

USE OF GLOBAL STANDARDS FOR SAMPLE IDENTIFICATION AND ANALYSIS REPORTING TO COMPLY WITH GOOD MANUFACTURING PRACTICE (GMP)

A key element of food safety programs are sample collection activities and the subsequent laboratory analysis results. These activities are as equally important for farmers growing produce as for meat processors exporting product around the world.

Consumers and regulators have an expectation that food is safe and wholesome, it is these food safety programs and GMP that underpin this trust. All food safety programs supported by GMP, must have robust systems in place to ensure the accurate identification of collected samples and analysis reporting.

When a food product is harvested, processed, or shipped from location to location, there are processing management systems that track and trace all related trade and commercial activities.

These systems are based on global trade and commerce standards developed and implemented over many years to ensure they are accurate, along the entire supply chain.

Historically, the process for sample collection, reporting and analysis reporting have been largely

manual based activities. **Now** the practice of manually recording samples and analysis results is no longer acceptable and outdated.

The processing management systems and GMP standards moved away from relying on manual recording and reporting many years ago due to the high level of errors introduced by manual recording.

Instead, they utilise a high level of machine data capture, automated processing and computerised systemic reporting. However, Food safety programs are still heavily rely on pen and paper with all the inherent human error and time delay.

As the food industry moves further in to the digitalisation of supply chain information the activities of sample identification, Certificates of Analysis identification and digitalisation of food safety information must also move to meet the needs of the global digital supply chain. This is imperative to remain commercially competitive in today's global food industry.

