

Suitability and adaptability of Lean manufacturing in Indian pharmaceutical sector

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Abstract. Today's manufacturing companies are measured by how fast they meet the customer and user requirements, how responsive they are to the changing market demands and how capable they are in producing good quality products and supply them at optimal cost. Lean manufacturing is a manufacturing concept which has demonstrated results of successful implementation especially in discrete manufacturing companies. This paper presents a case study of an Indian pharmaceutical firm to outline the scope of a successful lean based manufacturing strategy implementation in this sector. Analytic Network Process (ANP) is applied to measure and rate the present leanness of a pharmaceutical firm. A multi-level model along with the questionnaires developed by the authors was used for the initial assessment. The approach helped to assess the current leanness level. Since inhibitors for lean interventions were identified the authors studied them and established the correlation among different parameters using Interpretive structural modelling (ISM) approach. The model was also validated through MICMAC analysis. The results of ANP, ISM and MICMAC showed the root causes for the unsuccessful implementation of lean in the firm. They were the lack of a responsive supply chain and the excessive Quality regulations and enforcements by the Authorities. This study gives guidelines to companies planning for lean implementation to deploy methods to remove the inhibitors of lean at the initial stages. Identifying the barriers can guide managers in developing strategies to eliminate them at the inception. This paper recommends supplier qualification programmes which managers can use to get the suppliers be part of their extended lean family. Through this supplier's involvement can be improved with an aim of improving the product lead time.

1. Introduction

The philosophy of Lean management was pioneered by Toyota Motor Company in the 1950's. Competing with US automakers they realized that to be profitable they should manufacture high quality products with very short lead times. This management philosophy focuses on waste elimination in all business processes. The authors Womack *et al.*, (1990) claim that lean methods make the companies specify value, make a best sequence of value creation activities, run these activities with no interruptions whenever there is a request and perform them continuously aiming for perfection. The primary interest in doing this research is to investigate whether pharmaceutical industries feel that Lean is a useful technique for them. A detailed study of pharmaceutical sector becomes indispensable to understand the scope of lean implementation. From literature review we realize that process industry which includes chemical, pharmaceutical, food and beverage, rubber, paper, steel, plastics, textile, and cement industries have not utilized lean techniques to the extent possible. [1] Applied lean tools in a steel plant to bring the lead time down by 50 % and production cost by 8 %. [3] in a case study in a chemical plant showed lead time reduction by 25 % and inventory reduction through JIT In textile industry. [2] implemented SMED and could bring down



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the setup time. Kanban pull production and levelling to be used once the product becomes discrete during the last stages of production in food and chemical industry [3]. According to [4] for lean to be implemented in a cGMP environment it should be done in an equal partnership [5] explained how lean sigma can be successfully implemented in pharmaceutical sector. They mention that structured change management programmes are essential for sustained results of lean sigma implementation. [6] have showed positive results like reduced lead time, throughput time, WIP and walkthrough time. in a pharmaceutical company.

The pharmaceutical firm selected as a case for our study is located in South India. It is a WHO-GMP certified medicine manufacturing facility with around 30 years of experience with emphasis on quality... The data for our study was collected from twelve senior level Managers with immense experience in the firm, working in Production, Quality and Logistics department. All the forty products manufactured go through four major processes which are Dispensing, Blending, Filling, and Packing. Based on the extensive literature review we developed a framework which includes all the elements of lean pillars and lean tools. The model developed should help to identify the strong lean practices followed and also should hint about the neglected ones which company should address so as to increase the leanness level of the firm.

