完全 KANZEN INSTITUTE
Towards Perfection

Performance Improvement of Pharmaceutical SMEs through Lean Management

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1 Introduction

1.1 Background

GTZ is currently implementing the SME Financing and Development Programme in Hyderabad region with the focus on Pharmaceutical and Textile SME clusters. The key objective is to strengthen growth and competitiveness of the SMEs mainly by helping them improve their processes.

The ability of SMEs to grow in a sustained manner depends on them being able to ***consistently*** manufacture and ***deliver in time*** a product that is competitive in terms of **quality** and **cost**. This is severely constrained by various factors:

- Lack of resources – equipment, space, inspection and testing facilities
- Lack of awareness on best available management practices
- Shortage of trained people with skills to make best use of existing resources
- No well defined organization structure and support systems to facilitate the core product delivery process

There is an urgent need to address the above factors if an SME has to compete and grow in a sustained manner in the current market environment. *The current recession in the global markets and financial crunch has made it all the more imperative for the SMEs to cut costs and working capital requirements*.

The goal of this pilot initiative of implementing **Lean Manufacturing** practices in SMEs is to guide them on the path to sustainable growth keeping in mind the constraint of limited resources.

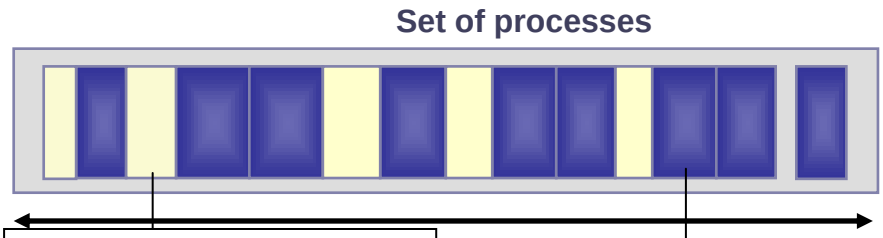
A seminar on "Performance Improvement through Lean Implementation" for Pharmaceutical SMEs was held on 1st August 2008 to build awareness on this methodology which is relatively new to the pharma sector. Expert consultants from Kanzen Institute Asia Pacific Pvt. Ltd. presented the topic to more than 30 entrepreneurs and senior managers from various SMEs.

Subsequently, plant visits were made to each interested SME during which the scope for improvement in each unit was assessed first hand. Each entrepreneur was also given a further understanding of how Lean could help specifically in addressing his current concerns.

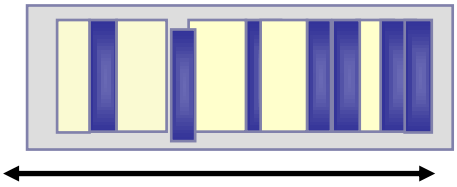
A detailed proposal including implementation schedule and financial cost was submitted to each of the interested SMEs. Following their approval, a pilot cluster of three interested SME units was formed for doing the actual process improvement and the implementation started in October 2008.

1.2 Lean Manufacturing - a brief history

Lean manufacturing is a philosophy born out of the Toyota Production System; widely considered to be the management system best equipped to deal with the complexities of the current global business environment. Simply defined, Lean is ***"Doing more and more with less and less through elimination of waste"***



By eliminating waste, the lead time can be cut drastically thereby crunching the cash cycle. Process improvements needed to do this help increase production volumes, reduce defect rates and cut costs. And all this without any investment!



The value adding activities remain as before; only waste is minimized

Lead time after Lean

Reduced throughput time = reduced inventories = reduced risk of contamination/damage during storage + reduced risk of product obsolescence

1.3 Implementing through Kaizen

Considering the limited resources available with the SMEs, a low cost but effective approach was required to implement lean. The focused improvement model using Kaizen approach was ideally suited to this need.

KAIZEN =

KAI (CHANGE)

+

ZEN (NEXT ELEVATED STATE)

Kaizen is

- *Significant Process Improvement*
- *In strategically important areas*
- *Under new (lean) paradigms*
- *Speedily executed*
- *With zero investment*
- *Sustainable improvements*
- *Giving Clear Business Benefits*

2 Approach to Implementation

2.1 Cluster formation

A pilot cluster consisting of 3 SMEs was formed after detailed discussions individually with each entrepreneur. A joint session was held with all three entrepreneurs to explain the cluster implementation model and their concurrence obtained. Schedule for implementation was drawn up with four major steps

