Quality Inadequacies in Supply Chain Management of Pharmaceutical Products - A Preliminary Study in India

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Abstract

Quality in pharmaceutical products is a quintessential requisite. Indeed, the difference between medicine and poison is that of quality/quantity and not of kind. Same medication can cure a patient or kill him/her depending upon the quality levels inherent into it. Quality therefore is ardently built in the products and is sought to be maintained throughout their shelf-life by the regulatory authorities as well as the marketers themselves. Good manufacturing practices have evolved exceptionally well in the pharmaceutical companies due to regulatory pressures and technological developments. The human integrity also has improved in this context. Yet the question remains whether or not quality is preserved with the same commitment during the supply chain of pharmaceutical products. This study was undertaken to measure the good distribution practices of pharmaceutical products in India. Three variables namely temperature control, humidity control and microbiological control were selected and the awareness, knowledge, willingness, availability of equipment/facilities, availability of power to run the facilities and log book of records about these variables was measured. The results clearly establish that existing mechanisms are grossly inadequate in the existing supply chain of pharmaceutical products.

Key Words, Quality, Pharmaceutical Products, Supply Chain and Distribution Practices

JEL Classification : C 19, G13, G 14
1. Introduction

The level of quality has emerged as fundamental to competing in today’s highly competitive world. Quality indeed is the key non-price consideration that affects the purchase decision of customers across the markets and geography (Anonymous (2013)). Quality in pharmaceutical products is a quintessential requisite. Indeed the difference between medicine and poison is that of quality/quantity and not of kind. Same medication can cure a patient or kill him/her depending upon the quality levels inherent into it. Quality therefore is ardently built in the products and is sought to be maintained throughout their shelf-life by the regulatory authorities as well as the marketers themselves.

There has been an intense and continuous awareness for the significance of the quality of the pharmaceutical products (Woodcock, 2004). Sheer quantum of literature on this issue establishes the special nature of the product-customer relationship of medicine and patients and it is the most regulated market globally (Woodcock, 2004). The practices evolved by the manufacturers and the regulatory bodies to ensure better quality are commonly known as Good manufacturing practices (GMP). These principles have been pioneered by WHO and US FDA.

Good manufacturing practices (GMP) is a part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. The effective implementation of GMP entails deep knowledge about the different components of GMP that should be incorporated from the inception of the manufacturing building and product development till the production (Kumar N et al (2015a) and (2015c). Quality by Design (QbD) that prevails now for pharmaceutical products, the focus is on inbuilt quality instead of inspected quality (Roy et al., 2012)

Strength of a chain lies in its weakest link. This adage stands true for pharmaceutical markets too. Whereas focus on quality of pharmaceutical products has primarily being on the manufacturing arena, it has remained sketchy once the drugs are outside the factory gates and are handled by people not conversant with quality principles, are ill equipped and perhaps lack the will to follow those norms. Good distribution practices (GDP) have emerged much later and are still being debated, discussed and developed. This discrepancy in manufacturing and distribution phases needs to be identified measured and removed to ensure the well being of health care sector and the society as a whole. It needs no emphasis that quality of pharmaceutical products is affected by environmental conditions encountered during transport, storage and use, and length of time between manufacture and usage (Troy, D.B. 2006).
As per WHO, Good Distribution Practices (GDP) is a part of quality assurance which ensures that a pharmaceutical product is maintained throughout all stages of the supply chain from the site of manufacturer to the pharmacy or person authorized or entitled to supply medicinal products to the public. Are the GDP norms as evolved as the GMP norms and are being implemented with the same vigor is an important question that needs to be explored in-depth.

India being a major global producer and consumer is important in this respect. There are gaps in quality approaches of Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) here also. Exploratory studies have been conducted in India that confirms that GDP remains less evolved in comparison to GMP norms in India also ((Kumar N et al (2015b) and (2015d). The pharmaceutical qualities have intense focus during manufacturing operations which depend upon scientific tools. GMP is driven by pharmaceutical scientists, whereas GDP is led by supply chain managers. The understanding of manufacturing managers and distribution managers about quality largely differ due to educational background of personnel deployed in GMP and GDP ((Kumar N et al (2016a) and (2016b), K. Nirmal, Jha A. (2016c)

Evolving trends in this respect include responsibility for cold chain management to reside with the manufacturer; enhanced oversight, management, and control of environmental conditions across the entire supply chain (from manufacturer to consumer/patient) and Increased importance of temperature control and monitoring to mitigate and identify risks and heightened priority of patient safety (Bishara, R. H. (2006))

Issue is significant as at times such deterioration may result to toxicity of the drug substance (Carter, S.J. 1986; Martins, A. et al 1983).

