The Track & Trace Guide

Building an Effective Program

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Contents

Page

Welcome to this Guide

Welcome to this guide to Track & Trace, which will explain the purpose, technology, and functionality of Track & Trace in the manufacturing and production process. The guide will also explore the reasons Track & Trace applications have become important in modern manufacturing environments, particularly when it comes to the pharmaceutical industry.

With the help of this guide, you will obtain a clear working knowledge of the role Track & Trace plays in the modern supply chain, as well as its uses in preventing counterfeiting and improving brand protection for manufacturers.

Track & Trace processes are currently seeing an explosion in popularity as more industries begin to look into these anti-counterfeiting abilities. A growing concern among consumers about the sourcing of raw materials has also become a factor, particularly in the electronics industry. Manufacturers wish to be able to reassure their customers that no raw materials were obtained from conflict zones; accomplishing this necessitates a careful tracing of these materials from the source.

Similar concerns exist for electronics manufacturers after their products are created. The rise of online marketplaces, generally poorly-regulated, have contributed to an expansion in the gray and black markets for stolen or counterfeit electronics. In this case, it becomes useful for manufacturers to be able to identify where stolen goods came from, or to quickly prove the legitimacy (or illegitimacy) of a given retailer.

Notes

An Introduction to Track & Trace

Track & Trace applications first started in the postal industry as a way of ensuring that parcels were successfully reaching their destination. Early Track & Trace systems were paper-based, but by the 1970s technological advances led to the implementation of electronic Track & Trace systems. The ability of these early systems to record and store large volumes of data rapidly led to other applications which functioned within the Track & Trace framework, including counterfeit prevention, customer security and brand protection.

1

An Introduction to Track & Trace

Track & Trace can be defined as any of a series of actions performed by manufacturers, distributors and retailers.

For manufacturers and distributors:

- Recording receipt of products by noting the case serial number, 'ship to' and 'ship from' serial numbers, and noting the time and location of these recording events ('receive events')
- Recording products' onward delivery to customers by noting case serial numbers, 'ship from' and 'ship to' serial numbers, and then noting the time and location of these recording events ('dispatch events')

For retailers:

- Recording products' arrival by noting case serial numbers, 'ship to' and 'ship from' serial numbers, then noting the time and location of these recording events ('dispatch events')
- Recording case serial numbers and product serial numbers, plus noting the time and location of these recording events ('disaggregate event')
- Recording product serial numbers, plus noting the time and location of this recording event ('sale event')

All of this information together with product and order information is entered into the database of the relevant company and uploaded into an event repository, effectively providing a complete history of the movement of the product from production to point of sale. The usefulness of this information collection has led to the implementation of Track & Trace requirements in numerous industries for a variety of reasons.

In the pharmaceutical industry, for example, Track & Trace requirements are in place as part of efforts to counteract the sale of counterfeit products. This has especially become a concern as counterfeiters have begun to attempt to introduce drugs for serious diseases such as diabetes, heart disease, cancer and HIV into the market, making counterfeit detection quite literally a matter of life and death. Government and regulators within the

pharmaceutical industry are still coming to grips with the way to implement these regulations – and many governments are still in the process of drafting their regulations.

Other industries of tightly-controlled substances such as explosives have Track & Trace requirements to let manufacturers and government agencies know where such materials are and who owns them. Players from different industries have come to Track & Trace technology as a method of improving product recall processes to better protect both consumers and brand reputation. The more efficiently a product recall is run, the less damage it will do to a company's brand image. This rationale has led the food industry to begin exploring the implementation of Track & Trace requirements, although no firm government or industry regulations are currently in place. The exception is in China, where the infant formula market is heavily regulated after a rash of infant deaths caused by adulterated milk.

Marking products with unique and traceable serial numbers also makes it easier to detect gray market (i.e. the selling of products by unauthorized retailers) business. A serial number can identify where a product is meant to be sold – identifying products that are being sold in countries outside of the intended sales channel. The rise of online marketplaces has made this ability increasingly important, particularly when it comes to online pharmaceutical sales.

All Track & Trace applications rely upon the same technology and work on the same basic principles, which will be detailed further in the upcoming pages. The basic idea, however, is this: Track & Trace is a method of data collection, storage, and reporting. This is accomplished by the processes of serialization and aggregation. It is already widely used in the logistics industry, and in other industries (particularly electronics), and it is becoming widely regarded as an inevitable addition to the industry's ongoing fight against counterfeit and gray market sales. The only industry to have significant government requirements for serialization, however, is the pharmaceutical industry. Obviously, the danger counterfeit pharmaceuticals pose to consumers is behind the drive for regulation in that area, but there are benefits to regulation in other industries, such as protecting companies from lost sales and tarnished brand reputations.

Industry Drivers for Track & Trace

While Track & Trace has been a reality across many industries for decades, the last few years have seen a significant increase in government regulations, which have made the use of Track & Trace technology mandatory. This is particularly true in the pharmaceutical industry, where increased concerns about the propagation of counterfeit drugs has driven a significant amount of legislation set to take effect in the next few years. That is not to say that other industries do not have – or are not investigating the implementation of – Track & Trace regulations. The food, electronics and logistics industries all have their own planned or already implemented regulations driven by, as in the pharmaceutical industry, concerns over counterfeiting and consumer health.

Counterfeiting is far from the only reason manufacturers have been considering Track & Trace applications. Product traceability makes it easier to spot and combat gray market businesses and identify leaks in the supply chain. Serialization also has a benefit to consumers: if they are willing to scan the codes on their products and automatically register their purchases, it opens the door for highly targeted marketing campaigns and creates an easy way to reach consumers in the event of a product defect or recall.

2.1 Pharmaceutical Serialization Requirements

A study from the World Health Organization conducted in 2009 estimated that 10% of drugs sold worldwide were counterfeit. This number is on shaky ground due to under-reporting and a general lack of infrastructure for the detection of this problem in many countries, and it is likely that the number has only become larger. The rise of online drugstores, shortages of medications and the increasing size of the generic drug market makes the sale of counterfeit drugs a profitable and attractive undertaking for criminals.

In developing areas such as South America and West Africa, it is estimated that 40% and 70% respectively of all drugs are counterfeit. As a result of these shockingly high rates, countries are rushing to implement legislation that will enable the tracing of pharmaceutical products from the point of origin to the consumer. These requirements will affect all levels of the pharmaceutical production and distribution process, including pharmaceutical manufacturers, drug wholesalers, pharmacists, and regional and local distributors. This is particularly true for European markets, where some of the strongest legislation has been drafted and is in the process of being implemented.

2.1.1 United States Legislative Programs

The United States has two separate agencies which are both in charge of the production and distribution of pharmaceuticals in the country: the Federal Drug Administration (FDA) and the Drug Enforcement Administration (DEA). Both organizations have worked to create a wide-rating Track & Trace system covering the entire production and distribution lifecycle of legitimate pharmaceuticals.

A full complement of US requirements becomes law between 2015 and 2023, and in January 2015, the Drug Supply Chain Security Act (DSCSA) came into force. The Act comprises regulations for tracing drug product transactions, serializing products at the smallest saleable unit level, as well as verifying product identity and transaction histories. DSCSA required that, by November 2017, manufacturers mark packages with a product identifier, serial number, lot number, and expiration date. In addition, DSCSA requires unique marking of cases with a serial number. On July 3, 2017, FDA published a guidance document announcing the regulation would not be enforced until November 2018, giving market participants another year to become fully compliant.

2.1.1.1 Product Tracing Requirements

By January 1, 2015, all supply chain businesses (except dispensers) needed to have achieved lot-based traceability by sharing transaction histories with all those partners to whom they sold products. The law did not prescribe standard formats for data exchange, so companies had to be able to receive transaction data in many configurations.

2.1.1.2 Verification Requirements

If there is an inquiry about a suspect product, supply chain companies must be able to produce relevant transaction documentation within 24 hours (dispensers have 48 hours), so businesses need a robust and fast-acting storage and retrieval mechanism to ensure that these response times can be met.

