Impact of Track and Trace (T&T) in Industrial Revolution 4.0 of the Pharmaceutical Industry (Pharma 4.0)

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Abstract. Industrial revolution 4.0 is a challenge and opportunity for most industries, including the pharmaceutical industry, called Pharma 4.0. In order to bring adequate, agile, and adaptable pharmaceutical manufacturers that produce high-quality drugs with compliance consideration during the era, this sector focuses on strategic area technology development. Hence, pharmaceutical companies concern on ensuring pharmaceutical products' traceability through managing Supply Chain Management (SCM) functions, such as Track and Trace (T&T). In the pharmaceutical industry, traceability systems' are various, such as (1) management of inventory control and material; (2) monitoring of distribution and sales; and (3) prevention of counterfeit, deviation, and theft. T&T functionality needs particular embedded software and hardware in the IT architecture during implementation. To sum up, T&T, as one of the SCM systems, is an integrated system to ensure unique serial number management during the packaging process. It allows pharmaceutical companies to track and trace products information accurately and efficiently. The companies, therefore, would be able to take a fast and correct decision about inventory control; return and recall; and prevent illegal action regarding pharmaceutical products' distribution. It is proven to guarantee security and people's quality of life and increase private companies' competitive advantages.

1. Introduction

Industrial Revolution 4.0 is part of the industrial era that arose in the 18th century, transforming agricultural civilization into industrialized massively. The first modern steam engine initiated the revolution as part of mechanization. Then, as a result of the industrial revolution 2.0, mass production, conveyors, and electricity were implemented, while industrial revolution 3.0 was demonstrated by the developing of an automated system. Currently, most industries are in or welcoming industrial revolution 4.0, which integrates the automation systems by the cyber network. In this era, the term the Internet of Things (IoT) emerged, which is a condition when systems and devices have sensors, software, and other elements to connect and exchange data. During this era, Big Data is an essential thing, defined by data sets with beyond capability from conventional data in data capturing, managing, dan processing [1]. It allows data to be integrated and centralized in database storage. Accordingly, an integrated system will be formed if implemented within the company.

For the pharmaceutical sector, the vision on risk-based current Good Manufacturing Practices (cGMPs) is an adequate, agile, and adaptable pharmaceutical manufacturing sector to produce high-quality medicine with regulation compliance, so this sector focuses on developing the technology of the strategic area [2]. Pharmaceutical companies, therefore, also focus on managing Supply Chain Management (SCM) Systems technology, for instance, Track and Trace (T&T), which is required to ensure the pharmaceutical products' data traceability. T&T implementation may be stated as the ability to manage comodities along the supply chain by documenting critical product information (e.g., history, location), hence enabling for data verification. Through the data, information would be able to be traced in both a forward and backward way [3]. Nowadays, the competitive economic condition leads to traceability as a pivotal role to differentiate by preventing the distribution of counterfeit drugs and targeted recalls and reducing any crime related to pharmaceutical products. This

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study aims to analyze the impacts of implementing T&T towards the pharmaceutical supply chain (for instance, inventory control; return and recall; and prevent illegal activities regarding pharmaceutical products' distribution), logistics and production process, and provide an overview of current technology T&T.

2. Literature Review

2.1. Supply Chain Management (SCM)

Based on definition by Turban, *et al.,* supply chain management (SCM) is a management term that encompasses the material, data, and payment flows from suppliers to consumers. SCM systems are designed to diminish any variability or unpredictability to enhance forecasting accuracy and increase process control on the part of inventory levels, cycle time, and customer service optimizing [4]. In a generic term, SCM refers to order creation, order acceptance, order fulfillment, and product and service distribution. Numerous critical parties are involved in the supply chain process, including material suppliers, channel supply partners (e.g., wholesalers/distributors, retailers), and consumers. SCM has evolved from a merely functional perspective to one that is more process-oriented. SCM solutions are able to handle the entire process with several integrated participants, needing an end-to-end supply chain perspective [5]. To coup the complexity of current global supply chains, executives of the Supply Chain are leveraging business innovations and digital technologies. In the past, companies overcame supply chain challenges by minimizing internal cost and improving operational performance. Meanwhile, supply chains become more interconnected, with higher stakeholder expectations and more risks. It causes the traditional approaches are less effective. Consequently, companies are examining a lot of method to improve the supply chain system [6]. In SCM, technology and information systems are employed to simplify the flow of materials, information, and money from upstream to downstream outcomes activities by utilising. This classification concept is well-known as value chain analysis. The principle's primary activities are Inbound Logistic, Operational, Outbound Logistic support, Sales and Marketing, and Services while Firm Infrastructure, Technology Development, and Human Resources Management support those main tasks. Value Chain Analysis is used to establish the operations that comprise a business's value chain, the costs associated with each activity, the potential for measurement development, and the development of business's competitive advantages [7].