This study was undertaken to measure the level of differences in GMP and GDP of pharmaceutical products in India.

2. Methodology

The methodology followed has been empirical in nature. The study design is exploratory, descriptive and analytical.

The objective of the study is to find if significant difference exists in the manufacturing and distribution environment of pharmaceutical formulations in India. The Null Hypothesis accordingly was stated as no significant difference exists in the manufacturing and distribution environment of pharmaceutical formulations in India.

The variables for the study were identified through an exploratory study that involved conducting unstructured interview with drug regulatory authorities and marketing experts from the pharmaceutical industry. As the study is preliminary in nature, only three most relevant variables namely temperature (Given that pharmaceuticals tend to be temperature
sensitive, the cold chain has become an increasingly important component of the overall pharmaceutical supply chain (Anonymous, 2003, Lucas, T. I., Bhishara, R. H., and Seevers, R. H (2004)), humidity and microbial presence were focused upon. Awareness, knowledge, willingness, availability of appropriate equipment, continuous availability of power to run the equipment and maintenance of historical data of these variables included in the study.

The exploratory study was followed by a survey for collecting data. The respondents once again have been drug regulatory authorities and marketing experts from the pharmaceutical industry in India. In all data was collected from 127 respondents and of which 7 were discarded for being incomplete. Of these 37 were drug regulatory authorities and 83 were marketing experts from the pharmaceutical industry – mainly regional and zonal managers. Their belief regarding the awareness, knowledge, willingness, availability of appropriate equipment, continuous availability of power to run the equipment and maintenance of historical data regarding temperature, humidity and microbial control in manufacturing and distribution environment was measured on a continuous scale of 1 to 10 with 1 being lowest and 10 signifying highest value.

The data was found to follow normal distribution as kurtosis and skewness were within ±1. Significance of differences if any of all the variables in manufacturing and distribution was measured using independent sample t-test. If the calculated t-value was found to be more than the tabulated t-value (1.96 at 95% CL) the null hypothesis was rejected, else it was accepted. Confirmation for this has been derived from the corresponding significance values. If it is found to be above 0.049 the null hypothesis is rejected else it is accepted. Significance values below 0.00099 were considered as zero.

3. Results and Discussion

Result of the study has been summarized in table-1. Discussion on the results is as follows:

a. Awareness of Temperature Norms: From the table-1 we find that the mean of the held belief on awareness of temperature norms awareness in manufacturing and distribution environment are 9.32 and 7.52 respectively and the standard deviation of the same are 0.708 and 1.971 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that awareness of temperature norms are higher amongst personnel working in manufacturing premise than those working in distribution of pharmaceutical products. As the corresponding t-value is 65.5, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

b. Knowledge about Temperature Norms: From the table-1 we find that the mean of the held belief on knowledge of temperature norms in manufacturing and distribution
environment are 8.932 and 5.64 respectively and the standard deviation of the same are 1.065 and 2.136 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that knowledge of temperature norms are higher amongst personnel working in manufacturing premise than those working in distribution of pharmaceutical products. As the corresponding t-value is 28.43, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