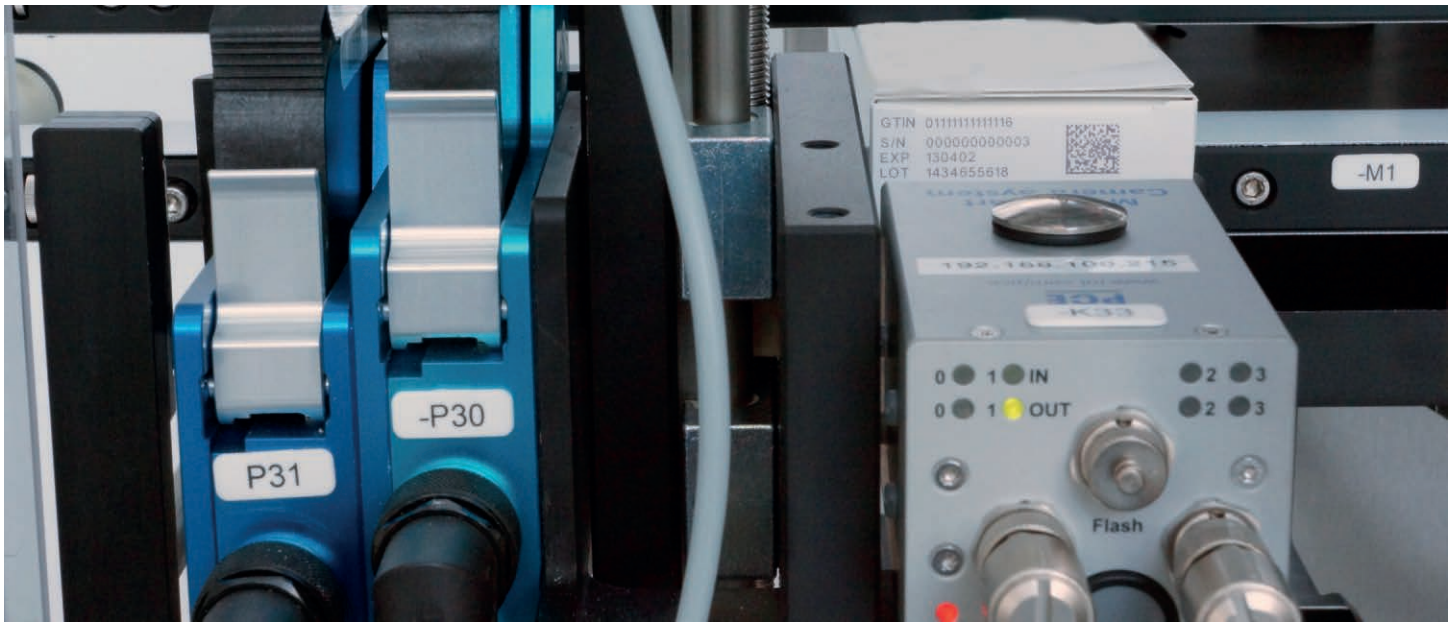
2.1.1.3 Serialization Requirements

For some time, the pharmaceutical industry has been aware that, during lot level preparation, completing one transaction between two parties can be challenging and time-consuming. When serialization takes effect, businesses will need to manage a high volume of transactions, involving billions of items moving between possibly hundreds of partners - including outsourcing partners. This poses both communication and data volume challenges as businesses generate, process, and store an unprecedented amount of data and transactions. In the USA, even the smallest saleable unit and sealed homogeneous cases need to be serialized. While aggregation is not yet legally required (the DSCSA has a deadline of 2023 for aggregation to be implemented), there has been pressure on manufacturers to implement it early. Several pharmaceutical manufacturers in the United States, including Johnson & Johnson and McKesson, are requesting aggregation be implemented as a means of improving product traceability.

In 2012, the FDA Safety and Innovation Act (FDASIA) gave the FDA the right to collect financial contributions from industry to fund reviews of innovative generic or specific drugs, medical devices, generic drugs and biosimilar biologics (a copy of a drug manufactured by a different company).

The Drug Enforcement Administration

The United States has a somewhat unique structure when it comes to pharmaceuticals – the Food and Drug Administration (FDA) shares responsibility with the Drug Enforcement Administration (DEA). More specifically, the DEA is concerned with the distribution and proper use of more powerful drugs, specifically those which are known to be addictive. The DEA's requirements for reporting and record-keeping under its purview are below.



2.1.1.4 ARCOS Reporting

This drug-reporting system monitors DEA-controlled substances all the way through the journey from manufacturer and commercial distribution to the point-of-sale, which includes hospitals, pharmacies, doctors, and teaching institutions. These reports are distributed quarterly to the DEA and are meant to provide a view of the number of controlled substances being distributed; it is not necessarily a way to track the movement of individual packages.

2.1.1.5 Pedigree

This process requires product serialization, and is applicable right down to the lowest unit of sale continuing all the way along the supply chain. Every trading partner must authenticate receipt and transfer of products via a universally accessible means of electronic data exchange. Since 2006, drugs distributed by wholesalers, distributors or repackagers must have Pedigrees, unless the seller is an Authorized Distributor of Record (ADR) for that drug.

2.1.1.6 ePedigree

This is an electronic record of all data required by Pedigree laws; ePedigree data is exchanged using Electronic Product Code Information Services (EPCIS) standards.

2.1.1.7 National Drug Code (NDC) Numbers

These unique, three-segment numbers are used for identifying drugs listed in the FDA's Drug Registration and Listing System (DRLS). The FDA extracts data from the DRLS and publishes it on a monthly basis in the NDC directory.

2.1.1.8 DEA License Validation

This is the DEA's registration system, which authorizes medical professionals, researchers and manufacturers who make, distribute, research, prescribe or dispense controlled substances. Distributors must verify the validity of their customers' licenses at entry and picking points along the supply chain.

CSOS (Automated Form) DEA Form 222 (Manual Form) - the Controlled Substances Act demands that Schedule I and II controlled substances must be distributed only by written orders issued in accordance with the DEA Office of Diversion Control. Order forms are presented in triplicate and must contain the DEA registrant's name, address, date requested, number of packages ordered, size of package and name of substance. The purchaser retains one copy and the supplier retains one copy and sends the third to the local DEA agency. The purchaser and supplier must retain their copies for at least two years and make them available to DEA officials on request.

2.1.1.9 Suspicious Order

In 1998, the Suspicious Orders Task Force developed the voluntary Suspicious Orders Identification Criteria guidelines for recognizing suspicious orders. The guideline supports laws that require regulated persons to report suspicious circumstances to the Attorney General's office. These circumstances can include orders for extraordinary quantities of drugs, unusual methods of payment or unusual methods of delivery in relation to any listed pharmaceuticals.

2.1.2 European Legislative Programs

There are several different legislative bodies in Europe which are producing and implementing European pharmaceutical regulations. These organizations include the European Federation of Pharmaceutical Industries & Associations (EFPIA), the Group International de la Repartition Pharmaceutique (GIRP), the European Directorate for the Quality of Medicines (EDQM) and the Pharmaceutical Group of the European Union (PGEU).

The Falsified Medicines Directive (FMD), due to be applied by February 2019, requires serialization of drug products, reporting of product master data and serialization data, and the verification of drug products at point of dispensation. This Directive poses considerable challenges for manufacturers carrying out business in Europe. The reason for this is that European medications are generally packaged and sold at unit level, so the volume of product to be serialized and the volume of transactions will be two to five times larger than in the USA or other markets – in fact the universe of data to be produced and managed will be massive.

2.1.2.1 Serialization Requirements

The FMD requires only unit level serialization, with the manufacturer issuing and printing a unique GS1 standard serial number together with the GTIN, a batch number and expiry date. Also a National Trade Item number (NTIN) may be added, all in data matrix code and human readable format.

2.1.2.2 Reporting Requirements

After a product has been serialized, the manufacturer must submit master data to a central European hub. If manufacturers have subsequent status updates about the product, these updates must also be uploaded to the hub.

2.1.2.3 Product Verification Requirements

As the drug moves into the supply chain, dispensers must take responsibility for Track & Trace compliance, verifying products by scanning a unit barcode at the point of dispensation. In most cases, a dispenser is a pharmacy – the endpoint of the distribution chain where the drug is given to a consumer. This can also be a healthcare facility (such as a hospital), but in both cases the packages must be scanned. The scan should confirm that the serial number was actually created and applied to a drug product, and will also allow dispensers to perform risk-based supply chain verification. By accessing product updates from the manufacturer, dispensers can check whether the product has been identified as stolen or possibly counterfeit.

ESM (European Stakeholder Model) Project – this pan-European system requires electronic product verification at the dispensing point for all prescription medicines. Manufacturers must label prescription medicine packages with a product code in machine-readable format in the form of a 2-dimensional data matrix barcode. As with the FMD, product codes must be in human-readable formats as well as data matrix codes, which must include the global trade item number, batch code, expiry date and serial number. Interlinked national databases are to record product codes and serial numbers, as well as managing data exchange of from across every ESM member state.

Re-packagers or parallel distributors must assign a new serial code to the database in connection with the original product.

eTACT is a planned end-to-end coding system that will create an additional Unified Medicine Identifier (UMI) to be added to every package. The UMI is to include product numbers, non-sequential and unpredictable serial numbers, batch numbers, and expiry data. Initial plans call for machine-readable 2D data matrix labels on each package, with a possible switch to RFID labeling at a later time. This is part of the European Directorate for the Quality of Medicines (EDQM) mandate to ensure access to good-quality medicines and health care.

2.1.3 Chinese Legislative Programs

China implemented its first Track & Trace regulations for pharmaceutical serialization in 2013 with the creation of unique Chinese codes for identification. At the same time, the China Food and Drug Administration (CFDA) implemented drug product event reports, requiring medicines listed on the 2009 Essential Drugs List (EDL) to have their movements tracked. The number of entries on the list was increased by legislation in 2013, bringing the total number of drugs from 307 to 502. By the end of 2015, all pharmaceutical products – not just those on the EDL – were required to have serialization processes and government reporting up and running.

2.1.3.1 Serialization requirements

All levels of product – from unit to bundle, from case to pallet – must be serialized with a government-issued number; aggregation is also an enforceable regulatory requirement. Manufacturers must utilize the China Drug Identification, Authentication and Tracking System in order to register the products they intend to sell in the country and obtain serial numbers. If they have queries, Chinese pharmaceutical companies must use a Chinese government system to create and record serial numbers, which are then issued to the packaging lines. After the serial numbers have been issued, manufacturers must report back on product events. In addition, the CFDA has drafted guidance for increased scrutiny of ingredient suppliers as a response to several scandals involving poor-quality ingredients causing issues with product efficiency.

The unique factor regarding these requirements is the source of the serial numbers. Unlike other regulations, the Chinese control the assignment of numbers, which are unique to the country. This gives China a firmer control over the products sold in the country, but (unfortunately for global pharmaceutical manufacturers) it means that serialization needs to be handled inside the country. Fortunately for manufacturers, this does not necessarily mean they must have a full-fledged facility in the country – drug makers can designate a local pharmaceutical company, wholesaler, subsidiary, or other organization as their official monitoring agent in the country.