Step	Activity	Implementation mode, schedule	Purpose
1	Diagnostic	Company specific , Oct'08	Identify goals and improvement opportunities
2	Focused Improvement workshop	Joint participation, one workshop per unit (Nov'08 – Jan'09)	Demonstration of improvement
3	Sustenance	Company specific, Feb'09	Sustain improvements done, continue to improve and grow
4	Documentation and closure	Offline, March'09	Record for future use, extend learning to other organizations

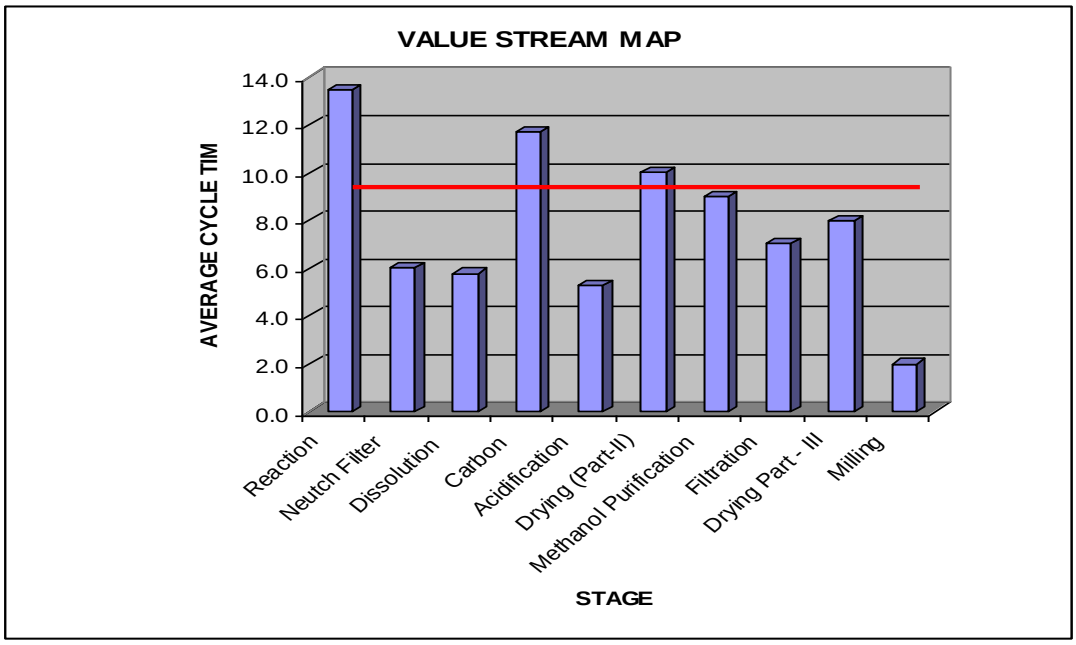
2.2 Diagnostic

A two day diagnostic exercise was carried out in each unit involving the functional heads, the top management of the unit and the entrepreneur. The exercise started with a session on basic lean philosophy and concept of value addition. The participants then developed an understanding of the 3 Ms – *Muda* (waste), *Muri* (physical strain) and *Mura* (inconsistency) through practical observation at the *Gemba* (workplace).

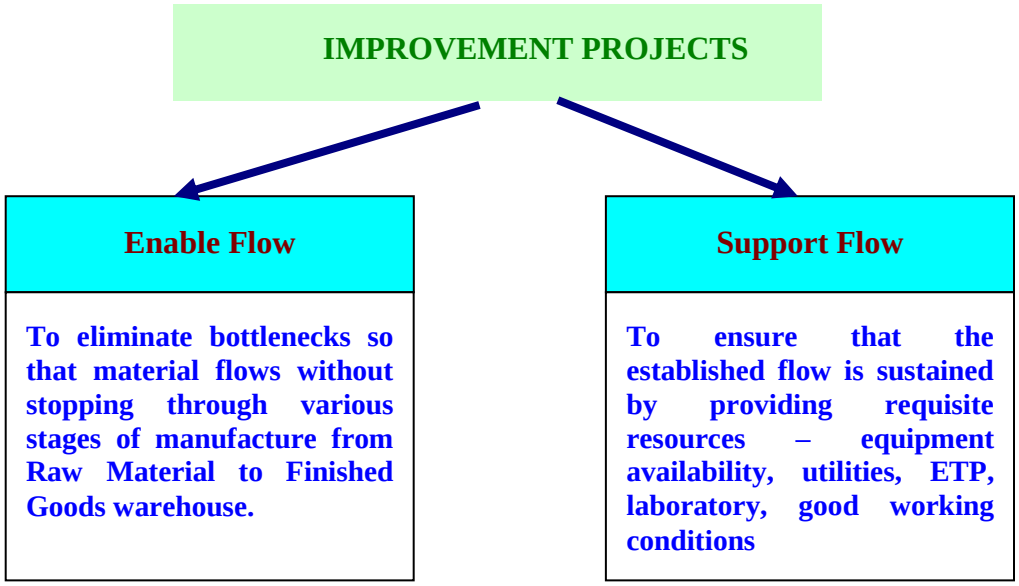
The team compiled the process data from the batch records of recently completed batches and prepared a Value Stream Map for the major product(s). This was then analyzed to identify the bottlenecks in the current process and areas for improvement. The physical walk through of the shop floor helped in identifying specific improvement opportunities with respect to the working conditions, safety and environment as well as upkeep of the plant and machinery.

