Abstract—The purpose of this paper is to focus on security and safety issues facing by pharmaceutical industry globally when counterfeit drugs are in question. Hence, there is an intense need to secure and authenticate pharmaceutical products in the emerging counterfeit product market. This paper will elaborate the application of radio frequency identification (RFID) in pharmaceutical industry and to identify its key benefits for patient’s care. The benefits are: help to co-ordinate the stream of supplies, accuracy in chains of supplies, maintaining trustworthy information, to manage the operations in appropriate and timely manners and finally deliver the genuine drug to patient. It is discussed that how RFID supported supply chain information sharing (SCIS) helps to combat against counterfeit drugs. And a solution how to tag pharmaceutical products; since, some products prevent RFID implementation in this industry. In this paper, a proposed model for pharma industry distribution suggested to combat against the counterfeit drugs when they are in supply chain.

Keywords—Supply chain, RFID, pharmaceutical industry, counterfeit drugs, patient’s care.

I. INTRODUCTION

PHARMACEUTICAL industry operates for the sake to provide healthcare facilities to human beings and animals. It produces and market drugs and it is one of the major industry, playing vital role globally. This industry is different from any other industry, since in this industry a product with little defect, cannot be sold. The authorised company has to meet certain quality parameters to produce drug. This paper focuses on how to prevent counterfeit drugs in pharmaceutical industry, mainly when drug moves in pharma supply chain.

In order to make pharmaceutical chain of supplies more secure, the most influential technology worldwide Radio Frequency Identification (RFID) has been selected to elaborate its importance and contributions for the most sensitive industry. Further it will explain how much benefits can be derived from successful implementation of this technology.

Radio Frequency Identification (RFID) is an emerging technology, (see Figs. 1 and 2) and in shorter epoch it gained fame in Life Sciences Industry [1]. RFID is developed by the Auto-ID centre at the Massachusetts Institute of Technology to track and identify the objects with the assistance of radio waves [2]-[5]. RFID works with the combination of EPC (Electronic Product Code) (VeriSign, Inc. 2004). It has become an influential technology, which has a foremost impact on organizations. And it has designed more effective IT systems, which assist industry with an intention to achieve their results more accurately and rapidly than ever before. It detects, and detains data through wireless (AIDC), which is used to thwart hazards in industries [6].

A delve has proved that embracement of RFID technology improves the company’s product availability, process control, inventory management, thwart hazards, and security [7]-[10]. Insofar, professionals from industry and researchers concentrated on it, since it has abundant paybacks for industry globally. World’s well-known organizations the Wal-Mart, U.S. Food and Drugs Administration, U.S Department of Defence have recommended this technology to be implemented in supply chain, especially to thwart the counterfeit drugs worldwide [11]-[13].

This study aims to expand the discussion mentioned above. First the importance of RFID will be explained and its use in pharmaceutical industry. Second, issues related to counterfeit drugs, role of pharmaceutical industry and negative impact of counterfeit drugs will be explained. Third, counterfeit drugs detection through RFID will be discussed. Finally a proposed model will guide to supply chain managers/directors how RFID enabled supply chain delivers a genuine drug to patient. Last but not least the systematic review of literature will help researchers and also the proposed model can be further attested in the pharmaceutical industry.

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RFID was expected an increase in 2013 approximately 3.1 billion US dollars, which is about 6.5 times larger as compared to 474 million dollars in 2008 [21]. According to a research conducted by ABI in 2009 the generated revenue from the RFID services, readers, software, and transponders was approximately around 5.6 billion dollars. Another report presents the amount of entire RFID market 5.56 billion dollars [22]. In many countries almost half of the proportion of spending in healthcare industry is wasted.

For instance, in the U.S healthcare industry 30% to 40% of whole spending is wasted, since it is spent on worthless activities. The fact is U.S proportion of GDP (Gross Domestic Product), which is dedicated to healthcare industry is larger as compared to other countries in the world, which is around 50% and it is still increasing. A report in 2009 of Joint Commission Public Policy Initiatives, there is still no evidence that the healthcare industry in the country is improving. When counterfeit drugs are in question; this technology would bring the desired outcomes in U.S after its implementation throughout the pharmaceuticals supply chain. This technology contributes for the accurate tracking of products, when it is in chain of supplies.

