Global Pharmaceutical Supply Chain: A Quality Perspective

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Abstract

Maintaining a good level of quality in global supply chains is a real challenge when the level of cooperation is low between partners. In pharmaceutical supply chains, ultimate levels of coordination and quality are sought. This industry cannot afford quality issues of almost any level, which creates costly tests and validation processes. In this paper we reveal some well documented issues and recalls that took place due to imperfect aspects of the drug supply chain. We also reveal a model to evaluate all tests based on benefits, cost and harm caused by that test. Lastly, we present a framework used by a Jordanian pharmaceutical company in order to use the proposed model in a manner aligned with the organization practices. The presented framework guides organizations to find various solutions to supply chain quality issues and select the most ideal solution based on benefits and costs.

Keywords: pharmaceutical supply chain, quality, ideality, cost of quality, Jordan

1. Introduction

Pharmaceutical industry is gaining enormous global importance, and the industry's supply chain structure is getting more and more complicated. By contribution of size, the pharmaceutical industry is dominated by US, Europe and Japan. Led by those markets, the total world consumption in sales of pharmaceutical products has displayed large growth and is expected to grow even more with expanding popularity in emerging markets.

The World Health Organization (WHO) defines a drug as: *Any substance or mixture of substances manufactured, sold, offered for sale or represented for use in the diagnosis, treatment, mitigation or prevention of disease, abnormal physical state or the symptoms thereof in man or animal.*

From this definition we realize that the sensitive nature of drugs requires consistent, safe, effective and high quality products delivered to the consumers. With supply and demand extended across the world, sensitive products and raw materials, and as the supply chains have many players, collaboration and quality measures are extremely important. Enterprises may compete and win in international markets by integrating quality practices along their supply chain (Biotto, De Toni, & Nonino, 2012).

There are number of key players in the pharmaceutical industry (Shah, 2004), including:

(i) Large research and development based multinationals with global presence and branded products, both ethical/prescription and over-the-counter.

(ii) Large generic manufacturers, who produce out-of-patent ethical products and over-the-counter products.

(iii) Local manufacturing companies which operate in their home country, producing both generic products and branded products under license or contract.

This paper is mainly concerned with the second group. We focus our attention on generic drug manufacturers, which seem to have supply chains extending across the globe. Under this category, we present –as an example- the Jordanian pharmaceutical industry that has customer base across the world and suppliers located mainly in Asia, Europe and the US.

Pharmaceutical industry is highly regulated. Regulations cover many areas of operation including quality, testing, auditing, manufacturing, final product specifications, raw material specifications, packaging, etc. Successful drug manufacturers abide by these regulations and add their own regulations. Main sources of regulations are the US, European and Japanese pharmacopeias. These sources are updated regularly and are

considered a reference for most drug manufacturers serving global markets.

This paper presents the main issues in the pharmaceutical industry generally and the generic drugs manufacturing specifically. These pressing issues are traced back to conditions in the global supply chain (Maruchecka, Greisb, Menac, & Cai, 2011). We present a holistic model in pursuing high level of quality. The model is applied to all entities of the drug supply chain including; raw material supplier selection, auditing, inspection, manufacturing, packaging, warehousing, and transportation.

The goal of using any quality model is to avoid product recalls and deliver effective and safe medications to consumers. In the pharmaceutical industry recalls are proven to be devastating to the company's financial being and reputation. As an example, Merck's stocks collapsed and lost about a quarter of its value one day after recalling their acute-pain medication, Rofecoxib in 2004 (Oberholzer-Gee & Inamdar, 2004). The company lost even more of its stock value after an article in Wall Street Journal suggested that Merck had known about issues with the drug for years and did not do anything. Such recalls cause fatal blow to customers' trust in a company.