These unique Chinese serial numbers are displayed using EDMC barcodes rather than a GS1 compliant data matrix code, which can further complicate matters for manufacturers, in part because the serial numbers are twenty digits long and make for a longer barcode than packaging may be able to accommodate. This may necessitate a redesign of a package in order to allow the display of the code. In the event that the package is too small, special dispensation can be sought from the CFDA to display the code on a larger package containing the minimum package. A recent proposed update to regulations indicates China may be moving away from this system and toward a serialization system that more closely resembles the US and EU's regulations, but for the moment the requirement remains.

2.1.3.2 Reporting requirements

All reports must be manually uploaded in China to the China FSDA system – and like the assignation of the serial numbers, reports must be uploaded within the country and cannot be managed remotely. The local monitoring agent handling the serialization of packages in the country (as mentioned before) is also responsible for this regular upload. Moreover, there is a size restriction of five megabytes for the uploaded report. If reports cover a large batch of data, the file size can easily exceed five megabytes, in which case strict guidelines must be followed as to how to split up the file. In addition, there are rigorous protocols about header information, and the sequence in which to upload the multi-part report. China recently indicated it would be overhauling its approach to this system – including a possible change of service providers – which will make the current requirements obsolete, but currently there is no firm timetable for this shift.

2.1.4 Argentinian Legislative Programs

Like China, Argentina now has a number of serialization and reporting demands and the country has introduced several new requirements based on product type. Unlike China, though, Argentina has adopted a set of familiar standard-type requirements.

2.1.4.1 Serialization Requirements

Those manufacturers who sell pharmaceutical products in Argentina must ensure that every unit for sale has been serialized in accordance with GS1 standards. This applies to both the serial number and bar code format.

2.1.4.2 Reporting Requirements

Argentinian pharma regulations insist that a broad range of product events should be recorded and submitted to the government.

2.1.5 Brazilian Legislative Programs

It is popularly thought that Brazil has probably the world's most complex and involved serialization Track & Trace regulations. Demanding serialization, tracking and government reporting, they are making considerable demands on manufacturers - although wholesale distributors and pharmacies must also undertake a range of reporting duties. A lawsuit brought by a Brazilian drug manufacturer has thrown the timetable for complete implementation of these serialization and aggregation programs into doubt – the government was forced to draft a completely new law (Law 13.410/2016) in order to provide a fix to the initial law establishing the National Drug Control System (SNCM). The new timeline for implementation is to have the full force of the law in effect by the end of 2021.

2.1.5.1 Serialization Requirements

Product serialization at single item level is required, as well for cases, pallets and containers. Also required is the aggregation relationship between case and unit. Brazil also demands that product manufacturers ensure that the serial number is unique on a worldwide basis – with application to the legal entity rather than the specific product.

2.1.5.2 Tracking and Reporting Requirements

The product manufacturer must track drug product movement from the manufacturing process all the way to dispensation to the patient. Consequently, when a product travels from wholesaler to wholesaler and then on to the pharmacy, every one of the parties involved is obliged to send data to the manufacturer's system – then all the data must be sent to ANVISA (Agencie Nactional de Vigilance Sanitaria). This process puts the responsibility onto manufacturers for establishing reliable links with direct and indirect supply chain partners – in other words, any party in the Brazilian supply chain who might purchase the product. In this way, all relevant shipment and receipt information can be recorded. Like the USA, the government of Brazil does not specify how compliance information should be shared between companies – instead, the Brazilian government is allowing industry to decide on compliance data sharing methodologies.

2.1.6 Indian Legislative Programs

India's requirements for serialization, Track & Trace are straightforward – though the country's Directorate General of Foreign Trade has asked supply chain companies to record product-related events. However, there is no system currently in place today for government reporting. A system has been in development for several years, but there is no scheduled implementation date yet – and manufacturers are unclear whether they should be retaining current data for future reporting. This overall lack of clarity makes a proactive approach in implementing some form of serialization more attractive – otherwise manufacturers risk finding themselves suddenly on the hook for failing to serialize.

2.1.6.1 Serialization Requirements

India follows GS1 standards in terms of numbering systems, and serialization procedures are required to multiple levels from individual units upwards to case level; however, India currently has no aggregation requirements. At the individual product level, the barcode should be printed as per GS1 Global standard, but it is not currently being enforced. At the secondary and tertiary level, a barcode displaying the GTIN, batch number, and unique serial number is required, but this does not need to include any aggregation of the products contained within the secondary or tertiary packaging – aggregation (or "maintenance of the parent-child relationship") is an optional activity until notification is given that it is no longer optional.

These requirements are only applicable to exported products; there are no requirements for pharmaceutical products sold within the country.

2.1.7 South Korean Legislative Programs

Beginning in 2016, serialization of all pharmaceutical products in South Korea became mandatory. This makes the use of GS1's standards for global serialization and allows for the possibility that aggregation may become required in the future; some pharmaceutical manufacturers are already requiring aggregation from their supply chain partners.

2.1.7.1 Serialization Requirements

GS1 standards must be applied, although the country requires the use of a unique Korea Drug Code (KDC) and not a GTIN. Also included in the barcode should be the expiration date and lot number – and obviously, this information must be present in a human-readable format as well. Imported products must be serialized before arrival into South Korea. All data must be submitted in regular reports to the Korean Pharmaceutical Information Service (KPIS). Reporting is the responsibility of

pharmaceutical manufacturers, importers and, starting in 2017, wholesale distributors were also required to begin submitting reports to KPIS.

2.1.8 Turkish Legislative Programs

Turkey has one of the world's most long-standing and well-established Track & Trace systems in place. Serialization and government reporting requirements cover all pharmaceutical products.

2.1.8.1 Serialization Requirements

Turkey requires serialization at unit level and also has aggregation requirements, both in accordance with GS1 standards.

2.1.8.2 Reporting Requirements

All supply chain businesses are responsible for reporting events to Turkey's national ITS pharma data Track & Trace recording system.

2.1.9 Russian Legislative Programs

In Russia, there is an ambitious plan for serialization which not only provides supply chain security to manufacturers, but also adds extra functionality for end users. The Russian federal drug database and tracking system is known as the FGIS MDLP, and allows consumers to access information about the drugs they are taking, including price comparisons. Also included would be information relating to the logistics and storage of products, and federal agencies would have access to data related to the movement of pharmaceuticals to facilitate adjustment of price controls and other trade analysis.

The first phase of the rollout was a pilot program which started in 2017. 2018 was the deadline for manufacturers of so-called vital and essential medicines, and the country is expected to have complete serialization implemented by early 2019.

2.1.9.1 Serialization Requirements

The coding on individual packages must include country of manufacturer, the manufacturer name, batch number, expiration date, and a unique identifier code. State authorities assign company and country codes, and the information can be transmitted using codes which conform to GS1 standards.

2.1.10 Regulations in Development

Track & Trace is not a requirement in all countries, of course, but regulations governing traceability are in a state of almost constant development. Saudi Arabia is piloting its own serialization requirements which are set to be adopted by other members of the Cooperation Council for the Arab States of the Gulf (CCASG) depending upon how well its implementation goes. Egypt is also working on its own serialization requirements, and South Africa has also taken its first steps toward a complete set of Track & Trace requirements.

As seen in the regulations outlined previously, even well-established programs are undergoing improvements and revisions. These improvements are either spurred on by further developments in technology or (less ideally) triggered by scandal. Occasionally, as in the case of Brazil, a change is spurred by a lawsuit. It is important to stay informed on these regulations – particularly on the timelines for implementation, which shift most of all, and even more particularly for international manufacturers.

Fortunately, there are organizations such as the GS1 which are involved in traceability operations across the globe – as well as equipment manufacturers who can provide overviews of current regulations.

2.2 Logistics

The logistics industry is where the Track & Trace industry got its start, but the use of Track & Trace in the industry is not necessarily a requirement. Simply put, it depends on the product being shipped (and how many angry customers one is willing to deal with in the event of lost products). Being able to trace any freight no matter where it goes helps those in the logistics industry uncover where shipments are at any moment, and identify where those shipments went should they become lost. It allows customers the ability to know where their goods are at any given time, and depending on the level of Track & Trace technology it can even provide close to real time updates on the movement of a given piece of cargo. The nature of the modern world all but demands the ability to know where anything is at a given time, and it is no surprise to see shipping companies promoting their tracking capabilities.

2.3 Electronics

The modern electronics industry is currently dealing with a massive push for serialization much like the pharmaceutical industry – though much like in the logistics industry, serialization is not a government requirement. Instead, it is the pressure caused by the increase in counterfeit technology, considered by some industry leaders to be the most important problem in the industry. Counterfeit electronic products are responsible for millions of dollars in lost profits, as well as irate consumers who are left with no recourse when they discover they spent money on a fake product.

In addition, the electronics industry is perhaps the most aggressive in the idea of using Track & Trace technology and registration in order to provide continuous support to customers throughout the life of the product. These applications along with a need to stay on top of the distribution chain in order to prevent counterfeit products from hitting the market are sufficient reasons for electronics manufacturers to move toward Track & Trace applications.

2.4 Food Industry

In the food industry, the push for Track & Trace stems primarily from fears of ingredient contamination. While Track & Trace is not currently a requirement in most countries, it is becoming increasingly likely that such requirements are on the horizon. This is in part due to an increased awareness of the dangers of allergens, which has caused an increased focus on the ingredient supply chain. There is a growing understanding that increased traceability protects consumers, safeguards manufacturers' reputations, optimizes food quality and preserves the integrity of well-known brands. Traceability allows manufacturers to quickly ascertain the date, time and location of foods in the event of a product recall, which in turn helps to identify the source of the contamination sooner.