This emerging technology helps to co-ordinate the stream of materials, accuracy in chain of supplies, maintaining trustworthy information, and to manage the operations in appropriate and timely manner. The worlds influential and authoritative departments U.S Department of Defence and FDA (Food and Drug Administration), life sciences industry [23], the multinational, multicultural, and multimillion dollar companies, [24], automotive companies [25], [26] and Information Technology [27] are engaged in taking sturdy actions for embracement of this tool. When RFID is utilized with ERP system, it facilitates the information sharing within the whole supply chain. Supply Chain Information Sharing (SCIS), which is supported by the RFID technology, develops the performance of the chains of supplies on the whole. This paper focuses on the counterfeit drugs in the pharmaceuticals supply chain, and to prevent it with implementation of RFID technology.

III. ISSUES RELATED TO COUNTERFEIT DRUGS

A medicine that is fraudulently and intentionally labeled of a company’s name and logo (which has the patent rights) by some other company is called counterfeit drug. The medication counterfeiting means products with fewer ingredients, devoid of dynamic ingredients, inaccurate ingredients, insufficient ingredients, or fake packaging WHO (World Health Organization).

A drug made by other than genuine manufacturer, imitating the original product without having the rights and authority, copied and marketing the imitating product to deceive and defraud (Black’s Law Dictionary).

Counterfeit drug is a fake drug. Which may contain, wrong or no active ingredients or right ingredients with wrong dose. These drugs are illegal and may be harmful FDA (Food and Drugs Administration) U.S.

A counterfeit drug (fake or reduced-dose drug) is produced by a manufacturer with an intention to sale and target to those
areas, where the information about healthcare is almost not available. These areas are the rural areas and remote areas. Those companies produce such drugs; neither have the patent rights nor a qualified team, to produce the drugs with the right ingredients. This is very harmful for a patient to take such drugs, which may lead to death due to non genuine or less ingredients of dose. We will take a look on studies of RFID technology implementation.

However, not much literature is available on RFID implementations in the pharmaceutical industry. The available literature is by [20], [28]-[30]. These are useful literatures, however, provide a practical picture of the RFID implementation. These four (4) literatures are focused on the technical issues, organizational and social influences on RFID.

The study how information technology can bring the change and can help the healthcare industry to improve was conducted by [28]. The study was conducted by the researchers in Tennessee at Regional Shelby Country Medical Centre, Memphis, USA. The data for research was collected through documented analysis, observations from the participants, and the interviews. The results of study found that the implementation of RFID in the industry could help in controlling, measuring and workflow processes. It suggested that the habitual and non-habitual Information System (IS) exercises are necessary for thriving functioning of this technology.

Reference [29] conducted a study on RFID implementation in Taiwan Medical University Hospital. This study opted investigatory approach, in which contributors were requested to share their experiences. It explained the growth, planning and implementation strategy of the project. This study focused on how long term benefits can be derived from the implementation of RFID as a tool.

Another study by [20] was purposeful, in which the technology implementation impact was studied on the society and how it effects on the staff of the hospital. For this study, qualitative method of data collection was used. The research data was collected from healthcare industry, consultants and three hospitals staff members from the United States. In this study, findings show that the qualms were found, especially in nursing staff at hospital, regarding scrutiny and supervision feature of this tool. It proved that this technology influence on organizational factors as well as on social factors and this either will make it successful or show it the door of failure.

Reference [30] conducted a study focused on the RFID value in the businesses. This study was generated, and values were identified, from the case studies of five (5) hospitals, who implemented the technology, specifically to confront, the hazard of Severe Acute Respiratory Syndrome (SARS) in the year 2003. A number of intentions were identified, to measure the value of this technology at execution stage. Those intentions included; process enhancement of patients care, to enlarge the utilization of assets, and effectiveness in communication. The researchers concluded that, successful implementation of RFID technology, is only possible, when it has been included, in the whole business framework. Furthermore taking into account, the importance of RFID, the pharmaceutical sector needed such a technology, which can prevent the risks in pharma supply chain, when their product moves universally.

FDA (November, 2004) has published a compliance policy guide, for implementation of the RFID technology in the pharmaceutical industry. FDA believes that the compliance guide, will clear regarding tagging the packaging, specifically for those products, which are high likely to be counterfeited. The goal defined by the acting Commissioner FDA Dr. Lester M. Crawford as: “Creating the ability of tracking the drugs from the producer to the pharmacy would increase the security and safety of the drug that patient’s consume.”

