Original Research Article

Serialized Barcode Printing Solution for Drug Traceability: An Architectural Design and Approach

ABSTRACT:

The pharmaceutical industry is one of the most requisite industries for human health and well-being; it has very strong recognition amongst other healthcare industries because it accommodates a great deal of worldwide and local pharmaceutical manufacturers, producing high-quality medicines. The industry has been suffering due to counterfeit drugs, and besides different hurdles from both competitors and government protocols, the action of the pharmaceutical manufacturers is focused on subduing drug trafficking. Medicine serialization seems to be a key to both counterfeiting and the complex supply chain of the pharmaceutical industry, including recalls and returns. Though there are countries that use serialization as a legal necessity, it is still a developing topic within the industry. Serialization is not just for anti-counterfeit technology but also to use supply chain and stock management more proficiently. The design of the Barcode is a fundamental requirement as per Healthcare Distribution Alliance (HDA) guidelines for serialized products. Encoding Barcodes on pharmaceutical drugs with critical product attributes is necessary for tracking and validating product sources. Since the serialization guidelines are regulated, small-scale pharmaceutical companies are struggling to comply with regulations due to heavy investments. Printing Serialized labels with barcodes required specialized third-party systems and software. The cost of third-party systems that integrate with ERP and Serialized systems for exchanging data is very expensive. On the other hand, the operational and sustainability costs of these systems will be an additional year-to-year cost for the company. A case study has been carried out at a USA-based generic pharmaceutical company to print serialized labels using their enterprise Resource planning (ERP) integrated with the packaging line. In this paper, we implement and validate a dynamic solution to print 2D data matrix and 1D Linear barcodes within an ERP system by eliminating the need for a specialized third-party printing system. This dynamic solution for serialized label printing saves the company a significant number of resources and money, as they do not need to buy any specialized third-party system to print the label or send back the product to the packaging line.

Keywords: *Pharmaceutical Barcode, 2D Data-Matrix, Healthcare Distribution Alliance, e-Pedigiree, Pharmaceutical Serialization, Digital Drug traceability, Enterprise Resource Planning, SAP.*

1. INTRODUCTION

The pharmaceutical industry significantly contributes to the world economy since it directly affects human life and well-being. Even though it is highly regulated, drug counterfeiters are more attracted to supplying illegal and legitimate drugs that are costly and vital to the market. Since the 19th century, drug counterfeiting has been one of the major concerns within the pharmaceutical industry. In the supply chain, products can exchange hands as many as 10 times before reaching the final consumers. It provides an opportunity for drug counterfeiters to supply contaminated and falsified medicines to the market. Different research shows that one in every five people using an online platform to purchase drugs is at risk of getting counterfeit medicines. The pharmaceutical industry has specialized processes that involve recalls, returns, and having stock in hand of special or controlled substance medicines. These processes need to be managed more efficiently to deliver drugs to patients as quickly as possible.

Counterfeit or illegal products threaten patients' health and safety by containing none or less active ingredients or completely different chemicals than the prescribed medicine (Tim and Gaurvika, 2016). In addition to having a significant impact on patients who depend on medicines for their personal health and wellbeing, it also has an adverse effect on the billion-dollar pharmaceutical industry and raises the government's expenses on healthcare. With the high investment and time spent to develop the licensed drug, pharmaceutical businesses now have additional obligations to deal with counterfeiting, for which we may observe cases every day. The pharmaceutical serialization system helps regulatory agencies track the product during its recall whenever an adverse event happens. With information on every transaction in the supply chain from manufacturer to patient, pharmaceutical manufacturers or brand owners can easily trace the medicine recipient to inform them about a recall or withdrawal of medicine. The use of Radio-Frequency Identification (RFID) in track-and-trace systems, also known as e-pedigrees, is one technical strategy that is hailed for reducing counterfeiting (Wyld, 2008). However, poor nations cannot afford or use RFID systems because they are too expensive (Gogo and Garmire 2009). Product traceability must be implemented so that individual pharmaceutical products may be recognized using barcodes or RFID IDs in various downstream supply chain locations (Tengler, 2020).

