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He also worked previously in different functions for Energy, Oil and Gas industries, always focusing on deployment of technology to solve complex business problems. Leandro had the opportunity to visit 40+ countries either for tourism or working reasons, has led hundreds of professionals and teams spread across many countries and has lived in 3 countries so far in Latin America, Europe and Asia. A thought leader passioned about supply chain management, convergence of technology and automation solutions, always looking for effective ways to implement them.

In 2021 he founded WeDigit, a boutique management consulting firm that aims to provide an enhanced experience for organizations around the globe when adopting technology. Leandro also has a B.S. degree in System Analysis, MBA in Project Management by Fundação Getúlio Vargas (FGV Brazil) and University of California, Irvine (UCI US), also holding the Project Management Professional (PMP) and APICS Certified Supply Chain Professional (CSCP) certifications.

Reviewer

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Ricardo has a degree in Pharmacy and Biochemistry, also master degree in Business Administration by FGV Brazil, MBA in Project Management by FGV Brazil, a CPIM - APICS certification and green belt certification. Currently is the ISPE ® president and chair of the cold chain committee.

Disclaimer

The recommendations contained in this guideline are not a replacement to existing regulatory and other trading partner traceability and compliance requirements and processes. Rather to be used as a guide for improving the ability of an organization to properly plan and execute traceability projects; in a consistent way, exploring business opportunities and benefits internally and externally in collaboration with customers and/or consumers.

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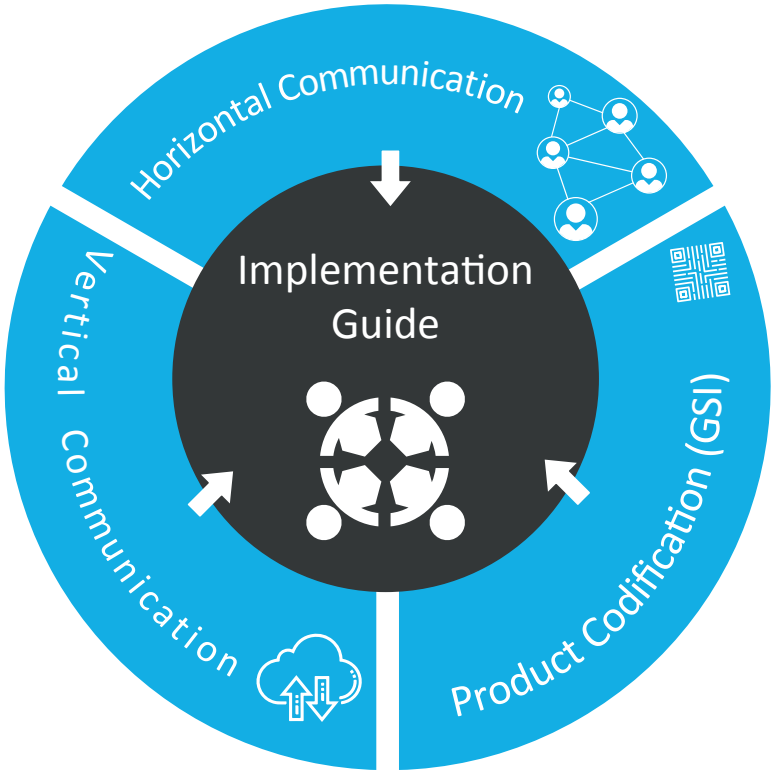
1 Purpose of the Implementation Guide

This guide is intended for managers and professionals from companies that are part of supply chains, regardless of the industry sector, who need to implement product serialization and traceability processes, and are seeking guidance and references of best practices to deploy projects in this area of knowledge.

This document may not cover all topics relevant to serialization and traceability projects, but addresses the ones considered critical to a successful implementation, helping teams to plan and execute projects in their respective companies.

As shown in the picture below, this guide is embedded into a context of interdependence with other guides and technical documents.



Picture 1: Integration among serialization and traceability guides and technical documents.

Technical documents detailing connectivity methods with regulatory agencies (vertical communication), connectivity and integration with supply chain trading partners (horizontal communication), and product codification, serve as a basis for requirements documentation and therefore determining the project scope.

The content of this guide was compiled based on the experience of the Author, who have led in the past 20+ years, projects and teams focused on IoT, in small and large corporations, working both as part of the industry and solution providers, with complex projects in Latin America, Europe, Middle East and Asia.

2 Relevance of Product Traceability

Technologies that enable product serialization and traceability are part of the body of knowledge of IoT.

According to Deloitte's definition, "IoT refers to a world of products that are connected to a network, such as the Internet, a company intranet or a network using industrial communication protocols. IoT products can be anything, from an iPhone, to a wind turbine, to a refrigerator, as long as they have a way of communicating to a 'home base', to send or receive data. Connected products generate data for automating business processes or enabling new services. This data can be used to improve the technical characteristics or the usability of a product, or to offer new services to customers, or it can be sold to a third party." [16]

In this context, the implementation of product serialization and traceability at the sellable unit level can be considered as a foundation for IoT adoption in the supply chain.

The use of unique product-level identifications has now become a norm in various industry sectors. Some examples are tobacco, pharmaceutical, automotive, electronics, clothing, food, household appliances and other types of consumer goods and industries.

Solutions are becoming more accessible every day, best practices are being disseminated, global and local suppliers help to create an environment of competition and innovation that brings concrete benefits to the supply chain players.

Whether due to regulatory pressure, the need for a greater integration across supply chain members, or pressure from consumers, the adoption of traceability concepts is increasing exponentially worldwide:

- Traceability is one of the most important pillars within the Food Safety Modernization Act (FSMA) by the U.S. Food and Drug Administration (FDA).
- In the Pharmaceutical sector, traceability regulations worldwide are present in more than 50 countries, and serialized products are currently covering more than 80% of the global volume of medicines [2].
- Multinational companies such as Cargil, Olam, and others in the food area are creating traceability portals to give transparency about product provenance [3 4].
- Luxury clothing brands consistently investing in enhanced visibility about the flow of their products in the supply chain [5].
- Decathlon implementing RFID throughout its product portfolio globally, exploring benefits with inventory management, enhanced product flow visibility and retail automation [6].
- GS1 Global Working Group called Visibility4Cargo starting activities in 2021 to create an implementation guide to connect both product and cargo traceability worlds together [17].
- Many other examples of traceability adoption within the context of Industry 4.0 can be found online.

Many companies are nowadays using traceability concepts in a much broader perspective, as a strategic complement for business models, as well as a foundational capability for future competitive advantage.

The combination of unique product identification technologies (serialization), distribution flow visibility (traceability), and consumer engagement initiatives (customer intelligence) can create the foundation, the cornerstone that will enable opportunities for automation, innovation and tangible benefits that go far beyond simple compliance with a regulation or basic connection with customers and consumers.

The Challenge 3

Traceability projects involve internal and external coordination. They are by nature disruptive and can positively or negatively impact business processes related to manufacturing, distribution, and logistics.

From an internal point of view, a set of functional areas in an organization need to collaborate for the project to succeed. From an external point of view there is the need for alignment with partners along the chain, interoperability among systems and identification of mutual benefits. In some cases, as the pharmaceutical sector for example, it is also necessary to ensure interoperability with platforms created by health authorities, that consolidate traceability data for a given market centrally.

Several factors are essential to ensure a successful adoption of product traceability concepts. Correct understanding of regulatory requirements (where applicable), robust mapping of business and user requirements, engagement from top management within the company,

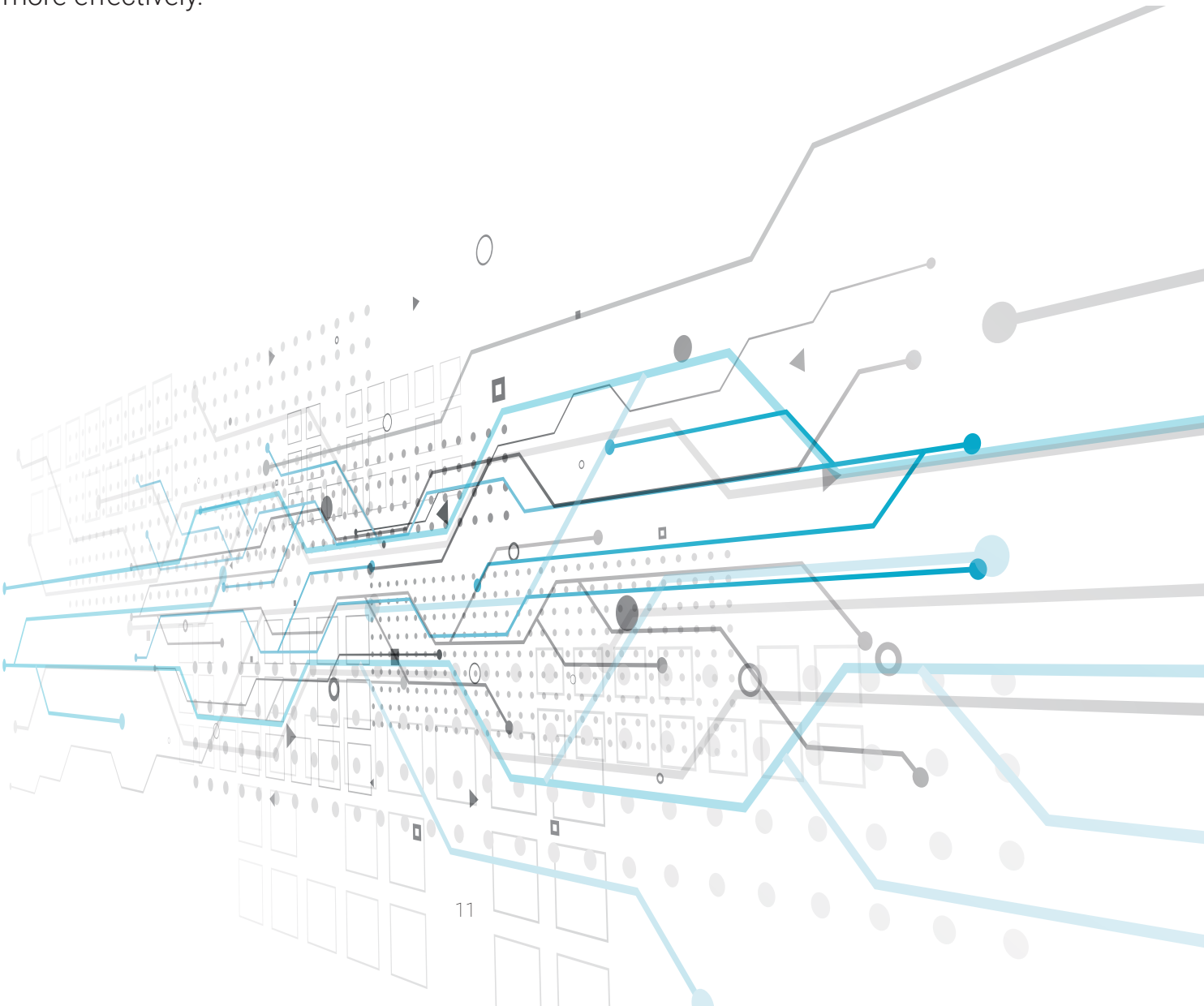
establishing long-term partnerships with technology solution providers, are some of the examples. Other factors have to do with the company's previous level of experience with the subject of traceability:

- Previous experience with the implementation of traceability solutions.
- Understanding how technology affects manufacturing and logistics processes.
- Knowledge of common risks and problems, lessons learned.
- Experience with application of global standards and best practices.
- Knowledge of global and local solutions and providers, as well as experience with different types of solutions and their applicability in specific business models.

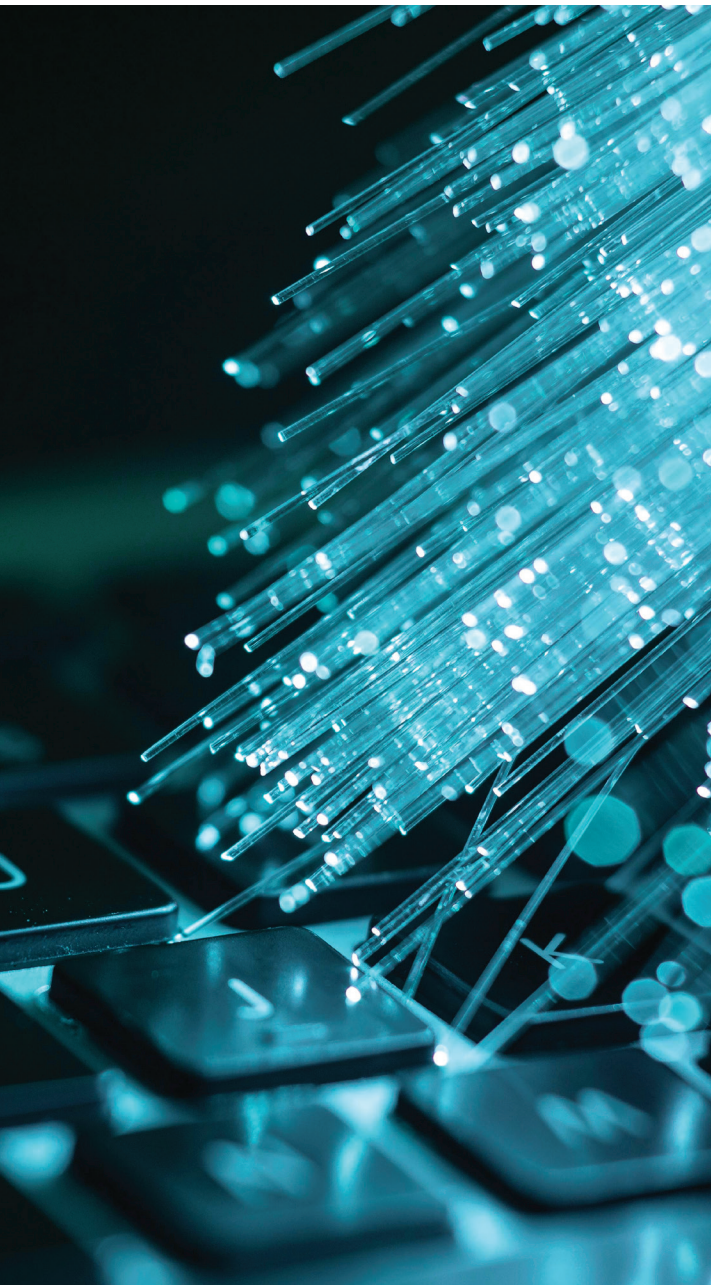
- Expertise with the application of change management concepts. Due to the very disruptive nature of these projects, it is critical to have this area of knowledge also covered well.

Within the context that previous experience will increase the chances of a successful adoption of these types of technologies, the great barrier to overcome then becomes the scarcity of human resources that can bring this knowledge in a practical manner.

This guide brings content, recommendations, and examples that will fill a portion of this knowledge "gap," and help managers and professionals from business areas, IT, engineering, and others, to plan and conduct their projects more effectively.



4 Basic Technical Concepts



When dealing with IoT concepts applied at product level and visibility of their flow throughout the supply chain, some basic initial concepts need to be properly understood. They are Serialization, Aggregation, Traceability, Verification, Authentication, Consumer Experience.

