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Implementation of a Pharma Enterprise Ecosystem for Medical Drugs Traceability

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ABSTRACT
Today, the various pandemics affecting the economy and the social disruption are likely to increase the deaths from other causes due to the non-availability of health service delivery and routine immunizations. Many scientific advisors have discussed and suggested preparedness towards future unsolicited diseases that can affect the citizens. Most implementation takes time due to federal government processes and priorities that often change with time. We are all aware of various challenges that have been identified in the last decade to ensure patient safety. One of them has been the counterfeit of medical drugs and their illegal sales which had a direct impact on patient safety. So we haven't learned our lessons. While we continue to sit across the discussion board contemplating what best remedial measures need to be taken, another pandemic strikes. We must have a process to ensure compliance with various federal regulatory authorities in the Life science Industry. The objectives would be to ensure the traceability of medical drugs and real-time alerts to the consumers, thus ensuring that the drugs consumed are not spurious. In addition, with a heavy burden in uncontrolled manufacturing cost spiking, the manufacturers are forced to keep the product cost on the higher side, and hence there is a need for some Innovative marketing schema that needs to be introduced and expand the outreach to the consumers by implementing effective strategies. Many submissions with respect to the drug traceability has been revolving around implementing the same using "block chain" technology but I do not intend to get into the specific technology used behind achieving the traceability objective but rather focus on adapting to "simple to use" technology that is available to us. I would rather emphasis to focus on easily adaptable solution that can be easily deployed within an organization. I propose to provide a complete overview of where the initiation of drug traceability should begin and will take you through various workflow processes that will add value to the implementing firm in terms of accountability, ease of use, simplicity, quick adaptability. I will identify the "Need" factors that should be driving the traceability implementation which would require me to discuss on the pharma supply chain aswell.

KEYWORDS
Drug Traceability, Pharmaceutical Supply Chain, DSCSA, FDA, MHRA, TGA, DGFT, TrackNTrace

I. INTRODUCTION: ASK, WANT, AND NEED FACTOR?

Unique identification of packaged drugs will be an excellent enabler for running advanced analytics programs to gather deep insights into consumption patterns, geographical penetration, sales and marketing spend effectiveness, etc. Based on the purchase of drugs by consumers, a mechanism can be developed to instantly verify if the drug being purchased is a legitimate drug, i.e., it has been manufactured using the required compliance policies. To aid in innovation marketing schema, improved inventory monitoring at various supply chain nodes can assist in forecasting demand more accurately, thereby avoiding revenue loss due to stock-outs.

The primary goal of research being undertaken is to prevent and reduce counterfeit and spurious drugs, which have become a menace as the creditability of a true drug manufacturer is affected as the spurious drugs firms are trying to manufacture and sell placebo drugs with the same look and feel as the original drugs. Through this research, I intend to close the gap by introducing real-time monitoring techniques. The second major impact has been to stop the smuggling and illegal sale of drugs. Many drug manufacturers have to take a cost over burn due to the misrepresentation of drugs in their inventory, referred to as loan-licensing agreements between the drug manufacturing and licensee. In such contracts, there is always a social impact that ensures that the drug manufacturers provide grants to low-income countries and meet their demands for medical drugs to save their citizens from

harmful diseases. But many firms are taking advantage of these shipments and diverting the freight to the open market by smuggling drugs.

Finally, the research focuses on ensuring patient safety enhancement, medication recording compliance improvement, designing and developing enterprise-level solutions that cater to the Lifesciences industry, and ensuring the use of web technologies are leveraged to benefit this industry.

Until now, the focus of the life science industry was to work on the "Ask" and the "Want" factors only and to ensure minimal compliance goals are met. This research paper is focused on taking it to the following levels, i.e., the "Need" factor- No more short gaps, focus on completeness of an emerging solution.

1.1 The Scope of Research accomplished so far:

Based on pre-guidelines published in early 2014 by various compliance agencies, I was part of the life science Innovations Team at SolutionsMax Technology Services, has designed and developed a proof of concept (PoC) to demonstrate the efficacy and ROI for taking up this project on a larger scale. Since 2014, many regulatory agencies affiliated with Lifesciences have developed their guidelines. Our firm has allowed me to lead the team to create a sustainable ecosystem for the Lifescience industry. Our PoC was deployed and demonstrated at various conferences, and we got a significant buy-in to our ideas, and hence we formed a team to collect and research further in-depth with multiple working groups. I have shared some of the workflows in the section "Outcomes and Design Wireframes."