Table 1

<table>
<thead>
<tr>
<th>S.N.</th>
<th>Variables</th>
<th>Mean</th>
<th>Std. Dev</th>
<th>GMP</th>
<th>GDP</th>
<th>t-value</th>
<th>Signi.</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Awareness of temperature norms</td>
<td>9.32</td>
<td>7.52</td>
<td>0.708</td>
<td>1.971</td>
<td>65.5</td>
<td>0</td>
</tr>
<tr>
<td>b.</td>
<td>Knowledge about temperature norms</td>
<td>8.93</td>
<td>5.64</td>
<td>1.065</td>
<td>2.136</td>
<td>28.43</td>
<td>0</td>
</tr>
<tr>
<td>c.</td>
<td>Willingness to enforce temperature norms</td>
<td>8.8</td>
<td>5.57</td>
<td>1.112</td>
<td>2.204</td>
<td>33.46</td>
<td>0</td>
</tr>
<tr>
<td>d.</td>
<td>Availability of equipment/accessories to enforce temperature norms</td>
<td>8.76</td>
<td>5.42</td>
<td>1.101</td>
<td>1.973</td>
<td>25.55</td>
<td>0</td>
</tr>
<tr>
<td>e.</td>
<td>Continuous Availability of power to run equipment to enforce temperature norms</td>
<td>8.93</td>
<td>5.37</td>
<td>1.065</td>
<td>1.821</td>
<td>21.3</td>
<td>0</td>
</tr>
<tr>
<td>f.</td>
<td>Maintenance of historical data of temperatures maintained on continuous basis</td>
<td>8.91</td>
<td>1</td>
<td>1.074</td>
<td>0</td>
<td>75.16</td>
<td>0</td>
</tr>
<tr>
<td>g.</td>
<td>Awareness of humidity norms</td>
<td>9.32</td>
<td>4.23</td>
<td>0.708</td>
<td>2.172</td>
<td>57.66</td>
<td>0</td>
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<tr>
<td>h.</td>
<td>Knowledge about Awareness of humidity norms</td>
<td>8.75</td>
<td>3.57</td>
<td>0.967</td>
<td>1.641</td>
<td>17.55</td>
<td>0</td>
</tr>
<tr>
<td>i.</td>
<td>Willingness to enforce humidity norms</td>
<td>8.69</td>
<td>4.48</td>
<td>0.961</td>
<td>1.759</td>
<td>27.75</td>
<td>0</td>
</tr>
<tr>
<td>j.</td>
<td>Availability of equipment/accessories to enforce humidity norms</td>
<td>8.73</td>
<td>4.57</td>
<td>0.949</td>
<td>1.639</td>
<td>24.78</td>
<td>0</td>
</tr>
<tr>
<td>k.</td>
<td>Continuous Availability of power to run equipment to enforce humidity norms</td>
<td>8.93</td>
<td>5.41</td>
<td>1.065</td>
<td>1.821</td>
<td>21.3</td>
<td>0</td>
</tr>
<tr>
<td>l.</td>
<td>Maintenance of historical data of humidity maintained on continuous basis</td>
<td>8.8</td>
<td>1</td>
<td>1.025</td>
<td>1</td>
<td>74.06</td>
<td>0</td>
</tr>
<tr>
<td>m.</td>
<td>Awareness of microbial control norms</td>
<td>9.3</td>
<td>2.41</td>
<td>0.978</td>
<td>1.831</td>
<td>27.63</td>
<td>0</td>
</tr>
<tr>
<td>n.</td>
<td>Knowledge about microbial control norms</td>
<td>9.21</td>
<td>2.32</td>
<td>0.708</td>
<td>1.628</td>
<td>44</td>
<td>0</td>
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<tr>
<td>o.</td>
<td>Willingness to enforce microbial control norms</td>
<td>8.67</td>
<td>4.02</td>
<td>0.967</td>
<td>1.47</td>
<td>17.82</td>
<td>0</td>
</tr>
<tr>
<td>p.</td>
<td>Availability of equipment/accessories to enforce temperature norms</td>
<td>8.55</td>
<td>2.39</td>
<td>0.846</td>
<td>1.667</td>
<td>42.38</td>
<td>0</td>
</tr>
<tr>
<td>q.</td>
<td>Continuous Availability of power to run equipment to enforce temperature norms</td>
<td>8.93</td>
<td>4.64</td>
<td>1.072</td>
<td>1.788</td>
<td>21.7</td>
<td>0</td>
</tr>
<tr>
<td>r.</td>
<td>Maintenance of historical data of temperatures maintained on continuous basis</td>
<td>8.61</td>
<td>1</td>
<td>1.017</td>
<td>0</td>
<td>92.71</td>
<td>0</td>
</tr>
</tbody>
</table>
c. **Willingness to enforce Temperature Norms:** From the table-1 we find that the mean of the held belief on Willingness to enforce temperature norms in manufacturing and distribution environment are 8.88 and 5.57 respectively and the standard deviation of the same are 1.112 and 2.204 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that Willingness to enforce temperature norms are higher amongst personnel working in manufacturing premise than those working in distribution of pharmaceutical products. As the corresponding t-value is 33.46, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

d. **Availability of Equipment/Accessories to enforce Temperature Norms:** From the table-1 we find that the mean of the held belief on availability of equipment/accessories to enforce temperature norms in manufacturing and distribution environment are 8.76 and 5.42 respectively and the standard deviation of the same are 1.101 and 1.973 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that availability of equipment/accessories to enforce temperature norms are better in manufacturing premise than those in distribution area of pharmaceutical products. As the corresponding t-value is 25.55, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