Serialization is one of the anti-counterfeit technologies among overt or visible features, covert or hidden markers, and forensic techniques. In this case study, we are mainly focusing on two suggested data carriers for pharmaceutical serialization: in general, 2D barcodes and 1D barcodes are mandated to be used for prescribed medicine in the pharmaceutical industry. As per regulatory compliance, all manufacturers also need to place an anti-tempering device in each unit to ensure the product is secure throughout the entire supply chain (Hutabarat, 2021).

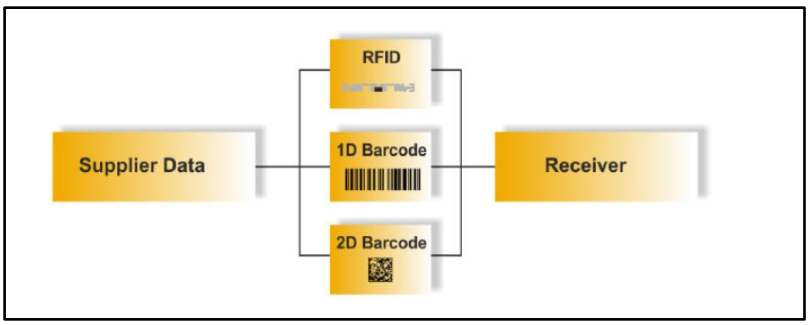

Figure 1. Common data carriers for item level identification including 1D and 2D barcode.

2D barcodes, also known as data matrix codes, are two-dimensional codes consisting of square modules that include data in a variety of ranges. The DSCSA regulation mandates the inclusion of a 2D Datamatrix barcode on each product package and homogenous shipper case. The 2D Data Matrix bar code, when encoded and printed on packages, must include product attributes such as Global Trade Item (GTIN), Serial number, batch, and Lot numbers on products as well as homogenous cases. (Patra, 2022) In contrast to RFID tags, 2D barcodes require a direct line of sight and require each individual item to be scanned, compared to mass barcode reading. The product identifier is represented as "a standardized graphic in both a human-readable format and on a machine-readable data carrier called a 2D Datamatrix barcode (Gao and Prakash). GS1 guidelines mandated that the GTIN include the application identifier (AI) (01), expiration date AI (17), lot number AI (10), and serial number AI (21) to create the DSCSA-compliant product identifier encoded in a 2D Data Matrix bar code (Tengler, 2020). After each variable input, a data terminator will be included in the barcode to show the end of the variable. Length of GTIN fixed to 14 characters, Expiry date in YYMMDD format with 6 characters, but batch and Serial number length very based on organization requirements (Holm, 2021). Product and (optional) quantity information should be clearly displayed on homogeneous cases. To swiftly ascertain the contents of a case, information should be indicated precisely for handling, storing, and picking cases, as well as automatic identification systems (Chiacchio, 2022). The encoded data in a 2D barcode should be used as follows:<FNC1> + AI (01) + GTIN + <FNC1> + AI (17) + Expiry + <FNC1> + AI (10) + Lot Number + data terminator + AI (21) + Serial Number

Attribute	Data Length	Data Type
Global Trade Item (GTIN)	14 digits (Fixed)	Number
Lot Number	20 digits (Variable)	Character
Expiry Date	6 digits (Fixed)	Number
Serial Number	20 digits (Variable)	Character

Table 1. Critical attributes of 2D Datamatrix barcode for Unit and Case level packages.

(01)003456478765257
(21) 123456789012
(10) AB001
(17)2024-12-31

Figure 2. 2D barcode for Unit level packages

Figure 3. 2D barcode for Shipper Case level packages

The logistics unit or SSCC label encoded with a 1D Linear Barcode with application identifier AI (00) should be affixed to pallets or partial cases. Pallets are created by placing shipper cases in an organized fashion and wrapping them in shrink wrap to protect them from damage. The encoded data in a 1D barcode should be used as followings:

<FNC1> + AI (00) + SSCC

Attribute	Data Length	Data Type
Serial Shipping Container Code (SSCC)	14 digits (Fixed)	Number

Table 2. Critical attributes of 1D Linear barcode for SSCC (logistics unit) packages