The implementation of RFID in the pharmaceutical and healthcare businesses worldwide is an organizational push from Food and Drug Administration (FDA), to combat against sales of the imitate drugs. The research has also reported that, the revenue from RFID will rise in the future dramatically. RFID tags using by the pharmaceutical manufacturing companies, is because of FDA interest to combat against counterfeiting drugs (Jeff Woods, Research Vice President at Gartner). FDA made efforts to make possible the safety, and security of the drugs by implementing, the state of the art technology Radio Frequency Identification (RFID). This technology allows the manufacturers, distributors, and retailers to track the drugs accurately throughout the supply chain. However, in Pakistan the counterfeit drugs are also a major issue, which need to be addressed.

IV. ROLE OF PHARMACEUTICAL INDUSTRY

Pharmaceutical industry is playing a vital role, since it is the most organized business in Pakistan. The multinationals are playing major role in Pakistani pharma sector, and it holds 55% of the market [31]. Pakistan has nearly 400 hundred pharmaceutical companies, out of them 100 companies handle the 90% pharmaceutical business. Top 100 companies includes 30 multinational companies, holds the 50% of countries pharmaceutical industry (South Asian Journal of Management Sciences, Vol. 3, No. 1, (Spring 2009). Top 50 pharmaceutical companies’ hold 80% of the market, however, the top 100 companies holds 90% of the pharmaceutical business [32]. Almost no raw material is produced locally so the pharmaceutical industry in Pakistan, imports the raw material as well as 20% of the medicines are also imported, since the production units in Pakistan only meets the 80% need of the country with in-house production [32].

It became a major risk in the pharma industry, however, in the Pakistan this risk exits and it is of severe kind. According to an estimate 50% of the marketed drugs are counterfeit in Pakistan [33]. However, according to the Pakistan Pharmaceutical Manufacturing Association (PPMA) the provided figures are overstated, and the proportion of counterfeits drugs is not more than 0.4% in Pakistan. Counterfeit drug is a major risk, which is not only being faced in Pakistan, but globally.

One of the major risks to life sciences and healthcare industry worldwide is counterfeit drugs. Pfizer has reported, for 200,000 bottles of their cholesterol pills Lipitor (see Fig. 3)
from outside the U.S continent, as fake drugs (total market value 55 million dollars). The counterfeit drugs have increased by 9% worldwide over the past year (Pharmaceutical Security Institute, 2010). The survey identified around 808 types of counterfeit drugs in 2009, which was a 36% increase from 2008 (detected in 118 countries in 2008). Food and Drug Administration (FDA) has taken this matter seriously in order to fight against such producers, and to prevent it from selling in the market. It is also working with the government, public sector, and private sector agencies in order to protect the humans from the hazard of counterfeiting.

It has become an intense need of the pharma industry, to enhance the detailed safety and security of their products, particularly in today’s technological business world; where the customer can order product online. To bring out customers from endanger of counterfeit drugs is the absolute tracking of drug’s packaging. RFID technology also provides the transparency in pharmaceutical logistics. However, this technology is not yet implemented in the small and medium sized industry at all. The main reasons are the high fixed costs, and the difficult technical implementations. Thus in this industry, the hazard is not only for those products available online, but also at hospitals and pharmacies. It not only causes endanger to human’s health, but also sales losses and damages the drugs manufacturers reputation.

An estimated report submitted by National Crime Prevention Council (NCPC), showed that 10% pharmaceutical products in global chain of supplies are counterfeited. World Health Organization (WHO) reported that in some of the developing countries the potential hazard of counterfeit drugs is about 70%, another estimation of countries (Australia, Canada, European Union, Japan, New Zealand, and United States) tells that 1% drugs are fake in these countries. However, the biggest problems were found in Latin America, and Africa where the fake drugs percentage is about 30%. In one continent of former Soviet Union, 20% sold drugs were estimated as fake.

The pharmacists and physicians are involved in the manufacturing of counterfeit drugs. These criminals are supported by the scoundrel pharmaceutical businesses, rebel groups, and dishonest national as well as international officials. This dilemma is of extreme kind, because the criminals are simply everywhere in the global supply chain.