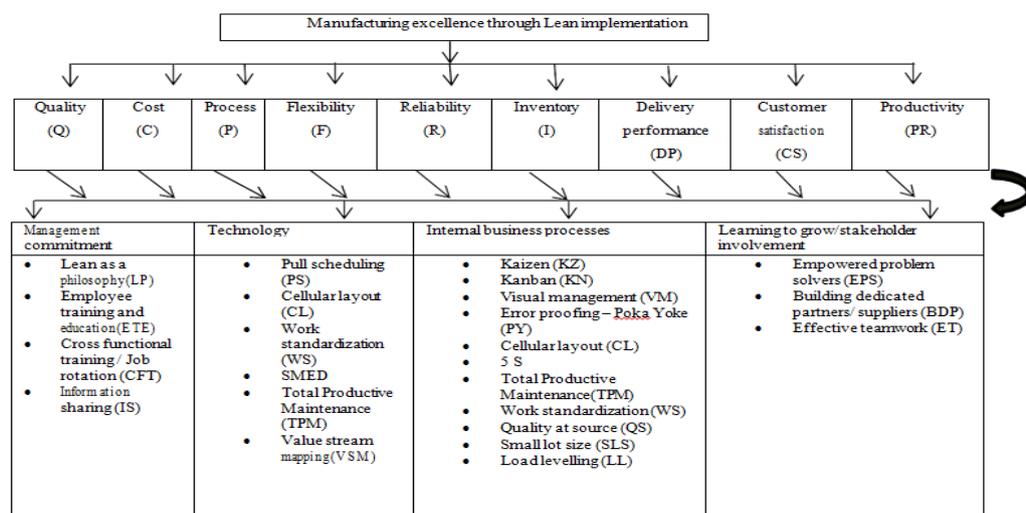


Figure 1. Model developed to assess the leanness of the firm

The model, the selection criteria, main clusters and their attributes were discussed with the managers. It was noticed that many factors in the model were interdependent. For example, improving the product quality can yield better customer satisfaction. Investment in process equipment can better the process. This in turn will reduce defects and improve quality. Reduced inventory can result in reduced manufacturing cost. Similarly delivery performance affects the customer satisfaction. This is at the top level of the model. Similar inter dependencies can be seen at the bottom levels as well. For example, effective teamwork in the cluster “Learning to grow” can happen only with a proper committed management which is the first cluster. Team work is vital in the second cluster as well. To practice Kanban (Third cluster) pull scheduling (Second cluster) is a required criteria.

Since managerial judgments, experience and knowledge are directly modelled, a tool which can solve strategic decision making problems is required. It should also account for the interdependencies among the main objective, nine selection criteria, four main clusters and twenty four criteria in all the four clusters. For this purpose we use Analytic Network Process (ANP) method for understanding the inter relationships and also to get the priorities for each of the clusters in relation to the top most objective, at the present functional level of the firm.

2. ANP methodology and results

ANP, developed by [6] considers the interdependencies among and between the various levels of top objective, criteria, clusters and its various elements. This method involves representing the elements in a hierarchical structure but allows for the dependencies among all the levels regardless of this hierarchy. ANP is advanced AHP which was developed by [6]. [7] used ANP to select an appropriate concept in attaining product sustainability. Lean manufacturing system was selected as the best strategy to implement in the operations department of a valve manufacturing firm by [9] and the method they used was ANP.

The method of ANP is applied to the conceptual model (Figure 1) developed to understand the level of leanness of the firm and its measurement. The overall organizational objective is to excel in manufacturing their products. There are nine selection criteria considered significant while trying to do so. However the list can be modified to suit any organization based on their requirements. The lower level in the hierarchy is the main four categories which are the areas where leanness is measured. Each cluster has own elements which are the lean enablers. It is clear from the model that these criteria are

interdependent. This multifaceted dimension necessitates the use of a multi decision modelling technique for which Analytic Network Process (ANP) modelling method is preferred.

Construction of ANP model

- 1) Identify the organizational objective which needs to be catered to by being lean
- 2) Identify the criteria for selection
- 3) Develop a hierarchical structure with the main objective at the top, selection criteria at the second, main clusters where leanness is measured at third level and at the next level include the sub-attributes for each cluster - the lean enablers.