2.2. Industrial Revolution 4.0 in Pharmaceutical Industry (Pharma 4.0)

The pharmaceutical industry, as one of the affected industry sectors, implements quality management (QM) processes in industrial revolution 4.0 (Pharma 4.0) in accordance with International Council for Harmonisation (ICH) Q10: "Pharmaceutical Quality Systems" (PQS). Pharmaceutical engineering illustrates the augmentation of ICH Q10 with technology elements and enablers in order to reap the benefits of new technologies. As shown below, the elements are related to the operating model, while the enablers are about designed data integrity and digital maturity:

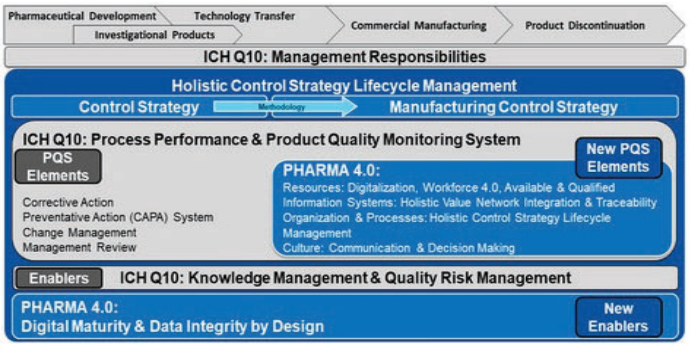

Fig.1. Holistic Control Strategy of Product Life Cycle in Pharma 4.0

The diagram above shows the pharmaceutical product life cycle, from pharmaceutical development until product discontinuation, managed by control strategy and manufacturing control strategy. During Pharma 4.0, PQS elements are not only about Change Management, Corrective Action Preventive Action Management System, and Management Review; it expands into resources, information system, organization & processes, and culture aspects. The focus is more on holistic value network integration and traceability in information systems. In Pharma 4.0, the information system serves as the foundation for integrating all computerized supporting systems (product life cycle and value chain network). It consists of (1) data interfaces, (2) an automated procedure to facilitate continuous process verification (CPV) by implementing technologies such as Process Analytical Technology (PAT), and (3) a control process designed to establish a real-time release process. Several prominent pharmaceutical businesses have built data clouds to meet system integration needs. Preventive maintenance, automation, CPV, real-time material release, bulk serialization, finished goods (batch) release, and track & trace are all included in one integrated system. These systems should be linked to Enterprise Resource Planning (ERP) systems. Furthermore, the integration concept must comply to international technological standards like International Organization of Standardization (ISO) and Good Automated Manufacturing Practice (GAMP) [8]. Connectivity integration, artificial intelligence (AI), and robotics are the main features of the industry 4.0 environment. Autonomous systems and

integrated robots generate online and real-time data with industrial manufacturing operations in order to develop production and control throughout the organization. Multiple statistics sources could be combined to connect external and internal data. Combining data sources, internal and external, makes unparalleled real-time responses, monitoring, control, and prediction possible. Hence, manufacturers' digital ecosystems and pharmaceutical value chains are well-managed, highly integrated, and digitized [9].

