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Measuring Supply Chain Compliance in the Pharmaceutical Industry
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Measuring Supply Chain Compliance in the Pharmaceutical Industry

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Summary: Our thesis proposes a model to quantify and measure compliance in the supply chain of a pharmaceutical company. Based on a method of analyzing non-compliance incidents we setup Key Performance Indicators (KPI's) for various compliance areas and a balanced scorecard for the supply chain.

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KEY INSIGHTS

1. Numerous diverse compliance areas affect the supply chain in a pharmaceutical company.

2. Recording and analyzing non-compliance incidents consistently can be an effective tool to measure compliance performance.

3. Generating a centralized database on compliance requirements and incidents increases visibility of compliance and it is expected to enable improved compliance.

Introduction

For any organization, compliance is about ensuring that business processes, operations and practices are in accordance with the prescribed set of norms. Pharmaceutical companies are subject to stringent compliance requirements set by governments and international regulatory bodies. Meeting these compliance requirements is a tremendous challenge due to the dynamic and diverse nature of the regulatory landscape and the complexity of the supply chains. Every day, within the global supply chain, thousands of raw materials sourced from suppliers around the world are brought to global manufacturing sites. The finished products are then distributed to various markets across the globe. Hence, several players interact in the supply chain to ensure compliance. Failure to ensure compliance can have a negative impact on any organization with consequences ranging from minor fines to economic sanctions to the complete closure of the business. More than 500 product recalls occurred due to non-compliance issues in 2011 alone and the costs related to regulatory infractions by 8 leading US pharmaceutical companies from 2007-2012 were $7.2 billion. Companies have to continuously monitor the regulatory norms and ensure timely completion of the compliance requirements. While compliance management is very important, currently there is a lack of metrics to track the compliance performance of the global supply chain, i.e., there is no systematic approach to compliance measurement. [Various articles have been written that analyze the different areas of compliance within the supply chain such as temperature control, serialization and labeling. However, we were unable to find any previous work that has been done in integrating all the different compliance areas affecting the supply chain into one holistic measurement concept or KPI.] The problem was to develop a quantitative measure for compliance of the entire supply chain that integrates the diverse compliance areas.

In order to structure our approach, we used the systems engineering methodology and the basic supply chain processes of Plan, Source, Make, Deliver, Return and Enable from the Supply Chain Operations Reference (SCOR®) model. Apart from literature review, Interviews were conducted with subject matter experts from different departments within the supply chain of our sponsor company to understand how their function is affected by compliance requirements, and the characteristics important for a compliance metric. One key finding from the interviews was the need of a centralized database within the company to keep a record all compliance related incidents.

Sources of Compliance

It is crucial for companies to understand all the regulations that affect them. In order to keep track of the requirements, it is important to identify the organizations responsible for approving and modifying regulations, because they will be a key part of the compliance control process. There are 3 types of bodies:

1. *National Bodies*: Each country has its own regulatory bodies that set regulations for compliance across the supply chain e.g., US-FDA, European Commission, Japanese Ministry of Health & Welfare.

2. *International Bodies*: These organizations help to homogenize the different regulations across countries e.g., WHO, WCO and ICH

3. *Internal company sources*: Most companies set rules to organize their own operations, so the company and its rules are itself a source of compliance regulations e.g., Standard Operating Procedures (SOP's)

Compliance Areas

Based on the interviews with various subject matter experts within the supply chain of our sponsor company, we have identified and then grouped and defined the following 12 areas of compliance that affect the supply chain in the pharmaceutical industry.
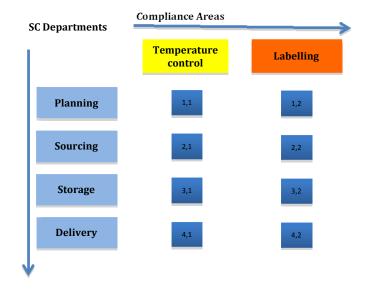
	Compliance Areas
1	Legal
2	Ethics
3	Safety
4	Temperature Control
5	Labeling
6	Serialization
7	Export Control
8	Trade
9	Storage, Handling and Transport
10	Sustainability
11	Electronic Data and Communication
12	Security