Enhancing quality aspects with pharmaceutical supply chains comes at high costs. Ford & Scanlon (2007) showed the relationship between quality levels and staggering validation costs in such supply chains. Starbird (2001) linked quality activities with costly efforts to make suppliers more effective. Walters & Lancaster (2000) and Walters & Jones (2001) developed value chain concepts based on minimizing validation cost of each activity in supply chains. Castillo-Villar, Smith, & Simonton (2012) show how these costs can be measured or calculated.

To create a balance between quality level and cost levels we create the ideality concept that includes all costs accrued from performing quality activities (testing). Our model also counts for indirect costs like production line stoppage cost or cost of destroyed test samples. The model assesses the ideality of a test based on the cost needed to perform the test, and since the pharmaceutical industry relies heavily on validation testing, it is important to have an idea about the cost of these activities, in order to improve the value of all quality activities.

1.1 Main Issues Facing the Pharmaceutical Supply Chains

The IBM Global Business Services report (2010) argues that pharmaceutical supply chains are ill-placed to cope with all the issues that face it these days. These supply chains are under enormous financial and competition strains. The biggest threat to the pharmaceutical industry however comes from issues it has with its customers concerning quality issues. Currently the policy used to face such challenges is adding more tests throughout the supply chain.

Caswell (2000) lists many problems facing the drug industry. These issues can be classified as:

1) Counterfeiting issues; the counterfeits are not typically at the same level of quality as the authentic drug.

2) Patient's unfavorable reaction to the drug.

3) Issues caused by entities of supply chain operations.

The first class is discussed well in literature as demonstrated by McFarlane & Sheffi (2003), Deisingh (2005), and Patterson, Grimm, & Corsi (2003). The second class in not the concern of this work since we are only concerned with generic drugs. The third class is the main focus of this work.

Many issues may be caused by supply chain entities including:

- Manufacturing issues like mixing incorrect input raw materials, or cross contamination due to manufacturing more than one drug in the same facility, or improper labeling of the final product.

- Raw material suppliers' issues like improperly prepared raw material, raw material with high impurity levels and mislabeling of raw material shipments.

- Transportation issues caused by mishandling, improper temperature controls, and the use of improper shipping mode.

- Storing and warehousing issues such as using improper temperature controls, improper handling in the warehouse and mixing products with raw materials.

- Retailers' issues including improper temperature controls and handling.

No matter which supply chain entity is causing a specific issue, this issue may grow to become a recall if it is not resolved before reaching the market. Pharmaceutical companies try to utilize the best quality tools to prevent these issues from getting this far. Literature includes studies about quality practices in supply chains; Ahmad, Awan, Raouf, & Sparks (2009) developed a scale for measuring service quality in the distributor-retailer

interface of pharmaceutical supply chains.

Medical literature is rich with drug issues and recalls caused by the reasons listed above; Lyles, Flynn, & Frohlich (2008) discuss several product recalls for products coming from China due to trust issues and cultural misunderstandings. Other literature detail certain recalls; Oberholzer-Gee and Inamdar (2004) revealed the dramatic financial effects of the Rofecoxib (Vioxx) on Merck's financials. Flach (2000) shows how Falcon Pharmaceuticals Ltd. recalled and stopped distributing some topical non-steroidal anti-inflammatory drugs (NSAIDs) due to observing few cases of corneal problems. Even though the root cause of these problems could not be found, the company felt it was supply chain related. Mathews & Burton (2008) wrote in the Wall street journal about a German company recalling blood thinner (Heparin) from the market with active ingredients from China. This recall had clear supply chain links. Each recall is followed by adding new bundles of testing and validation activities.

1.2 Generic Drug Industry

Generic drug companies draw their business mainly from producing out-of-patent ethical products that have been in the market for a long time before the original producers lost their sole patent rights. Since the drug stays in the market as an ethical drug for many years before it becomes generic, all issues related to unwanted human reaction to the drug are already handled by the original manufacturer. Almost all issues that generic drug manufacturers face are supply chain related issues.