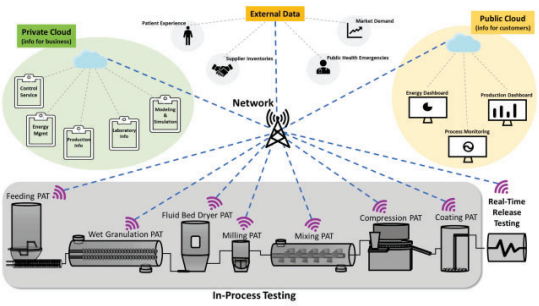

Fig.2. The diagram of CPS in Pharma 4.0

2.3. Track and Trace Technologies

Tracking refers to documenting the status of objects across time, whereas tracing refers to the evaluation of data to acquire process sequences. Moreover, marking technologies are classified as auto-ID and non auto-ID systems. Automated and technology-enabled approaches for identifying, registering, and transmitting data is encompassed by auto-ID. Also, individual systems can be classified as optical, biometric, or electronic [10]. Traceability, a tracking capacity that enables the identification of the sources of numerous quality issues, such as product recalls, has become a critical component of supply chains. With the evolution of blockchain and RFID technologies, traceability has become a critical supply chain component aimed at resolving product recalls [11]. Traceability systems can use various identification, from the simplest to the most complex. For instance unique serial numbers, barcodes, data matrix codes, holograms, and radio frequency identification labels or chips. Additionally, the majority of those identity could be implemented and integrated using distinct marking techniques, such as inkjet printing, laser labeling, or others. Nowadays, RFID technology is frequently alleged as better in reach, rate of reading, operational expenses, and data capacity [12].

3. Methodology

This study was conducted by the literature review method, academic writing of knowledge understanding of the particular topic from several academic pieces of literature in context. This method also includes a material critical evaluation. This method summarises and analyses previous research and theories and highlights any research gaps [13, 14].
The object of this result is one of SCM System, which is Track and Trace (T&T) impact, and the subject is the implementation of Pharma 4.0 (Industrial Revolution 4.0 of the Pharmaceutical Industry).

Here is the following step followed:
1. Collect information from credible sources, such as published papers, books, and accountable websites.
2. Read the obtained sources
3. Determine the relevancy of the sources towards the topic
4. Summarize the main idea of each related literature
5. Arrange the main idea of the sources and develop it into a paper

4. Result and Discussion

For centuries, supply chains have existed in society. It began with the first sold product or created service. However, SCM is becoming more sophisticated due to the advanced technology, allowing companies to produce and deliver goods and services nowadays. The current relevant supply chain strategies tend to be a demand-driven operating model that can integrate people, processes, and technology to deliver goods and services with incredible accuracy and speed. Albeit the fundamentality of SCM, the supply chain today is more crucial than before. If companies successfully manage their supply chain to adapt to the current business environment, which is volatile technology-driven, they will survive and thrive.
Pharma 4.0 might be accomplished by digitizing various complex pharmaceutical value chains and incorporating embedded cyber security. A fundamental principle in incorporating alternative manufacturers is the internet of things (IoT), which involves the interconnection of compromised cyber-physical systems (CPS) with online integrated sensors, instruments, computing devices, and equipment. It allows information exchange between instruments, equipment, or computerized systems that are related to supporting business processes. Moreover, data from each device will be integrated with each other and produce reliable information about products and processes. Advanced manufacturing technology will be necessary to overcome governmental, technological, and logistical constraints.
In this era, every decision should result in a more sovereign manufacturing system with improved process control and a robust quality management system. Any innovation should minimize the variation across lots and result in consistent product availability. However, considering the cost of investment in advanced technology is extravagant, new technology adaptation could not be implemented immediately and equally by all companies. Delays are also

understandable because of the extensive knowledge gained on current platform technologies [15].

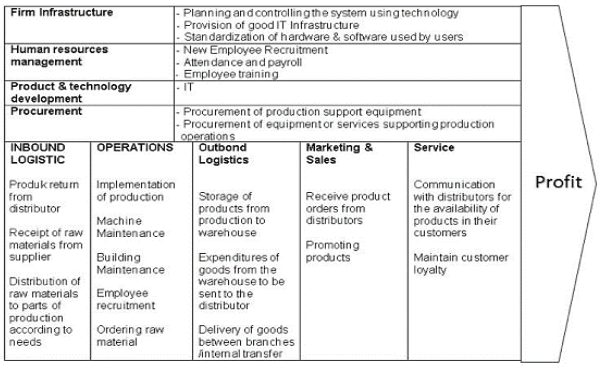

Fig.3. Value Chain Analysis in Pharmaceutical Company is assessed generally in the diagram above

Track and Trace (T&T), which accomplishes single-unit serialization, is one of the most widely used technologies in the pharmaceutical sector [12]. Tracking and tracing is a way for manufacturers to obtain and record important information about where and how products are produced and distributed. The T&T device is coordinated by a network and a server that relays information into a database for storage and access. The data will be along the product supply chain. This fully integrated paperless solution enables personnel to track products from raw materials to finished state, consumables, access pedigree data and set up unified operator interfaces, such as Supervisory Control and Data Acquisition (SCADA), Human Machine Interface (HMI), and more item serialization. T&T does more than just track products through the manufacturing process. It includes Overall Equipment Effectiveness (OEE), prescribing information, historical trends, etc. In addition, it can also request data from systems outside of Ignition, such as Enterprise Resource Planning (ERP) systems.