Calculation of rankings

- Make pair-wise comparison matrices to compare within each hierarchical level, to find the contribution of each criterion to the immediate upper level, to find the relative contribution of clusters to the higher levels. This was done by the experts in the firm once a consensus was reached among the managers on the weightages to be assigned to each factor when compared with another factor.
- Calculate the local priorities for selection criteria and the clusters
- Using those find the overall priorities for each cluster
- Use these priorities to rank the clusters.
- Choose the cluster with the highest priority.

ANP methodology calculations are quite tedious for this complex structure with one objective, nine criteria, four clusters and twenty four attributes as it involves determining interrelationships between all the factors in the model. Hence modelling the elements in the hierarchical structure, the pairwise comparison results given by the experts in the questionnaire survey and its result synthesis was done using Super decisions software. The final result analysis (Table 2) gives the current leanness level with respect to each of the category and makes the management aware of the scope for improvement.

2.1. Data collection using Contact survey

Questionnaires were distributed to the managers to get their input in a pair wise comparison mode. Since ANP methodology requires input in a matrix based comparison mode, the questionnaires were designed to gather inputs on a comparison scale (Table 1) and the comparison was made among

- Each of the nine selection criteria with respect to the main top level objective
- Each main four clusters with respect to the main top level objective
- The four main clusters with respect to each of the nine selection criteria
- The sub criteria factors in each of the four clusters with respect to the main cluster.
- Sub criteria factors in each main four categories with respect to each of the selection criteria factor. (For example pairwise comparison of Lean as philosophy , Employee training, cross functional training and information sharing with respect to each selection criteria Quality, cost, process etc.)

The pairwise comparison scale of 1 – 9 was used to rate the importance of each element over another. The table 1 below explains how the numbers were used. Here i correspond to the row element and j the column element. When comparing i to j, if i is 3 compared to j, then j is 1/3 when compared to i. (Reciprocals)

Table 1. Explanation of Numeric Values in Scale

Intensity of relative importance	Definition
1	Two elements in i and j contribute equally
3	i is favoured over j
5	i is strongly favoured over j
7	i is strongly favoured over j and dominance is demonstrated in practice
9	i favoured over j with the maximum possible confirmation
2,4, 6,8	Number in the middle of two adjacent judgments

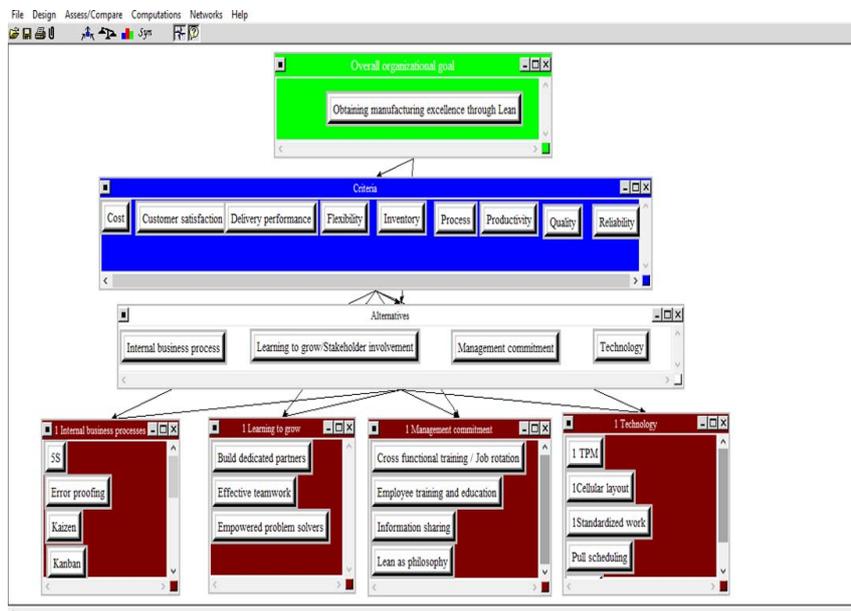


Figure 2. Model developed using Super decisions software

Table 2. Results obtained from Super decisions software

Cluster name	Normalized value	Rank
Internal business process	0.322840	1
Management commitment	0.250749	2
Technology	0.240343	3
Learning to grow / stakeholder involvement	0.186068	4