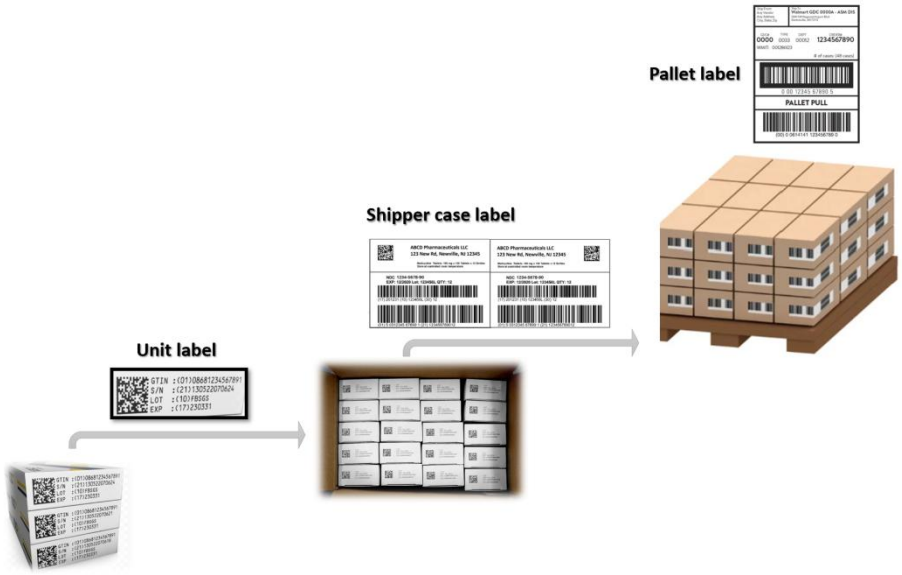

Figure 4. Serialized labels and package aggregation for different levels of packages

2. RESEARCH METHODOLOGY AND DESIGN

To manage the implementation of our system, we used several tools, including the SAP ABAP Code-enabled platform and Label Software. We have developed a Function Module (RFC-enabled data call program) to call the standard text-compatible script and input the variable information in variable fields. The approach of this study comprises detailed explanations for the need to print serialized labels with both Data Matrix and 1D Barcodes. This proposed solution uses other mechanisms to maximize the benefits of new technology with ERP and eliminate costly third-party systems for label printing. At the end of this case study, we expect to identify the potential benefits of printing serialized labels using the proposed solution.

The process of printing the serialized label in the packaging line starts with the design of the label in specialized software like Bartender or Label Matrix. During the label design phase, we specified the required label format to identify the barcode types to be used. In the case of the Datamatrix barcode, we need to specify the content of the barcode and the application identifier (AI) Codes to be used in it. For each data source, we need to assign the field name to make it compatible with systems using this file for label printing and transfer the input value to particular fields. Throughout our research in the USA-based pharmaceutical organization, we identified that the enterprise resource planning (ERP) system can be enhanced to use the printer code template generated from label software. To be used in an enterprise resource planning system for label printing, the proposed solution exports the printer code template in ITF format with information about the whole structure and variable field information. In the framework of the proposed label printing solution, this is particularly useful since the payload can generate a large number of labels and submit those results one at a time, eliminating high loads on the network. In the following data module pool screen, we need to maintain critical attributes of the 2Datamatrix barcode, including GTIN, Expiry, batch, and Serial number.

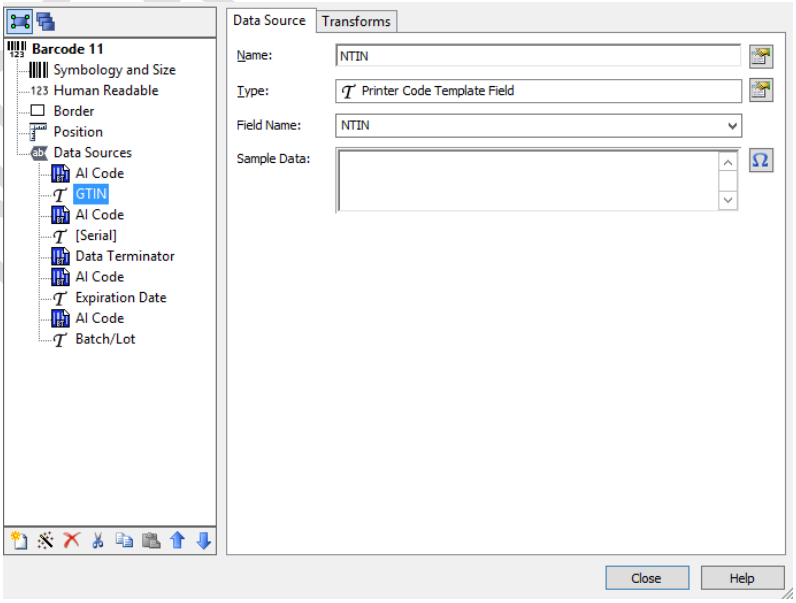

Figure 5. Label design modular software for 2D & 1D barcodes.