Counterfeiting of drug is a criminal act and it is premeditated and coldblooded murder said Nicholas White, a malaria expert at Mahidol University Bangkok, Thailand. Further he added, “You are killing people with counterfeit drugs”, a message to the counterfeit drugs mafia. The full knowledge about this crime is out of our sight. The population, which is most affected due to the counterfeit drugs are living in the countryside, since they do not have full but limited access to the healthcare facilities. None, of the countries go safe from this fraudulent activity. Most of such drugs are available for sale online. These medicines are cheaper, but are not for healing, because of the lack of information the companies have for production. If drugs are checked for their quality and controlled strictly, then a millions of human’s lives could be saved annually. Though, the business of bogus and imitated drug is a money-spinning and lucrative. This business has lofty margins and little hazard, which make it attractive for mafia, who are involved in counterfeiting. This kind of business is not even considered as illegal in some of the countries, and their government has no law for this specific crime. As said, “Where there is no opportunity, there is a thief.”

The negative impact of counterfeit drugs on human lives can be seen, from an example of disease called “Malaria.” The death rate with malaria: around 20% children died before their fifth birthday [34].

A disease spread by the Anopheles mosquito, following by its bite can cause fever, vomiting, headache, and sweating to humans. The estimated killings with malaria worldwide are more than 660,000 per year (FDA to Test Detection Device for Fake Drugs, April 25, 2013). International Policy Network (IPN) in 2009 estimated that killings because of fake malaria and tuberculosis drugs are 700,000 per year. According to an estimated report, 3.3 billion people live in the malarial areas in 106 countries and territories (Centers for Diseases and Prevention). Food and Drug Administration (FDA) U.S is intended to block the flood of fake and reduced dose (counterfeit medicines) medicines that are available worldwide. According to a report of FDA, fake malaria medicines are common in Africa and the parts of South Asia. The report added that the 35% anti-malarial drugs were substandard and 36% were counterfeit in southwest Asia, in Africa 35% of anti-malarial drugs were substandard and 20% were counterfeited. According to the commissioner of FDA Margaret A. Hamburg, “Fake or substantial drugs cause double damages”. Counterfeit drugs trafficking that contribute, to the health dangers are estimated 75 billion dollars annually (IPN, International Policy Network). According to another report of International Policy Network (IPN) in 2009 the World Health Organization (WHO) estimated 25% counterfeit medicines of the whole in medical supplies in the less developed countries (LDC’s).

It estimated that the 10% of medicines are fake, and this figure could go up to 50% in the coming years especially in poor countries. “A global effort needed to combat this threat”
Diabetes patients care but also there is a wider positive impact of the implementation of RFID technology in pharmaceutical and healthcare industry. This technology implementation gives a sustained competitive advantage to industry, in order to combat against the fake drugs available in the market.

![Fig. 4 VeriChip](image)

**V. COUNTERFEIT DRUGS DETECTION THROUGH RFID**

RFID implementation in the pharmaceutical industry makes it easier to guarantee, that drugs are genuine. This technological tool helps to maintain the records of raw material; or finished products from the point of production, to the point of sale. There are some barriers in-between the implementation of this technology in the pharma industry. According to the researchers from the Stuttgart University’s Institute of Mechanical Handling and Logistics (IFT), Germany “the RFID technology is rarely implemented or not at all.” The reasons they found metallic packaging (tubes or blister pack foils), and liquid pharmaceutical products interferes with the RFID readings. Researchers noted that, “after the successful implementation of RFID in pharma industry will enable advanced defence against counterfeiting of drugs and consumers will have secured and safe products to buy.” The work of researchers was supported by the Federal Ministry of Economics & Technology (BMWi), and German Foundation of Industrial Research Association (AIF) with assistance of German Logistics Academy (BVL). Although, it’s successful implementation has a great value for industry as well as for the patients. This technology works in a systematic way to track and identify, whether the drugs are genuine or not.

RFID tagged products are assigned the unique number for each product, which makes it easier to track, and identify the product throughout the supply chain. In the first line, drug ingredients authorised producers carefully tag at each item level, prior to its supply to pharmaceutical companies. So, the data of ingredients is stored by the manufacturer in their system. After a drug is manufactured the data of tags is scanned and reported for the further action. Information regarding the ingredients in drug serial number, manufacturing date, expiry date, components of ingredients and sources information is updated accordingly, which is then attached to the drug package. This way RFID chip placed on the
The packing of drugs is often of plastic cans. On such cans the RFID chips have two possible options to position; either on the lid or under the label of product, which is placed on side of the can. If drug cans are not of smaller size (smaller size of cans cause the tag get packed tightly), then the performance of reading ought to be 100% or at least near to it, since the RFID tags perfectly works with the plastic materials. The problem with RFID tagging arises, when the drugs packaging are of metal (i.e. tubes or blister packets) or if the drug is in form of syrup. However, there are the ways to overcome these barriers.