e. **Continuous Availability of Power to run equipment to enforce Temperature Norms:** From the table-1 we find that the mean of the held belief on Continuous Availability of power to run equipment to enforce temperature norms in manufacturing and distribution environment are 8.93 and 5.37 respectively and the standard deviation of the same are 1.065 and 1.821 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that continuous availability of power to run equipment to enforce temperature norms are higher in manufacturing premise than those in distribution area of pharmaceutical products. As the corresponding t-value is 21.3, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

f. **Maintenance of Historical Data of Temperatures maintained on continuous basis:** From the table-1 we find that the mean of the held belief on Maintenance of historical data of temperatures maintained on continuous basis in manufacturing and distribution environment are 8.91 and 1 respectively and the standard deviation of the same are 1.074 and 0 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that maintenance of historical data of temperatures
maintained on continuous basis are higher in manufacturing premise than those in distribution area of pharmaceutical products. As the corresponding t-value is 75.16, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

g. **Awareness of Humidity Norms:** From the table-1 we find that the mean of the held belief on awareness of humidity norms in manufacturing and distribution environment are 9.32 and 4.23 respectively and the standard deviation of the same are 0.708 and 2.172 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that awareness of humidity norms are higher amongst personnel working in manufacturing premise than those working in distribution of pharmaceutical products. As the corresponding t-value is 57.66, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

h. **Knowledge about Humidity Norms:** From the table-1 we find that the mean of the held belief on knowledge about Humidity norms in manufacturing and distribution environment are 8.75 and 3.57 respectively and the standard deviation of the same are 0.967 and 1.641 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that knowledge about Humidity norms are higher amongst personnel working in manufacturing premise than those working in distribution of pharmaceutical products. As the corresponding t-value is 17.55, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

i. **Willingness to enforce Humidity Norms:** From the table-1 we find that the mean of the held belief on willingness to enforce Humidity norms in manufacturing and distribution environment are 8.69 and 4.48 respectively and the standard deviation of the same are 0.961 and 1.759 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that willingness to enforce Humidity norms are higher amongst personnel working in manufacturing premise than those working in distribution of pharmaceutical products. As the corresponding t-value is 27.75, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

j. **Availability of Equipment/Accessories to enforce Humidity Norms:** From the table-1 we find that the mean of the held belief on availability of equipment/accessories to enforce Humidity norms in manufacturing and distribution environment are 8.73 and 4.57 respectively and the standard deviation of the same are 0.949 and 1.641 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that availability of equipment/accessories to enforce Humidity norms
are in better in manufacturing premise than those in distribution area of pharmaceutical products. As the corresponding t-value is 24.78, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

**k. Continuous Availability of Power to run equipment to enforce Humidity Norms:**
From the table-1 we find that the mean of the held belief on continuous availability of power to run equipment to enforce Humidity norms in manufacturing and distribution environment are 8.93 and 5.41 respectively and the standard deviation of the same are 1.065 and 1.821 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that continuous availability of power to run equipment to enforce humidity norms are better in manufacturing premise than those in distribution area of pharmaceutical products. As the corresponding t-value is 21.3, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

**l. Maintenance of Historical Data of Humidity maintained on continuous basis:**
From the table-1 we find that the mean of the held belief on maintenance of historical data of Humidity maintained on continuous basis in manufacturing and distribution environment are 8.8 and 1 respectively and the standard deviation of the same are 1.025 and 0 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that maintenance of historical data of humidity maintained on continuous basis are better in manufacturing premise than those in distribution area of pharmaceutical products. As the corresponding t-value is 74.06, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

**m. Awareness of Microbial Control Norms:**
From the table-1 we find that the mean of the held belief on awareness of microbial control norms in manufacturing and distribution environment are 9.3 and 2.41 respectively and the standard deviation of the same are 0.978 and 1.831 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that awareness of microbial control norms are higher amongst personnel working in manufacturing premise than those working in distribution of pharmaceutical products. As the corresponding t-value is 27.63, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

**n. Knowledge about Microbial Control Norms:**
From the table-1 we find that the mean of the held belief on knowledge about microbial control norms in manufacturing and distribution environment are 9.21 and 2.32 respectively and the standard deviation of the same are 0.708 and 1.628 respectively. The mean for manufacturing environment is found to
be higher than that of distribution environment implying that knowledge about microbial control norms are higher amongst personnel working in manufacturing premise than those working in distribution of pharmaceutical products. As the corresponding t-value is 44, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