The application of IoT concepts in consumer products has been growing significantly in recent years as part of a broader digital transformation strategy that companies are going through. The following factors are directly contributing to an acceleration in the adoption of these concepts:

- Innovations and cost reduction of tags for product identification (e.g., RFID, NFC, BLE, etc.).
- Technological innovations for data exchange and device integration (e.g., 5G, mesh networks, communication protocols, standardization).
- Mass adoption of traceability solutions involving real-time geo-positioning.
- Increased maturity of suppliers and professionals in the concepts of Industry 4.0 and IoT.

- Increased number of suppliers at global and local levels, bringing a natural reduction of implementation costs by increasing the offer of equipment and software platforms.
- Escalation in the use of global standards, which reduces complexity and increases interoperability of solutions and integration of systems and equipment. Besides GS1 standards, there are other initiatives to align best practices and generate standardization like the Open-SCS working group. Open-SCS is an open-source serialization and traceability communication standard which aims to allow interoperability across different devices and brands. It will eventually ensure a seamlessly integration when it comes to connecting Level 1 to Level 5 solutions (more information about Open-SCS to be shared in the chapter 7 of this guide, Serialization and Traceability Systems Architecture).
- Need for companies to look for competitive advantage through business intelligence related to the behavior of the product flow in the supply chain (e.g., lead-time, inventory visibility), and engagement of customers and consumers (e.g., automation, logistics efficiency, added value, consumer experience, loyalty programs, etc.).

GS1 is a global organization that sets standards for identifying, capturing, sharing, and using product movement information[10]. GS1 standards are the most accepted by partners operating in the supply chain, regardless of the type of industry.

I. SERIALIZATION

Serialization is the process of differentiating each sellable unit with a unique identification (serial number), which will accompany the unit throughout its lifecycle. The identification method can be standardized at the industry level, for a specific geographical area, at the company level, or by product line. The standardization in this case is related to the construction of the unique identification, which can be based on numbers, mix of letters and numbers, and other attributes such as the number of characters and digits, acceptance of special characters or not, among others.

This concept has been used for decades in the electronics industry (e.g., serial number on laptops, printers, IMEI for mobile devices, etc.), automobile

(e.g., chassis number, engine number), among other numerous examples from other industries.

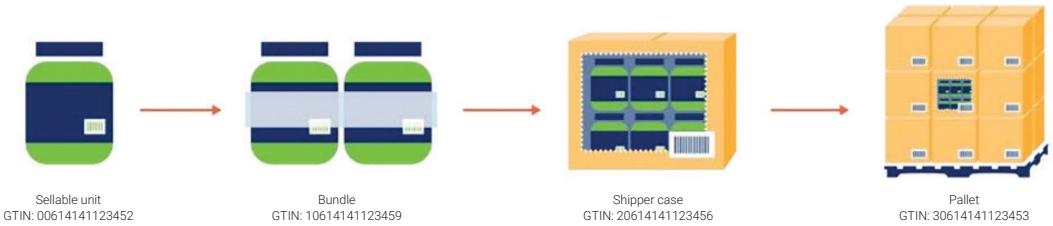
The unique identification is typically associated with a second attribute, the unique product identifier. According to the GS1 standards, products are identified using GTIN. The GTIN would typically have a one-to-one association with the SKU number in the ERP system. The combination of GTIN and a serial number will then unequivocally identify a sellable unit in the supply chain.

Conceptually, unique identification can be applied at different levels of logistic units as well. Some well-known examples are bundles, shipper cases and pallets. Technical requirements for unique identification at different packaging levels can vary depending on the industry, the supply chain itself, and business needs. The GS1 General Specification provides all the necessary details about global standards, including product identification rules and best practices [11].

II. AGGREGATION

Aggregation refers to the process of assigning the child serial numbers, to an aggregator serial number, called parent. Through this process, serial number hierarchies are constructed, creating automation opportunities as products move along the chain.

Aggregation enables logistics efficiency. Traceability systems have virtual and complete information of hierarchies and by reading the serial numbers available at the highest level of a hierarchy it is possible to move products easily, without the need to read the individual sellable units.



Picture 2: Aggregation example, font: GS1 [12].

III. TRACEABILITY

The intent of traceability is to provide electronic information about the history of product movements, including all custody changes over time. To be more precise, the act of tracking has to do with a supply chain partner to be able to determine in a certain moment, who is the current owner of a given product. On the other hand, tracing has to do with the recreation of the path of a product, where it has been, and which organizations have had ownership of the product. To facilitate the understanding, we are referring generically to Traceability as a business capability to do both things.

Conceptually, within an integrated traceability ecosystem, you can identify the exact location of a specific sellable unit, or the location of all units belonging to a given batch, all units of a given SKU, all sellable units in possession of a given company, and so on. It is also technically possible to define and configure what pieces of information each business partner would be able to access and work with.

For full product flow visibility in the supply chain, traceability systems must be integrated, either in a decentralized (e.g., blockchain) or centralized (e.g., traditional cloud solution) manner.

IV. VERIFICATION

Verification aims to mitigate risks related to illicit trade, using the unique identification at the sellable unit as a basis for confirming the product is valid. A sellable unit can be checked against:

- Its physical location: ensuring that the batch this unit came from was really destined for that country, or geographic region, or group of customers, whatever the manufacturer strategy is with the production of the batch.
- Its uniqueness: when the product is dispensed to the final consumer, the combination of the GTIN and serial number is verified in the traceability system and product is not active anymore within the supply chain. Warning messages related to possible illicit trade can be configured in case two or more scans happen for the same unique

identification (GTIN and serial number combination), for example.

It is important to mention that the integrity in the supply chain is not ensured solely by the serialization process. End consumer safety depends on interoperability among systems across the chain and the vision of the whole, which can happen with the implementation of traceability and/or verification processes, in addition to the serialization process.

V. AUTHENTICATION

Verification significantly reduces the risks of illicit trade, but it does not fully guarantee product's authenticity. E.g., in a scenario where the unique identification of a product is copied, there is no way to tell unequivocally at the moment the product is dispensed to the consumer, whether it is the original or the copy. A traceability system can issue alerts at the time it detects the same unique identification is being scanned a second time, or for any subsequent scans.

Product authentication can involve traceability along with other methods such as additional open and hidden security features by manufacturers (e.g., security seal, holograms, etc.).

VI. CONSUMER EXPERIENCE

Many brands have been sought to differentiate themselves by increasing the level of interactions with end consumers by using IoT concepts at the product sellable unit.

Apparel brands, industrialized and freshfoods, beverages, medicines, cosmetics, cigarettes, electronics, among others, are examples of industries currently exploring business benefits that IoT can provide.

Manufacturers of industrialized foods and beverages can offer additional information about products through integration with mobile devices, tips of other foods and beverages that can accompany their products generating a differentiated experience to the consumer. Recipes, loyalty programs, information about recalls and either product or ingredients provenance.

Pharmaceutical companies are actively exploring additional online content associated with serialized products such as information about drug-related

disease treatment, instructions for use for combination products, integration with patient care program apps, recall alerts, electronic product information (ePI), capabilities like keywords search, voice recognition with Siri/Cortana/Alexa integration, automatic text reading assistance, among others.

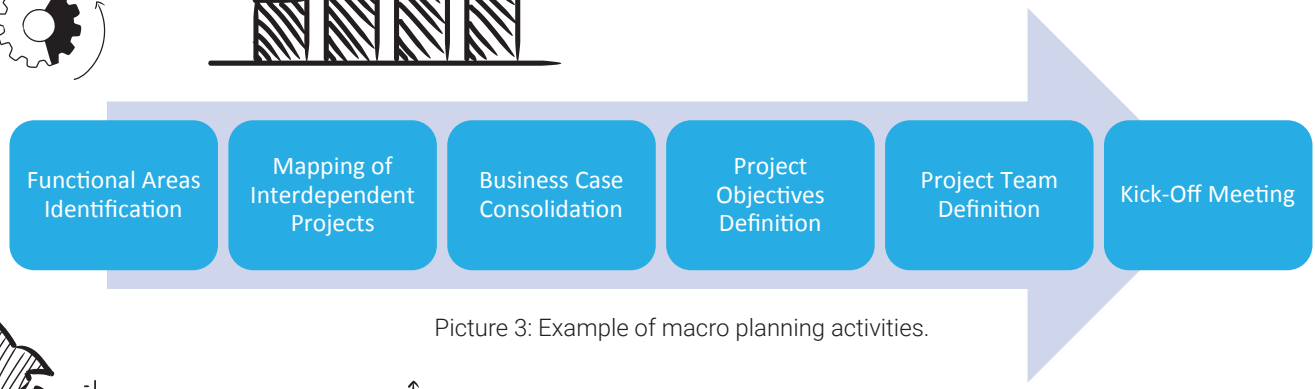
Other industry sectors are also actively seeking automation opportunities, supply chain visibility and greater interaction with consumers as tools to achieve competitive differentiation and brand loyalty.

By using mobile devices to scan products, it is possible for brand owners to capture relevant information about consumers behavior and preferences, which can then support retargeting initiatives. Data collected is typically anonymized, stored, and shared responsibly, in line with GDPR or other similar regulations. In addition to retargeting actions, insights about where products are being consumed, geographic distribution, consumption patterns, seasonality, weather and consumption correlation, the timestamp when products are consumed, consumer demographics (e.g., age, gender, etc.), may be key factors for future commercial initiatives (e.g., loyalty, rewards, others).

5 Project Planning

The planning phase for a traceability project in a first look, would follow the same process as other projects would. On the other hand, we know that the scope of a traceability project goes far beyond marking products with barcodes, the use of identification devices or tags (RFID, NFC, BLE, others) and the collection of the movement data of these products. When put into a broader perspective, traceability projects can include much more components, as well as many more benefits.

The following subsections will detail recommendations on how to plan for a serialization and traceability project deployment.



Picture 3: Example of macro planning activities.

I. IDENTIFYING THE FUNCTIONAL AREAS

Roles that form the project team can be from areas or departments that will suffer direct or indirect impact with the implementation of product traceability. Examples of functions with direct impact are: packaging engineering, internal and external manufacturing, distribution and logistics, IT, etc. Example of areas with indirect impact are HR, customer service, planning, procurement, among others.

HR leaders needs to be close to the project team and assuming its share of responsibility over change management, the communication plan, as well as possible needs to adjust the organizational structure due to the transformation that this type of project typically causes. Planning and procurement can help mitigating risks of packaging components write-off during the packaging artwork conversion process.

Other areas impacted indirectly would also have deliverables planned throughout the project implementation.

Functional areas can also be classified according to their required level of engagement and responsibility in the project (High, Medium, Low). Actions and decisions happening during the execution phase will consider all these initial alignments, which are part of the planning phase.

II. MAPPING INTERDEPENDENT PROJECTS

Interdependent projects are projects either in execution or that will be in execution before the end of the traceability project, and that are impacting business processes in areas considered critical to product traceability (manufacturing, distribution and logistics). An interdependent project can also be related to deployment of IT systems that exchange data with systems from these critical areas mentioned above, or even situations where a business or IT initiative would be impacting product data related to the product identification (e.g., GTIN, levels of logistics units, unit of measure, quantity of items in each logistics unit, etc.).

The act of mapping interdependent projects, performing a risk analysis related to potential conflicts of requirements and/or deliverables among these projects, evaluating the communication needs throughout their implementation, understanding the connection points and handovers, identifying stakeholders leading each project, constant communicating and monitoring their execution, are some of the mitigation strategies to reduce risks during the implementation of product traceability.

III. CONSOLIDATING THE BUSINESS CASE

After identifying and aligning expectations with all main functions involved, as well as having visibility of the interdependent projects, the construction of the business case can be started. The main objective of the activities related to the construction of the business case is to create conditions for the project team to formalize the following:

- High-level business requirements.
- Initial human resource allocation plan.
- The impacts that would occur to the business operations by consolidating all investment needs in areas such as human resources, software, equipment/devices, infrastructure, among others.
- The overall budget necessary to complete the project implementation.
- Main deliverables matrix.
- High-level schedule (milestones).

- Initial risks and assumptions.
- Return on Investment (ROI) expectations, if applicable.

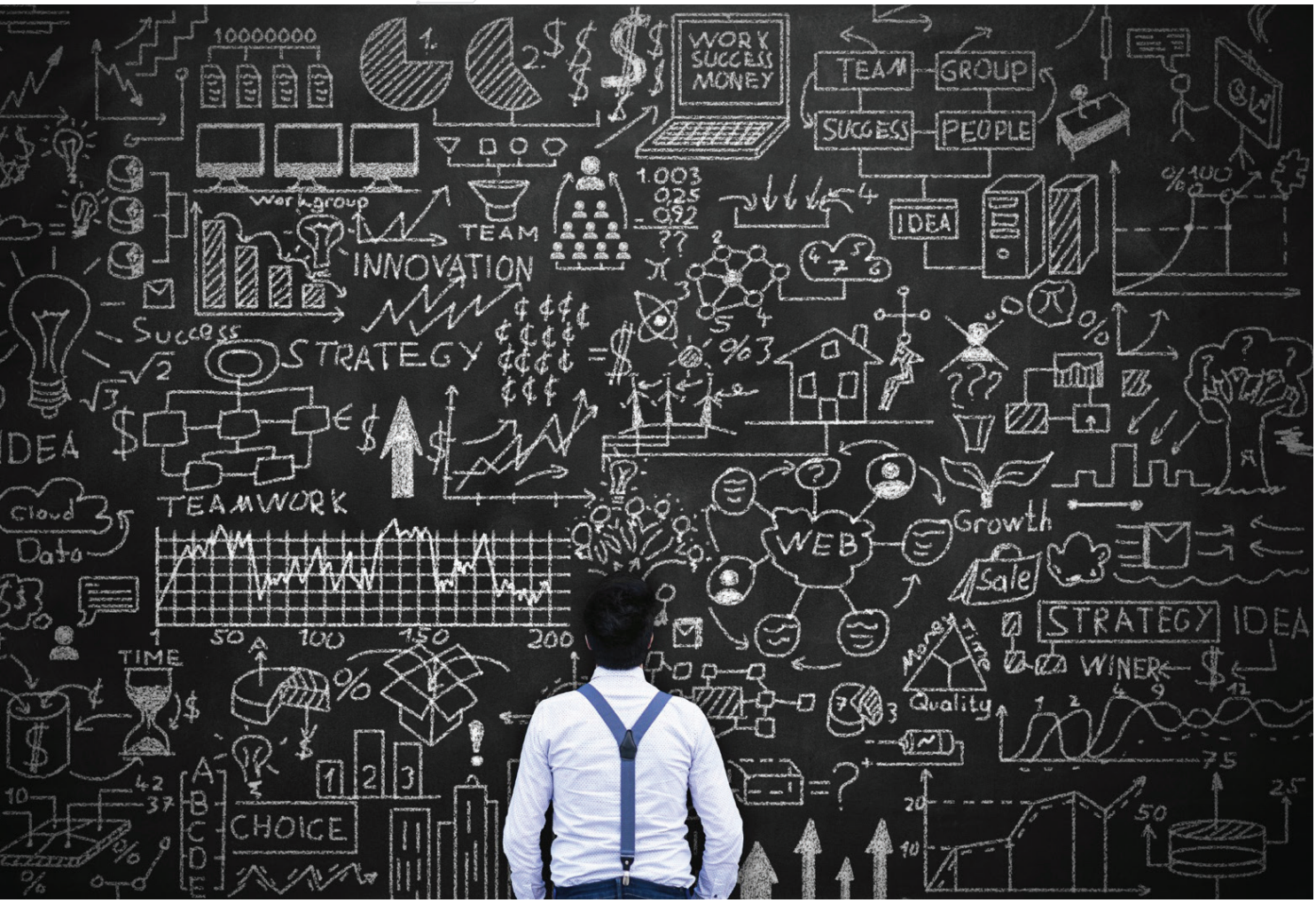
The business case development needs to happen with the involvement of all functional areas identified. This will avoid rework and eventual conflicts during project execution.