3. IMPLEMENTATION AND RESULTS

The proposed transaction process is built in ABAP (Advanced Business Application Programming) using the ERP platform. The proposed solution is to implement the business logic for printing serialized labels as per HDA (Healthcare Distribution Alliance) compliance. This case study also presents a step-by-step categorization of introducing technical events for label printing and interaction with the labeling system into the production process of medicine packaging. Following are the steps of process execution for label printing from a defined solution.

- After the completion of label design in the label software, the proposed solution generates a printer code template. A number of read-write authorizations can be defined in order to refine the rights of the users to modify label templates.

- The printer code template will generate the file with the specific coding that a particular printer can read and print the same label.

- The transaction processor represents a command that validates the generated template for code accuracy. The information required for the action to be successfully carried out is represented by the payload field. This modest approach gives enough flexibility to the users to send multiple label templates to the validator.

- The validation starts by detecting the different changes occurring in the label template and invoking the mapping variable component to identify the list of changes and accordingly update the mapping fields.

- When a data reading is reported by a module pool program based on the ABAP programming code, the transaction processor will find the corresponding label template and read the syntax. Then it will compute the location and identify where the data is stored in the repository.

- On the other hand, printer code templates are used in the Packaging line system to print the labels. The packaging line system stores the different types of templates in its repository and assigns particular format files to GTIN in the master data.

- This program will generate a new file with the same type of coding as the ITF file with the actual data of the variable fields and send it to the Label printer to print the label. The Label printer will read the code and act according, and print the label.

- During the packaging of the product, the solution fetches the file from the repository and decodes the data. It sends decoded information to the printer to print by replacing the similar field name with variable decoded data.

- Sample labels printed from the same initial printer to ensure data and barcode integrity. At the same time, the solution will specify the printer drivers and store the validated file in its repository.

- Physical verification of printed labels using label grading detectors for label readability and scanability for the supply chain.