The generic drug industry is highly regulated and controlled by international authorities such as US pharmacopeia, European pharmacopeia and Japanese pharmacopeia. These pharmacopeias serve as sources of best practices and lessons learned in the industry. The main contents of references are Monographs and general guidelines. The Monograph sections include a wealth of information about various raw materials and final products. Each Monograph contains information such as chemical composition, preferable packaging method, storage conditions, material characteristics, purity levels, method to test and proper test results, while general guideline sections represent best practices for selecting materials and following general testing practices.

The industry utilizes another source of information called good manufacturing practices (GMP). The US Food and Drug Administration issues a famous bi-weekly journal called GMP Trends. The journal publishes audits reports from visits to various drug manufacturing facilities. The report discusses testing and validation activities in the facility and proposes best practices in this regard.

2. Methods

There is an imminent need for holistic quality model in the pharmaceutical industry to face the staggering issues highlighted in the previous sections. In order to have a peace of mind, every entity of the supply chain needs to be armed with the information and tests that guarantee no drug related issue will be caused by this entity. Quality approach may be different for each entity; what works in a warehouse may not be applicable in a manufacturing facility. Retailers are totally different than transportation service providers, so it is important to deal with entities independently. At the end, however, a good model is a model that ensures the highest level of quality throughout the entire supply chain.

Our model, as illustrated in Table 1, relies on three pillars; quality tool selection (what test(s) to perform?), ideality level of each test (ideally, is this test needed?), and quality collaboration level of each entity. Each one of these pillars is evaluated to ensure that the holistic approach to quality is intact.

Table 1. Main pillars of proposed holistic quality approach

Item	Answer the following questions:
Quality Tool Selection	What tests need to be done?
	What authority is asking for the test to be done?
	Are we missing to validate any aspect of the process?
Ideality	What benefits (importance) does performing each test have?
	Do we have to perform this test?
	What is the cost of performing this test?
	What is the harm we may accrue from performing the test?
Collaboration	How the results of my test are used by other entities in the supply chain?
	Can we benefit from tests performed by other entities of the supply chain?

Quality tool selection is a guideline to select the proper test or validation method. For example, a chemical property test might be used to ensure purity level while a building inspection might be used to ensure no cross contamination of drugs. For each entity of the supply chain there are specific tests that can be performed. The success of any quality program depends on performing the proper tests in the proper sequence (Starbird, 2001). A good guideline for tool selection may come from any pharmacopeia or the GMP. Each manufacturer may also have its own lessons learned and good practices that can be used as a source for validation requirements. The challenge is to ensure that all relevant tests are selected and performed.

In the second phase, we determine the level of ideality for each test, validation, or inspection activity. Ideality is calculated as shown in equation (1). It has three main parameters: benefits (or importance), cost and harm. The higher the ideality rating for a test, the better that test serves to ensure higher quality levels at lower costs.

$$Ideality \ = \ Benefits \ \times \ (Cost \ + \ Harm) \tag{1}$$

Total ideality for all tests performed at an entity of the supply chain can be calculated as the average of all ideality computed for each validation activity, as shown in equation (2).

$$Total \ Ideality \ = \ (\textstyle\sum Individual \ Ideality) \ / \ Number \ of \ tests \tag{2}$$

Table 2 shows a guideline for estimating the "Benefits" rating. The "Cost" represents the dollar value of performing the test. This value includes material cost and all other related test costs. "Harm" can be viewed as the reason why a supply chain entity may resist performing a test. It can be estimated based on problems that performing a test can cause for the process. Examples of harm are; production line stoppage, destructive testing, shipment delays and stoppage etc.

The units of the cost and harm are in dollars or other currency, while the importance does not have a unit. It is suggested to make the entire ideality value as a unit-free quantity. In order to do that the cost of all tests may be estimated and each test is assigned a value between 0.1 and 1 depending on the relative cost of this test compared to all other tests done at a given entity in the supply chain; a test that incurs high cost will get 0.1 rating, while a very low cost test will get a rating of 1. The same approach can be applied to harm, for example we expect to see a production line stoppage get a harm rating close to 0.1 while destroying a small sample for test gets a value close to 1. This is due to the fact that stopping the production line is much more costly than destroying a small sample of medicine.