The application of T&T in the pharmaceutical business and its benefits to the manufacturing and logistics processes are numerous [16], such as:

1. *Management of inventory control and material*
   Inventory control management is concerned with supporting operations in deciding the appropriate time and amount to replenish various stock keeping units (SKUs). Inventories of materials (raw and packaging) and finished goods are kept in order to meet client demand while maintaining budget and a defined service level. When demand is contingent, materials requirement planning (MRP) techniques are used to schedule inventory control. T&T could be utilized to control the shelf life of the raw material, packaging material, and finished goods. Hence, the comprehensive identification of the raw or packaging materials and finished goods in the warehouse (manufacture or distributor) is appropriately monitored. Moreover, the expiry dates might be managed for First Expired First Out (FEFO), avoiding any additional costs associated with selling expired or about to expire products. Also, it is necessary to plan for the disposal process.
   Besides shelf life, this technology is required for backward and forward tracking. For instance, while there are non-conformities of the finished goods due to the unidentified change of material characteristics during raw material testing, personnel would be able to identify other impacted products and define follow-up actions.

2. *Monitoring of distribution and sales*
   The distribution of drugs should be monitored and the sales to ensure patients' safety. Returns or recalls are common in the pharmaceutical industry; even mock recalls require exact product name, type, location, distributor, retailer, and consumer information. Recalls are conducted when manufacturers' products fail to meet safety requirements, do not meet specifications, or have defects that could result in serious injury to patients. One line of research empirically analyse the economic consequences of product recalls and the variables that impact it. The findings indicate that product recalls have a detrimental effect on anomalous returns. Additionally, the researchers demonstrate that the overall impact is dependent on the recall approach, the degree of hazard, the operational features, and the business characteristics. As explained by The Delegated Regulation (EU) 2016/161, the holder of marketing authorization, pharmaceutical company, must ensure that the unique identifier (UI) of a recalled or withdrawn medicinal product is decommissioned in every national or global territory where another recall or withdrawal is to take place. A statement that the pharmaceutical product has been recalled should be included in the repository. It implies that, in compliance with cGMPs and the requirements of the Delegated Regulation, the pharmaceutical manufacturer must decommission the UI prior to conducting the actual recall. The non-marketable pharmaceutical product must be properly identified and recalled throughout the supply chain. Accordingly, the pharmaceutical company needs T&T to find that information efficiently and accurately. The manufacturer's follow-up action will only be initiated if there is a matched identity with the health authorities repository (updated from the manufacturer system). This system effectively minimizes recall frequency, and it will decrease the direct and indirect costs.

3. *Prevention of counterfeit, deviation and theft*
   Considering that pharmaceutical products tend to obtain large net profits, especially for patents with a costly price, it enables the growth of illegal secondary markets. The threat posed by counterfeit pharmaceutical items is not new; numerous national

governments have long waged their own war on counterfeit medications. According to the World Health Organization (WHO), substandard or counterfeit pharmaceuticals impose a burden on 10.5 percent of low- and middle-income nations, costing an estimated US$ 30.5 billion. Hence, in the last decades, the awareness of counterfeit drugs has been elevated by governmental regulations to strengthen the pharmaceutical products' distribution security level. Regulatory frameworks enforce pharmaceutical companies' implementing agile systems to serialize every product distributed to various regions according to each local regulatory requirement. Implementation of serialization is still recommended in certain countries, but it will be mandatory under worldwide laws to achieve compliance and prevent any loss of business opportunities in the future.