Wrapping a Track & Trace system up in a larger production monitoring apparatus can also help to identify troublesome spots in the manufacturing process, allowing for analysis and improvements. This in turn helps reduce the amount of raw materials wasted in day-to-day manufacturing operations. A strong recall prevention program, including foreign body detection and label inspection, further contributes to the overall efficiency of a production line, while the addition of traceability systems make it easier to conduct a product recall in the event that one is necessary.

By being able to quickly isolate and identify contaminated material, manufacturers are able to more effectively target recalls, preventing the waste of perfectly good products. This could reduce the size of the product recall and can even help to reduce the amount of damage a product recall does to brand image. These benefits, along with several high-profile product recalls (most notably the deaths of infants in China due to contaminated formula) have started to drive governments to begin the implementation of regulations which will in all probability feature the eventual inclusion of Track & Trace requirements.

2.4.1 USA Regulations for Food Tracing

In the USA, the Federal Drug Administration introduced the Food Safety Modernization Act (FSMA) in 2011, which applies to foodstuffs throughout the production process, from the location in which they are originally sourced, all the way through processing and packaging. FSMA builds on existing Hazard Analysis Critical Control Point (HACCP) rules which have provided definitive standards for food safety management since the 1960s; furthermore FSMA sets out the requirements for a risk-based, global systems approach to food safety, referred to as Hazard Analysis and Risk-Based Preventative Controls (HARPC). FSMA also includes enforcement of accurate labeling – an obligation that applies to American manufacturers and food from overseas too (which represents up to 15 percent of the entire US supply chain).

It is important to note here that this is not a full Track & Trace program – it does not require the ability to trace a given product's complete movement through the supply chain. Requirements for food labeling are restricted to clear ingredient markings and allergen warnings – lot codes and expiration dates are industry standards but not legally required. In addition, these lot codes do not have to be recorded as they move through the supply chain. Should stricter serialization requirements come into force, the processes required for labeling is already in place – it only requires the addition of data management in order to implement tracking.

2.4.2 EU Regulations for Food Tracing

In the EU, food tracing systems have been compulsory since 2002, when the General Food Law came into force. This required the keeping of records to monitor the movement of both products and ingredients with application to the entire food and feed industry. There was also sector-specific legislation for particular markets, such as meat products, and as applies in the USA, importers of foodstuffs into the EU must identify the source of products and where they were exported. In 2014, the 2002 General Food Law was supplemented by the EU Food Information for Consumers Regulation 1169 / 2011, which requires that food manufacturers must now provide extra information on food labels, such as the origin of unprocessed meat, as well as detailed nutritional information.

As with the regulations in the United States, there is no formal requirement for full Track & Trace – the labeling requirements are in place, but data management is not required at all. It is entirely possible that actual serialization requirements will come into effect further down the line; a movement to better-trace the origins of raw materials as well as the finished product is steadily gathering momentum and may end up being enshrined in law.

2.4.3 Chinese Infant Formula

In 2008, a massive scandal involving the adulteration of infant formula with melamine caused the hospitalization of nearly 54,000 and six deaths of infants. The fallout of the scandal damaged the reputation of Chinese dairy products so severely that years later Chinese consumers are still reluctant to purchase formula produced in the country; choosing instead to purchase baby formula from countries such as Australia online. Experts still are uncertain as to where along the supply chain the contamination occurred, which is a major part of why the Chinese government moved so quickly to implement firmer inspection and traceability requirements along the supply chain. In addition, China recently introduced a new approval process specifically targeting infant milk formula in an attempt to bring the same rigorous standards used for formula produced in the country to imported formula.

These standards require records to be kept covering the source of all ingredients – manufacturer, supplier, quality audit records, supplier approval records, and the name, size, date of production and batch number of all raw materials. Similarly, records of the storage environment including humidity and temperature monitoring must be available and tagged to the batch and lot number. Each product recipe must be registered and approved by the Chinese Food and Drug Administration (CFDA), and that registration number must be included in a product record including the batch number, date of inspection, method of inspection, test numbers, personnel and so on. Looking at the regulations which the CFDA has implemented for infant formula, it would be a simple task to adapt these regulations to serve as regulations for other segments in the Chinese food industry. It is also likely that other countries will use the CFDA's program as a guide should they wish to implement a similar program.

2.5 Agrochemicals

It is still early days for some industries when it comes to making any movement toward serialization, but the agricultural industry – more specifically the agrochemical industry – has started to move towards traceability in recent years. This is demonstrated by the European Crop Protection Agency's (ECPA) Communicating Reliable Information and Standards to Agriculture and Logistics (CRISTAL) standards. CRISTAL is an initiative started by the ECPA with a goal of establishing a communications framework for the agrochemical industry – and, eventually, any agribusiness supply chain. The guidelines published through CRISTAL use existing standards for barcodes and product labeling as defined by the GS1 system, and uses the existing Electronic Data Interchange for Administration Commerce and Transport (EDIFACT) in order to facilitate the exchange of data between entities.

It should be noted that these are not requirements, they are the equivalent of polite suggestions. The members of the CRISTAL workgroup are all involved in the agrochemical industry, and some of the larger companies have thrown their weight behind the standards, but participation is still strictly voluntary. It remains to be seen whether or not an increase in pressure occurs to push CRISTAL from suggestion to requirement, but as a method of controlling distribution of potentially hazardous chemical pesticides.

2.6 Cosmetics

In the cosmetics industry, there has certainly been a consideration of an implementation of traceability for reasons similar to those of electronics – specifically, to combat gray market sales and ensure protection against counterfeit products. By adding a serialization aspect to the production process, it becomes possible to ensure that unauthorized retailers are not able to sell a manufacturer's product with impunity. It also can give consumers additional confidence that the product is genuine – especially in the premium cosmetics market, where counterfeiting is a lucrative criminal enterprise.

While there are companies offering serialization solutions to cosmetics manufacturers, there are currently no industry standards requiring or recommending the implementation of Track & Trace in the cosmetics industry. As more manufacturers begin to see the benefits of a serialization program, however, it is likely that use of Track & Trace technology will grow in this sector.

Serialization and Aggregation

One could be forgiven for thinking serialization and aggregation to be the same thing – certainly at first glance this seems to be the case. Both processes, after all, involve the application, recording and tracking of codes and the recording of those codes in a larger database. The difference is in what those codes represent, and what their purpose is. Serialization is concerned with individual packs of product as a way of establishing the history of that pack's movements (this is referred to as a product's 'e-pedigree' in the United States). In contrast, aggregation involves taking multiple serial codes and filing them under a larger code – so by accessing this larger code one could gain database access to the codes of each individual package in a case. The combination of these two processes is the foundation of a complete Track & Trace process.

Both serialization and aggregation rely heavily on the ability of manufacturers to create, read and record codes, using a variety of standards and technologies, which are discussed below.

3.1 Coding Types

There are multiple methods of code generation, but the simplest way of looking at a serial number is to define it as a unique series of alpha-numeric characters which refer to a product, box, carton, pallet or container. The method in which these characters are assigned, and the length of the character string, depends upon the coding standard being used. In order for Track & Trace to accomplish its goals – be it tracking the movement of a package through the supply chain or making identification of counterfeit products easier – a fundamental structure is vital. In Track & Trace, that foundation is the Electronic Product Code (EPC); an open coding standard which can be freely downloaded from the EPCglobal Inc. website. The open nature of the standard makes it compatible with other coding schemes – including the GS1 system of identifiers which are used in 1D and 2D barcode applications.

3.1.1 GS1

GS1 is an international organization that develops and maintains standards for supply and demand chains across multiple sectors. With local Member Organizations in over 110 countries, GS1 works with trading partners, industry organizations, governments and technology providers in pursuit of adoption and implementation of global standards. It most frequently works in the areas of Consumer Goods & Retail, Healthcare, plus Transport & Logistics. One of its primary duties is the evolution of relevant codes for marking objects and recording information. Principal codes include:

Country Codes

The GS1 Prefix comprises the first three digits, which usually identifies the national GS1 Member Organization to which the manufacturer is registered – though it does not necessarily indicate where the product is made.

Typical examples:

USA and Canada: 000 – 019

United Kingdom: 500 - 509

Global Trade Item Number (GTIN)

The Global Trade Item Number (GTIN) is used to look up product information in a database (often by entering the number via a barcode scanner pointed at the product). The uniqueness and universality of the identifier helps to establish which product in one database corresponds to which product in another database, especially across organizational boundaries.

GTINs may be 8, 12, 13 or 14 digits long, and each of these four numbering structures are constructed in a similar fashion, combining Company Prefix, Item Reference and a calculated Check Digit (GTIN-14 adds another component - the Indicator Digit, which can be 1-8). GTIN-8s will be encoded in an EAN-8 bar code. GTIN-12s may be shown in UPC-A, ITF-14, or GS1-128 bar codes. GTIN-13s may be encoded in EAN-13, ITF-14 or GS1-128 bar codes, and GTIN-14s may be encoded in ITF-14 or GS1-128 bar codes. The choice of bar code depends on the application; for example, items to be sold at a retail establishment should be marked with EAN-8, EAN-13, UPC-A or UPC-E bar codes.

The GTIN format is relatively simple - every code can be written as a total of 14 digits, with leading zeros used to fill in empty spots for GTIN-13, GTIN-12 and GTIN-8. So a GTIN-8 number would be written as 00012345678, for example. It would be encoded as 12345678 in an EAN-8 format, of course.