In the early stage of planning, the project manager, together with an expert on serialization and traceability (in some cases the same person assumes both roles), dedicates time to individual sessions with each functional area to map the level of impact and budget required for the execution and completion of the project (e.g., human resources, equipment, external storage to be spent on the transition between non-serialized and serialized inventories, system adjustments, process automation opportunities, others).

The second step recommended is the careful analysis and consolidation by the project manager of all these needs coming from different functional areas, along with the identification of dependencies, adjustments in budget components and so son.

In the third and final step, the process can be completed with a workshop involving all functional areas, criticizing, and adjusting the final scope and budget required, ensuring all functions involved agree and are aligned for the next steps to follow.

Due to the technical complexity of this type of project, many adjustments that can impact the human resources allocation, scope, and budget, are identified during the execution phase itself. Bringing all the functions in a workshop focused on the construction of the business case, will also mitigate this type of risk.



IV. ALIGNING ON THE PROJECT OBJECTIVES

The project's objectives can and should be more comprehensive than the immediate and short-term needs. Let us remember that product traceability is about technologies to uniquely identify products and create visibility about their movements along the supply chain, and the fact these concepts are part of a broader domain called IoT. Serialization and traceability are together only one of the steps towards supply chain digitalization.

Focus on long-term benefits helps the organization to proper manage its digitalization roadmap. Long term focus also directly benefits the traceability implementation team in the following ways:

- Helps the organization to assess solutions that have adherence to the overall digital transformation strategy. E.g., a small size SaaS traceability vendor can be a great partner for a large company that wants to establish a long-term partnership and at the same time influence positively the future design of the platform itself.
- Supports the organization with decision making related to future business processes changes, to be adopted after the completion of the project. Decisions related to business processes can take into consideration different phases of implementation. In some cases, process changes and adoption of new technology concepts need to be phased out properly, respecting the time for human resources to mature in terms of understanding and acceptance of the culture of digitalization and automation.
- Helps the organization to define the strategy for training so human resources are ready for future innovations.

In addition to having a long-term perspective, the project objectives in a general way should be:

- Clear, aligned with the organization's top management and with the project team, free of risks of interpretation, still during the business case.
- Revised, confirmed, and adjusted if necessary, during the Project Kick-Off.
- Connected to the need for operational efficiency mainly in manufacturing, distribution and logistics.
- Specific, measurable, monitored and demonstrated as evidences of the project success.
- Used as a basis for defining macro activities, and guiding execution and decisions within the scope of the project.

See below some examples of clear, specific, measurable, and monitored objectives:

- Implement serialization on packaging lines with an average of 10% negative impact on the OEE in the initial three months, and no more than 2% after the fourth month onwards.
- Implement the traceability process in the finished goods warehouse with 50% efficiency increase in the goods receipt and put away processes.
- Design processes and system capabilities for goods issue, increasing customer orders fulfillment accuracy and thus reducing the incidence of complaints/returns/refusal by at least 50%.

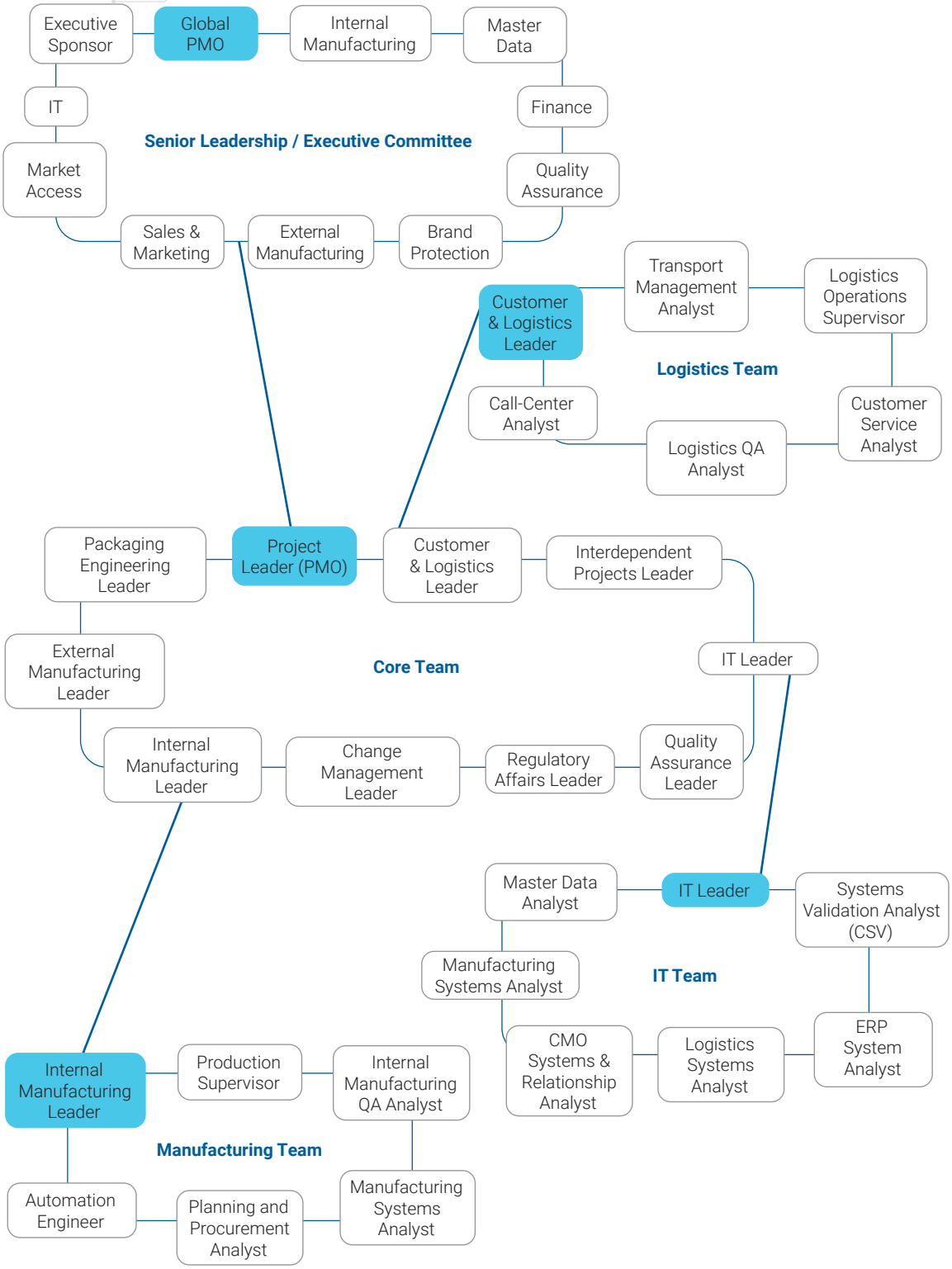
V. FORMING THE PROJECT TEAM

The formation of the project team is an essential step during the planning phase and identifying the right resources can directly influence the performance and outcome of the implementation.

The project leaders representing each one of the functional areas are not necessarily the functional managers. After the main deliverables are mapped, as part of the overall business case, the functional managers will then be able to define who will be the personnel representing their functions within the project team.

These project resources can be temporarily contracted externally or even internal resources that are eventually replaced on their roles by external temporary resources. This type of decision needs to be evaluated on a case-by-case basis.

It is important to have a balance between internal and external resources as part of the project team. The knowledge and experience gained during the implementation itself will be essential for some key functions after the project is finished. At the end of the project, it is recommended that the organization retains at least one key user with solid knowledge gained throughout the project on the internal manufacturing and distribution and logistics areas. Depending on the organization's complexity two key users or more may be required for each supply chain operations domain. This approach will facilitate planning and execution of future projects involving traceability systems or processes, digitalization, and automation in general.



Picture 4: Example of governance of a typical traceability project.

At the operational level, the activities are performed by the resources that are part of the Extended Teams (e.g.: manufacturing, logistics and IT in the picture above) with help from their peers, or not. The tactical level is the one responsible for the project management (Core Team). The strategic level involves the company's top management and gives guidance to the core team, which would then ensure execution with the help of the extended teams.

It is worth emphasizing the importance of an Executive Sponsor as someone who will defend the interests and objectives of the project within the organization's leadership context. This role is crucial because it creates in a practical manner, a connection between the core team and the top management. It creates a clear foundation for the project manager in cases escalations are needed, as well as decision-making alignment when considering the organization in a broader perspective.

The overall arrangement of the project team will though vary, depending on the reality of each company. Some functions described above may not be involved at all, and others considered critical may be included.

6 IoT Applied at the Product Level - Conceptual Evolution

One of the main purposes in the adoption of IoT concepts at the product level is to bring safety to both the brand owner and the consumers, in terms of the authenticity of the product. It has to do with enhancing supply chain security, mitigating risks with goods diversion, parallel trade, and counterfeiting.

However, over time companies have been exploring additional benefits, that go beyond the typical concerns with counterfeiting and goods diversion issues.

Picture 5: Evolution of perception of traceability projects.

I. BRAND PROTECTION

One of the best examples of a brand protection strategy comes from Amazon. In 2020 alone, US$ 700 millions were invested, and 10 thousand professionals were hired to combat illicit trade in the Amazon platform worldwide.

Amazon is dedicated to protecting brand reputation of companies that market products within its platform, and consequently protecting the reputation of Amazon itself. Also in 2020, 10 billion advertisements of suspicious products were disabled and 2 million products already in Amazon's distribution centers were seized and destroyed [7].

II. OPERATIONAL EFFICIENCY AND AUTOMATION

Operational efficiency, that in many cases is just the natural result of process automation and system capabilities, is a crucial element that is embedded into product traceability. With products uniquely identified, with master data aligned at different packaging levels, and with more information available at the product packaging level (e.g., barcodes, electronic devices, tags, etc.), it is natural that more opportunities for automation, process and systems optimization will arise.

Companies around the world are achieving concrete efficiencies through the implementation of traceability, accompanied by processes redesign. Johnson & Johnson published an article in the GS1's Global Reference Book in 2019, indicating a 50% reduction in product picking time, increased performance for goods receipt and 100% accuracy in some inventory cycles [9].

III. CONSUMER EXPERIENCE

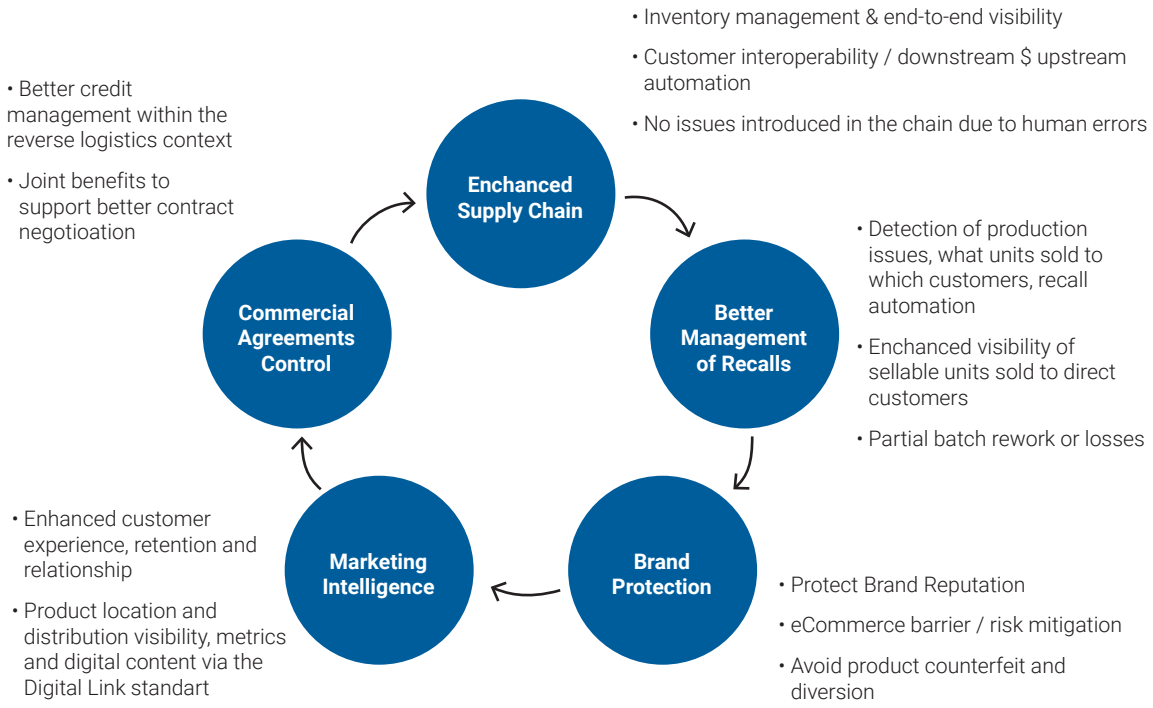
With the exponential increase of smartphones usage worldwide, as well as the time consumers spend on the digital "world", the opportunities for closer relations between brands and consumers have increased significantly.

GS1 is actively partnering with organizations everywhere, who are adopting the Digital Link standard [8] and generating a massive number of creative use cases focused on the dissemination of online content connected to products and even company's assets via mobile technologies. GS1 Digital Link is a global standard that has the ambition to connect consumers to digital content through product packaging, regardless of the identification technology used. Several multinationals from various sectors are already using Digital Link for this purpose.

Practical benefits related to enhanced consumer experience have already been discussed in this guide in the chapter called Basic Technical Concepts.