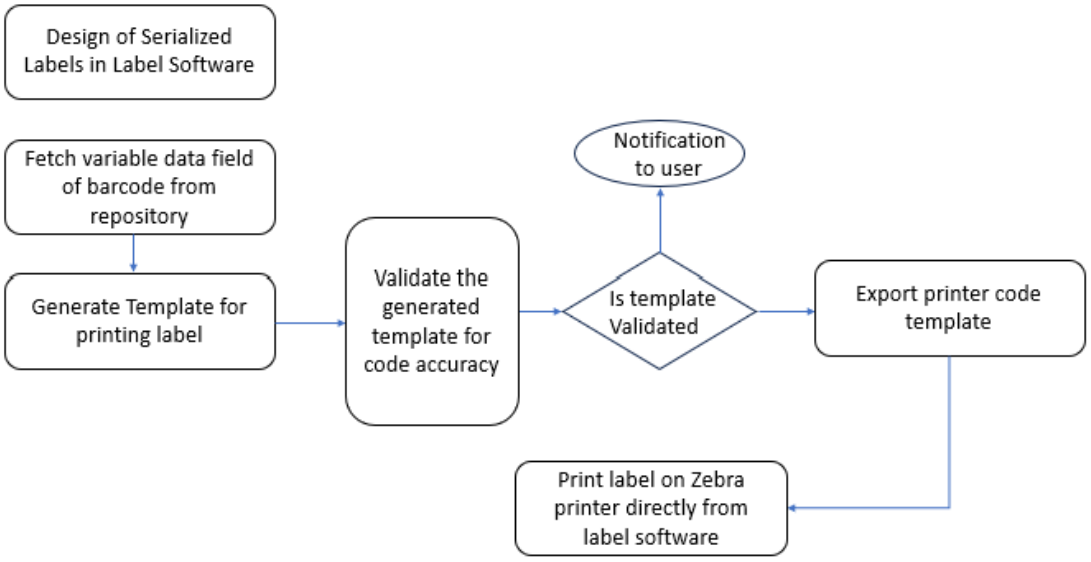

Figure 6. Label printing process flow using proposed solution

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^BCR,104,N,N^FN3^FH\^FD>;>817%Exp%>610%LOT%>830%Actqnty%^FS
^FT119,58
^A0R,28,38^FN4^FH\^FD(01)%NTIN% (21)%Serial%^FS
^FT673,242
^A0R,28,38^FN5^FH\^FDNDC: %spec%^FS
^FO599,58
^BY6^BXR,6,200,26,26,5,_^FN6^FH\^FD_101%NTIN%21%Serial%_117%Exp%10%LOT%^FS
^FT483,58
^A0R,28,38^FN7^FH\^FDEXP: %FCasE%      Batch:%LOT%      QTY: %Actqnty%^FS
^FT455,58
^A0R,28,38^FN8^FH\^FDGTIN: %NTIN%      SN: %Serial%^FS
^FT292,58
^A0R,28,38^FN9^FH\^FD(17)%Exp%(10)%LOT%(30)%Actqnty%^FS
^FT18,70
```

Figure 7. ITF file format for pulling data from enhanced solutions

We have evaluated the results based on the experiments dealt with in this stage of the work. A script-specific ITF file with standard text can be imported directly into the ERP system. Finally, we found that successfully printing the serialized label in the Warehouse in a controlled manner was a huge saving for the company, not only from a financial perspective but from a resource and time perspective as well.

4. CONCLUSION

In this paper, it was concluded that adopting the proposed label printing solution is able to print 2D Datamatrix and 1D Linear serialized labels successfully as per HDA guidelines. A custom transaction-based module pool has been proposed in order to generate and store serialized label templates in the repository in a validated, controlled environment. The Solution is based on the SAP ABAP Code-enabled platform and Label Software, which has been extended with a custom transaction family in order to keep track of label templates and print serialized labels. It is recommended that small manufacturers who do not have the budget to purchase and implement costly specialized label printing devices adopt the proposed technology for all serialized drug packaging and label printing.

5. REFERENCES

Mackey, T. K., & Nayyar, G. (2016). Digital danger: a review of the global public health, patient safety and cybersecurity threats posed by illicit online pharmacies. British medical bulletin, 118(1), 110-126.

Wyld, D. C. (2008). Genuine medicine? Why safeguarding the pharmaceutical supply chain from counterfeit drugs with RFID is vital for protecting public health and the health of the pharmaceutical industry. competitiveness review: an international business journal, 18(3), 206-216.

Gogo, A., & Garmire, E. (2009, October). Text messaging to authenticate products through matching hidden codes. In 2009 International Multiconference on Computer Science and Information Technology (pp. 353-359). IEEE.

Hutabarat, I. R. M. (2021). Application of 2D Barcode on Pharmaceutical Product Labels in Indonesia to Improve Drug Control.

Patra, S. (2022). Healthcare Distribution Alliance-Barcoding Requirement for Serialized Product. International Journal of Engineering Research & Technology, 11(7), 353-358.

Gao, J. Z., Prakash, L., & Jagatesan, R. (2007, July). Understanding 2d-barcode technology and applications in m-commerce-design and implementation of a 2d barcode processing solution. In 31st Annual International Computer Software and Applications Conference (COMPSAC 2007) (Vol. 2, pp. 49-56). IEEE.

Tengler, J., Kolarovszki, P., Mojský, V., & Filadelfiová, L. (2021). Proposal for Drug Monitoring in the Supply Chain. In Reliability and Statistics in Transportation and Communication: Selected Papers from the 20th International Conference on Reliability and Statistics in Transportation and Communication, RelStat2020, 14-17 October 2020, Riga, Latvia (pp. 318-327). Springer International Publishing.

Holm, M. R., & Poland, G. A. (2021). Critical aspects of packaging, storage, preparation, and administration of mRNA and adenovirus-vectored COVID-19 vaccines for optimal efficacy. Vaccine, 39(3), 457.

Chiacchio, F., D'Urso, D., Oliveri, L. M., Spitaleri, A., Spampinato, C., & Giordano, D. (2022). A non-fungible token solution for the track and trace of pharmaceutical supply chain. Applied Sciences, 12(8), 4019.