Global Document Type Identifier (GDTI)

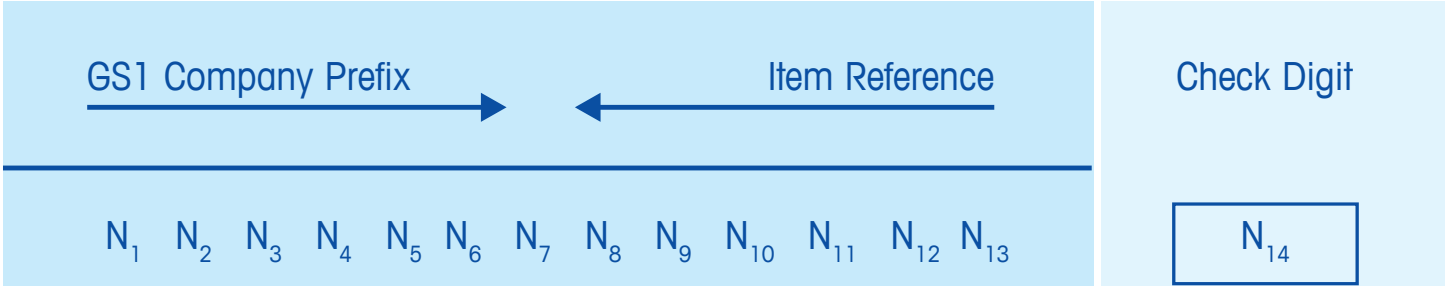
The GDTI identifies a document by type, and can identify documents uniquely where required. 'Document' means any official or private papers that infer a right or obligation upon the person to whom they are assigned. Examples of the kind of documents that could have a GDTI are proof of shipment forms, internal invoices etc. The GDTI should provide a link to the database that holds the master copy of the document. The GDTI may be produced as a GS1-128 bar code and printed on the document as a method of identification or for detail or information retrieval.

Global Location Number (GLN)

This number is designed to identify a location, and can identify locations uniquely where required. The GS1 Identification Key is used to identify physical locations or legal entities. The key comprises a GS1 Company Prefix, Location Reference, and Check Digit. The types of location identified with GLN could be a physical location such as a warehouse or a legal entity such as a company, customer - or a function occurring within a legal entity. It can also be used to identify something as specific as a particular shelf in a store. GLN is also used within companies to identify specific locations both electronically in a database and physically where the GLN can be produced in a bar code or GS1 EPC tag.

Global Shipment Identification Number (GSIN)

A GSIN provides a globally unique number that identifies a logical grouping of individual physical items for the purpose of a transport shipment. The key is composed of a GS1 Company Prefix, Shipper Reference, and Check Digit Shipments - and consignments can comprise one or many logistic units. If the shipment or consignment comprises more than one physical object, there is no requirement that they must be attached together. A consignment or shipment number identifies a logical grouping – and when a shipment or consignment number is read, it should communicate the fact that the physical unit should be associated with any other physical units carrying the same shipment or consignment number.



The complete GS1 structure. For shorter GTINs (8 digit, 12 digit, 13 digit) the leading digits are converted to zeros and left out of the bar code.

1. The 'Company Prefix' is a globally unique number assigned to a GS1 member company.

2. The 'Shipper Reference number' is the number assigned by the member company to the shipment. It is assigned by the consignor, and should be sequentially allocated.

3. The 'Check Digit' is a modulo-10 number calculated across the preceding digits to ensure data integrity.

The data carrier used to represent the GS1 Consignment Number is the GS1-128 barcode symbology.

Global Data Synchronization Network (GDSN)

The Global Data Synchronization Network (GDSN) is an internet-based, interconnected network of inter-operable data pools and a global registry collectively referred to as the GS1 Global Registry. It enables companies worldwide to exchange standardized and synchronized supply chain data with trading partners using a standardized Global Product Classification.

GDSN ensures that data exchanged between trading partners is accurate, as well as being compliant with universally supported standards. GDSN consists of supplier/retailer trading partner, data pools that hold and process trading partner data - and the GS1 Global Registry, which helps locate data sources and assists in keeping relationships between trading partners in sync.

Global Identification Number for Consignment

The GS1 Identification Number for Consignment is used to identify a grouping of goods (containing one or more physical items) that has been consigned to a freight forwarder and is intended to be transported as a single group. The key is composed of a GS1 Company Prefix and Consignment Information. Shipments and consignments can comprise one or many logistic units, and if the shipment or consignment comprises more than one physical object, then there is no requirement that they should be attached to one another or boxed together. A consignment or shipment number identifies a logical grouping, and simply indicates that this physical unit should be associated with any other physical units carrying the same shipment or consignment number.

GINCs are composed of an Application Identifier (401), a GS1 Company Prefix of the carrier and the actual consignment information.

1. The 'Company Prefix' is a globally unique number assigned to a GS1 member company.

2. 'Consignment Information' is the number assigned by the member company to the consignment. The data transmitted by the barcode reader ensures that the symbols representing the consignment information have been captured. The consignment number may be processed as stand-alone information where applicable, or it may be processed with other identification data appearing on the same unit. The data carrier used to represent the GS1 Consignment Number is the GS1-128 Bar Code Symbology.

Depending on the goal of the Track & Trace application, some of these codes will not be utilized. The pharmaceutical industry, for example, tends to only utilize GTINs – other numbers such as the Global Identification Number for Consignment would really only be used by shipping and logistics applications.

3.1.2 1D and 2D Barcodes

Most GS1 codes are displayed as 1D barcodes, which are a series of vertical lines varying in thickness which represent numbers. More complex codes – for example, codes including letters as well as numbers, or just longer strings of numbers, will utilize 2D barcodes. 2D barcodes utilize cells which form a rectangular shape. The patterns made up by the alternation of the cells and the spaces between them represent letters, numbers and symbols. There are two 2D code standards which are used in modern applications: Data Matrix codes and Quick Response (QR) codes. Data Matrix code was developed in 1989 and QR Code was developed in 1994.

A Data Matrix barcode can hold up to 2,335 alphanumeric characters, while a QR Code can hold nearly twice as many - up to 4,296 alphanumeric characters. Data Matrix code is believed to be more secure code (i.e. less susceptible to hacking) and so is the code of choice under circumstances where high security is important.

Both Data Matrix and QR barcodes store far more information than the older 1D barcodes. For some time, Data Matrix appeared to be growing in popularity and preference as the standard 2D barcode in North America, as indicated by the many organizations and government departments that had chosen to use it.

However, Data Matrix code was not designed for the usage of Japanese Kanji characters, and QR Code was capable of such usage. It was inevitable, therefore, that QR Code would become the prominent code used in Japan. QR codes have seen significant growth in Europe and North America as well, driven by easy access to smart phone apps which read QR Codes. In the pharmaceutical industry, the use of 2D Data Matrix barcodes is the standard, with most countries relying on the GS1 standards for coding and clarity.

China's State Food and Drug Administration (SFDA) uses its own unique eCode system, which is used to ensure the safety of food and healthcare products sold in China. SFDA drug regulation seeks to protect patients from counterfeit pharmaceuticals by assigning unique product identities ('eCodes') at various packaging units, a level of aggregation and verification through the country's Drug Electronic Supervision system.

The SFDA drug regulation states that the printed eCode should contain both machine and human-readable elements; furthermore, the regulation states that the associated data should be sent to the Chinese government for data storage

purposes. The code format is a 128C barcode with a 20-digit serial number. This 20-digit number must contain a 9 digit government-issued serialized number, which is purchased from the government as part of the certification process required for selling products in China.

3.2 Printing Techniques

There are many different types of 1D and 2D barcode printers, but essentially, there are four types:

1. Dot Matrix
2. Inkjet – Thermal and Continuous
3. Laser
4. Thermal

Barcodes can be printed on a range of materials, including different types of paper and card, but also on tags, adhesive labels, on glass or plastic packages – and even identity bracelets for use in hospitals and other environments. There are advantages and disadvantages in using this or that technology as described below.

3.2.1 Dot Matrix Printing

Dot matrix printing has existed for some years, and produces the barcode image by printing hundreds of dots in a matrix. This creates the series of lines and spaces that make up the barcode.

Dot matrix printers are cost-effective, readily available, and can print on various surfaces – plus multi-pass ribbons can reduce the costs of individual ribbons and label materials. Balanced against these advantages, barcodes are only low- to medium density and may not produce results of sufficient quality for some users. In addition, re-usable ribbons can result in the printing of illegible barcodes, so that the ability to read them is impaired.

Other technical problems can include ink saturation, where the ink bleeds over the paper, so as to distort the image – and while dot matrix printing can print on many different types of materials, a number of these materials may not be long-lasting, plus they may not be water-resistant or chemical-resistant. Furthermore, dot matrix printers have no graphics capability, plus slow print speeds may be necessary to attain the best ink coverage and most precise print results.

Dot-matrix-printed alphanumeric characters are, unfortunately, often difficult for machines to read, making automated inspection difficult. This is especially true for characters where the dots making up the individual characters are particularly far apart; the greater the distance between dots, the more difficult it is for a computer to connect them and form a recognizable character shape. While the human eye may be able to determine what the represented character is through context, that is not as simple of a task for a computer, though recent technology advances have made this less of an issue.

3.2.2 Inkjet Printing

Inkjet printing is usually used for the rapid printing of barcodes and human-readable fonts in sophisticated high-volume and high-speed production environments. The benefits of inkjet printing include the ability to print directly onto a carton or box, as compared to other forms of printing, which may require a two-step process, i.e. a blank adhesive label must first be printed with the barcode, and then attached to the carton or box.