3. Interpretation of the ANP results and suggestions

The ANP results show the overall leanness of the firm is low which implies several factors exist which prevent lean to be fully implemented. Looking at the results cluster wise:

The leanness of the cluster Internal business process is 32.28%, management commitment as 25.07%, technology which is very close at 24.03% and results show the least lean area 18.60% for the cluster learning to grow/ stakeholder involvement. Knowing that the lean implementation is improper, we tried to identify the main barriers for the implementation. Our literature survey has showed several positive results of lean implementation in pharmaceutical sector. Hence we extended our study to the adaptability of lean tools to this environment.

4. Identification of barriers of lean implementation

Following the expert discussions in the firm, we wanted to perform a root cause analysis study on the Inhibitors of Lean in the firm. This is based specifically on the case under study. Hence cannot be generalized. But majority of the factors do represent the actual production related problems faced by a pharmaceutical firm in India. The main problems in lean implementation - “inhibitors” were identified and shown in Table 3.

Table 3. Lean inhibitors

Lean Inhibitors	Causes for the inhibitors
1 Pull scheduling is difficult to attain.	The process is a continuous flow type. This required batching products along the assembly line. Single piece flow is almost impractical

2	Small lot sizing is not economical	Large setup time needed. Managers were apprehensive about minimum capacity utilization in case if they
3	Load leveling (Heijunka) could not be done	Large set up time and high inventory maintained.
4	Set up time reduction not possible	Long hours of machine cleaning needed and this was enforced by the
5	Very high quality regulations strictly followed (time consuming) and standards	Required as per WHO mandates. Hence difficult to reduce the lead time below a certain minimum
6	Lead time reduction not possible	Several point quality checks, some of which are out sourced due to non-availability of testing facilities which
7	Work standards already enforced	SOP's followed which are regulated by the health authorities and hence standardization through continuous
8	Supply chain responsiveness extremely low.	Suppliers located far away. Very few suppliers and hence autonomous
9	Minimum inventory impractical	All the above reasons

4.1. Interpretive Structural Modeling (ISM)

The result of ANP showed that lean is poorly implemented in all four clusters of the model. We wanted to understand the relation among the inhibitors (nine variables as inhibitors) if it exists and also make an informed judgement about the existence of a root cause for the poor implementation using ISM methodology. [12 & 13] have studied Lean in service sector and use of ISM in knowing about the contributing factors.

4.1.1. ISM applied to the case under study. Developing Structural self-interaction matrix (SSIM) of the lean inhibitors - SSIM provides the direction of relationships among the variables (Table 4). These are developed based on the interactions with experts from industry as well as from academics. Four symbols are used to develop the relationships between variables to form the SSIM. i represents row and j represents column.

- V – Factor i will influence factor j
- A – Factor j will influence factor i
- X – Factors i and j help to attain each other
- O – Factors i and j are unrelated

Table 4. Structural self – Interaction matrix of lean Inhibitors

Lean Inhibitors	9	8	7	6	5	4	3	2	1
1	A	A	0	A	A	A	A	A	I
2	X	A	0	A	A	A	A	I	
3	X	A	V	0	A	A	I		
4	V	0	A	V	A	I			
5	V	0	V	V	I				
6	V	A	0	I					
7	V	0	I						
8	V	I							
9	I								

4.1.2. Initial reachability matrix (IRM) of lean inhibitors: Here SSIM is converted to a matrix of binary representation called IRM (Table 5). For this conversion following rules are used.

- SSIM is V for (i, j) then replace IRM by 1 and (j, i) by 0.
- SSIM is A for (i, j) then replace IRM by 0 and (j, i) by 1.
- SSIM is X for (i, j) then replace IRM by 1 and (j, i) by 1.
- SSIM is 0 for (i, j) then replace IRM by 0 and (j, i) by 0.