Compliance Measurement Model: Matrix of Non-compliance

Our model is based on gathering information about detected non-compliance incidents, quantifying the negative impact of each such incident, determining the department within the supply chain responsible for the incident and the compliance areas affected by it. This information is organized into a matrix of non-compliance incidents. In this matrix, each row represents a department of the company and each column represents a compliance area that affects the part of the company under the scope of the model. The model is based on populating each cell of the matrix with the sum of the value (score) of the negative impact of each non-compliance incident for each compliance area. The score in each cell of the matrix takes into account all the incidents detected by the company using all the information available including the internal and external audit findings. A representative example of the matrix with 2 compliance areas is shown below:

The compliance score in each cell is the summation of the product of the number of incidents of non-compliance and the criticality of each such incident.

Compliance Score $=\sum_{i=0}^{i=I} n_i * C_i$, such that,

I = set of all possible incidents
n_i = number of incidents of type i
C_i = criticality of incident of type i

Mapping compliance and criticality concept

Each non-compliance incident must be recorded and mapped to a particular area of compliance and also to a specific department within the part of the company using the system. For example, if there is a temperature excursion during the transportation process of a product from a factory to a warehouse the mapping of this is reflected as a count of 1 in the temperature control compliance area within the transportation department. The procedure for recording non-compliance incidents is important for the measurement concept and is such that it is allocates the responsibility of non-compliance to the appropriate department in the supply chain. Investigations must be conducted when the root cause of the incident is not clear.

The appropriate criticality rating is given for each type of discrepancy that can occur within each area of compliance. The main drivers of the criticality are: financial impact, impact on people/patients safety, impact on reputation and whether the incident is detected in-house or by an external stakeholder (customers, suppliers, regulatory bodies and so forth). Based on to the characteristics of the company and its perception of risk, values must be assigned for each impact driver. For each incident, these values will be assigned to the four drivers and will be combined to calculate the final criticality score. Each incident can have low, medium or high impact and criticality values as follows:

IMPACT	VALUE
None	1
Low	10
High	100

Also, if an incident is detected by an external agency (regulatory body or channel partner) it will be twice the criticality than if it were detected in-house. Hence, the criticality score for in-house will be 1 whereas for external agency will be 2, e.g., a hospital reports that a product supplied has the wrong dosage information on the label. A non-compliance incident has occurred and the criticality rating for this incident will be calculated as follows:

IMPACT	CATEGORY	VALUE
A- Effect on patients	High	100
B- Economic impact	Medium	10
C- Impact on company's reputation	Low	10
D- Detection	External	2

Criticality score: (100 x 10 x 10 x 2) = 20,000

This flexible definition of the criticality concept allows for inclusion and evaluation of all types of incidents. Moreover it helps to deal with the great variety of potential incidents that the company has to face. For instance, the impact of each incident will change depending on parameters such as the product or products affected by the incident and the department where in the incident occurred. It also depends on the preparedness of the company to deal with compliance. For instance, if a company has in place good corrective processes, when a non-compliance incident occurs, it can react quickly and mitigate the impact of such an incident. Hence the criticality rating being user defined, the user will assign a low criticality to such an incident.

The criticality criteria are sensitive and should be defined carefully since for instance if a low criticality score is assigned to a high impact incident then the measurement model will provide a wrong picture of the compliance.

Compliance KPI and Scorecard

Compliance KPI is based on tracking all the incidents, assigning the criticality and feeding this information into our proposed measurement system to generate the KPI for compliance. All the incidents during a defined period of measurement say one month will be recorded. First, we analyze only the count of non-compliance incidents.