Track & Trace standards have strict grading requirements, making inkjet printing the least expensive printing solution. This lower cost comes with its own drawbacks, however, in order to maintain high levels of print quality, inkjet printing requires constant monitoring in order to prevent the clogging of inkjets which would have a negative effect on the print quality. Furthermore, the range of usable materials on which is it possible to print can be restricted due to potential bleeding or dark backgrounds, rendering the codes illegible. In such instances, it is important to use a separate label instead of printing directly onto the package's surface.

An important consideration when discussing inkjet printing is the determination of methodology – in other words, the nature of the jet conveying ink to paper. There are two methods used in industrial situations: continuous and thermal. Each method has its own particular advantages and disadvantages to consider when selecting a printer.

3.2.2.1 Continuous Inkjet Printing

A continuous inkjet printer is constantly circulating ink within itself. As the ink circulates, it is redirected out the nozzle when a pixel of ink is necessary on the paper. By circulating the ink continuously, it is possible to use inks which may otherwise coagulate quickly. This makes a continuous inkjet printer ideal for printing onto surfaces which might otherwise be difficult to print on – there is also the benefit of an increased throw distance, making it ideal for applications where information must be printed on a fast-moving target.

It is far from a perfect methodology however. Having a continuous flow of ink requires a fairly complex system, which requires extra maintenance and can be prone to breakdown. The process also tends to be fairly messy – by essentially diverting a continuous flow of ink every time, there is often additional spray or vapor that makes it out of the nozzle along with the intended ink. Modern continuous printers are typically able to minimize the amount of spray, but this constant spray requires more regular cleaning of the nozzles and other printer components.

In addition, a continuous inkjet printer must utilize certain additives in the ink in order to keep it flowing, which adds another element of cost to the regular maintenance of the system. Compared to other inkjet printers, a continuous inkjet printer tends to be more expensive up front as well, meaning it is often not worth investing in one unless its specialized capabilities (specifically its ability to print on uneven or irregular

surfaces at high speeds) are required.

3.2.2.2 Thermal Inkjet Printing

Thermal inkjet printers feature far fewer moving parts, as they do not need to keep ink in a continuous flow. The ink cartridge in a thermal printer, unlike a continuous printer, includes the nozzle. When ink is required, a small thermal element is heated up rapidly. This causes the ink around the element to vaporize, causing a bubble that in turn forces a droplet of ink out the nozzle and on to the print surface. This is a much simpler apparatus than seen in a continuous printer, which makes thermal inkjet printers much less expensive. It also makes maintenance much easier, as nozzles are less likely to clog and tend to provide a cleaner print – there is no spray, because the ink is not diverted.

This increased print quality is not without its drawbacks, however. Thermal printers have a much shorter throw distance than continuous printers, meaning that uneven or irregular surfaces can result in unsatisfying results. Certain surface compositions may also require specialized compositions of ink which may not work in a thermal inkjet printer – a continuous inkjet printer would be required to circulate the ink and prevent it from coagulating.

Ink composition is another factor to consider when discussing an inkjet print solution – specifically its drying time and durability. Most inks dry relatively quickly, but in certain applications, for example the application of a tamper-evident seal to a package, the ink must have sufficient time to set in order to avoid smearing of the print. Similarly, ink should be long-lasting, as a loss of important data and barcodes at any point defeats the whole point of having a Track & Trace program in the first place.

3.2.3 Laser Printing

The principles of a laser printer are much like those of a traditional photocopier, in that it uses a powdered toner instead of ink. Particles of paper are charged so as to attract oppositely-charged ions from the toner. The two particles (paper and toner) are then bonded together by heat generated by the laser printer and by pressure from the drum in the laser printer. The main advantage of a laser printer is that it can print high-quality text and graphics on paper documents – yet it can also act as a document printer when it is not being employed as a barcode printer. The density and resolution of laser printing are relatively high, which means that barcodes can be scanned at any wavelength when read with an infra-red scanner.

There are a number of things to keep in mind when utilizing laser printers. A laser printer relies on high heat and pressure to produce printed materials, so it is important when printing labels that the adhesive does not negatively affect its reliability. In addition, laser printers cannot produce water-resistant or chemical-resistant labels, and laser printer toner costs can be exceptionally high, since laser printers need around five times more toner than normal text-printing photocopiers. These higher costs must be weighed against the higher-quality results.

3.2.4 Thermal Printing

Thermal printing includes two different types of printing, known as Direct Thermal and Thermal Transfer:

3.2.4.1 Direct Thermal

Direct Thermal printing is based on a relatively old process which was originally designed for use with photocopiers and fax machines, in which chemically coated papers were used. The print-head of a Direct Thermal printer comprises a long, linear array of tiny resistive heating elements, with between 100 and 300 heating elements per inch – and these are arranged in such a way as to be perpendicular to the flow of the paper.

Every print-head element within the array heats a small corresponding area directly below it on the paper, and the image is produced by the generation of rows of dots, whose appearance is the result of chemical reactions that occur when the media to be printed on travels underneath the active edge of the print-head.

The benefits of Direct Thermal printing include the assurance of sharp print quality with results that can be easily scanned. Direct Thermal printing is appropriate for short-shelf-life applications, including shipping labels and receipts, plus Direct Thermal printers are easy to operate and inexpensive to maintain; what's more, they don't require any ink, toner or ribbon. Batch or single-label printing can be undertaken with the assurance that there will be minimal waste – and thermal printers are usually more robust than dot matrix or laser printers.

On the negative side, Direct Thermal printers can be particularly sensitive to changing environmental conditions, such as varying degrees of heat and light. Furthermore, the paper used for Direct Thermal printing remains chemically coated after printing, and sometimes needs an extra coating to protect the paper from UV light exposure, from chemicals and abrasions.

3.2.4.2 Thermal Transfer

Thermal Transfer printers are similar to Direct Thermal printers, but instead of using chemically coated paper, a non-sensitized face stock is used in combination with a specially inked ribbon. A hard-wearing polyester ribbon film (coated with dry thermal transfer ink) is then placed between the thermal print-head and the label to be printed. The thermal print-head transfers the ink onto the label surface, where it cools down and adheres to the media surface. The polyester ribbon can then be peeled away, leaving an image that is both passive and stable.

Thermal Transfer printing creates crisp, high-definition text, graphics, and barcodes for optimum readability and long-life scanability, plus it can produce batch or single-print labels with the minimum amount of waste generated. In addition, very little long-term maintenance is required as compared to dot-matrix,

inkjet, and laser printers, which need far more on-going attention to obtain consistently satisfactory results. Thermal Transfer printing is also applicable to a wide range of media stock, with results being both long-lasting and hard-wearing.

By contrast, when compared to Direct Thermal printing, supply costs for Thermal Transfer printing can be a little higher. This is because Thermal Transfer printing needs regular ribbon replacement, plus ribbon usage can be wasteful if little is printed from it. In addition, recycling options are limited for spent printing items, plus ribbons and media must always be compatible.

Depending on the function of the code, codes may be applied to a label before or after the label is on the package. Pre-printed codes are generally printed by a laser printer, but codes printed directly on package surfaces rely on the use of inkjet printers.

3.3 Camera Verification

Once the codes are printed, they need to be verified for accuracy. This is accomplished by having a system read the codes and compare them against a list of the codes which are expected to be present. There are a variety of different ways to verify codes, but the most common is to use cameras to capture images of the codes, allowing either separate or on-board software to read the code and ensure it is correct.

3.3.1 Scanners and Smart Cameras

The cheapest method for verifying a barcode's content is to use a simple barcode scanner. These are not "cameras" in the strictest sense, and instead use a much simpler methodology. Scanners rely on the reflectiveness of barcodes in order to read them – the scanner fires a laser at the barcode and the lighter surfaces reflect the light back, while the darker sections absorb it. What a scanner cannot do, however, is read alphanumeric text or more complex 2d barcodes (such as a Data Matrix or QR code) – it is only capable of reading 1d barcodes. That means that a scanner-based system would be incapable of checking a barcode against a human-readable code – doing that requires the use of a camera.

A smart camera (also known as an 'intelligent camera' is a vision system which captures images, but can also extract application-specific information from captured images, as well as generating event descriptions and make the kind of decisions that are required for an intelligent and automated system. Self-contained and stand-alone, a smart camera vision system contains all necessary communication interfaces, and possesses impressive processing power and functionality. Smart cameras are typically cheaper than using a PC controlled vision system, and are capable of performing Track & Trace applications such as ID code reading, text verification, print quality assessment and label inspection.

Most up-to-date smart cameras offer advanced networking, communication and integration capabilities which can be linked to a common operator interface for easy management and operation. Depending on a number of factors – production environment, package size, print size, etc., manufacturers have to carefully consider the precise technical details of the cameras they need. This means taking into consideration any possible illumination needs, the field of view of the camera or the adjustability of the camera lenses for different products.

Combined with the self-contained nature of smart camera software, which eliminates the need to keep a control PC's software up to date, smart cameras have become the technology of choice for manufacturers seeking a low-cost, compact and effective Track & Trace solution. There are more factors to consider than when selecting a simple scanner, obviously (and the cost is naturally higher as well), but the benefits that come with the cost have won smart cameras their place at the forefront of the Track & Trace conversation.