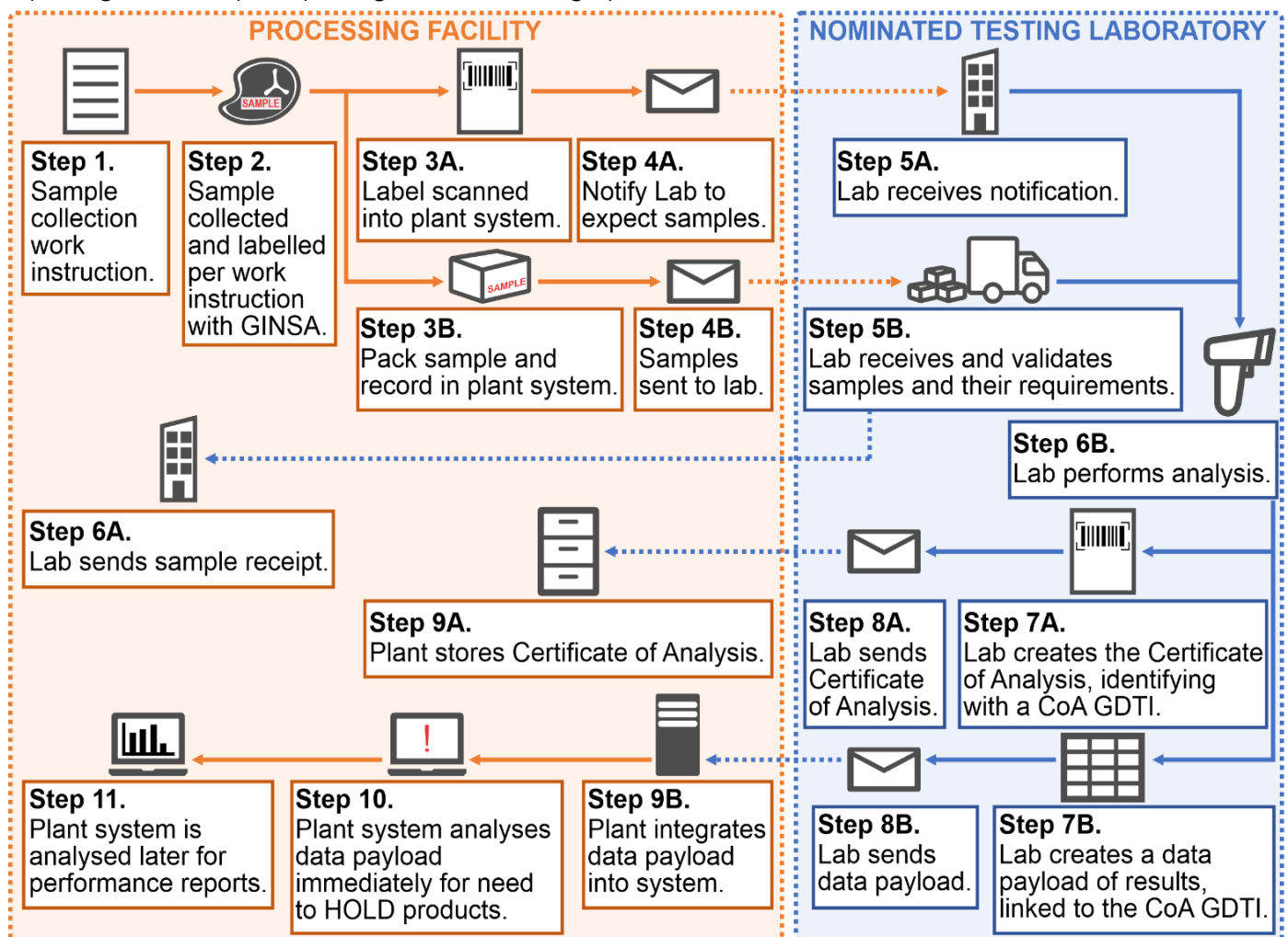


Figure 1: Ideal information flow between a processing facility and laboratory analysing samples and sending results.

Global Standards for sample identification and analysis reporting

Information standards used in global trade and commerce are suitable for food safety program activities. There are standards for sample collection, identification, recording, transport, and analysis reporting.

Global trade and commerce standards are derived from ISO and UN EDIFACT standards and are collectively called the GS1 standards.

The global GS1 Standards provide an open standard, and non-proprietary model that can be implemented royalty free into any production processing or laboratory management system. They operate on the principles of identifying, capturing, and sharing critical pieces of information, using standards that are agreed upon by both the global and local business community.

Many historic information management systems used in food manufacturing QA departments and laboratory service providers use proprietary identification and numbering schemes. These systems may work perfectly well within the organisation but fail when the proprietary data is attempted to be used along the whole supply chain.

An example is when two food processing companies apply their own proprietary numbering and barcodes sample IDs to their respective samples and send them to a laboratory for analysis. Unfortunately, both samples by chance have the same barcode sample IDs and inadvertently the analysis results are mixed up and sent to the wrong companies. If global standards for barcode sample IDs were in use by the food companies this error would not have occurred.

When any business uses proprietary number and identification systems to communicate to another, it creates inefficiency and misinterpretation between the systems that result in errors as they are not talking a common language.

Multiply this by the number of businesses along a supply chain, the resulting inefficiencies and the errors can have devastating consequences.

Figure 1 is a high-level, best practice example that aligns with the requirements of GMP for information passed between a food processor and a laboratory

following global trade and commerce standards. It illustrates the intricacies involved in identification and transporting a sample through different stages from collection through to the final analysis results.

There are two key entities based on this example that have been identified the global standard for numbering and identification of samples, and the global standard for the numbering and identification of Certificates of Analysis (or simply analysis results).

Why utilising a Globally Unique Identifier is key element of Good Manufactory Practice

Using proprietary systems for identification creates duplication of sample numbers. Because there is no standard for verification, each business can use whatever identification codes they wish. To avoid potential duplication and achieve **universal uniqueness** across samples, each sample would have a globally unique identifier, a machine-readable barcode attached to it, and digitally sent using globally recognised messaging standards.

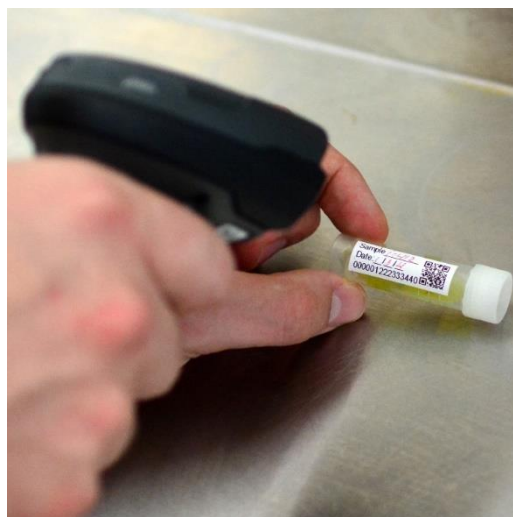


Figure 2: GINSA used in a GS1 QR Code to identify a sample.