1. Analysis of the various compliance regulations, document the guidelines and establish traceability matrix of the features that need to be implemented.
   - Document the requirements in a Functional Specification (FS) document after a couple of brainstorming sessions with the stakeholders
   - Release of Design Specifications (DS) document after consultation with business and cross-referenced with the guidelines.
2. Design the wireframes to demonstrate the functionality in decomposed modules and generate the required database component elements (tables, views, stored procedures, functions, triggers, etc.)
   - SQL Server Management Studio was used to design the database objects components. (Microsoft, 2014)
3. The decision to develop the solution using Microsoft ASP.net technologies and SQL server databases, web services;
   - Setting up the DEVELOPMENT environment, which includes the Web servers, IIS Installation, Domain registration, and binding it to localhost.
   - All required Software components have been enabled.
4. Followed the Unified Process - Iterative and incremental
   - Milestones were elaborated.
   - Constructed components were released in Increments and tested
   - Reviews were conducted at each release cycle with the Customer Team (our early adopters).

II. THE 3S ARCHITECTURE: SERVICES, STRATEGY, AND SOLUTIONS

Through my initial research work, it has been imperative that an enterprise software system needs to be put in place, and the groundwork for the same has been initiated with the first proof of concept architecture/ flow of methodology design.
The solution will comprise of using the following research areas:

- Database Systems and Applications: Proper planning of various design elements enables one to create a robust data model process.
- Web Technologies: The Microsoft framework 4.5 & above has been chosen to develop the software.
- Software Quality Management is one of the most important aspects to ensure patient safety.
- Supply Chain Management has been identified and limited to internal warehouse logistics within the manufacturing firm and their production activities.

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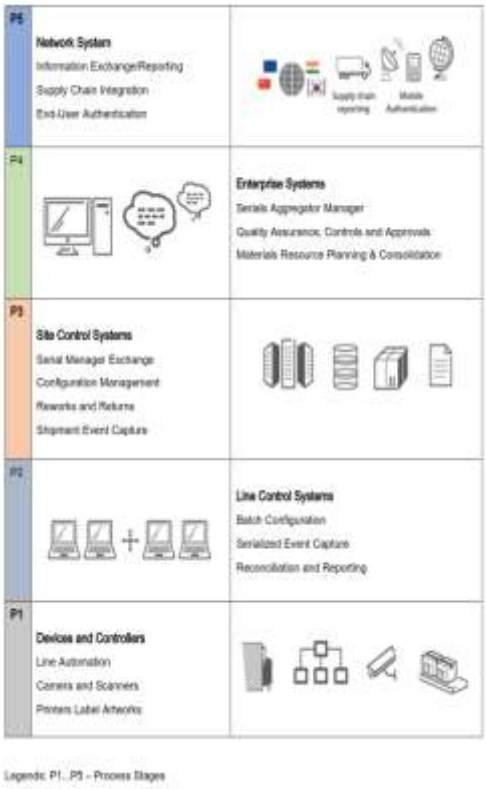

Figure 1

Source: [26]. (An Enterprise Solutions for the Pharma Ecosystem, 2016-2021)

Overall the system architecture and processes have been divided into 5 phases (Refer to the process diagram below). Once we achieve the final phase (P5), the research outcome will be achieved.

III. CURRENT SCENARIOS RELATED TO THIS RESEARCH

There are numerous guidelines from federal regulatory agencies representing various countries. Some of them are highlighted below:

Initiatives are taken up by the Government Agency- DGFT (Directorate General of Foreign Trade). Establishment of DAVA (Drug Authentication and Verification Application) to check fake drugs export. Guidelines were released in 2014; as per the guidelines, all manufactured medical drugs and devices need to be barcoded as per guidelines and reciprocating representation from compliance agencies of the partner countries. Establish a tracking protocol by establishing procedures for interoperability among the countries that participate in the data exchange program. Some non-scalable development of track-and-trace solutions within the pharmaceutical supply chain has evolved, but their implementation was not foolproof. Governmental and Regulatory agencies are exerting pressure to ensure medication product security. Focus on interoperability and scalability. [27]. Based on the initial research (20 Shocking Counterfeit Drugs Statistics, 2016), the following alarming facts have been learned.