It is obvious that higher ideality indicates importance of the test. But low ideality may just indicate high cost or high harm values. In this case, the job of quality personnel is to improve ideality values by finding ways to lower testing cost or harm. Similarly we can conclude that the higher the total ideality, the better performance for this specific entity. Hence, the two values give an indication on the performance of specific process or entire supply chain entity. We can also evaluate the performance of the entire supply chain by calculating the total ideality for all entities in the supply chain.

Table 2. Benefits or importance ratings

Condition	Benefits Rating
Test is mandated by FDA or designed to detect potential product liability issue, or can result in a severe safety issues, or listed in the contract with customer	9 – 10
Test that detects major drug issues but not safety related	7 – 8
Test that detects minor issues that any customer may notice	4 – 6
Test that detects minor issues that customer will not notice, or redundant tests	2 – 3
Test is not required: no follow up takes place regardless of the result of the test	1

The last phase in table 1 is concerned with evaluating the linkage between supply chain entities. This phase tries to assess the level of quality collaboration in the supply chain. We assign each test an *association rating*. The higher the value of this rating, the more important this test is for other entities in the supply chain. In a way, this rating provides an idea regarding the level of collaboration between quality activities across the supply chain. Suggested values for the association ratings are shown in table 3.

Table 3. Suggested values for association rating

Condition	Association Rating
The performance quality of other supply chain entities depends on the test result	9 – 10
Test results are requested by more than one other supply chain entity	7 – 8
Test results are requested by one supply chain entity	4 – 7
Test results may be requested by other supply chain entities under certain circumstances or problems	1 – 3
Test result is not used by any other entity in the supply chain	0

Calculating both Ideality values and association ratings, results in the following conclusions:

- Highest value for ideality is 20 and for association the highest value is 10.

- Tests with high ideality or association values should not be cancelled unless thoroughly justified.

- Tests with importance values of 7 or more should not be cancelled unless thoroughly justified. Other tests with low ideality and low importance may be considered for cancellation.

- Low ideality value does not mean an unimportant test necessarily, but it could result from high test cost or high damage (harm) caused by the test.

- Quality teams should work on finding better ways to perform tests with low ideality values caused by test cost.

- Quality teams should work on finding better ways to perform tests with low ideality values because of damages or stoppage caused by test.

- Quality teams should contemplate cancelling tests with low ideality and low association.

- Continuous improvement activities should strive to ensure that all tests have high ideality and association or at least one of two ratings.

Section 2.2 reveals a framework used by a Jordanian Pharmaceutical company to capture the above conclusions.

2.1 Example with Calculations

To understand how the model works we discuss an example for a supplier; the supplier of Chlorothiazide (an active ingredient raw material) which is essential for producing diuretic and antihypertensive drugs. This material is shipped in barrels to drug manufacturers.

The supplier performs many tests. One of them is an in-process validation test called 'loss on drying test'. This test is performed to ensure that drying heat will not cause the material to lose more than specific amount of weight. Production line is shut down for an hour to test two samples in the lab. This test is typically mandated by the customer (which is the drug manufacturer).

They perform another test to the same batch of Chlorothiazide before it leaves to the manufacturer. This test is final inspection of the barrel and its contents. It is obvious that this test is not as costly or harmful as the first test. The second test is not mandated by a contract, but it does affect the next entity of the supply chain, the drug manufacturer.

Based on prescribed selection methods for benefits, cost and harm as revealed in section 2.0 and Table 2, the values for the first and second tests respectively are:

Benefits: 9, 4, since the first test is mandated by the customer, and the second test is not.