3.3.2 High Resolution Cameras

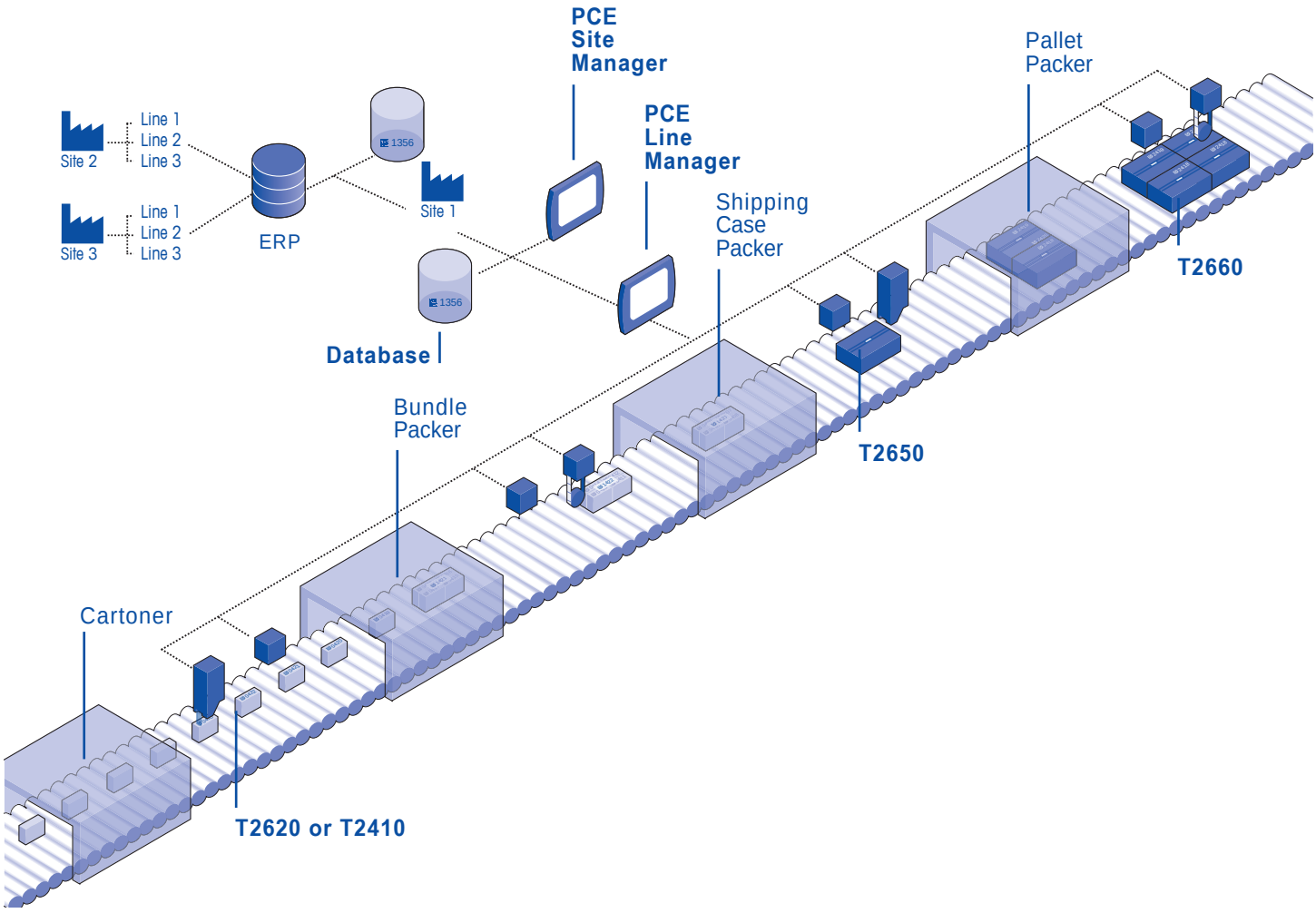
Not all inspection applications are necessarily well-suited to smart cameras. Some manufacturers may need the ability to switch over multiple inspection profiles at once, maybe even across several production lines. There are, of course, software solutions which can solve this problem, but it adds potential points of failure to the process. In addition, each smart camera is its own miniature computer, so each camera must be switched over individually. This adds time to the changeover process and increases the chances of user error. It is possible to mitigate this problem by linking cameras to a central control screen, but even then the changeover must proceed camera by camera.

This difficulty extends to creating solutions that work well on unique packaging. Inspecting an un-oriented product requires linking cameras together. While this is possible with smart cameras, it requires heavy customization and careful coordination. The more specialization required to deal with a particular package type, the less practical a smart camera solution becomes. PC-controlled high resolution cameras (HRCs), in contrast, can be networked together and set up from a single, centralized location. This allows for easier coordination of camera settings. Configuring unique lighting and lens settings also becomes much easier when a central program is controlling every component of the system rather than serving as a go-between for a series of discrete, self-contained systems.

Where the real advantage of HRC systems lie, however, is in resolution. Smart camera resolutions currently top out at 4-5 megapixels, while a high resolution camera can capture images at over twice that – 12 megapixels or more. This makes capturing large areas more cost-effective than purchasing the additional lenses and lenses which would be required to bring a smart camera's field of view up to a level at which accurate inspection would be possible. Aggregation scenarios – the bundling together of multiple individually-serialized packages – become less expensive and more efficient when using an HRC-based solution.

Of course, a Track & Trace system requires more than just cameras and a printer – the system also needs product handling tools, electrical components to network everything together, and software to manage all the data. This guide goes into more detail about each individual step of the Track & Trace process in the next section.

Serialization and Aggregation



A sample production line equipped with a complete Track & Trace process

How Track & Trace Works in the Pharmaceutical Industry

As the Track & Trace industry is most heavily regulated in the pharmaceutical industry, the best way to explain the full capabilities of a Track & Trace system is to walk through the steps of how a pharmaceutical Track & Trace program is organized. The Track & Trace process begins after the pharmaceutical product has been individually packaged on the production line.

The way this process proceeds is based on a number of factors:

1. Code printing

Alphanumeric coding (human-readable, such as date and lot code) should be established for each individual product – whether in blister-pack, bottle or other container. An appropriate bar code should also be created, which should be machine-readable (e.g. a Data Matrix 2D code).

2. Code verification

An appropriate bar code reader or vision system should be established to match the coding system chosen.

3. Serialization

Each individual drug package component (such as a blister pack, bottle, carton, case, pallet, etc.) should be marked with its own unique identifying code – and codes must be unique, random and unduplicated.

4. Database storage

A central database should be established, which allows manufacturers to track and store the location and status of each product as it travels through the supply chain until sold to the customer.

5. Code application and verification

The unique identifier code applicable to the individual product needs to be applied and verified in several different places along the production line, especially at points where packaging processes are being undertaken. These can include:

- On individual blisters containing a number of individual products
- On bottles containing individual products
- On folding cartons containing bottles or blisters
- On shipping cases containing cartons
- On pallets containing shipping cases

4.1 Ranks of Packaging

The packaging of pharmaceutical products generally moves up through several different ranks which begin at the individual tablet to move up all the way through a pallet of containers:

1. Individual Tablets: The smallest possible unit of a given pharmaceutical; these are contained either in a blister pack containing several other tablets or in a bottle.
2. Several blister packs are placed inside a folding product pack, or in the case of a bottle it is placed into a folding carton.
3. These packs or cartons are then dealt with in one of two ways:
    a. Several packs/cartons are placed into larger bundles, which are then placed into a shipping case
    b. The packs/cartons are placed into a shipping case without being bundled together
4. Several shipping cases are then placed together on pallets.
5. Pallets are placed in transport vehicles or in containers for onward shipping to their destination.

4.2 Levels from 1 to 4

Much like the individual ranks of packaging, each step of the Track & Trace process begins at the individual carton and expands to include integration into an Enterprise Resource Planning (ERP) system for inventory management and reporting to government agencies when necessary.

4.2.1 Level 1

The first level of Track & Trace refers to a single printer on a production line. This is the printer which will mark the individual cartons or bottles of pharmaceutical products with a code which corresponds to the individual serial number. Depending on the country, the codes may be generated on site or they may be assigned as part of a larger, pre-purchased block of codes.

4.2.2 Level 2

At level two, Track & Trace operations are concerned with all activities on a single production line, running from the initial printing of a code through to the assembly of a shipping case and an aggregation of those cases on a pallet. In addition, level two includes management of any re-work which may be necessary due to printing errors or other quality assurance issues.

4.2.3 Level 3

Level three deals with the management of serialization activities across all production lines in a single production site. This would include storage of all serial numbers which have been assigned, production numbers and other important data. This level three data is then sent up to the next level, although some newer Track & Trace offerings bypass level three entirely and go directly from level two to level four.

4.2.4 Neutral Players

Sitting in between levels 3 and 4 are a new realm of so-called "neutral" players. These are from data-management companies which handle the organization of the data before and after transmission to an ERP system. This step stores order information, usually on a cloud server, and allows a secure transmission of serial numbers between the production site and the ERP.

4.2.5 Level 4

At the top level of Track & Trace activity, the system is integrated into an ERP system which monitors Track & Trace operations across multiple production sites. All production data from a given site is collected and uploaded to a corporate ERP database, which then monitors the movement of finished products through the supply chain on their way to consumers. Level four is also where the serial numbers assigned to a given product are uploaded and passed on to government regulatory bodies where necessary.

4.3 Track & Trace Data Management

At its heart, Track & Trace – no matter the industry – is all about the management of data. This begins with generating (or obtaining) serial numbers and moves up through the final sale of a carton in a retail environment, allowing for a complete history of the product. This requires a significant investment in data infrastructure so all members of the supply chain can store and transmit production records, which must be kept for multiple years.