- An estimated 10%–30% of medicines sold in developing countries are counterfeit.
- The percentage of counterfeit drugs sold in the industrialized nations: 1%.
- The value of the counterfeit drug market annually: $200 billion.
- A 10-day crackdown against counterfeit drugs coordinated by Interpol in May 11-21, 2014 led to 8.4 million doses of counterfeit drugs being confiscated.
- 237 people were arrested worldwide and 10,603 websites that were selling counterfeit medicines were shut down in 2014.
- An estimated 80% of the counterfeit drugs that are consumed in the United States come from overseas.
- Internet sales of counterfeit drugs account for $75 billion of the total market.
- Most of the counterfeit drugs that are made have been manufactured in either India or China.
- The WHO also estimates that between 1% and 10% of drugs sold around the world are counterfeits, but it may be as high as 50% in some countries.
- About 60 different Pfizer medicines and products were being counterfeited around the world as of 2014.
- One of the leading counterfeited items is actually ChapStick.
- The prescription drug market is vast and lucrative – up to $900 billion worldwide annually.
- Pfizer's own investigative work into counterfeit drugs leads to about 50 or 60 convictions each year.
- About 85% of the world pharmaceutical market is in the developed world.
- WHO estimates that 16% of counterfeit drugs contain the wrong ingredients, while 17% contain the wrong levels of necessarily ingredients?
- More than 30% of the counterfeit drugs that are available today don't contain any active ingredients whatsoever.
- Eli Lilly has invested $110 million into stamping unique codes and serial numbers on every drug package that it sells around the world so they can be effectively tracked.

- In late 2013, Chinese authorities reported detaining 1,300 suspected counterfeiters and confiscating $362 million worth of fake drugs and raw materials.
- A recent survey of seven African countries by WHO found that between 20% and 90% of all anti-malarial failed quality testing.
- European statistics show in particular a strong increase of drug counterfeit seizures at the European customs, with a total of 2.7 million of drugs seized in 2006, representing a growth of 384% compared to 2005.

IV. PROPOSED SOLUTION: TAKEAWAY FROM THE RESEARCH WORK PAPER. WHAT TO EXPECT?

Understanding the whole spectrum of related tasks to counter the threat to counterfeit drugs and stop the illegal sale of drugs and identification of current gaps in ensuring that guidelines are well adapted.

Build a robust supply chain to be incorporated into an enterprises ecosystem solution that comprises of drug traceability, quality assurance, quality controls, and material & warehouse management. The research author has prior experience working in various business domain verticals related to compliance within the pharma and Lifescience industry.

As compliance isn't limited to a single work zone or department, it is imperative that many dependencies should be strictly evaluated for compliance to the highest quality standards. The approach needs to be agile as in the Lifescience domains the guidelines are always revised to bring larger benefit to the end-users.

It would endeavor to ensure "Patient Safety" while implementing a foolproof enterprise ecosystem solution. The researcher along with his extended team is focused on bringing together various functional areas and ensuring complete compliance. With over 20 plus hands-on experience dealing with the shop personals to the high-level management, there could be no better opportunity to be served to the researcher.

The prototype has been adopted to use dedicated virtual private servers, but with the extended implementation of the proposed solutions, discussions are on to host it on a cloud platform. In addition, the use of machine learning techniques is planned for if there is a requirement to build multi-carton lines to automate various segments (as described in P1-P3 of figure-1). It is very primitive at this point of research to make a deterministic need for the use of machine learning.

At the present time, the focus of the research is going to be on designing and developing an enterprise platform to aid pharma and life science firms to be compliant with the traceability guidelines.

V. IMPLEMENTATION AND BUSINESS PROCESS: MY APPROACH

1. Develop a prototype to demonstrate the requirements shared via the guidelines of the DGFT/DAVA Team.

Learned how the GS1 enabled 2D/1D barcodes will be associated with each drug pack and document the shortcoming in any.

2. Involved an early adopter to participate in our Traceability CRM Solution.

We had two early adopters from the Pharma Industry based out in Kothur, Hyderabad, and another firm based out at Pashamylaram, Hyderabad. The former allowed us to gather requirements at the factory and allowed us to work with production packaging /warehouse teams.