Cost: 0.1, 0.6, since the first test uses lab resources and damages specimen, while the second test does not.

Harm: 0.2, 0.8, since the first test stops the production line, the second test does not.

Based on equation 1, ideality for the first test is 2.7, and for the second test is 5.6.

Note that neither value is considered great. The first test has high cost and high harm, and all efforts should focus on minimizing both, while the second test has low benefits rating, and efforts should be focused on eliminating the test, simplifying it, or combining it with other tests.

2.2 Case from Pharmaceutical Industry in Jordan

The Jordanian pharmaceutical industry generally produces out-of-patents drugs (Generic drugs) only. The supply chain consists of players located all over the globe; raw material suppliers, manufacturing facilities, warehouses, distributers, and retailers. This makes it necessary to abide by global health and drug authorities.

However, the industry also abides by the regulations of every country they sell their products in. From a quality perspective, Jordanian pharmaceutical manufacturers go to extreme measures to guarantee highest level of product quality. Quality is part of everything they do. This has made the Jordanian pharmaceutical industry one of the most respected in the world.

The validation process used in the industry (shown in figure 1) consists of the following qualification phases:

- Design Qualification (DQ): this phase ensures that the proposed (or existing) design satisfies both the User and Functional Requirements Specifications (URS) and (FRS); it also includes setting vendor selection criteria.

- Installation Qualification (IQ): this phase ensures that process and equipment meet specifications, installed correctly, and that all needed components and documentation for continued operation are installed correctly.

- Operational Qualification (OQ): this phase ensures that all machines and surfaces needed for the process and equipment are correctly operating.

- Performance Qualification (PQ): this phase ensures that process and equipment perform as expected in a consistent manner over time. During the phase, the performance plan is prepared and then test are conducted.
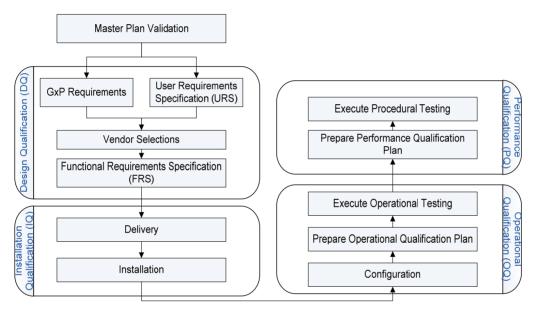

Figure 1. Typical validation process (Note 1)

Raw material suppliers are typically selected to be able to conform to one of the listed pharmacopeias and other requirements that may be listed separately. Vendors' performance history is also checked to find out the quality level of their services.

Number of tests, type of tests, frequency of tests and desirable test results are typically listed in the contract with vendors before they are granted any new business.

Warehouses are typically owned by the manufacturer, however some are not. In both cases, a rigorous quality system is enforced to perform well as part of a successful Cold Chain or supply chains with controlled temperatures (Bishara, 2006).

In the manufacturing facility, the quality group that controls quality activities in the entire supply chain performs in three departments; Quality assurance department that is ultimately responsible for releasing any product batch to customers. This department plans and orders all quality related tests. The second department is Quality Control, it performs tests, monitors production, and alerts any supply chain entities when test results are not favorable. The last department is called Compliance department. This department is responsible for receiving and analyzing customer complaints, performing internal and external quality audits and performing investigations about compliance issues.

Some tests and validation performed include 100 % inspection with rejection, cameras on production lines and

in warehouses, scales, chemical testing, physical properties testing, machine validation, cross contamination prevention tests, and visual tests. A full cooperation between the three departments is important to reach excellent levels of quality everywhere in the supply chain.

The transportation system is the weakest link in any drug supply chain. The implementation of cold chain management principles remains a challenge due to employing shipping companies that are not specialized in pharmaceutical products. It is not cost effective, however, to own transportation systems, and thus manufacturers maintain continuous quality training and monitoring programs.