IV. ADDITIONAL BENEFITS

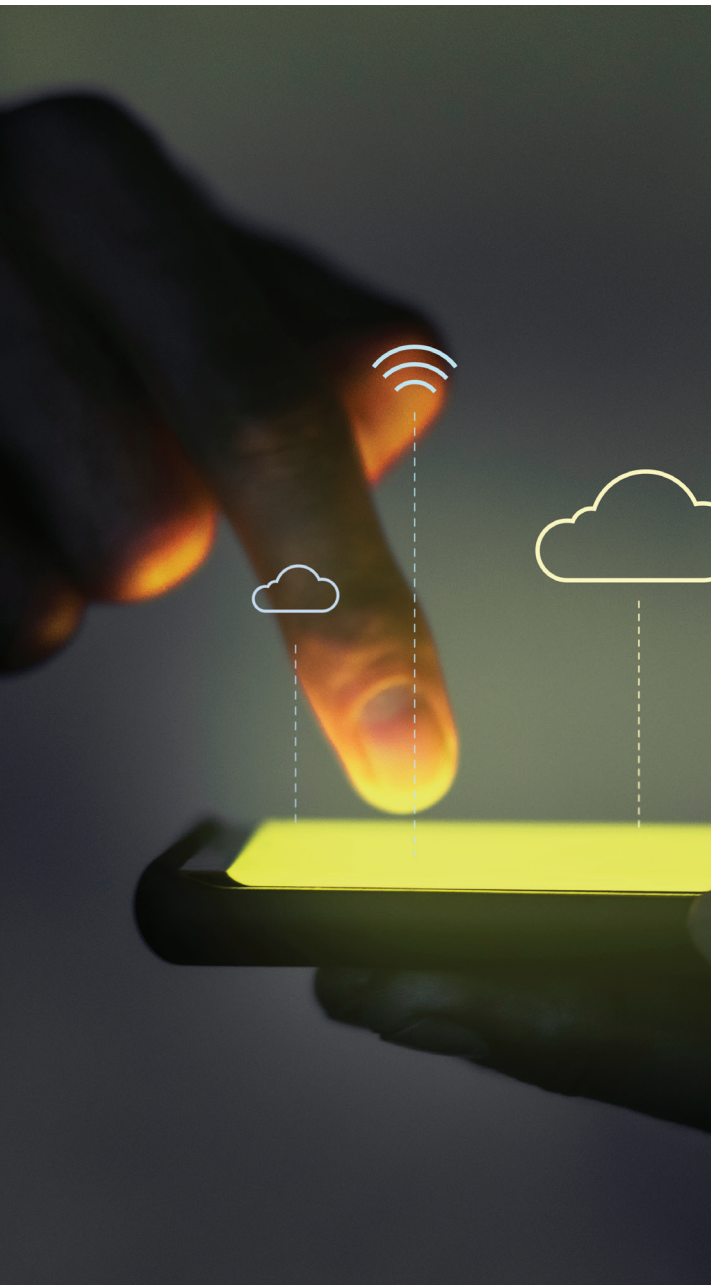
There are many real examples of benefits associated with product traceability. Articles and success stories are published frequently on the worldwide web. Some of these benefits are consolidated as additional examples through different categories in the picture below.



Picture 6: Tangible benefits from product traceability.

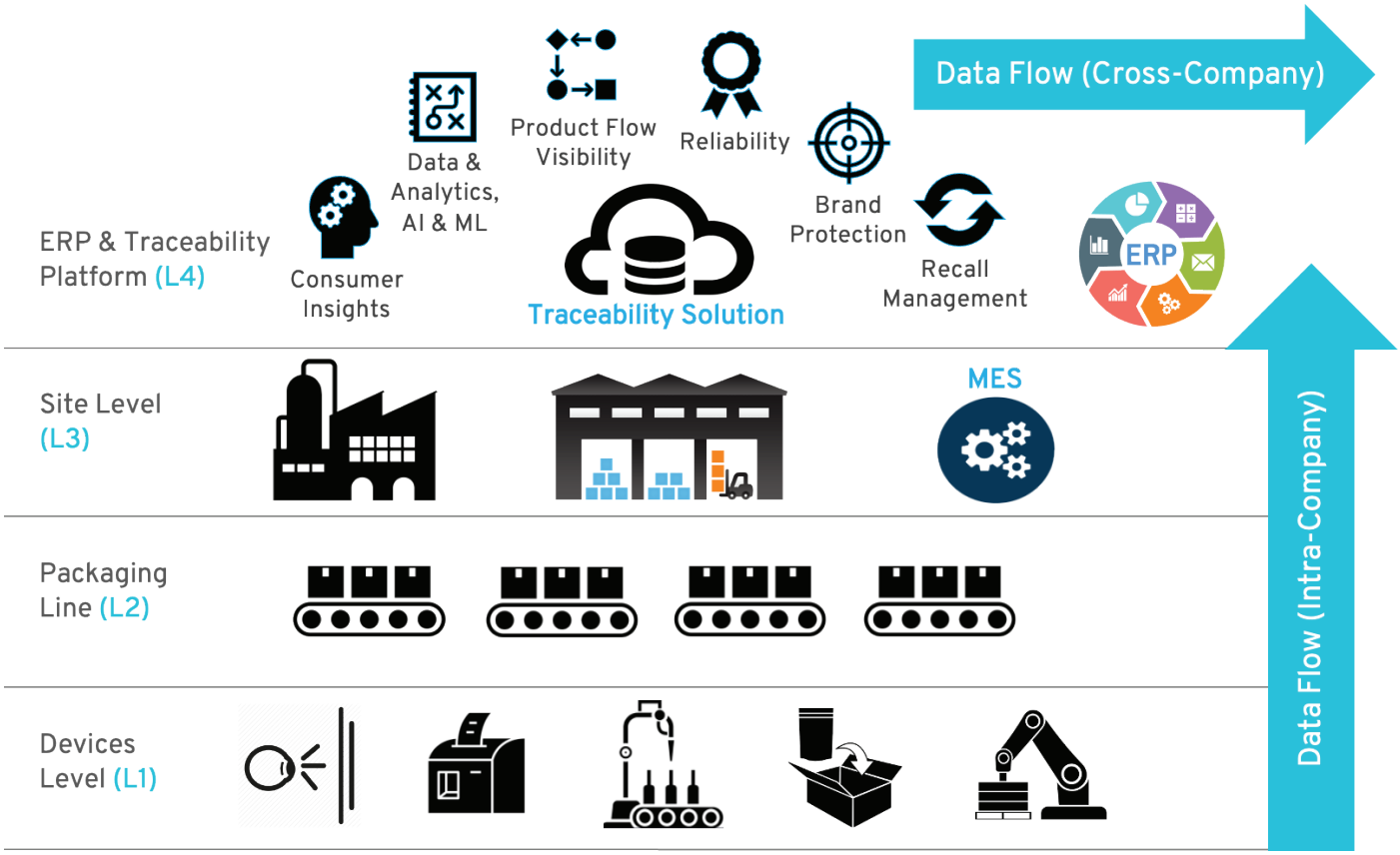
Other benefits can be explored, depending on the organization's business model and its supply chain partners digital maturity.

7 Serialization and Traceability Systems Architecture



The most known and used international standard for automation and systems integration is the ANSI/ISA-95. It was created by the International Automation Society. The main objective of this standard is to promote a vocabulary and a methodology that serves as a basis for data exchange between equipment and systems for different industrial and business applications.

Within a manufacturing plant for example, there are pieces of equipment and systems from different vendors, at different levels, exchanging serialization data and traceability data vertically. The same concept can apply to warehouses, or distribution centers. The higher the level of automation, the greater the number of integrated equipment and software layers.



Picture 7: Simplified example of a traceability system architecture.

Data flows vertically within different automation levels and are consolidated into an IoT platform (with more comprehensive functionalities) or purely product traceability (more niche platform). This platform can be centralized (traditional cloud solution) or decentralized (e.g., blockchain). In some cases, regulatory bodies may request traceability data to be sent to centralized platforms as well, which conceptually speaking is still vertical type of communication.

Communication between trading partners in the supply chain happens conceptually in a horizontal manner, and we can think about it as an intercompany data flow.

The experience dealing with solutions for each level of this architecture, as well as good practices related to data exchange between systems, understanding of the level of maturity of trading partners in the supply chain, exposure with integration and convergence of technologies, experience dealing with global

and local vendors, are all important background skills that a project team needs to find either with internal or external resources, to increase the chances of success in a traceability project.

The organization can be exposed to serious risks when it depends entirely on the technical knowledge of suppliers. Suppliers in general terms have a natural limitation in terms of skillsets as they are specialized mainly on their own products.

Independent consultants, or internal resources who have been exposed to such projects can better help organizations not only with the definition of systems and solutions architecture, but also with the project planning and conduction.

Project Budget Components

8

One of the common questions people debate about is on the total investment required. As we have seen before, there are functional areas with direct and indirect impact, areas with bigger or minor responsibilities for the project delivery. This does not mean that areas with indirect impact will need less investment. For example, customer service, quality control systems (e.g., LIMS) may require complex adjustments depending on the internal business needs and requirements.

Each of these areas will need investment to be planned and approved, so the project happens as expected. The list below gives some hints about budget required during the implementation of traceability projects:

- Hiring external consultants, or temporary employees for activities related to PMO, experts (SME), functional project leader, analysts, engineers, change management analysts, etc.).

- Computer Systems Validation consulting in case of lack of internal resources.
- Deploying an integrated traceability platform (Level 4) solution.
- Automation equipment and solutions for Levels 1, 2 and 3 for manufacturing and logistics processes.
- Procurement of servers and qualification of hardware and software in data centers (if applicable).
- Software licenses (Level 2, 3 and 4) in multi-year projects.
- Development and/or adjustments in legacy systems, among other IT activities.
- Adjustments in IT infrastructure (firewall settings, new wi-fi antennas, equipment repositioning and cabling).
- Adjustments of physical layout of plants (construction). E.g., in cases there are needs to adjust physically equipment in packaging lines, installation of automation equipment in distribution centers.
- External storage of goods (third parties) during the transition between non-serialized and serialized inventory, or eventual needs to build-up inventory to support SKUs conversion.
- Review of contracts with partners in the supply chain with inclusion of new requirements and expectations for serialized inventory to be tracked, communicated among parties, and other situations that would increase operational expenses. In a multi-year project these expenses should be handled as part of the project budget.
- Revision of artworks, including internal and external costs (e.g., packaging vendors, graphic design agencies).
- Costs from external agencies supporting communications under the overall change management strategy.
- Costs related to workforce training, materials, costs with external venues (if required).
- Destruction of old versions of packaging components at the moment the first serialized batch would be produced.
- Travel expenses, meetings, communication material, others.
- Overtime planned for staff during the project execution.

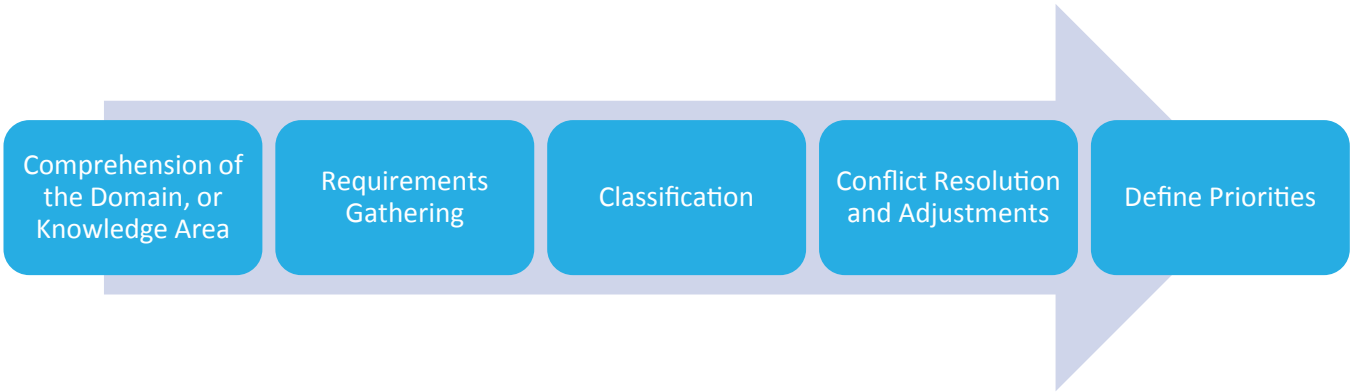
- Recognition events for the project team, gifts, bonuses.
- Budget contingency, typically 10% of the total project value.

Not all the points above would be applicable in every project. Also, other budget needs not listed here may be required, depending on each organization needs along with the long term digital roadmap envisioned.

9 Requirements Documentation

Mapping business and user requirements is one of the most important project activities. All business needs that will have a direct impact on the traceability systems, systems that interface with traceability solutions, or even business needs that will impact operational procedures, should be documented.

A multidisciplinary team needs to be together to map, consolidate, adjust, and prioritize requirements. Even areas with indirect impact can add a lot of value with discussions and final alignment of business requirements. The use of professionals with different knowledge and background is exactly what enriches the outcome.



Picture 8: Example of a requirements documentation process.

I. SUPPLIERS SELECTION

With regards to the selection of suppliers, it is a good practice to choose the solutions objectively and pragmatically, based on the business requirements documented and shared with the suppliers beforehand. A big trap is to try to adjust the business to a particular solution. A process of selecting and reviewing suppliers with well-defined criteria is the best way to avoid decision risks taken subjectively, or purely by commercial appeal.

The requirements documentation can be a great tool to serve as a foundation for suppliers' selection, to help the project team to define the to-be business processes, as well as to monitor the development and validation of each one of the business needs.

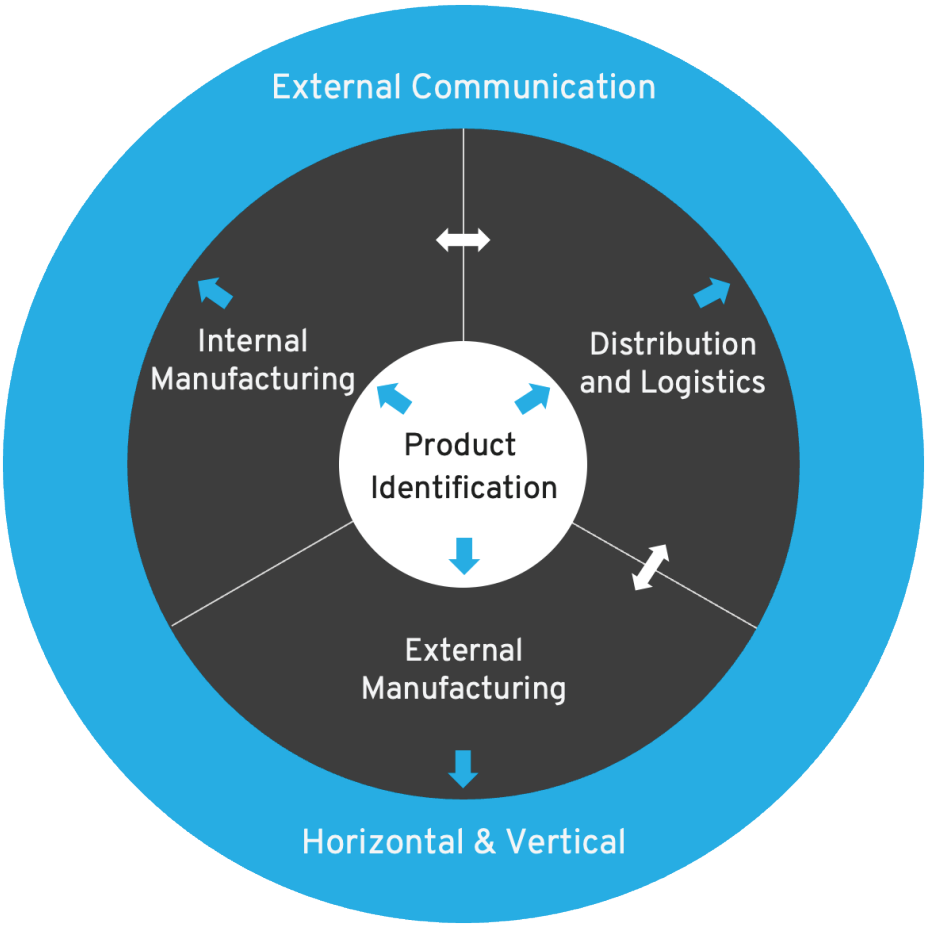
For traceability machinery implementation it is a good practice for an organization to plan for a multi-year project schedule. Negotiations with potential suppliers would take months and spending time with detailed technical conversations and understanding of their solutions, is key to mitigate risks in this area. In most cases, production line machinery is imported and a rule of thumb of minimum six months is typically used by global vendors for each production line traceability deployment. Also, since resources are limited on both sides (vendor and client), traceability solution deployment in production lines typically do not happen in parallel. As a rule of thumb, each production line would be deployed two or three months apart as a general best practice.