A. Tagging the Liquid Bottles with RFID

The bottles, which contain liquid, should be tagged on the lids, to keep away the liquid from the tag, as a condition to let the tag be readable by the RFID reader. However, bottles should not be packed in the same sealed card board box on the top of each other, since it reduces the reading performance of tag.

B. Tagging the Blister Packs (Bubbles Pack) with RFID

To tag the blister pack (also called bubble packs) is not an easy task due to material it contains. Though, the best way to place a tag would be separately on surroundings of each card board box. Generally drugs are packed in the bigger boxes for the purpose of transportation. Thereby, the card board boxes shall be placed separately in bigger transportation boxes, which enable the readability of tags. While packing we need to focus that tags are well close to the readers. After the transportation box is well sealed, it is imperative to tag it as well, which contains the information of every single medicine packed inside the bigger box. This process makes it easier and abolishes the need to untie boxes time and again, due to non-readability of any single item packed inside.

C. Tagging Drug Container Tube Made of Metal with RFID

These kinds of containers are generally used to pack vitamin pills, that can be melt in water. The process of packing for these can be very same way as blister packs; however, these shall be packed separately in card board boxes. Occasionally, tags can be positioned inside the card board box on the plastic display plate. It is suggested that the tag must be attached on the lid of such containers; since, these are made of plastic. It also helps to keep it away from the metal surface, which can reduce the readability.
Metal is a barrier for the implementation of RFID on item level. However, there are hard tags available in the market, specially designed to place on the metal surface. The hard tags designed for metal surface are more expensive than the label tags. Since, hard tags are more expensive these can be placed on the most expensive drugs and the price of tag paid will be of benefit.

This study proposed a framework that can be implemented in pharmaceutical industries supply chain in order to combat against the counterfeit drugs.

**Proposed Change Made in Drug Distribution for Dealing with Counterfeit Drugs through RFID**

![Proposed Model Diagram]

**VI. DISCUSSION AND CONCLUSION**

The proposed model explains how RFID help to combat against counterfeit drugs in pharmaceutical industry, and help to deliver genuine drugs to patients. RFID enabled distribution process starts from drug ingredient suppliers. In the first phase of proposed model, ingredient suppliers apply RFID tags at packaging level, and through a process shown in model tag is read by readers, which transfer the information to host system (Ingredients Management Information System, IMIS), with the help of middleware system. Further the information available on tag is transferred to the e-pedigree. The e-pedigree will be updated at every level as shown.
In the second phase, ingredients start to move in supply chain, and delivered to pharmaceutical manufacturing for production of drugs. The same process is being followed by the pharmaceutical manufacturing for updating the host system, called Pharmaceutical Management Information System (PMIS) and information available on RFID tag is then transferred to drug e-pedigree, which will be updated at distributor, wholesaler, hospitals, and pharmacies-level respectively. The pharmaceutical manufacturing will add information on RFID tag, i.e. ingredients origin, manufacturing & expiry date, components quantity, weight, size, colour, shape, and serial number.

In the third phase, manufactured drug will move further for its supply to pharmaceutical distributors/wholesalers, where the information will be updated in Distributor Management Information System (DMIS), and Wholesaler Management Information System (WMIS). In the next step prior to its supply to hospitals and pharmacies drugs journey information will be updated on drug’s e-pedigree as well.

In the fourth phase, distributor/wholesaler will deliver the products to hospitals or pharmacies. As soon the drugs are received at the hospitals or pharmacies, it will update their host systems called, Hospital Management Information System (HMIS), and Pharmacy Management Information System (PMIS). And the information will be updated on drug e-pedigree.

The fifth phase would be to sale genuine products to consumers (patients). This model provides a solution to combat against counterfeiting of drugs. As we can see in the proposed model, the right arrows tell that by following this procedure information stored in Ingredients Management Information System (IMIS), will be updated and stored in the Pharmaceutical Management Information System (PMIS), which then will be updated and stored in Distribution Management Information System (DMIS), Wholesaler Management Information System (WMIS), Pharmacy Management Information System (PMIS), and Hospital Management Information System (HMIS) respectively. It is concluded; that RFID enabled pharmaceutical distribution system will help to prevent the hazard of counterfeiting in this industry, and will make it possible to deliver the genuine drugs to patients.

REFERENCES

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