With its high commitment to quality, the Jordanian industry did not incur major recalls in its history and almost all issues that were encountered were caught before they reached the customer. Some of the issues this industry prevents include cross contamination, final product contaminated with foreign materials, contamination with packaging material, mixed raw material, high level of impurities in the raw material, manufacturing issues, mislabeling, etc. The industry has been successful preventing almost all major issues that faces it through vigorous testing. This is a costly way to perform, however, it guarantee high level of quality and eliminates chance for recalls.

The model provided in this paper helps pharmaceutical companies to eliminate costly tests that do not have high benefit. It allows companies to search for ways to minimize harm and cost of testing, or maximize the ideality of tests. The model also allows the industry to assess the level of cooperation supply chain entities have, which reveals areas that need improvements and areas which perform at high cost levels. Based on the model described thus far, we created the following framework (shown in figure 2) which is considered by one of the elite manufacturers in Jordan. The designed framework is a step-by-step methodology to use the model and enhance the continuous improvement culture at the company.
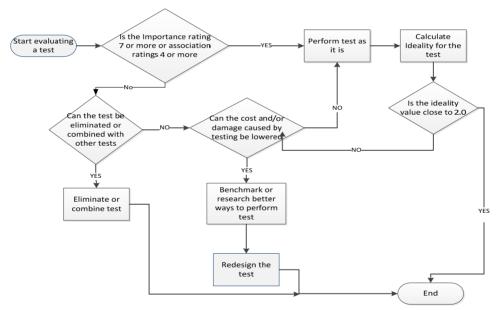

Figure 2. Proposed framework

3. Discussion

A global pharmaceutical manufacturer may use certain quality policy, say Total Quality Management (TQM), to work along all good practices mandated by global health authorities. In such policy the manufacturer may mandate certain tests to be done by the suppliers or by their own manufacturing facility. These tests are typically great in number and not all tests have valid reasons. The model provided in this paper can be used to help systemize the way we deal with each entity in the supply chain by asking the questions in each step as shown in Table 1. So we always ask questions toward assessing the need for a test, the cost and harm of test, and the level of resistance we may get from a supplier.

By performing ideality analysis to all supply chain activities and within all entities we can produce information for each entity such as cost of quality validation and cost of harm or inconvenience these tests may have caused. This information can be used to minimize test costs and harm and increase the ideality.

The association analysis can be used to assess level of collaboration in the entire supply chain. This action combined with reliable information sharing system can be a powerful tool used to reach ultimate collaboration levels in the quality actions throughout the supply chain.

The proposed framework is a step-by step methodology than can be used by all the entities within the supply chain to decide which tests should be conducted, which tests could be removed or combined with others, and which test is conducted by other entities within the supply chain. This paper proposes a model to select tests and a framework to implement such model.

4. Conclusions and Future Work

Drug recalls and pharmaceutical quality issues are devastating to the company's reputation, financial being and consumers' trust. Many recalls are related to one or more of the supply chain entities. Companies tend to increase the number of testing and validation activities in order to minimize the chance of a recall. This, however, is a costly approach.

Our model ensures all relevant validation tests are included and each test is evaluated based on the benefits, cost and harm. This formula allows us to analyze each test and improve it by increasing its ideality or replacing the test with one that is less harmful or less costly or more beneficial. The model also assesses the level of collaboration across the supply chain quality activities.

For future work, researchers may assess the use of Failure Mode and Effect Analysis (FMEA) in order to ensure all issues and all tests are counted for. Also future work can validate this model, conduct calculations of ideality for an entire supply chain and check the model validity; in addition future work might build on this work to venture how value chain can benefit from ideality concept in order to improve cost structure of the pharmaceutical supply chains. Finally future work can link this work with quality by design (QBD) trends which are becoming popular in many pharmaceutical organizations.

Acknowledgment

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Note

Note 1. GxP: Good Practices for x, where x could be manufacturing or others.