II. KNOWLEDGE AREAS

Each knowledge area in a traceability project has specific requirements. A recommendation is to create task forces to map requirements for each one of these areas below, individually, including professionals with different types of expertise:

- Internal Manufacturing
- External Manufacturing
- Product Identification
- Distribution and Logistics
- External Communication

There is a significant conceptual integration among these knowledge areas, which is depicted in the picture below.



Picture 9: Integration among knowledge areas within product traceability projects.

The product identification requirements serve as a foundation for serialization and aggregation processes that occur both at manufacturing environments (internal and external) and distribution and logistics. The business need to record all product movements will generate interdependent requirements that may be documented separately (e.g., goods issue at the manufacturing plant with the sASN generation is an Internal Manufacturing requirement, whereas the goods receipt with system processing of the sASN is a Distribution and Logistics requirement). Every relevant change of serialized product status regardless the context (internal/external manufacturing, distribution and

logistics), needs to be communicated to external organizations such as trading partners or regulatory agencies (depending on the industry sector).

For better results, requirements could be gathered via formal workshops, and as mentioned earlier, with a multidisciplinary team. Each organization would map its own requirements for its own business model.

It is not the intention of this guide to detail the actual requirements. However, in the sessions below, examples of requirements would be grouped into different categories. These categories are to be used as a reference only, an initial framework suggested which can also facilitate the process mapping exercise.

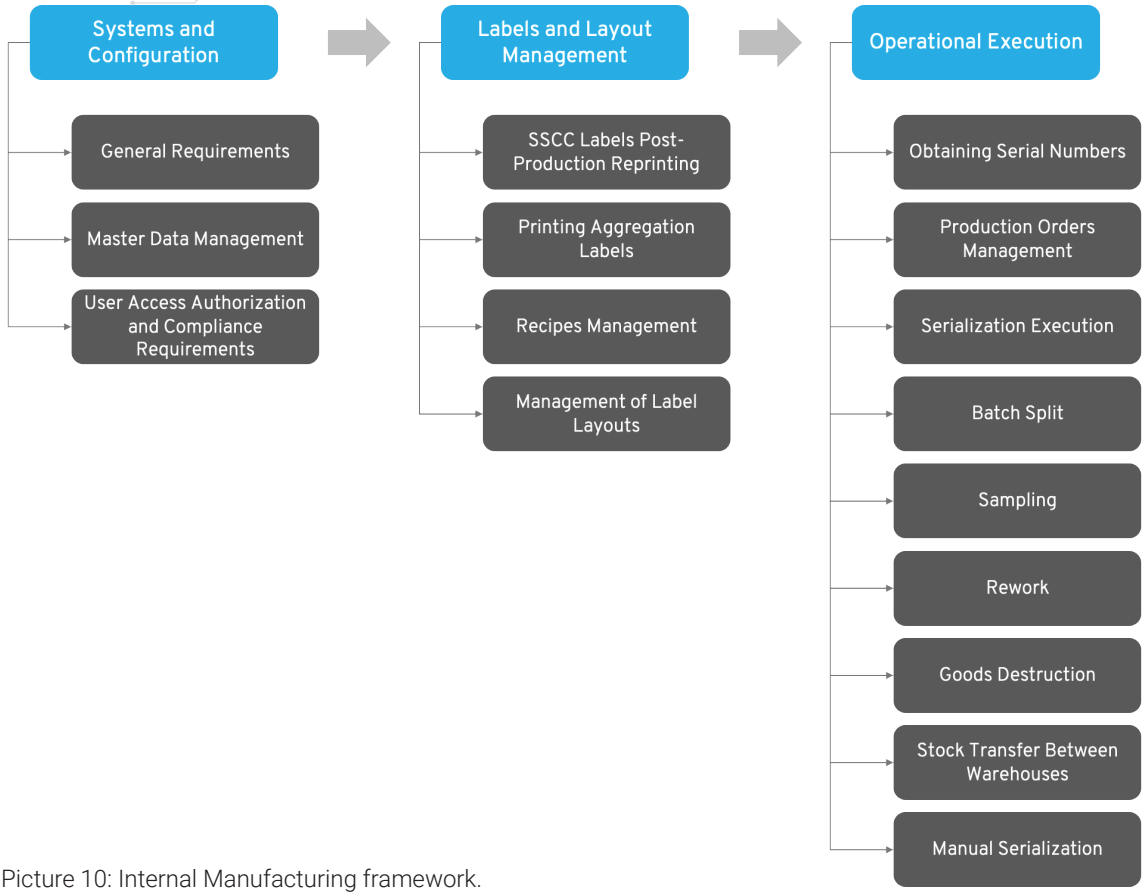
The requirements mapped during the workshops can be linked to one of the categories in the sections below, or totally new categories and ways to classify the requirements can be explored.

Each knowledge area detailed in the sections will have a suggested framework. Each organization will need to generate its own framework during the Requirements Documentation phase.

III. INTERNAL MANUFACTURING

Internal manufacturing requirements apply to production operations happening at a company's own facilities, regardless of their geographic location.

The serialization and aggregation process can be done manually, semi-automatically, or fully automated, depending on the level of automation of the production lines.



Picture 10: Internal Manufacturing framework.

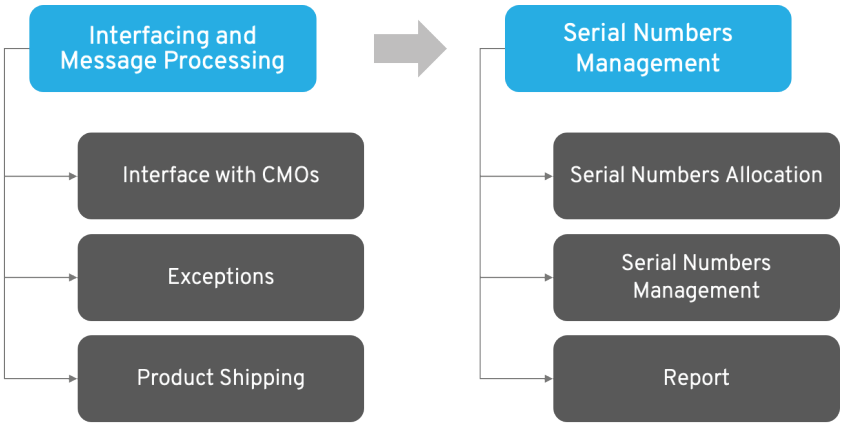
Group / Category	Description and Examples
General Requirements	General requirements related to serialization and traceability systems for internal manufacturing operations (e.g., number of packaging levels required for hierarchy creation, different access levels for different business roles, basic serial number management and GLN allocation, connections and interface with existing equipment, interface with legacy systems, management of serialized and non-serialized goods in the same packaging lines, reasons codes used to finalize serial numbers, others).
Master Data Management	Requirements related to the exchange of master data information between their source of truth and manufacturing plant's serialization and traceability systems (e.g., mapping of critical master data fields such as GTINs/Unit of Measure/Quantities/Control Flags/Others, integration requirements between systems, master data fields management, others).

User Access Authorization and Compliance Requirements	Requirements related to user access management in the traceability system as well as compliance requirements (e.g., recurring review of users and authorized accesses, active directory authentication of users, user data protection, password management, data encryption, records retention, audit logs, others).
SSCC Labels Post-Production Reprinting	Reprinting SSCC labels in exceptional cases when the pallet is already finalized in the production line (e.g., reprinting the SSCC label via pallet ID).
Printing Aggregation Labels	Requirements for hierarchy generation, printing and reprinting of aggregation labels manually (e.g., possibility of using mobile devices, identification of SSCC or sGTIN from logistics units by scanning one of the sellable units sGTIN, changing hierarchies, reprint of serialized and non-serialized labels, others).
Recipes Management	Requirements related to recipe management in the traceability system (e.g., storage of recipes in the traceability system including master data, batch data and labels layout, recipe creation by production operators, recipe editing, minimum fields for a recipe to be saved, recipe version control, others).
Management of Label Layouts	Label layout management requirements for sellable units, logistics units and pallets (e.g., access to saved layouts, creation of new layouts, deactivation of layouts, approval, or rejection of layouts by authorized users, others).
Obtaining Serial Numbers	Requirements related to the requisition, validation, and storage of serial numbers (e.g., requirements for receiving new serial numbers, visualization of numbers used, unused, discarded, others).
Production Orders Management	Requirements that handle automatic receipt of production orders from the ERP system, or manual setup directly at the Level 2 or 3 systems (e.g., expected product and batch data fields to be received via interface, or manually fed into Level 2 or 3 software, adjustments allowed after production orders creation, others).
Serialization Execution	Requirements related to the application of serial numbers at all packaging levels in the production process (e.g., serial numbers status changes, creation of aggregation and relationship among serial numbers and packaging levels, communication between Level 3 and Level 2 systems for the production order to be started, visibility of production orders, allocation of serial numbers in a production order, usage of SSCCs or sGTINs, exchange of pallet ID data with the ERP system, link between pallet ID and SSCC, visualization of serial numbers and hierarchies, others).

Batch Split	Requirements related to serial number management in cases where a batch needs to be split in two (e.g., finalization of serial numbers and hierarchies of goods that are put apart for rework, creation of a new batch, allocation of serial numbers to the new batch, others).
Sampling	Requirements related to the serial numbers management in different types of sampling processes (e.g., finalization of serial numbers only after indication of the reason code, automatic adjustments of hierarchy).
Rework	Requirements related to the serial numbers management in different types of batch rework conditions (e.g., finalization of serial numbers in case of sellable unit packaging changes, indication of the reason code for finalization, keeping the existing sellable units' serial numbers when rework is about creation of new hierarchies, link between the pallet SSCC and the pallet ID, others).
Goods Destruction	Requirements related to the finalization of serial numbers in case of destruction of serialized goods (e.g., finalization only after indication of the reason code, traceability system suggesting a predefined list of reason codes, finalization of children serial numbers in case the parent is finalized, children's serial numbers being finalized to inherit the parent's reason code, others).
Stock Transfer Between Warehouses	Requirements related to the shipment of products from the finished goods warehouse to a distribution center (e.g., traceability system allowing change of custody with the complete shipment of the goods hierarchy, others).
Manual Serialization	Requirements related to the generation of serialization labels/stickers to be applied at sellable units (e.g., manual entry of SKU and batch information, manual data entry on the quantity of serial numbers foreseen for the batch, activation of serial numbers, others).

IV. EXTERNAL MANUFACTURING

External manufacturing requirements apply to business scenarios happening as a result of a commercial partnership established between the brand owner and its manufacturing partners (CMOs), regardless of their geographic location. Business scenarios can involve shipment of serialized goods between the partners, exchange of serialization and traceability data, among others.



Picture 11: External Manufacturing framework.

Group / Category	Description and Examples
Interface with CMOs	Requirements related to the system interface between the brand owner and its CMOs (e.g., confirmation of processing and receipt of messages, data exchange protocols, others).
Exceptions	Requirements that support the reconciliation of serial numbers allocated to a CMO (e.g., activation and finalization of serial numbers, serialization of partial logistics units, inconsistencies with data transmission, others).
Product Shipping	Requirements that support shipment of serialized goods from a CMO to the brand owner (e.g., trigger for shipment notification, expected data included in the messages, message splitting (if applicable), standards, date format in the messages, others).

Serial Numbers Allocation	Requirements that support the allocation of serial numbers to a CMO (e.g., allocation of serial numbers at the GLN and GTIN levels, request for serial numbers, amount of serial numbers in each message, threshold for obtaining new lot of serial numbers, acknowledgment messages between traceability systems, randomization rules, management of unused serial numbers, others).
Serial Numbers Management	Requirements that support the management of serial numbers allocated to CMOs (e.g., data retention period by the CMO, triggers for systems interfaces, serial numbers finalization, changes of serial number allocation rules, others).
Report	Requirements relevant to investigations between a CMO and the brand owner (e.g., data search for serialized goods at CMO by batch/GTIN or other attributes, serial numbers reserved but not used, others).

V. PRODUCT IDENTIFICATION

The collection information around product movements within the supply chain, can only happen if the goods are properly identified at the sellable unit and logistics units levels, regardless the type of technology used. The most common technologies used for product identification are barcodes and RFID. Other technologies such as NFC, BLE, among others, are also used depending on the industry sector and business application, but not yet in a massive way compared to barcodes and RFID.

We can summarize the technical difference between barcodes and RFID as follows:

	Marking Complexity and Costs	**Difficulty to Read Along the Chain**
Barcode	Low	High
RFID	High	Low

As explained earlier in this guide in the Basic Technical Concepts chapter, to mitigate risks related to the difficulty to read barcodes along the supply chain, the concept of aggregation is used, as a best practice in many industry sectors.

Serialized products following GS1 standards will use linear barcodes such as the GS1-128 for logistics units, and bi-dimensional barcodes such as the DataMatrix, or QR Codes.

Each company needs to document what will be the internal standard adopted for product codification. The method to apply barcodes or RFID tags, what data components will be encoded, what human-readable information will be used, need to be standardized internally. Some level of flexibility may be necessary for the organization to meet specific market needs, geographic regions requirements, regulatory requirements, or factors related to consumers or different product lines.

Picture 12: Product Identification framework.

Minimally, an internal product identification requirements document needs to include:

- Data that will be encoded in barcodes or RFID tags at each packaging level.
- Human-readable information that will be printed on every packaging level.
- Proposed label layout for all levels of logistics units (packaging levels).
- Exceptions (if applicable), depending on geography, regulatory requirements, space constraints at the sellable unit level, others. E.g., sellable units with small packages may require the human-readable information to be split in different faces of the package.