	Electronic data & Communications	Ethics	Export control	Labeling	Legal	Total
Plan	0	0	0	0	1	1
Source	0	1	0	0	0	1
Make	0	0	0	0	0	0
Deliver	1	0	3	1	0	5
Total	**1**	**1**	**3**	**1**	**1**	**7**

Next, we add the criticality rating and calculate the compliance score for the entire matrix.

	Electronic data & Communications	Ethics	Export control	Labeling	Legal	Total
Plan	**0**	**0**	**0**	**0**	**2000**	**2000**
Source	**0**	**10**	**0**	**0**	**0**	**10**
Make	**0**	**0**	**0**	**0**	**0**	**0**
Deliver	**200**	**0**	**24000**	**20000**	**0**	**44200**
Total	**200**	**10**	**24000**	**20000**	**2000**	**46210**

According to the criticality concept defined, the KPIvalue measures the effect of the non-compliance incidents on the organization The global compliance KPI would be the sum of the criticality of all the incidents during the control period. For this case, the value of the KPI is: 46210.

The higher the score the worse is the performance of the company. Therefore the ideal or best compliance score would be zero. To provide more meaning to this compliance KPI value, it would be advisable to use a range of allowable values for each area of compliance. The range of values for the KPI should be chosen carefully by each user of this model. For example, the company should decide this range depending on its own risk evaluation and the level of stringency desired.

With this, we will be able to generate a scorecard that displays how compliant each department is within the supply chain and also display the performance of the company with respect to all the identified areas of compliance. The last step will be defining alarms in the system. For example, if the value of a particular compliance KPI goes outside the allowable range (or over the threshold limit), it should be color coded with Red, indicating high danger. Another powerful tool as shown below is a trend indicator that shows how the compliance score for an area has changed over previous time periods (increase, decrease or no change).

COMPLIANCE PERFORMANCE KPI
46,210

FUNCTIONS	
Plan	2,000 (2,000)
Deliver	44,200 (3,419)
Make	0 (70)
Source	10 (1,005)

COMPLIANCE AREAS				
Electronics Data and Communication	200 (10)	=	↑	↓
Ethics	10 (1)	↓	↓	↓
Labeling	44,000 (20,000)	↑	↑	=
Legal	2000 (70)	=	=	=

Continuous Improvement Process

Compliance requirements change over time, so the system must be flexible to adapt. The analysis of the database generated of non-compliance incidents is a tool for the company to detect areas of improvement. Also, the evolution over time of the compliance performance of each department will help to detect to identify problems and plan corrective or preventive

action. As the system offers a KPI for measuring compliance of each department, this will help to set clear goals and targets for the company.

Steps necessary for implementing the model

To implement the proposed measurement model, the following tasks need to be performed:

1. *Scope definition*

2. *Procedure definition* – The procedure defining the procedure for recording compliance incidents, i.e., who, where and how will the information be recorded.

3. *Database and Interface creation* - An interface to help users introduce information should be created, ensuring consistency of the data by defining controls within the interface.

4. *Information and training*- All stakeholders using the system should be trained

5. *Review of parameters of the system* – The criticality criteria may need to change depending on the risk assessment and changing regulatory requirements.

Conclusion

The proposed methodology can be applied to a whole company or parts of it for compliance control and to serve as a central control tower. It provides a clear picture of how well each area of the company is performing and identifies areas for improvement. It also enables the company to monitor the effect of improvement actions.

The limitations of the measurement model are that it does not provide a predictive tool on compliance nor can it predict sudden disruptions to the supply chain as a result of non-compliance issues. Based on historical performance, the tool serves as an indicator of areas with a higher likelihood of non-compliance if no corrective action has been taken.

Our results show that our model can be successfully applied to the supply chain to provide a quantitative measure for the compliance performance in each compliance area. The system is very flexible and can be modified to include new regulations and risks that affect the company.