- **Willingness to enforce Microbial Control Norms:** From the table-1 we find that the mean of the held belief on willingness to enforce microbial control norms in manufacturing and distribution environment are 8.67 and 4.02 respectively and the standard deviation of the same are 0.967 and 1.47 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that willingness to enforce microbial control norms are higher amongst personnel working in manufacturing premise than those working in distribution of pharmaceutical products. As the corresponding t-value is 17.82, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

- **Availability of Equipment/Accessories to enforce Microbial Control Norms:** From the table-1 we find that the mean of the held belief on availability of equipment/accessories to enforce microbial control norms in manufacturing and distribution environment are 8.55 and 2.39 respectively and the standard deviation of the same are 0.846 and 1.667 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that availability of equipment/accessories to enforce microbial control norms better in manufacturing premise than those in distribution area of pharmaceutical products. As the corresponding t-value is 42.38, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

- **Continuous Availability of Power to run equipment to enforce Microbial Control Norms:** From the table-1 we find that the mean of the held belief on continuous availability of power to run equipment to enforce microbial control norms awareness in manufacturing and distribution environment are 9.32 and 2.39 respectively and the standard deviation of the same are 0.708 and 1.971 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that continuous availability of power to run equipment to enforce microbial control norms are better in manufacturing premise than in distribution area of pharmaceutical products. As the corresponding t-value is 51.5, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

- **Maintenance of Historical Data of Microbial Control maintained on continuous basis:** From the table-1 we find that the mean of the held belief on maintenance of historical data of microbial control maintained on continuous basis in manufacturing and distribution
environment are 8.61 and 1 respectively and the standard deviation of the same are 1.017 and 0 respectively. The mean for manufacturing environment is found to be higher than that of distribution environment implying that maintenance of historical data of microbial control maintained on continuous basis are better in manufacturing premise than in distribution area of pharmaceutical products. As the corresponding t-value is 92.71, much higher than the tabulated t-value, it is concluded that significant differences exist in this respect. This is further confirmed by the corresponding significance value which is zero.

4. Conclusion

The results emphatically bring out the stark differences existing between GMP and GDP status in the Indian context. Our null hypothesis that no significant difference exists in the manufacturing and distribution environment of pharmaceutical formulations in India stands rejected as for all 18 variables under the study we find that significant differences exist at GMP and GDP levels as is evinced by the calculated t-value being higher than the tabulated t-value and the corresponding significance levels being almost zero and below 0.5. This reflects a massive fault-line in the pharmaceutical market and needs to be understood in greater details. A more in-depth study needs to be undertaken measuring the actual practices and not merely the beliefs held by regulatory authorities and pharmaceutical marketing experts. This is essential to bring GDP at par with GMP and to design a frame-work to integrate these two practices to remove the fault-lines as identified through this research. It is reported that as many as Thirty-six percent of all critical and major deficiencies recorded by the Medicines and Healthcare Products Regulatory Agency’s Good Distribution Practice (GDP) inspectors during 2003/2004 related to the control and monitoring of storage and transportation temperatures (Taylor, J., 2005). In view of this a quality management system (QMS) and risk assessment process become essential (Bishara, R. H., 2005).

Quality assurance during supply chain become even more critical when the pharmaceutical products need to be shipped to far away locations. It has been suggested that each shipment between countries and within areas of large geographical area should be treated as unique in terms of the range of temperatures the goods may experience (Taylor, J.,(2005), Antonetti, T. (2005)). This may get further more complicated as temperatures during transportation have been recorded as high as 60°C (Okeke, C. C., et al (1997), Okeke, C. C., et al (1998), Okeke, C. C., et al (1999), Okeke, C. C., et al (2000).

Other researchers too arrive at similar findings and hence uniform use of good cold chain management practices (GCCMP) needs to be evolved and which will be valuable for all the stake-holders in handling, storing and distributing environmentally sensitive pharmaceuticals. Reddy, C et al (2012), Xie, T., & Taylor, L. S. (2017), Ong, K. Y., Lim, W. C., Ooi, S. M., Loh, Z. H., Kong, M. C., Chan, L. W., & Heng, P. W. S. (2017), Mehta, P., & Bhayani, D.
The study has far reaching implications for the pharmaceutical industry, the supply chain managers and the regulatory authorities. Pharmaceutical industry must assume the responsibility for Good Distribution practices as it concerns them the most, they have the resources and knowhow and also because primary accountability lies with them. Supply chain managers need to develop awareness, knowledge and capability to address quality issues during the supply chain as they too are accountable in this respect. Regulatory authoritative must evolve GDP norms in consultation with pharmaceutical industries and implement them with the same rigor as they do for GMP.

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