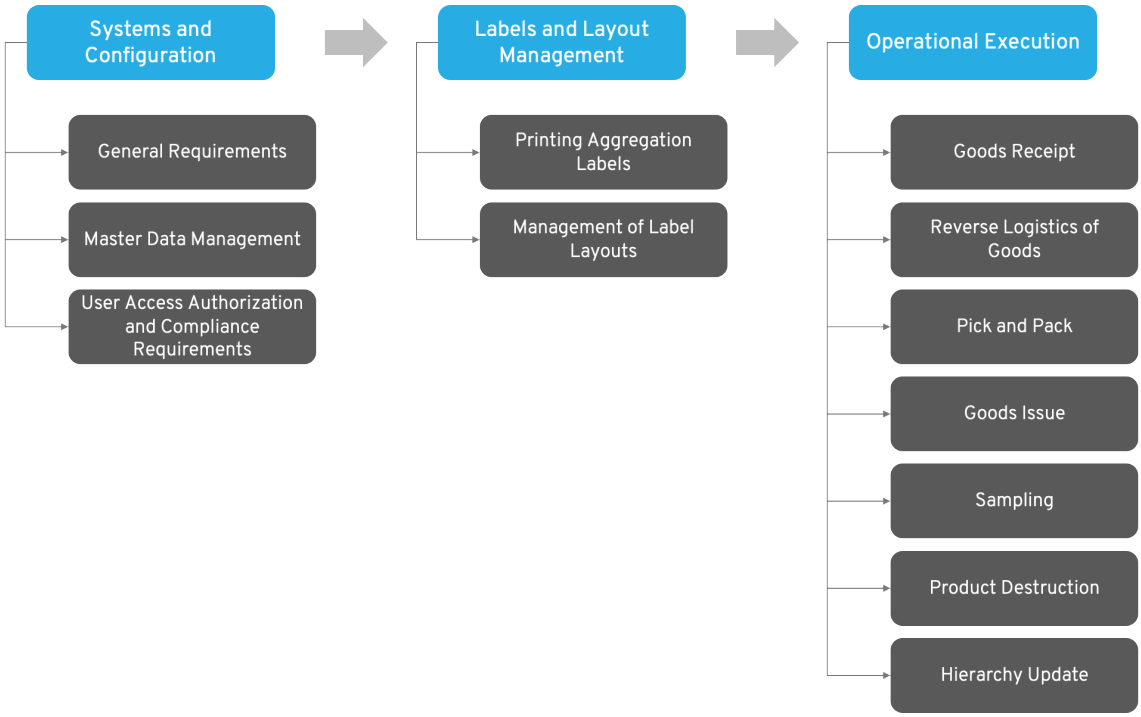
In addition to ensuring the alignment among all functional areas, the product identification requirements document can also be useful to create a standard product visual identity in the market for the brand owner, alignment of product identification rules with upstream and downstream trading partners, such as CMOs and customers.

VI. DISTRIBUTION AND LOGISTICS

Distribution and logistics requirements are associated with the handling and tracking of serialized goods in finished product warehouses or distribution centers.

In case the organization works with a logistics operator (3PL), the requirements will be defined on a case-by-case basis. The business requirements under this scenario will be in line with the commercial agreements formalized in contract, detailing IT systems interfaces, as well as the level of data exchange when it comes to product movements and inventory management.

Traceability solutions for distribution and logistics by nature tend to be more customized than solutions for manufacturing operations. Before defining requirements, it is necessary to understand the level of automation and sophistication of business operations, inventory and warehouse management systems used, operational volume, number of SKUs and customers in scope, number of sourcing plants sending goods to the warehouse, product flows, needs for interfaces with legacy systems, among other variables that can bring higher or lower complexity.



Picture 13: Distribution and Logistics framework.

Group / Category	Description and Examples
General Requirements	General requirements related to serialization and traceability systems for distribution and logistics operations (e.g., transactions processed with mix of serialized and non-serialized goods, connectivity to mobile devices, different levels for user access, reason codes setup for serial numbers finalization, finalization of children serial numbers in case the parent is finalized, children's serial numbers being finalized to inherit the parent's reason code, others).
Master Data Management	Requirements related to the exchange of master data information between their source of truth and warehouse's serialization and traceability systems (e.g., mapping of critical master data fields such as GTINs/Unit of Measure/Quantities/Control Flags/Others, integration requirements between systems, master data fields management, others).

User Access Authorization and Compliance Requirements	Requirements related to user access management in the traceability system as well as compliance requirements (e.g., recurring review of users and authorized accesses, active directory authentication of users, user data protection, password management, data encryption, records retention, audit logs, others).
Printing Aggregation Labels	Requirements related to generation of labels in cases of new hierarchies created in the warehouse (e.g., printing SSCC labels for new hierarchies, reprinting damaged labels by scanning child serial numbers or pallet ID, actions to be performed on mobile devices, choice of printing device, choice of different label formats for different business situations, others).
Management of Label Layouts	Label layout management requirements for logistics units and pallets (e.g., access to saved layouts, creation of new layouts, deactivation of layouts, approval, or rejection of layouts by authorized users, others).
Goods Receipt	Requirements related to the receipt of goods in the warehouse (e.g., system automatic identification of serialized and non-serialized goods and batches, scanning of delivery notes with mobile devices, link between pallet ID and pallet SSCC, receipt confirmation, scanning of different types of barcodes by mobile device, change of custody in the traceability system, others).
Reverse Logistics of Goods	Requirements related to reverse logistics of goods (e.g., goods receipt reversal or new goods issue, change of custody in the traceability system, goods received moved automatically into quarantine, others).
Pick and Pack	Requirements related to the preparation of goods for shipment to customers (e.g., system identification of serialized and non-serialized batches, handling of serialized and non-serialized goods in the customer order, shop floor operator guided by the system depending if goods are serialized or non-serialized, scanning barcodes with mobile devices at any packaging level, automatic update of hierarchy on the source pallet, automatic validation of SKU/batch/quantity/expiration date during packing, creation of new aggregations, others).
Goods Issue	Requirements related to the shipment of goods from the warehouse to customers (e.g., shipment of complete and partial logistics units in a pallet hierarchy, shipment of serialized and non-serialized products in the same customer order, goods issue reversal, serial numbers status change after shipment, others).

Sampling	Requirements related to the serial numbers management in different types of sampling processes (e.g., removal of goods at any packaging level > sellable unit/bundles/shipper cases, finalization of serial numbers with indication of the correct reason code, finalization of serial numbers only after indication of the reason code, automatic adjustments of hierarchy, finalization of children serial numbers if sampling occurs for the entire parent logistics unit, others).
Product Destruction	Requirements related to the finalization of serial numbers in case of serialized goods sent for destruction (e.g., finalization only after indication of the reason code, traceability system suggesting a predefined list of reason codes for finalization, finalization of children serial numbers in case the parent is finalized, finalized children's serial numbers to inherit the reason code from the parent, others).
Hierarchy Update	Requirements that allow adjustments of product hierarchy as part of warehousing operations (e.g. querying hierarchies using mobile devices by scanning barcodes at any packaging level, possibility to include or exclude products from a hierarchy, automatic adjustment of hierarchies that had products removed, children serial numbers automatically removed from a hierarchy when the parent is aggregated into another hierarchy, warning/error message in case of inconsistency of serial numbers scanned, indication of which pallet ID a product belongs to when it is found in the wrong location, indication of orphaned serial numbers, others).

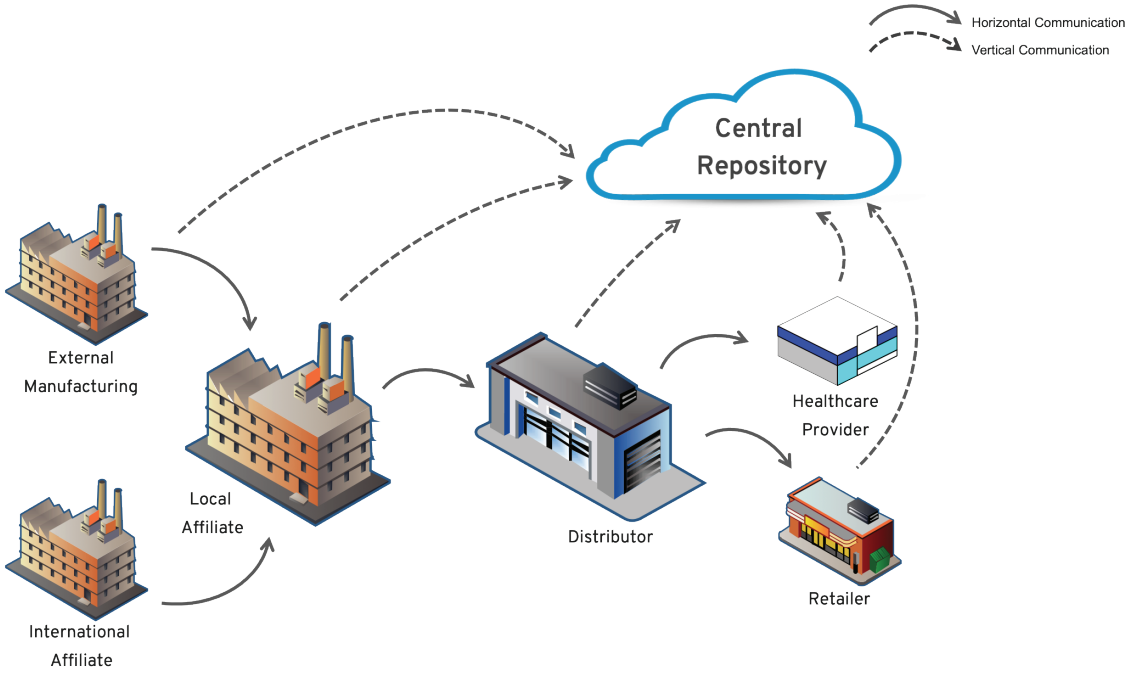
VII. EXTERNAL COMMUNICATION

External communication requirements are related to establishing communication with trading partners in the supply chain (horizontal) and with regulatory agencies (vertical), where applicable. Communication with external entities includes:

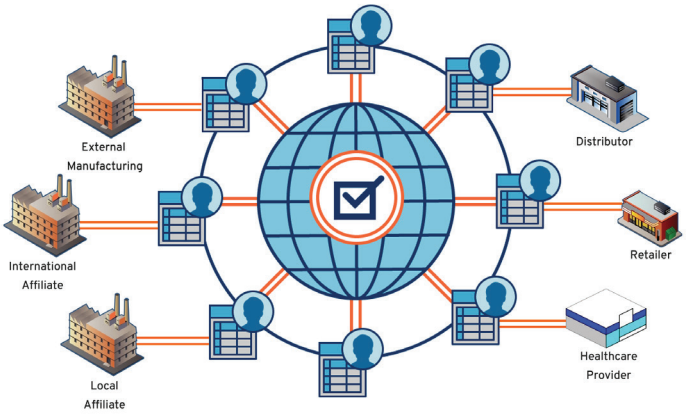
- Communication protocol (layout/file structure for data exchange between systems).
- Technical connectivity details (connection type, authentication methods, encryption mechanisms).
- Transactional data (event type, event timestamp, serial numbers and hierarchies, source location, target location).
- Critical products master data and locations (manufacturing plants, warehouses, etc.).

The utilization of global standards for machine-to-machine communication brings concrete benefits to trading partners in terms of integration simplification,

decreasing implementation costs and other benefits. The GS1 EPCIS standard is currently the most widely used model for data exchange between different traceability platforms, by most of the global software platform vendors, mainly for horizontal communication in the supply chain.

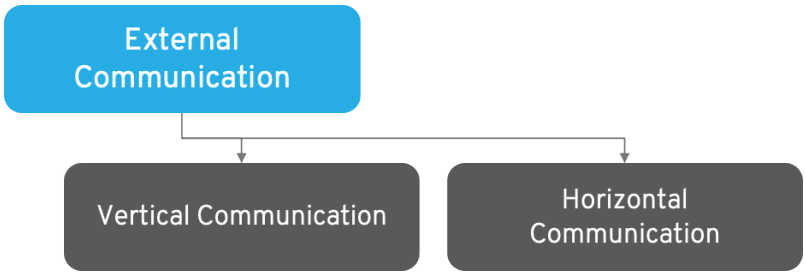


Picture 14: Simplified example of supply chain data exchange using a typical centralized cloud database.



Picture 15: Simplified example of supply chain data exchange using a decentralized database concept (e.g., blockchain).

In the previous sub-topics in this chapter the term “finalization” of serial numbers was being used, since the operations described so far are within the context of the company’s operations. As a convention, we are calling serial number “decommissioning” the act of finalizing serial numbers internally but also formally communicated (where applicable) to external entities such as CMOs, customers, regulatory agencies, etc.).



Picture 16: External Communication framework.

Group / Category	Description and Examples
Horizontal Communication	Requirements related to data exchange about movement of goods between trading partners in the chain (e.g., automatic generation of the sASN including serialized goods hierarchy information, sending a correction message, acknowledgment of messages, others).
Vertical Communication	Requirements related to communication about serial numbers status changes to a centralizing entity (e.g., serial number decommissioning communication due to destruction/sampling/internal consumption/others, serial number activation communication, goods issue reporting, goods receipt reporting, cancelation of a previous message, others).

10 Process Mapping

Due to the nature of serialization and traceability projects, changes on business processes are simply inevitable. Process changes as we know, can have positive or negative consequences.

One of the best practices used by companies around the world to have a holistic view about their business processes and business models, and rethink everything in the light of automation and innovation opportunities. E.g.: goods receipt process can be automated and not depending anymore on visual inspection of materials, not depending on manual data entry in ERP systems. The picking process can be reviewed to eliminate the need for manual entry of SKUs or batch information. Number of times a product, logistics units or pallets are scanned manually can also be optimized.

Another best practice recommended is to take advantage of the effort and organization structure created to implement a traceability project (teams, investment, alignment with functional areas and top management, momentum, visibility), to

enhance the project scope with additional investments seeking innovative ways to execute business operations, automating processes, conceptualizing incremental automations, which will generate concrete opportunities and benefits for the business.

Such incremental benefits can be phased within a broader roadmap. This long-term vision well planned and executed can be the difference between simply complying with regulatory or consumers demands, and something that would really bring competitive advantage to the organization.

Relying on professionals who have implementation experience, knowledge of best practices for product traceability, knowledge of solutions available in the market, advantages, and disadvantages of different business models, among others, can definitely be a success factor in implementation.

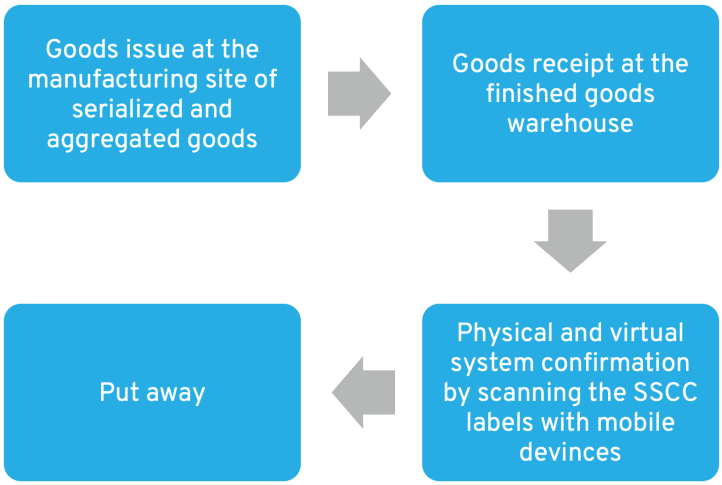
It is recommended that organizations have the as-is processes well documented and reflecting the reality of the operations. The to-be processes documentation, to be applied after the completion of the traceability project, needs to happen after the documentation of all project requirements, before any IT development is started, before any systems configuration or customizations are initiated, to avoid rework.

The mapping and alignment of to-be processes among the various functional areas can also be used as a tool for final adjustments to the requirements mapped, confirming business needs with a higher level of confidence.

Workshops can be held to define the to-be processes, involving all functional areas with direct and indirect impact in each operational field (internal manufacturing, external manufacturing, distribution and logistics, etc.). The Picture 4 in this guide, under the chapter called Project Planning, can also be used as a reference to which functional areas need to be involved in discussions of manufacturing, logistics, and other processes.