GS1 standards use what are called GS1 Identification Keys to identify an item of interest, such as a product, sample, or document. In the case of samples being sent to a laboratory for analysis, the sample Identification Key is called the **Global Identification Number for Sample Analysis**, or **GINSA** for short.

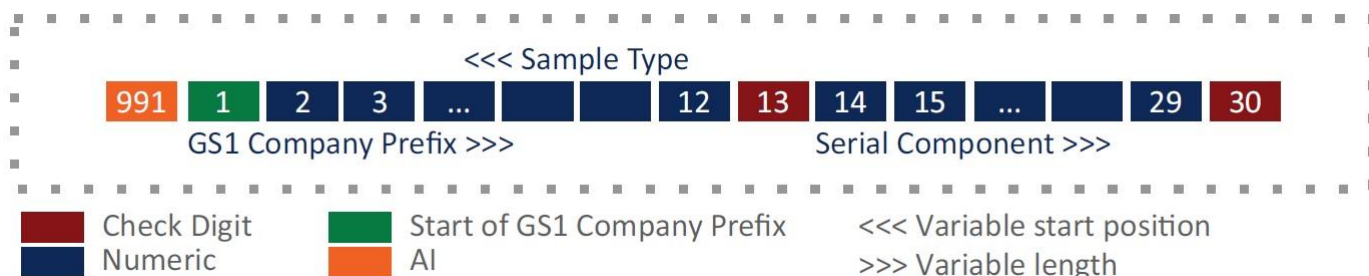


Figure 3: GINSA Identifier breakdown

The GINSA combines five main parts: its GS1 Application Identifier along with a GS1 Company Prefix and a Sample Type number, a Check Digit, and a Serial Component (as seen in Figure 3). Together, these parts create a globally unique identifier for a sample.

The GINSA Application Identifier is a 3-digit code that tells you that this number is being used to identify a sample. The GS1 Company Prefix identifies which business the sample came from. The Sample Type numbers identify the “sampling matrix” or type of sample for that sample.

A sampling matrix is assigned by your company, and details the sampled material, the context in which collected, and the handling and storage requirements for it.

Each instance of a sample being collected receives its own serial number. This allows additional attribute information to be linked back to that specific sample through a database. A swab sampling a carcass during chilling that is kept in a container at below 4°C, or a soil sample taken from a facility to be stored in a sealed bag, are such examples where globally unique identification numbering and barcodes are applied.

Sample Type numbers are assigned sequentially, with each new or changed sample matrix being given another sample “type” number.

Finally, the Check Digit is a single digit number that is used as a form of error checking. It is calculated based on the GS1 Company Prefix and Sample type numbers and is used to ensure the numbers scanned in are correct.

Together, these parts link any information about a sample through its GINSA identifier.

A barcode, such as a QR code, can be attached to a samples container, and scanned into an information system (as seen in figure 2). This way, the unique GINSA identifier is physically tied to the sample, and electronically tied to its digital record.

GS1 messaging standards, that are not covered here, are then used to share that digital record with a laboratory.

How laboratories use GS1 standards to achieve GMP for identifying Certificates of Analysis



Figure 4: Example of GDTI (top-left) being used for a Certificate of Analysis document type. It is in both a human-readable format and as a machine-readable GS1 QR Code.

The Certificate of Analysis is uniquely identified through use of the GS1 **Global Document Type Identifier (GDTI)**.

The Certificate of Analysis GDTI ID is comprised of its Application Identifier (253), GS1 Company Prefix, a Document Type number, and a Serial number, as seen in Figure 5. When creating a GDTI ID for a Certificate of Analysis the Document Type number and Serial number are fixed length numbers, assigned by the organisation that creates the documents.