Table 5. Initial Reachability matrix

<i>Lean Inhibitors</i>	1	2	3	4	5	6	7	8	9
1	1	0	0	0	0	0	0	0	0
2	1	1	0	0	0	0	0	0	1
3	1	1	1	0	0	0	1	0	1
4	1	1	1	1	0	1	0	0	1
5	1	1	1	1	1	1	1	0	1
6	1	1	0	0	0	1	0	0	1
7	0	0	0	1	0	0	1	0	1
8	1	1	1	0	0	1	0	1	1
9	1	1	1	0	0	0	0	0	1

4.1.3. *Final reachability matrix* .Transitivity is checked while forming the final reachability matrix (Table 6). According to the transitivity rule, if variable 1 leads to variable 2 and variable 2 leads to variable 3, then variable 1 leads to 3. Following this rule, a final reachability matrix is formed. For instance, value in row 3 (variable 2) and column 4(variable 3) is changed to 1. This is because variable 2 is related to variable 9 (implied by value 1) and variable 9 is related to variable 3 (implied by value 1 in the initial reachability matrix) which imply variable 2 is related to variable 3. Hence changed the value in (3, 4) from 0 to 1. Similarly checked for transitivity for each cell value. (Table 7)

Table 6. Final reachability matrix

<i>Lean Inhibitors</i>	1	2	3	4	5	6	7	8	9
1	1	0	0	0	0	0	0	0	0
2	1	1	0*	0	0	0	0	0	1
3	1	1	1	0*	0	0	1	0	1
4	1	1	1	1	0	1	0*	0	1
5	1	1	1	1	1	1	1	0	1
6	1	1	0*	0	0	1	0	0	1
7	0*	0*	0*	1	0	0*	1	0	1
8	1	1	1	0	0	1	0*	1	1
9	1	1	1	0	0	0	0*	0	1

Table 7. Final reachability matrix with transitivity's included

<i>Lean Inhibitors</i>	1	2	3	4	5	6	7	8	9	Driving power
1	1	0	0	0	0	0	0	0	0	1
2	1	1	1	0	0	0	0	0	1	4
3	1	1	1	1	0	0	1	0	1	6
4	1	1	1	1	0	1	1	0	1	7
5	1	1	1	1	1	1	1	0	1	8
6	1	1	1	0	0	1	0	0	1	5
7	1	1	1	1	0	1	1	0	1	7
8	1	1	1	0	0	1	1	1	1	7
9	1	1	1	0	0	0	1	0	1	5
Dependence power	9	8	8	4	1	5	6	1	8	

4.1.4. *Level partition.* Levels are partitioned based on Reachability matrix. The reachability set of each inhibitor is obtained by adding the number of factors that have value one in the rows corresponding to that inhibitor. Likewise the antecedent set of each inhibitor is obtained by collecting the elements that have value one in the column corresponding to that element. A diagraph (Figure 4) is constructed using the reachability matrix. The level partitions in Table 10 are used to form the final ISM model (Figure 5) after the transitivity's are removed.

Table 8. Iteration 1

<i>Lean Inhibitors</i>	<i>Reachability set</i>	<i>Antecedent set</i>	<i>Intersection set</i>	<i>Level</i>
1	1	1,2,3,4,5,6,7,8,9	1	I
2	1,2,3,9	2,3,4,5,6,7,8,9	2,3,9	
3	1,2,3,4,7,9	2,3,4,5,6,7,8,9	2,3,4,7,9	
4	1,2,3,4,6,7,9	3,4,5,7	3,4,7	
5	1,2,3,4,5,6,7,9	5	5	
6	1,2,3,6,9	4,5,6,7,8	6	
7	1,2,3,4,6,7,9	3,4,5,7,8,9	3,4,7,9	
8	1,2,3,6,7,8,9	8	8	
9	1,2,3,7,9	2,3,4,5,6,7,8,9	2,3,7,9	

Table 9. Iteration 2

2	2,3,9	2,3,4,5,6,7,8,9	2,3,9	II
3	2,3,4,7,9	2,3,4,5,6,7,8,9	2,3,4,7,9	II
4	2,3,4,6,7,9	3,4,5,7	3,4,7	
5	2,3,4,5,6,7,9	5	5	
6	2,3,6,9	4,5,6,7,8	6	
7	2,3,4,6,7,9	3,4,5,7,8,9	3,4,7,9	
8	2,3,6,7,8,9	8	8	
9	2,3,7,9	2,3,4,5,6,7,8,9	2,3,7,9	II

Further iterations showed final level partitions as shown in Table10.