Each individual serial number needs to go through the same basic lifecycle:

1. The number is generated, either by a system in-house or by a government agency which provides it to a manufacturer.
2. The number is sent to the printer, where it is applied to a carton or bottle (depending on the package type).
3. A quality check on the printed code is performed to ensure a successful printing; this can also include an online grading process to ensure a pre-defined print quality.
4. The code is added to the order, which is sent off to its destination – either a supplier's warehouse or a store; the code might be scanned for full traceability at each stage throughout the supply chain.
5. The code in most cases (although not in the United States) is scanned one last time when it is purchased by a consumer.

This lifecycle requires that systems be able to easily talk to one another – ideally, using the same communications protocol throughout the process in order to allow for easy access of data at any point. Equally important, however, is the protection of that production data (particularly in cases involving government-provided serial numbers) in order to prevent easy falsification of serialization data. Such functionality is built into the software for encoding information but it could also be provided by the previously mentioned "neutral players " in the serialization process.

At every stage of this lifecycle, there should be a way to quickly access the location and history of the product package by scanning or entering the serial number into a database. Depending on the local regulations, it may be necessary to have this information sent to a government agency in real time.

4.3.1 The OpenSCS Initiative

The creation of a proper Track & Trace dataflow is the goal of the OpenSCS initiative, which seeks to implement a standardized methodology for serialization data. Its proposed T&T Standard defines two categories of connection points: Mandatory Services and Secondary Services.

4.3.1.1 Mandatory Services

These are the bare minimum required for a proper serialization process. When first proposed, the goal was to have them encompass all government requirements and regulations which were in development as of 2014 with a first release standardizing data management between level 3 and level 4 in October 2017. These would cover the following functions:

1. Serial Number Manager: This covers the issuing of valid and unique serial number ranges to the serialization system – either in sequential or random order.
2. Electronic Product Code (EPC) Repository: A database for recording and securing the status of any and all EPCs created by the packaging line. This can be on-site or off-site.
3. Batch and Master Data Repository: A site or enterprise-level central repository which stores the batch and master data needed to configure serialization equipment on a packaging line.
4. Unused Serial Number Return: The purpose of this service is to record and return unused serial numbers to the Serial Number Manager. Once a production run has been completed, the remaining numbers need to be sent back to the Serial Number Manager in order to allow the numbers to be used in a future production run.
5. Full Batch Import: Data collection and accompanying interface to obtain the disposition and aggregation status of all EPCs linked to a batch identifier.
6. Serial Number Inquiry: An interface allowing for the disposition and aggregation status of a specific EPC to be obtained.

4.3.1.2 Supporting Services

As with the mandatory services described above, these are the bare minimum required for a packaging line serialization process. These cover the following functions:

1. Work and re-work in the Supply Chain (i.e. warehouse and distribution center functions)
2. Packaging, rework and shipping orders
3. Exception handling tasks
4. Re-work of closed batches
5. Re-packing/re-labeling tasks
6. Re-aggregation of closed batches within the supply chain
7. Conversion of packaging orders to shipping orders
8. Re-working packaging orders at the packaging line
9. Inspection and checkout of damaged goods
10. Re-printing of existing package labels
11. Support of manual processes, e.g. re-work and aggregation steps on the packaging line level
12. Request by product ID initiated by an upper-level system ("replenishment" of serial numbers)

4.4 Tamper-Evident Requirements

In the European Union, there is an additional requirement for pharmaceuticals beyond serialization. The Falsified Medicines Directive (2011/62/EU) not only requires that each pharmaceutical package receive a unique serial number, but also that each package be sealed in such a way that allows for easy tamper-verification. There are several different methods which manufacturers can use to comply with this requirement:

- Folding Boxes
- Induction Cup Sealing Technology
- Induction Wads
- Film Wrappers
- Blister Packs
- Strip Packaging
- Bubble Packs
- Heat-shrink Bands or Wrappers
- Foil, Paper or Plastic Pouches
- Bottle Mouth Inner Seals
- Tape Seals
- Breakable Caps
- Sealed Metal Tubes/Plastic Blind-end Heat Sealed Tubes
- Capsule Sealing Technologies

These sealing methods cover everything from individual capsules of medicine up to cartons of multiple pills. There are even some technologies intended to show tampering at the pallet level, although pallet-level protection is not required by the EU. Further information on the EU's requirements for tamper-evident packaging can be found in the METTLER TOLEDO white paper Are You Prepared for EU Compliance: Tamper-Evident Pharmaceutical Packaging.

Notes

Implementing a Track & Trace Program

Implementing an effective Track & Trace program is by no means a simple undertaking, particularly when taking care to ensure that one's program will be flexible enough to accommodate future regulations. It requires strong project management and a close working relationship with an experienced Track & Trace equipment provider through all steps of the process.

5.1 Project Set-Up

When beginning the Track & Trace implementation process it is important to keep in mind a realistic time frame. Depending on the number of production lines and available space, a full implementation of a Track & Trace program may take several years. During the initial planning stage, one should keep in mind that the key to a successful program is not just having each individual component of the serialization and aggregation process function properly, but each component must be able to work in harmony as an overall solution. In other words: do not lose sight of the overall program by focusing on individual components.

Sketch in the broad strokes of the program before worrying about the minutia. How many lines are in operation? Which products run on which lines, or do multiple products run on the same line? What is the current layout of the production area, and (if it has not already been done) what would it take to run network cables to points on the line? From there, an actual list of requirements can be created, along with a to-do list.

5.2 Requirements and To-Do List

As discussed earlier, different countries may have different requirements for serialization. Be certain to educate yourself on the particular current Track & Trace requirements are in your markets, and also what they are likely to be in the future. Many countries are still implementing their Track & Trace requirements, so it is important to stay up-to-date on what regulations are upcoming. Once you have a clear idea of the requirements for what needs to be done in order to achieve compliance, it becomes possible to create a comprehensive to-do list outlining what equipment is needed and where.

This is also the point at which it becomes necessary to begin considering costs and who to use as an equipment supplier. The cost of implementing a Track & Trace program is significant regardless of provider, but that does not mean comparing costs is a fool's errand. Consider the complete offering of a given Track

& Trace provider and compare it to your list of objectives. It goes without saying that this phase of implementation is critical. If at all possible, you should work with an experienced Track & Trace provider in order to ensure the right equipment and software will be installed. Assuming that you have done sufficient research, it should be relatively easy to determine the best provider for your needs. Only after this to-do list is complete should you begin the actual implementation of the Track & Trace program. The goal is to exit this process with a complete plan and budget for the launch of the project.

5.3 Project and Program Management

Once the plan is in place, it is merely a matter of execution. Naturally, the success or failure of this plan rests on the shoulders of those in charge. It is important to have a single project management team which can oversee implementation from the early planning stages all the way through to the moment the final piece of equipment is turned on – and it should not actually stop there. Part of implementing the Track & Trace program should include creation of a comprehensive guide on how the program should be run, as well as documentation covering all facets of the various equipment and software in use.

Any potential project management team should not be seeking to complete its duties and then disband. Track & Trace is a continuous process, and those who elect to aid in its implementation must be willing to stay informed on the latest regulations and developments in software and technology. Flexibility of technology is important - ideally, project managers should seek to future-proof equipment and processes as much as possible. This circles back to the initial planning phase of the project.

Part of ensuring good project and program management comes with selecting an experienced equipment provider. Your provider should be able to supply you with not just the equipment and software, but also advice on how to most effectively use it as well as the documentation required for effective program management. In addition, an experienced provider can help you to assemble a program management team that will not only see the implementation of Track & Trace through to completion, but will be well-suited to provide continued support of the program well into the future.

5.4 (Global) Services

For companies with a global presence, a uniform Track & Trace program requires a global provider. Implementing Track & Trace in multiple facilities is best accomplished from providing the same equipment and documentation to every facility - this allows for a unified approach, easier movement and training of personnel between countries and ensures faster troubleshooting of potential problems. There is a strength in uniformity that allows for an employee to show up in any facility and know how to operate the equipment and what the process for Track & Trace (if applicable) is.

This carries over to performing regular service checks on the equipment. It becomes easy to run every production line on a similar service schedule - certainly there may be some variation depending on the operating hours and workload for each given facility, but knowing the amount of time which every system is expected to maintain uptime until service is recommended or required makes determining scheduled service visits easier. A global Track & Trace provider will be able to offer a service program that keeps all production sites online, and equipment designed to be flexible enough to adapt to new regulations as the global community continues to develop serialization requirements.

Summary

Worldwide, Track & Trace processes are constantly being developed, revised, and updated. This is in response to global conditions in which the threat of counterfeit products continues to increase across a wide range of products, from pharmaceuticals and tobacco to timber and minerals.

6 Summary

6.1 Growing Legislation

In response to these threats, global Track & Trace legislation continues to grow, with local, regional, national and international governing bodies drawing up laws aimed at reducing and eventually eliminating counterfeit products by making it impossible for such contraband to be introduced without it being immediately known by manufacturers, shippers, distributors and end customers.

6.2 Enhanced Productivity

At the same time, Track & Trace is being developed so as to ensure enhanced efficiency, productivity and profitability in the supply chain, starting at the point of manufacture, continuing through the production process all the way to shipping, wholesaling, retailing and final acquisition by consumers.

6.3 Protection of Brand and Corporate Reputation

Manufacturers worldwide must be vigilant in keeping a close watch on changing developments in track and trace legislation and technology. Sufficient investment must be made now, in addition to forward planning to allow for future developments. However, if manufacturers plan and execute their track and trace strategies carefully, they can be assured that their products, their brands and their corporate reputations will be safeguarded now and in the future. In turn, this will ensure the satisfaction of stakeholders and shareholders while securing all-important revenue and profits.

Notes

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