The Document Type number and Serial number are assigned sequentially, as opposed to having any internal logic (such as a date of issue). Instead, additional information can be attributed to the document through other GS1 Identification Keys or

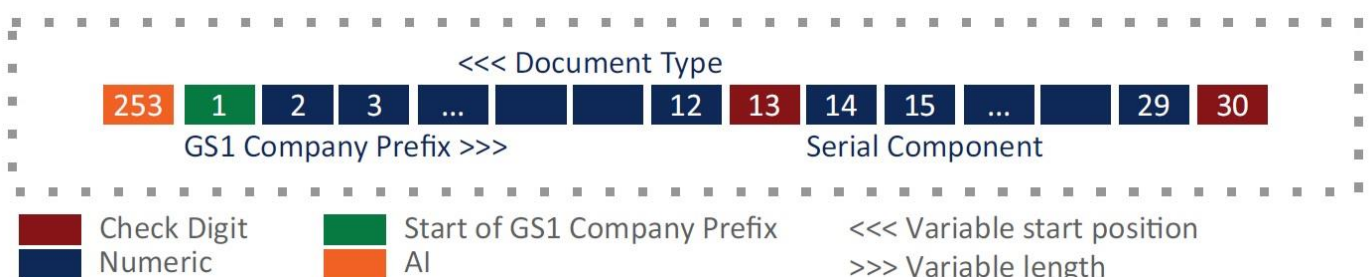


Figure 5: Certificate of Analysis GDTI Identifier overview.

directly to the Certificate of Analysis GDTI ID in a database.

The identification number is captured using a GS1 QR Code (barcode).

The use of the GDTI standard for identification of Certificates of Analysis ensures no two certificates anywhere in the world have the same identification number. This is key for GMP. The Certificates of Analysis GDTI can be communicated digitally along the supply chain with confidence that it can never be mistaken for a different Certificate of Analysis. Another major benefit is that the GDTI contains the GS1 Company identification of the laboratory that issued the Certificate of Analysis, so any one along the supply chain can digitally and instantly identify the issuing laboratory and contact them for confirmation and clarification. Again, this is a requirement of GMP.

Benefits of GS1 standard identifiers for samples and test result documents.

Adopting these Application Identifiers for your samples and analysis results provide the following five benefits:

1. Each sample is unique.

The power of these identifiers means that the information can be passed on between any company, anywhere in the world, without losing that relationship between the original material, its sample, and the test results.

Identifiers operate in conjunction with a globally unique information directory that categorises products based on certain validation codes. Creating a globally unique identification system gives importers and exporters a common language for identifying products in the same way **everywhere in the world.**

It also reduces replication of identification codes and improves harmonization across industries.

2. Improved efficiency and accuracy.

With a global identification on samples, organisations will increase their efficiency of identification. Time spent creating and translating unique identifiers for proprietary systems is eliminated.

In addition, the barcode standards improve the accuracy of item verification. They include error detecting check digits, reducing the likelihood of barcodes scanning incorrectly due to obscured or dirty labels.

Together, this means laboratories can improve the accuracy of item verification which will

improve the efficiency in product traceability in the supply chain.

3. Easy to implement.

Organisations can incorporate these standards within their current systems without compromising current processes. When these systems are used correctly, they work both within and outside your organisation.

Using GS1 standard enables the information to be used cross-sectoral between organisation to organisation which creates strong working partnerships and alliances within their industry.

4. Critical for any type of organisation.

Large-scale organisations can have extremely complex systems to manage their business processes and there are some organisations that use excel to manage their inventory.

Whether an organisation manages one product or thousands, globally unique identifiers are important. The collection of GS1 messaging standards (GS1 EANCOM and XML) have benefited from multiple data accuracy improvements; and together with the GS1 GDSN, Identifiers and barcode standards, is strong and scalable.

5. Improved Safety.

Creating easily accessible barcodes and product numbers reduces errors caused by misidentification of product devices. Standardised codes quickly and effectively identify locations important to the origin of the product.

Taking the next step

Help your business save time by converting your identifiers into a global standard.

You and your partners can communicate with each other efficiently and accurately with a global, standardised language.

For more information, ask your IT service professionals, and check out the GS1 website and resources below.

Resources

- [GS1 AU Numbering and Barcodes](#)
- [GS1 General Specifications](#)
- [GS1 EDI \(GS1 eCom\)](#)
- [GS1 GDSN](#)