Table 10. Final level partitions

No	Elements	Level
1	1	I
2	2,3,9	II
3	6	III
4	4,7	IV
5	5,8	V

5.0 Barrier classification using MICMAC Analysis

The ISM model developed is validated using MICMAC Analysis (Figure 3). The idea of using MICMAC is to identify the driving power and dependence of all inhibitors and classify them into autonomous, dependent, linkage and independent factors. This is obtained from the final reachability matrix in ISM model. Table 7 above shows the driving power and dependence power of each inhibitor.

5.1. Driving and dependence power of variables

The driving power of each inhibitor is the entire number of elements it may assist to achieve, including itself. The dependence power is the total number of variables including itself which may assist to achieve it. Driving power of an inhibitor is the total number of ones in the equivalent rows of the final reachability matrix and dependence power is the total number of ones in the corresponding columns for each inhibitor. Higher dependence value for an inhibitor means that to eliminate this barrier several

other inhibitors would have to be removed. Higher driving power suggests that if this inhibitor is removed many others can be eliminated.

	Quadrant IV				Quadrant III			
5	Independent factors				Linkage factors			
8			4		7			
							3	
				6			9	
							2	
	Quadrant I				Quadrant II			
	Autonomous factors				Dependent factors			
								1

Figure 3. MICMAC Analysis

Autonomous factors (Quadrant I): The factors in this quadrant have weak driving power and weak dependence power. They are aloof from the system. They neither affect nor get influenced by the system. Our study did not find any barrier of this sort in this segment. This means that all the nine variables or inhibitors in the system are significant and all needs attention from the managers in the organization.

Dependent factors (Quadrant II): The factors in this quadrant have weak driving power and strong dependence power. In our analysis factors 1 and 2 belong to this cluster. Pull scheduling (1) has driving power 1 and dependence of 9. Similarly small lot sizing (2) has driving power 4 and dependence of 8. These values are plotted in the MICMAC graph. This falls in the Quadrant II. It means these factors do not drive the other inhibitors but many factors (9 for inhibitor 1 and 8 for inhibitor 2) may assist in achieving them. Hence to remove these inhibitors several other factors would have to be removed earlier.

Linkage factors (Quadrant III): The factors here have high driving and dependence power. Hence actions taken on these inhibitors will have high influence on all other inhibitors. Management should focus on these factors as entire system improves if steps are taken to prevent them from occurring. Linkage factors in our model are Load levelling (3), Lead time reduction (6), work standardization (7), and minimum inventory (9).

Independent factors (Quadrant IV): The factors have very high driving power and low dependence power. These factors are Setup time reduction (4), very strict quality standards (5), and very less responsive supply chain (8). These factors drive all other inhibitors and are not dependent on them. These factors are usually the ones which need proper attention. Hence termed as “key factors” in our analysis. These constitute the root causes for improper lean implementation and management focus should be on removing these so that it won’t drive more inhibitors into the system. If these inhibitors can be eliminated several others can be easily removed.

6. Results of ANP, ISM and MICMAC analysis

- Our study captures the operations in a pharmaceutical company. The ANP analysis showed that business processes in the firm are comparatively leaner than the other areas. This means the company practices maximum lean in their processes. This is because of the enforcement of Quality throughout. But the leanness value is still very low at 32.28%.
- Management commitment is found high at 25.07% since employee training and employee involvement, job rotation, information sharing are practiced.
- Technologically lean is lagging behind at 24.03%. This was clearly visible as Pull scheduling, cellular layout, SMED and work standardization by means of continuous improvement was lacking in their operations.
- The lowest leanness value for the stakeholder involvement which is 18.60% is due to the least priority given to supplier partnership.