Unique code would be a specific identity that distinguish the original product and the counterfeit. The implementation should be annouced to the customer and society in general so they will be aware how to acknowledge them. Deviation during production system will be avoided by ensure the integrity of the data from production to distribution procss. Also, through this program, all transactions and product journeys will be recorded so that illegal product sales are more likely to be detected and prevented. Regarding the pharmaceutical supply chain, trace and trace aspects are reviewed to support anti-counterfeit technologies to optimize and synchronize the supply chain. As one aspect, the impact of radio frequency identification (RFID) technology has been intensively investigated for serialization, but the current focus has shifted to implementing single unit traceability. The basis is GPS technology which allows information at any time where the product is located [17]. RFID-based anti-counterfeiting tracking and tracing has sparked great scientific interest. In order to ensure a strong supply chain and prove products authentication, anti-counterfeiting tracking and tracing requires a reliable electronic pedigree (e-pedigree) that tracks finished goods from manufacturers to retailers. The initial e-pedigrees' formation and synchronization during the production process is critical for the reliability of subsequent e-pedigree processing and authentication of finished goods. Since it entails a plethora of practical concerns, e.g., insufficient tag writing and locking, environmental disruptions, and the possibility of data fabrication, it is a critical stage. An innovative anti-counterfeiting track-and-trace system suggests a tag data processing and synchronization (TDPS) for generating the first e-pedigree for generic and tangible products. The establishment of an RFID reader in the packing line enables the performance of TDPS to be validated and the bottleneck of e-pedigree creation to be identified [18]. The use of traceability technologies can significantly increase the cost of imitation. According to preliminary assessments, they are making the most considerable overall contribution to reducing the economic attractiveness of counterfeit activities. Despite the wide variety of methods available, easy and safe authentication of physical objects continues to be a technical issue, with no standard solution available.

Referring to logistics and supply chain efficiency, T&T is non-invasive because it does not affect the product quality. Meanwhile, the process, such as storage and delivery, tends to be slower, which is compensated for by reducing costs, safety enhancement, and regulatory or standard compliance. T&T has various direct effects on a business's IT and production infrastructures. Adequate connections between the new T&T system and the current ERP system are becoming crucial, starting at the global corporate level. Advanced technologies, such as specialized software and hardware components embedded into the existing IT architecture, are necessary to deploy track and trace capability. To ensure proper serial number management during the packaging process, the system should be connected into centralized systems. Also, the system should be constructed so that data exchange and storage in a common industry database can be managed. In more detail, personal computers should be connected to the local information technology network to manage shop floor operations and ensure that product data is updated in real time. They should be installed in each line of the production area to allow serialization of line master systems (SLMS). In order to ensure the traceability of the products, each product should be encoded with unique serialization information and consequently validated to confirm the accuracy of the data and the system's accuracy. At this stage, printing devices are required to print the code (barcode, QR code, etc.) and vision systems (cameras or scanners) should be installed for the verification function. Serialization line slave systems (SLSS) are required in addition to SLMS. Both will perform nearly identical functions and will be linked to the transmission line control system and the internet network so that one may facilitate information exchange. Meanwhile, data transfer between systems is not required. Once all packaging activities on the shop floor have begun, all product information should be collected and reconciled in the system. Further, the serialization server (SSVR) would store the data and generate all reports at the completion of the batch or lot via the MES interface . The report would include all pertinent information about each packaged item (e.g., bottles, blisters, bundles, cases, and cartons). Then, the SSVR will transmit the serialization data to the ERP system, so all of the corporate sites can monitor or evaluate the data.

T&T brings various impacts on current production and data handling processes, as follow:

1. From printing stations for cartons, blisters, or bottles, SLMS/ SLSS should connect to the controlling devices to obtain the correct data to be printed. This procedure necessitates using a high-quality or at least adequate

printing technology. Companies should ensure that they produce products with clear identities that can be notified. If the current device cannot support it, upgrading to a new sort of technology is essential.
Furthermore, the artwork for the packing materials should be examined to ensure that the available area can accommodate the unique code or required information correctly. If companies ignored this aspect, they would find any non-conformities during the packaging or distribution process. For instance, too small a printing area leads to unique unreadable code.

2. Verification is a critical step after the printing process. The manufacturer should install verification system. For instance, optical character recognition (OCR) to capture the unique code, and optical character verification (OCV) to verify the unique code. The computerized system should connect to the SLMS/ SLSS systems for data transfer. In this stage, there is a selection process, printing result that meets specifications can continue to the next step, but if it does not meet specification, the product would be expelled by the rejection system.