3. I began with the bottom-up approach while documenting the requirements. As per guidelines from FDA (Implementation in a hospital pharmacy in Argentina" GS1.org, 2014) , (GS1 Standards in the Pharmaceutical Supply Chain, 2018), from MHRA (GOV.UK, 2021) , From GS1 (Traceability system a must for drugs: GS1 chief , 2021)

Based on the expectations, we learned from three guidelines from DGFT-DAVA/US FDA-US DSCSA /MHRA-FMD (Falsified Medical Directives).

4. Understanding the component of Serialization requirement. As per the initial user specification document composed by SolutionsMax Technology Services (An Enterprise Solutions for the Pharma Ecosystem, 2016-2021)

Organizations need to identify various components such as the readiness of the ERP system as a master data repository, changes in artwork for all affected Stock Keeping Units (SKUs), and new systems such as the enterprise serialization manager, packaging line system, and edge systems.

5. Types of Business Reports measuring compliance attributes. . As per the initial user specification document composed by SolutionsMax Technology Services (An Enterprise Solutions for the Pharma Ecosystem, 2016-2021)

Emphasis was to understand the various quality and business reporting that would be required to be

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established. Establishing a parent-child relationship between the packs that are being packaged so that traceability can be reported

VI. OUTCOMES AND DESIGN WIREFRAMES

Shared with permission from the "Research Innovation Team" at SolutionsMax Technology Services. The author of this research work is the team lead on developing a life science Ecosystem Solutions (An Enterprise Solutions for the Pharma Ecosystem, 2016-2021) includes Figure 2 to Figure 6.

6.1 Site Configuration process elements

Figure 2

6.2 All interdependent business process identified for the serialization repository.

Figure 3

6.3 Various Business Processes were identified to manage various

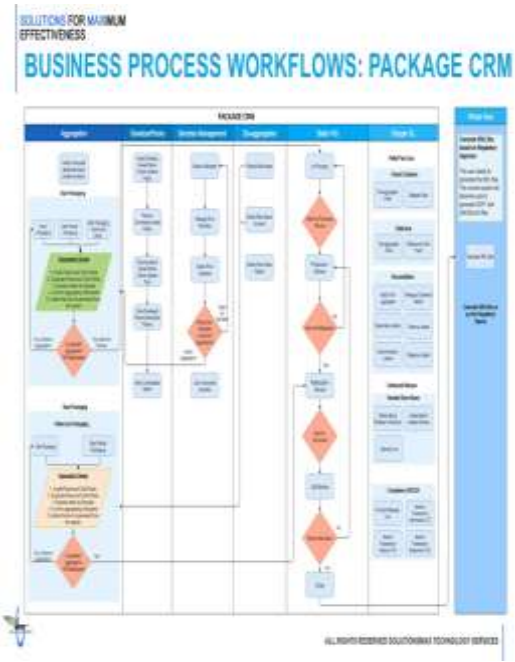

Figure 4 - (Tasks (identified in P2 & P3 – refer to Figure 1)

6.4 Establishing Accountable Business Process

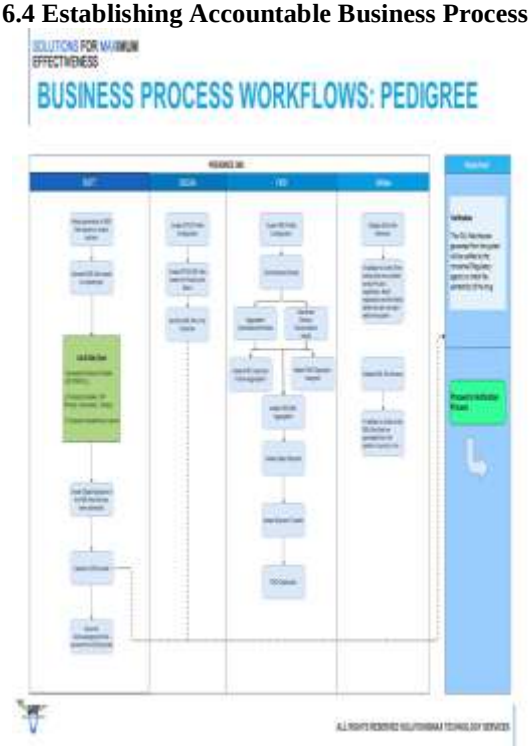

Figure 5 - (Identified in P4 – refer to Figure 1)

6.5 Verification and releases process – Transaction Information, Statement, and

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History

Figure 6 - (Identified in P4/P5 – refer to Figure 1)