The images below serve as a simplified example of how an as-is process can be optimized. In the context below we are using a hypothetical scenario of goods receipt in a finished goods warehouse, or distribution center.

Picture 17: Example of a simplified as-is goods receipt process.



Picture 18: Example of a simplified to-be goods receipt process.

For this optimization and automation of the goods receipt process to occur and be cascaded down to the supply chain, a high level of alignment is needed among trading partners to guarantee the best possible accuracy at the goods issue process. One of the best operational practices when handling serialized and aggregated products, is to consider the shipment process as the most critical one. Inconsistencies between physical and virtual inventory should not be propagated to partners along the chain.

These are just a few simple examples on how processes can be reviewed, redesigned, and optimized. Opportunities to increase operational efficiency should be explored on a case-by-case basis in the process mapping stage.

11 SKUs Management

SKUs management in a product traceability project refers to all planning and execution activities related to the application of Product Identification requirements (described in the Requirements Documentation chapter) at the sellable unit as well as all the different packaging levels (or logistics units, where applicable). It also refers to managing both serialized and non-serialized inventory of goods during the post-implementation transition period.

I. CONVERSION OF SKUS

The adoption of unique identification at sellable units implies that each SKU in the organization portfolio will be converted from non-serialized to serialized during the project implementation. In a certain moment, within the overall project plan, a first serialized batch will be produced for each SKU, indicating that the SKU has been converted.

Typically, when changes occur in packaging components, the SKU needs to be revalidated from a production point of view. Production lines may

be shut down for the validation to occur. The process validation can involve a test batch before the SKU is formally approved by quality assurance to be released from a serialization perspective. Close communication and alignment with planning is also important as production line shutdowns can impact the production schedule.

The usage of an SKU list, as a live and dynamic document throughout the project, brings an important level of visibility to the project team and creates a level of control which is essential to the success of the implementation. The list needs to be a live document as planning activities are by nature dynamic, and the exact dates aimed for each SKU to be converted will most certainly require small adjustments throughout the execution of the project.

II. LIST OF SKUS

A control at the SKU level serves as a basis for aligning expectations and deliverables across all teams involved in the project. Regardless of what the layout or format of this document would be (e.g., shared file on collaborative platforms or off-line, MS Project, Excel, others), it needs to contain at a minimum:

- SKU information: SKU code in the ERP system, description, and other relevant attributes.
- Sourcing site: SKU sourcing site, indication if local or international site, coming from internal manufacturing or from a CMO. Sourcing information helps the project team to visualize the complete product flow within the organization's internal supply chain.
- Packaging line: production line where the SKU is sourced from. This information also assists the project team in prioritizing the serialization implementation on each production line.
- Estimated date for artwork revision: expected date when the packaging artworks will be adjusted, revised, and approved internally by all involved areas.
- Estimated date for the SKU conversion: Expected date when the first batch for each will be serialized. This date will serve as a foundation for preparation to take place in all operational areas involved (e.g.,

procurement of revised packaging components, serialization go-live in the production line based on the date of the first SKU planned to be serialized, necessary adjustments within the production planning, alignment with logistics team for receiving and storing the first serialized batch for each SKU, among others).

- Annual forecast: important information for planning possible stock build-up during the SKUs conversion, mitigation of supply risks.

The above examples were shared as a reference only. The list of SKUs can contain additional fields according to the needs of each organization.

III. PACKAGING ARTWORK REVIEW

The changes required at the sellable unit packaging (when applicable) for serialization to happen is considered simple since no changes are made in texts visual identity and other aspects of the packaging.

One of the biggest challenges is in packaging components with reduced printing area, with reduced space for example for additional two-dimensional barcodes to be printed, along with the applicable human-readable information.

It is recommended that the organization keeps a close alignment of expectations with the packaging components vendor, to mitigate procurement and planning risks. The SKU list is a tool that can be used to coordinate activities both with packaging components vendors and the project team.

In regulated sectors (e.g., tobacco, pharmaceuticals, others), regulatory requirements related to packaging components adjustments and communication to regulatory agency may bring additional complexity. The Packaging Engineering and Regulatory Affairs internal resources are typically responsible to keep the project on-track from that perspective.

Each organization has its own internal procedures and systems for reviewing and adjusting packaging artwork. These adjustments will always happen in line with the Product Identification requirements document, already mentioned in this guide in the chapter called Requirements Documentation.

IV. INVENTORY AND SYSTEMS MANAGEMENT

Dealing with serialized and non-serialized inventories during a transition period is a reality that all organizations going through this transformation will have to manage. ERP and WMS systems need to be prepared to work with serialized and non-serialized batches for the same SKU. Operational procedures also need to address this transition phase and cover parallel shop floor processes for each type of situation.

Even after all inventory is transitioned to serialized, systems and procedures must stay in place and able to handle non-serialized products. Due to very specific reasons, an organization may still produce non-serialized batches and they still need to be processed and moved along the supply chain. Reverse logistics may be another reason why non-serialized goods should be able to move along even after the internal organization inventory is fully serialized. Expired products also can be received from downstream trading partners years after the batch was manufactured.

When the project team decides to integration the traceability systems with ERP/WMS systems, it is recommended flags to be defined both at the SKU and batch level in the ERP system. For the WMS system for example to be able to handle serialized and non-serialized products at the same time, it must “consume” the flag information from the ERP system. This topic will be covered in more details in the next chapter, Master Data Management.

12 Master Data Management

Master data is crucial for any organization, it is used for during business transactions and typically suffer minimal changes over time.

I. CONTROL FLAGS

The most efficient way for ERP/WMS systems to manage serialized and non-serialized SKUs and batches is through the usage of flags. The SKU level flag can indicate whether a product has already been converted or not. The batch level flag will differentiate serialized and non-serialized batches from an inventory perspective as well as the WMS procedure to be adopted in warehousing operations.

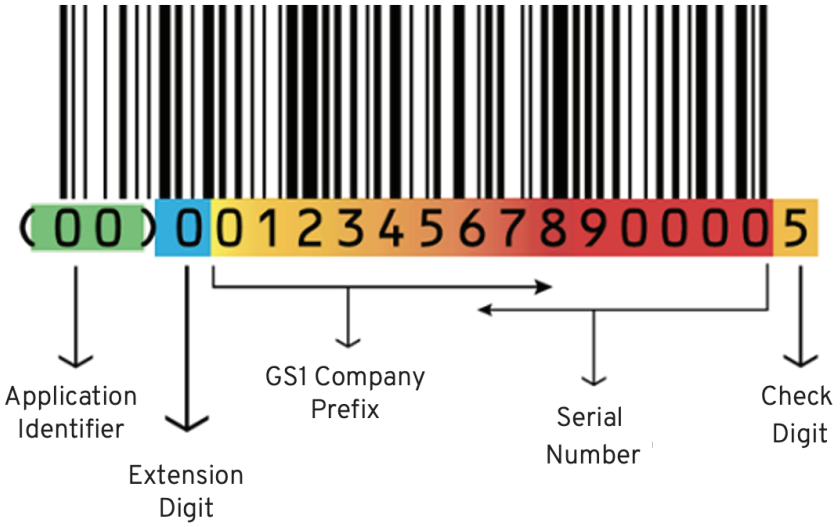
Procedures performed at the WMS level for example, or via mobile devices, can have different step sequences depending on the situation (serialized or non-serialized goods), with higher or lower level of automation, higher or lower level of transaction control, or with different transactional results at the end of the operation. This approach also helps manufacturing shop

floor and warehouse operators to perform automated processes intuitively, productively, with no operational risks.

II. PACKAGING LEVELS

Another important aspect to be considered with regards to master data refers to the data management at different levels of packaging. According to global best practices, and based on GS1 standards, the sellable unit requires a unique number at the SKU level, the GTIN. The combination of a GTIN and a serial number will then create a unique identity for the sellable unit itself.

The use of a GTINs in a logistics unit (bundles, shipper cases, etc.) combined with a serial number is also possible. In this case the logistics unit becomes a potential sellable unit as well (e.g., a homogeneous box can become a manufacturer's main sales unit). The SSCC can also be used as a unique identifier by itself, eliminating the need to use GTINs for logistics units. The SSCC by nature is a serial number, consisting of 18 digits, which includes the serial number and other attributes that follow the GS1 standards.



Picture 19: Data components in a SSCC barcode (source: GS1 Help [13])

All packaging levels require specific settings at material master records. Minimally the following information requires configuration: unit of measure, quantity of items, GTIN (for sellable unit level and in case logistics units will also be considered sellable units).

The ERP should be the system of truth for Master Data, the place it is primarily maintained. Other manufacturing and warehouse automation systems, as well as traceability systems, will "consume" the necessary master data from the ERP system.

III. EXCEPTIONS

Exceptional business scenarios involving the relationship between the SKU code in the ERP system and the GTIN is something that needs to be considered by the project team. Situations where there are two or more GTINs for the same SKU is something that can be managed from a systemic point of view, but the opposite scenario will cause operational problems.

From an automation and systems point of view, when a serialized barcode is scanned, the GTIN will refer to the product number, and if there is no direct relationship to only one SKU at the ERP level, the systems will not be able to properly manage the transaction being processed.

In exceptional cases involving rework of finished goods batches, there may be situations where the same SKU has more than one GTIN. In this case, the differentiation will take place at the packaging itself, with the correct GTIN codified in the barcode.

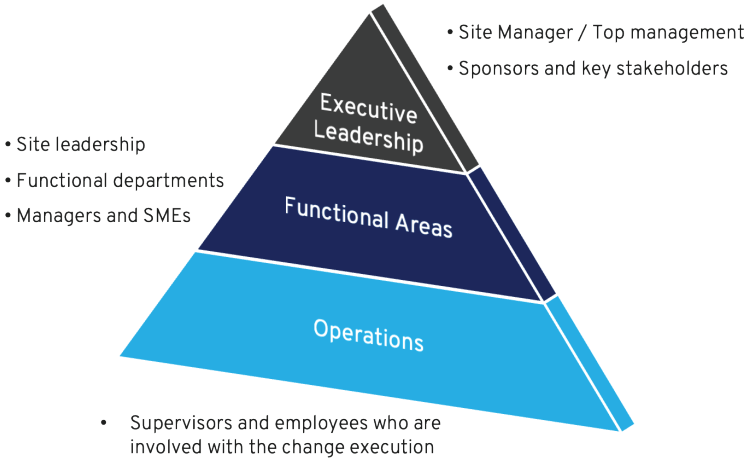
It is recommended that all operational exceptions involving the relationship between SKU codes and GTINs (1-to-1 relationship) should be analyzed during the project planning phase, with all system requirements related to the correct management these attributes being mapped from the beginning of the project.

Change Management

13

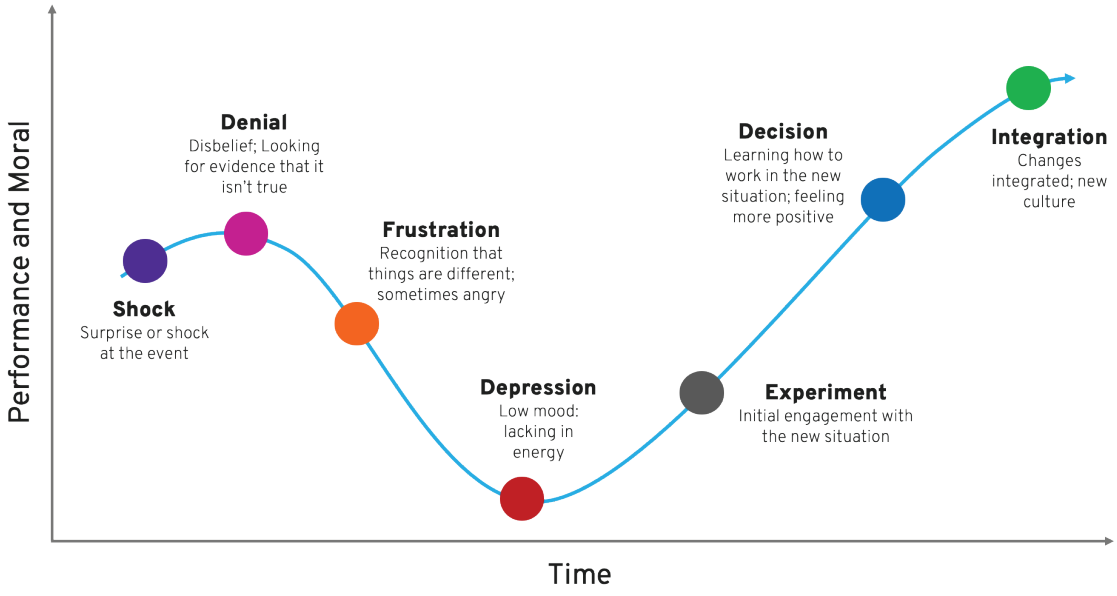
In a 2019 Gartner survey with more than 6,500 employees and more than 100 HR executives around the world, it was identified as one of the key success factors in managing changes, the need for engagement and execution of by the workforce itself, rather than the sole engagement of top management.

Nowadays more than 80% of the organizations globally speaking still rely solely on top management for strategic decisions, creation and implementation of change management plans, creation of communication plans to engage employees and other related activities. In general, this approach is outdated and diminishes the organization's ability to adapt rapidly to change [14]. Change management is something that needs to involve all levels of an organization.



Picture 20: Change management applied at all levels of an organization.

Another important concept to be addressed is about the change curve. The change curve concept was defined by Kubler-Ross, a Swiss psychiatrist and author of the book "About Death and Dying," and is one of the most accepted concepts worldwide to describe the emotional journey that individuals experience when they go through a process of change.



Picture 21: Stages of the change process.

Change is about what you want to achieve, and the transition is about how the result will be achieved and how expectations will be managed while you are in the process. In this chapter, we will address the most common macro activities that are part of a successful change strategy.

I. IDENTIFYING CHANGE CHAMPIONS

From the point of view of change management, all functional areas, all departments within an organization, without exception, are considered. Every employee part of the organization needs to perceive the change of direction towards digital transformation, which is exactly the context in which the adoption of serialization and traceability solutions occurs.

The entire workforce needs to feel part of the business transformation. Employees directly absorbing new technologies and processes, or simply adjusting and fine-tuning processes and systems, or just supporting other working colleagues more directly involved with the change, all of them, need to be fully engaged in the process.

A Change Champion is someone who has a natural internal networking within the organization, a respected leader, and an influencing agent. He or she is not necessarily an executive, or a manager. In fact, hierarchies are irrelevant when a project team is identifying change champions.

The project team needs to identify within the organization, these leaders who will act as "intermediates" between the project team and the operational teams. They will be closer to the project team, to the progress of the main deliverables, will be receiving relevant information in advance. They will be invited to contribute with ideas and insights to the project team and will be fully engaged motivating and captivating the workforce, contributing to a more positive perception of change, being true agents of change.

In addition to the typical recurring meetings part of the project governance, the project team needs to maintain a specific communication channel with the Change Champions. E.g., more high-level project status updates, workshops to identify risks/problems, planning and execution of change readiness surveys, adjustments to the communication plan, planning and execution of training sessions.