Based on the final ISM model, strictly enforced quality regulations and irresponsible supply chain are identified as the root cause and the worst barriers for effective implementation of lean practices in the pharmaceutical sector. These factors are driving all the other barriers and making lean implementation difficult. MICMAC refers to the inhibitors such as irresponsible supply chain, inability to reduce set up times and excessive quality regulations as independent drivers of all other barriers.

6.1. Conclusions from the study

cGMP quality checks makes less scope for work standards to be updated as they follow routine procedures without a continuous improvement approach. These result in inability to reduce the set up time. This further leads to difficulty in shortening the product lead time. The fact that lead time cannot be reduced makes it impossible to manufacture in small lot sizes. Hence big lots result in high inventory and Load levelling becomes impractical. All these lead to the top level inhibitor which is difficulty to maintain pull scheduling which is the basic requirement for lean implementation. Hence for lean to be implemented in a cGMP environment, both have to be made adaptable to each other if results are to sustain in the long run.

7.0 Managerial and research implications

Governmental / health authority enforced rules and policies also act as the major hindrance.

- Since this industry demands quality as highest priority and with all regulatory checks it is indeed a hindrance to improving the Lead time of the product. Hence options should be weighed as to how lead time can be reduced. Our recommendation is supplier partnership which is detailed in next section.
- If the Quality procedures are little relaxed without compromising on quality it can be a main contributor of lean since improved quality in processes will make the system defect free which means elimination of waste.

Major problems due to suppliers can be eliminated by installing a supplier qualification process as necessitated by FDA (Food and Drug Administration, 2006). This begins with identification and specification of type of materials, service and product needed from them. Proper audits, contractual obligations defined within a quality agreement and supply agreement are critical aspects. The compliance of the selected suppliers with the requirements and user requirement specification should be demonstrated and covered in the audit process. The compliance should be periodically evaluated. Any change if made by the supplier, which could have an impact on the GMP status or the production, have to be mutually agreed to before any such changes are implemented. A supplier must also notify the manufacturer immediately upon discovery of any deviation or non-conformance that may have impact on the services provided and corrective actions need to be taken immediately.

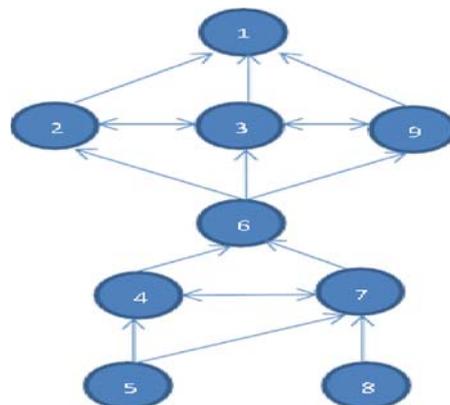


Figure 4. Development of Diagraph

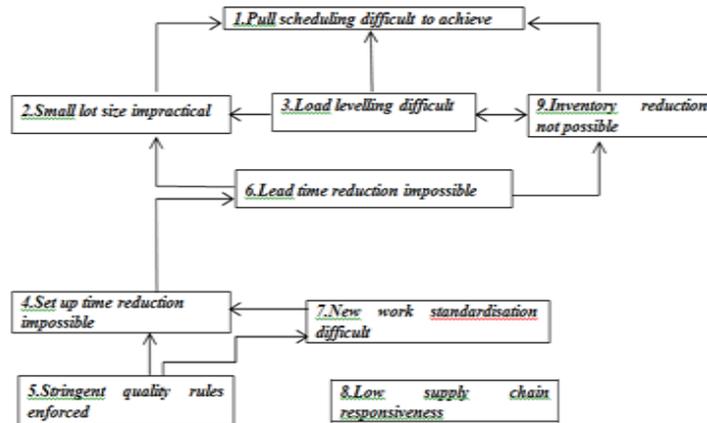


Figure 5. Final ISM developed

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