6.6 Business process for managing the security of the solutions like established user roles and responsibilities.

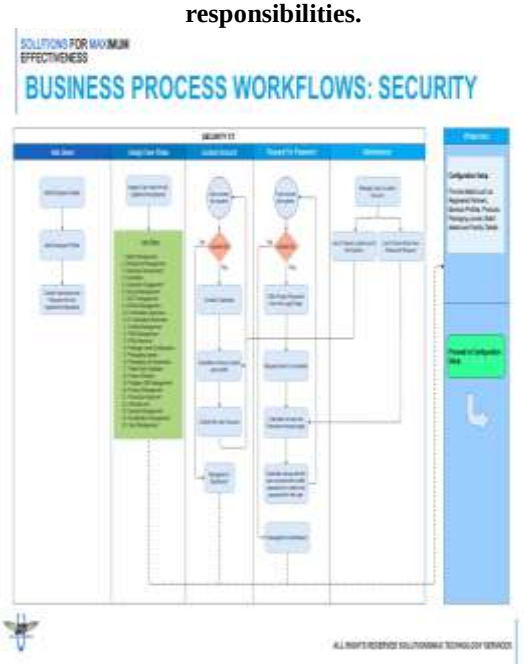

Figure 7

CONCLUSION

WHAT TO EXPECT NEXT?

The focus and the real challenge would be to incorporate various guidelines that keep regularly updated based on the process improvement lifecycles. An Proof of Concept(PoC) application would be developed and will be based on enhancing the business intelligence regime, plans to build a barcode label artwork component that leverages an end-end electronic review and approval process, and generate an ODS mapping technique to consolidate and standardize.

Our pilot (early adopters) customers have provided us with their additional requirements on business reports they wish to generate for submission for their business partner audits.

REFERENCES

[1]. eOnisa Obrusnik (2013). DRUG TRACEABILITY AND PATIENT SAFET. https://www.gs1.org/docs/healthcare/9h20_GS1_DataMatrix_in_hospital_pharmacy_LeonisaObrunsk_eng.pdf

[2]. (2017) HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain. Retrieved from https://www.hda.org/resources/hda-guidelines-for-bar-coding-in-the-pharmaceutical-supply-chain

[3]. (2021) HDA Research Foundation: 2021 Understanding Pharmaceutical Distribution. Retrieved from https://www.hda.org/resources/understanding-pharmaceutical-distribution

[4]. (2021) HDA Research Foundation: EPCIS Implementation Benchmarking Survey. Retrieved from https://www.hda.org/resources/epcis-implementation-benchmarking-survey

[5]. (2021) HDA Research Foundation: HDA Guidelines for Trading Partners on Downstream Product Actions. Retrieved from https://www.hda.org/resources/hda-guidelines-for-trading-partners-on-downstream-product-actions

[6]. (2021) HDA Research Foundation: HDMA ASN Exceptions Guidelines for the Drug Supply Chain Security Act. Retrieved from https://www.hda.org/resources/hdma-asn-exceptions-guidelines-for-the-dscsa

[7]. (2021) HDA Research Foundation: SERIALIZATION READINESS SURVEY. Retrieved from https://www.hda.org/~/media/pdfs/center/2021-serialization-survey.ashx

[8]. Alonso-Rorís VM, Álvarez-Sabucedo L, Santos-Gago JM, et al. Towards a cost-effective and reusable traceability system. A semantic approach. Comput Ind 2016; 83: 1–11.

[9]. Bali, V., Khanna, T., Soni, P., Gupta, S., Chauhan, S., & Gupta, S. (2021). Combating drug counterfeiting by tracing ownership

transfer using blockchain technology. International Journal of E-Health and Medical Communications, 13(3), 1.

[10]. Behner, P., Pisani, J., Ehrhardt, M., Edmunds, R., Fricker, R., & Hotz, D. (2017). Fighting counterfeit pharmaceuticals: New defences for an underestimated and growing menace. PwC Strategy. Available: https://www.strategyand.pwc.com/gx/en/reports/fighting-counterfeit-pharmaceuticals.pdf

[11]. Benatia MA, Remadna A, Baudry D, et al. QR-code enabled product traceability system: a big data perspective. In: Thorvald P and Case K (eds) Advances in Manufacturing Technology XXXII. IOS Press,

[12]. Clements, C., Cushley, S., Davies, S., & Mone, A. (2017). Accurate, audited and secure: How Blockchain could Strengthen the pharmaceutical supply chain. Price Waterhouse Coopers LLP. https://www.pwc.co.uk/healthcare/pdf/health-blockchain-supplychain-report%20v4.pdf

[13]. da Silva RB and de Mattos CA. Critical success factors of a drug traceability system for creating value in a pharmaceutical supply chain (PSC). Int J Environ Res Public Health 2019; 16(11): 1972.