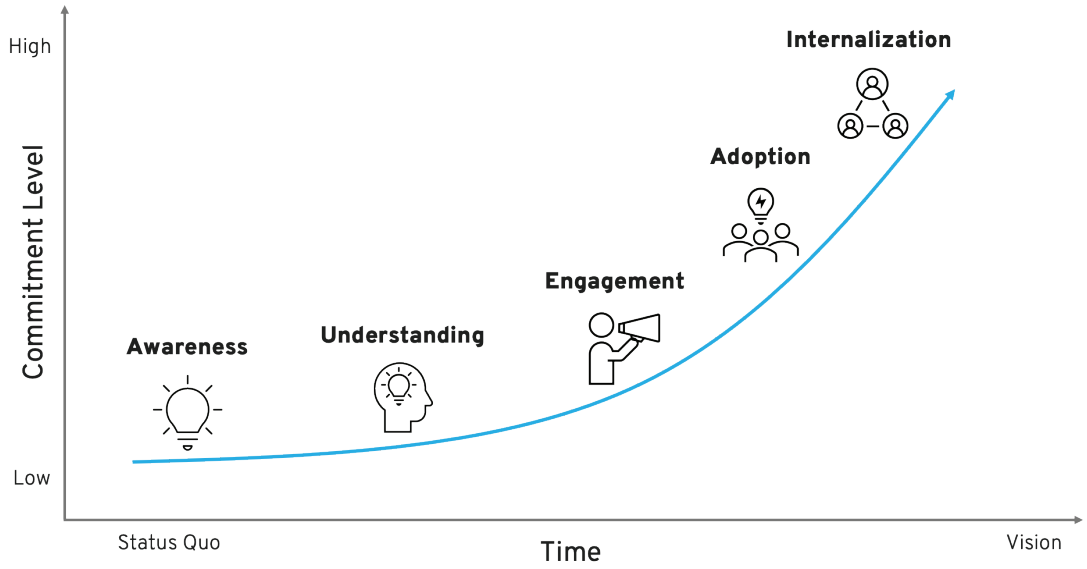
In transformational projects, such as the implementation of product

serialization and traceability, the Change Champions will be the eyes, ears and the extension of the project team within the organization.

II. CHANGE READINESS SURVEYS

Internal surveys that can bring visibility into how prepared the workforce is moving towards the change that is about to happen are great indicators for the project team to adapt specific aspects of the change management plan, in line with the needs of the workforce. All the strategy can be tuned according to the results found on these surveys.

The progress identified across surveys executed in different phases of the project or program, is usually measured against the Change Adoption Curve, indicating the level of commitment from the workforce with the change, over time.



Picture 22: Change adoption curve.

Depending on the duration of the project, these surveys can be repeated over time. In a project for example lasting 18 months or more, 2 or 3 change readiness surveys can be conducted, with similar questions, which will indicate the progress of the efforts focused on change management within the organization.

III. ADJUSTMENTS TO THE ORGANIZATIONAL STRUCTURE

It is common that at the end of the project, new roles are created in the business, IT and/or engineering structures. Two or more positions can be combined into a smaller number of roles, for example. A classic example of adjustment within the organizational structure is the creation of an expert function (SME) focused on serialization and traceability. The product traceability SME is similar to an SAP key-user role but focusing on these IoT concepts and solutions implemented in the organization.

After the project is finalized, the SME becomes the focal point to all business areas both for base business support when it comes to traceability operations, and as a go-to person for future demands of digitalization capabilities integrated with traceability systems.

Another example is related to the formal adjustments of roles and responsibilities to be aligned between functional managers and HR. Additional responsibilities may be necessary to support systems and process solutions implemented during the project, to support incident management and future enhancements, as well as a support for other projects that become interdependent with product traceability solutions.

IV. COMMUNICATION PLAN

The communication plan objective is to ensure the dissemination of correct and relevant information, at the appropriate time, to the previously defined audience, through effective channels, therefore helping the organization to move smoothly through the change adoption curve.

A project is made almost entirely of communication, and it can happen in a formal or informal way. Meetings and project progress updates with Change Champions, conversations 1-to-1, recurring emails aiming specific audiences with a proper planning of the content, information exchange between the project team and functional areas, workshops and brainstorming, communication through corporate channels (internal magazines, internal TV circuit, intranet, others), endomarketing campaigns, communications about the project at corporate events, all of them are examples among others that could be explored, to communicate and

influence the workforce to a positive perception about the changes the project is bringing.

It is recommended that in addition to the core functional areas involved (e.g., manufacturing, distribution and logistics, IT, engineering, etc.) the project team also involves the HR and Communication departments, among others that can add value to the communication strategy and execution.

V. TRAINING AND REVISION OF OPERATIONAL PROCEDURES

Training activities conceptually should be managed within the context of change management as well. The technical content created during the planning stages of the project (e.g., requirements documentation, to-be process mapping, etc.) can serve as a foundation for the construction of training materials and for revision of operational procedures.

Another recommendation is for the project leader responsible for the change management deliverables, also to be appointed to coordinate the training strategy, as well as the coordination of activities related to revision of the operational procedures. There is a lot of synergy that can be explored among these deliverables, a great level of technical knowledge overlaps as well. This strategy will surely bring benefits to the project team, that will be addressing changes and business transformation with a more holistic perspective.

Several initiatives can help to increase the performance of the training cycles and mitigate project risks both during the implementation and during the post go-live support period:

- Change Champions' involvement in training sessions.
- Executing the training sessions as close as possible with the project go-live. People tend to easily forget concepts and procedures when they do not apply them in the daily routine.
- Involve operational employees as much as possible on informal testing cycles, so they get familiar early in the process on how systems and process automation would behave.
- In projects involving IoT concepts, it is important to use materials that generate interaction, interest, and visualization of processes

during the training sessions. E.g., smaller scale models, devices, maquettes, staples and/or objects that help with the storytelling of the to-be operations, dummy products that can be used to exemplify aggregation processes, movement between site locations, etc.

- Involve operational employees during the idealization of the training sessions and to generate ideas for revision of operational procedures. People engage more when they have the opportunity not only to participate in the implementation, but to directly influence and contribute to the method, the approach used throughout the project execution.

These are just a few examples among many others that can be explored to increase the chances of success during the training and procedures revision phase.

VI. READINESS PLAN

The readiness plan is something more comprehensive than the typical IT cutover plan involving the typical technical activities preceding a project go-live.

The readiness plan aims to identify activities from a business point of view that need to occur, before, during and after go-live, to avoid business disruptions and increase the chances of the project go-live to succeed.

The activities that are mapped into the readiness plan can be started months or weeks before go-live. This should not be confused with the overall project plan, or project implementation schedule. The readiness plan is the basis for the coordination of specific activities aiming the business transition between the old operation model and old IT solutions, to the new business model. This is also handled within the context of change management.

Each one of the activities mapped into a readiness plan may have the following information associated with:

- Topic: e.g., business process training, system training, change control, equipment qualification, infrastructure qualification, operational procedures revision and approval.
- Sub-topics (details): e.g., specific training sessions with different functions, different change control systems (if applicable), functional

areas with their respective change controls, purchase/receipt/installation/qualification of equipment and devices, others.

- Description of the activity.
- Expected result.
- Responsible for the activity.
- Priority.
- Indication if mandatory or optional.
- Activity deadline.
- Percentage of completion.

VII. EVENTS AND CELEBRATION

Individual and collective recognition is one of the most powerful tools in a change management plan. In a recent survey published by the Harvard Business Review [15], several aspects of recognition were discussed and recognized as determining factors of personal motivation, among them:

- Importance of choosing the person who makes the recognition public.
- Recognition needs to take place close to the act. Simple, symbolic, and higher-frequency recognitions tend to generate better results.
- Making the recognition public increases the chances of engagement and commitment.
- Importance of communicating specific details of the action that generated the recognition.

Events during the project implementation that create an environment favorable to celebration and recognition of teams and people is a determining factor of success in any transformational project.

Common Risks and Issues

14

Risk management concepts apply similarly to any project. So, in this chapter, some real examples of risks and issues during the execution of product traceability projects will be discussed. Other known and unknown risks may be identified by the project team during implementation.

I. PROCUREMENT OF HARDWARE AND SOFTWARE SOLUTIONS

- Delays with procurement and importation process (if applicable) due to customs problems: In exceptional cases, equipment may be retained by customs and additional documentation may be required.
- High demand for automation equipment and systems in case of reduced regulatory deadlines: It is recommended that companies plan and conduct their projects in advance of regulatory deadlines when possible

(e.g., pharmaceutical sector, tobacco, others). In times of high demand, equipment suppliers and software platforms may not have enough capacity to meet all market demand at once. In the best-case scenario, vendors can hire to resources available in the market without the proper time required for training, with high chances of the quality of services expected by customers to not be met.

- The choice of hardware and software solutions can be a slow process: The number of global and local vendors has increased in recent years. Each vendor has its advantages and vulnerabilities. It is necessary to analyze the strengths of vendors considering the business needs and long-term partnership opportunities. It can take weeks, even a few months for this relationship and sense of trust to be achieved during the selection process.
- Issues with alignment between the project team and the procurement team: Buyers will naturally have several other priorities during the project execution. Seeking alignment with upfront with the procurement area so that a resource is dedicated to the project needs or hiring a temporary resource (depending on the need on a case-by-case basis), can avoid problems and negative surprises during the implementation.

II. IMPACTS ON PROJECT SCOPE

- Difficulty to define requirements: in situations where the technical knowledge of serialization technologies and product traceability, as well as experience related to the impact that these technologies will cause to operation are scarce in the company, hiring specialized consultants is a good strategy to guide the project team and increase the chances of success with the overall implementation.
- Failure to interpret business needs and requirements: In an implementation following Agile methodology for example, the product owner needs to have access to functional areas, Change Champions and all key users who have knowledge in every aspect of the organization's operations. In a team that communicates well, scope-related risks tend to be significantly reduced.

- Requirements management: It is necessary to ensure that there is a single tool and source of data related to the scope of the project (e.g.: Jira, Trello, Helix, others), and that governance on scope management is followed to the letter. In the case of software development using agile methodology, this means creating discipline with daily meetings and other formal processes within the methodology best practices.
- New requirements and critical business needs found throughout the implementation: In traceability projects it is natural that business needs considered critical have not been fully mapped during the planning phase. The technical nature and complexity of this type of project increase the chances of this type of risk. Budget and schedule contingencies are the best way to mitigate unknown risks.

III. SCHEDULE IMPACTS

- Schedule delays due to lack of engagement and prioritization of support areas: In complex matrix organizations, there are activities related to the Computer Systems Validation and evaluation by areas such as Software Quality for example, which are not functional areas with resources dedicated to the project. Early identification of these dependencies would avoid future delays and internal conflicts.
- Lack of integration and collaboration: There are proven productivity gains when software development, system validation, business SMEs, and other personnel are in the same physical environment. In case this setup is not possible, the project team needs to amplify attention to issues related to communication, risks of misunderstanding of business needs, assumptions, expectations, among others.
- Project team performance issues: In many cases some of the resources dedicated to the project team are not fully familiar with the tools, processes, and culture of the organization. In other cases, the difficulty that resources may have to understand technical concepts from other functions (e.g., system validation resource who has no experience with supply chain processes) can also bring risks to the project. Most of these risks can be mitigated through a pre-project training plan.

IV. TESTING PHASES

- Problems related to scanning of labels by mobile devices: Whenever there are adjustments to logistics unit labels, with the addition of bar codes, product related information, or tags for automatic reading, it is crucial that these labels are tested with real life mobile devices in a quality environment. This is an activity often forgotten, and in case of incompatibility problems, the failure will only be detected in production, bringing a huge risk to the business operations.
- High number of issues encountered during system testing phases: A recommendation is to anticipate user testing, which typically occurs in a Quality environment, so that business users are already running informal tests in Development environment along and in partnership with the developers. This approach will improve the overall testing performance, mitigating unnecessary rework during the formal testing period.

About WeDigit Consulting

WeDigit is a boutique consulting agency specialized in supply chain management and digital technologies, established in Brazil and Singapore. Within product serialization and traceability, we have experience with best practices implementing projects in countries such as Brazil, Argentina, Russia, United States, China, India, Indonesia, and others.

Since July/2021 we are members of the GS1 Global Healthcare Leadership Team and bring proven experience to contribute to your digital transformation journey.

Do you need help with digital roadmap planning, process design, solutions and vendors evaluation, project governance, combined with operational efficiency and customer engagement? Count on us!

Our mission is to help organizations to transform business needs into solutions using best practices and the best technology combinations. We believe that innovation and technology should be used to improve the quality of life of human beings above all.

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Glossary

Term/ Acronym	Meaning
3PL	Third-party logistics. Product distribution operations performed by an external partner.
sASN	Serialized Advanced Shipping Notice. An anticipated electronic document received before the actual serialized physical goods, containing all details about the delivery (e.g., products, quantities, batches, serialization hierarchy, etc.)
Aggregation	The act of assigning serial numbers of products considered children (e.g., sellable units) to a serial number considered parent (e.g., bundle, shipper case), creating a hierarchical relationship. The concept is agnostic in terms of number of hierarchy levels (e.g., sellable unit > bundle > shipper case > pallet).
BLE	Bluetooth Low Energy. Technology that uses the same frequency as the traditional Bluetooth, but with important application advantages such as: low power consumption, small device size and low cost.
CMO	Contract Manufacturing Organization. Manufacturing operations performed by an external partner.
Cutover	Technical activities of preparing ITinfrastructure and software, aswell as transition toa new solution. It is usually accompanied by a communication and business plan, ensuring the planned cutting of operational activities, as well as the resumption of operations.
EPCIS	Electronic Product Code Information Services. GS1 global standard for creating and sharing product movement information.
ERP	Enterprise Resource Planning. Information system linking all data and processes from an organization in a central software platform.
GDPR	General Data Protection Regulation. European regulation focused on privacy and personal data protection.
GLN	Global Location Number. Unique identifier based on GS1 standards to identify site locations (e.g., manufacturing site, finished goods warehouse, distribution center, others).

GS1	Global Standards One. Global agency that sets standards to identify, capture and share product data for seamless supply chain automation.
GTIN	Global Trade Item Number. Unique identifier as per the GS1 standards for product identification, defined at the SKU level.
IoT	Internet of things. Concept that is part of the set of technologies within the Industry 4.0.
NFC	Near Field Communication. Wireless data exchange technology by approaching two devices, which can be used for various business purposes. The most common use is on debit and credit cards, with NFC chip for payments.
Mesh Networks	It is a technology that allows the creation of wireless networks formed by two or more devices that function as routers distributing the network signal in a more uniform way and with a wider range.
HR	Human resources.
SaaS	Software as a service. The vendor makes all the software components and infrastructure available, and the client subscribes to the service paying a recurrent fee.
sGTIN	Unique identification at the sellable unit level. Typically generated by combining a GTIN with a serial number.
SKU	Stock Keeping Unit. Unique product identifier used by a company for inventory management.
SME	Subject Matter Expert. An expert in a certain area of knowledge.
SSCC	Serialized Shipping Container Code. Serial number formed by 18 digits and used in packages that aggregate other products with their respective serial numbers.
IT	Information technology.
WMS	Warehouse Management System, used to automate operational processes within warehouses. In the context of this guide, it is agnostic to vendors and brands (e.g., SAP WM, eWM, RedPrairie, Infor, others).

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