3. Serialization line slave systems (SLSS) are required in addition to SLMS. Both will perform nearly identical functions and will be linked to the transmission line control system and the internet network to facilitate interchange of information. Meanwhile, data transfer between systems is not required. Once all packaging activities on the shop floor have begun, all product information should be collected and reconciled in the system. Further, the serialization server (SSVR) would store the data and generate all reports at the completion of the batch or lot via the MES interface. The report would include all pertinent information about each packaged item (e.g., bottles, blisters, bundles, cases, and cartons). Usually, the aggregation is not documented. To support the needs, vision systems are necessary, and they should be supported by Standard Operational Procedure (SOP). Aggregation might be performed differently by item-by-item, row-by-row, and layer-by-layer. The aggregation is finalized and added to the database if the data is correct. If there is unsuitable data, the machine rejection system will also expel the products.

However, the proper solution for each company should be assessed based on relevant requirements and business strategy. The trend of track and trace may not lead companies to invest just for technology's sake. Therefore, the implementation of traceability function in pharmaceutical companies is about sophisticated technology and considering the strategic instinct that supports operational goals.
The related business process should be appropriately defined and derived to establish SOP before the implementation. Furthermore, to ensure that related personnel could run the process to meet operational goals, training programs about business processes and T&T should be developed. Companies often ignore those aspects, but without them, the implementation of T&T would not work accordingly.

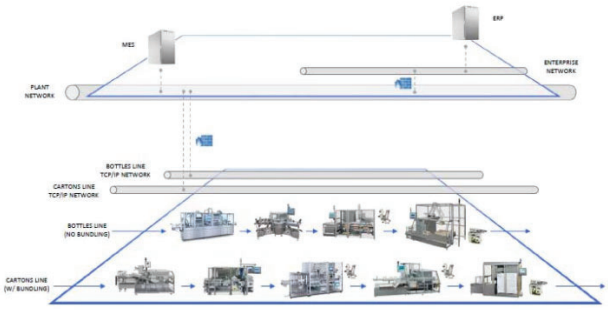

Fig.4. Ilustration of IT and production architecture without T&T implementation

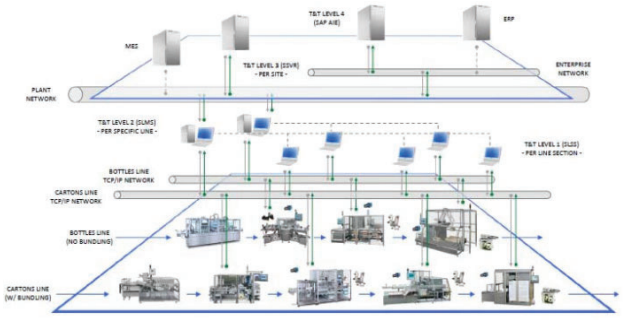

Fig.5. Ilustration of IT and production architecture with T&T implementation

Those changes towards process operational will impact OEE of the production line. The complexity and duration of the process, such synchronization and the loading process, may affect overall line speed reduction. Consequently, there would be loss of performance efficiency (Ep). Even though the analysis is performed quickly, the accumulation time may have an influence on the overall time for communication. Moreover, Quality (Q) component on OEE will be affected by false negatives reading of the camera that leads to rework. This issue could be solved by doing validation of the computerized system or defining challenge test in the begining of utilition. Nonetheless, the impact on availability (A) could minimize the packaging area OEE.

5. Conclusion

Currently, the pharmaceutical industry is a sector with strict regulation and intense competition, so industrial revolution 4.0 (Pharma 4.0) could be a threat or even an opportunity to develop. Pharmaceutical companies that

focus on obtaining competitive advantages by increasing capability to prevent any drugs thefts and counterfeiting, could implement SCM systems, such as T&T. This system effectively minimizes return or recall frequency and costs since follow-up action by manufacturer will be initiated if there is a matching identity with the health authorities repository (updated from manufacturer system). In this case, the health authorities and pharmaceutical companies have total control of the distribution of drugs, includes identity and quantity in the market. In implementing T&T as part of the SCM system, the company also needs to consider many factors and prepare carefully, whether from the internal of the company to implement the system and be careful of the unacceptable system risk due to improper needs assessment. To sum up, T&T, as one of the SCM systems allows the companies to take a fast and correct decision about inventory control; return and recall; and prevent any illegal activities regarding pharmaceutical products' distribution is not only proven to guarantee security and people's quality of life but also contribute to increasing private companies' competitive advantages.

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