[14]. Dai H, Ge L and Zhou W. A design method for supply chain traceability systems with aligned interests. Int J Prod Econ 2015; 170: 14–24.

[15]. Drug Supply Chain Security Act (DSCSA). (n.d.). Retrieved from http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct.

[16]. Finan, T. (2018). Blockchain and the pharmaceutical supply chain: driving security and transparency. Retrieved from https://aws.amazon.com/blogs/apn/blockchain-and-the-pharmaceutical-supply-chain-driving-security-and-transparency/

[17]. Haji, M.; Kerbache, L.;Sheriff, K.M.M.; Al-Ansari, T. Critical Success Factors and Traceability Technologies for Establishing a Safe Pharmaceutical Supply Chain. Methods Protoc. 2021, 4, 85. https://doi.org/10.3390/mps4040085

[18]. Haq I and Esuka OM. Blockchain technology in pharmaceutical industry to prevent counterfeit drugs. Int J Comput Appl 2018; 975: 8887.

[19]. Leonisa Obrusnik (2013). DRUG TRACEABILITY AND PATIENT SAFETY, Retrieved from https://www.gs1.org/docs/healthcare/9h20_GS1_DataMatrix_in_hospital_pharmacy_LeonisaObrunsk_eng.pdf

[20]. Mansi Sharma, Dr. Geeta Sikka, 2021, Blockchain based Approaches For Preventing Drug Counterfeit: A Survey, INTERNATIONAL JOURNAL OF ENGINEERING RESEARCH & TECHNOLOGY (IJERT) ICACT – 2021 (Volume 09 – Issue 08),

[21]. McBride A (2019) How the supply chain can become the backbone of health care anywhere, Retrieved from https://www.ey.com/en_gl/health/how-the-supply-chain-can-become-the-backbone-of-health-care-anywhere

[22]. Medi Ledger. (2017). Building an Open Network for the Pharmaceutical Supply Chain. https://www.mediledger.com/

[23]. Nagar, R., Aggarwal, D., Saxena, U. R., & Bali, V. (2020). Cancer prediction using machine learning techniques based on clinical & non-clinical parameters. International Journal of Advanced Science and Technology, 29(4), 8281–8293. Retrieved from http://sersc.org/journals/index.php/IJAST/issue/view/263

[24]. R. Gottipolu, "Securing the Pharmaceutical Supply Chain with Full Traceability," Pharmaceutical Technology 44 (10) 2020.

[25]. The Voyage of Discovery: Block chain for Pharmaceuticals and Medical Devices," IEEE, April 17, 2017. Retrieved from http://beyondstandards.ieee.org/generalnews/voyage-discovery-blockchain-pharmaceuticalsmedical-devices/

[26]. (2016-2021), An Enterprise Solutions for the Pharma Ecosystem. Retrieved from SolutionsMax.com: https://solutionsmax.com/Traceability.aspx

[27]. 20 Shocking Counterfeit Drugs Statistics. (2016). Retrieved from HealthResearchFunding.org: https://healthresearchfunding.org/20-shocking-counterfeit-drugs-statistics/

[28]. (2021),GOV.UK. Retrieved from The EU Falsified Medicines Directive (2011/62/EU). Retrieved from https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features

[29]. (2018), GS1 Standards in the Pharmaceutical Supply Chain. Retrieved from GS1us.org: https://www.gs1us.org/DesktopModules/Bri

ng2mind/DMX/Download.aspx?Command=Core_Download&EntryId=614

[30]. (2014) Implementation in a hospital pharmacy in Argentina" GS1.org, Retrieved from GS1.org: https://www.gs1.org/docs/healthcare/Presentation%20Haydey%20Wimmers%20FINAL.ppt

[31]. (2021) Traceability system a must for drugs: GS1 chief. Retrieved from Thehindubusinessline.com: https://www.thehindubusinessline.com/news/national/traceability-system-a-must-for-drugs-gs1-chief/article34887861.ece