A lean roadmap was then made listing out the performance goals and the improvement projects to be taken up for achieving these. *The value stream below clearly shows the processes that need to be improved so that they can be completed within the target time of 9 hours. The unit is currently producing 28 MT/month but can achieve 40MT/month if this target time is met by all processes.*

Pictorial Value Stream Map for one unit

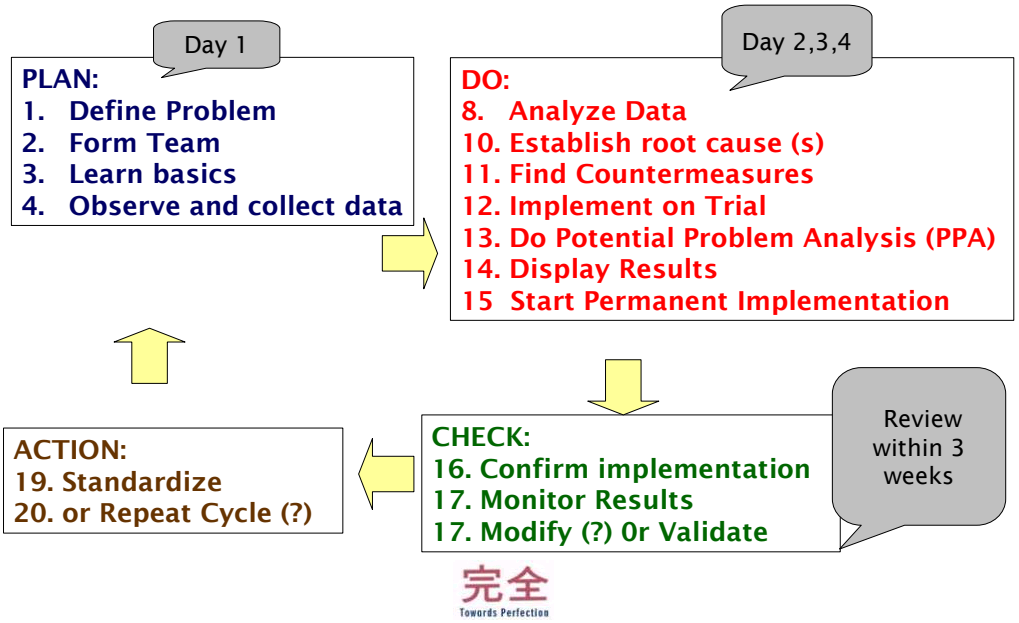


The **core concept of lean is material flow** – all improvements are done to support this.



2.3 Focused Improvement Workshop

Improvement projects were implemented through **four day** focused improvement workshops; one workshop was conducted at each unit during which the critical projects identified for that unit during diagnostic exercise were taken up. The unique cluster workshop model wherein employees from all three units participated paved the way for cross organizational learning. The workshop followed the basic Plan Do Check Act (PDCA) approach to problem solving and was followed up by a review after 2-3 weeks to verify results and standardize improvements made.



Cross functional teams were formed during the workshop – each team comprising members from across departments and across organizations took up one improvement project under the guidance of the consultants. The teamwork and enthusiasm of the participants provided a rare opportunity for cross learning across organizations as well as helped breakdown functional barriers.

After each workshop, employees from the guest units went back to their own workplaces and made improvements based on the concepts learned.

Though about 6-8 projects were identified for each unit, the cluster model gave them the opportunity to do up to 20 projects each – **maximum impact with minimum resources**.

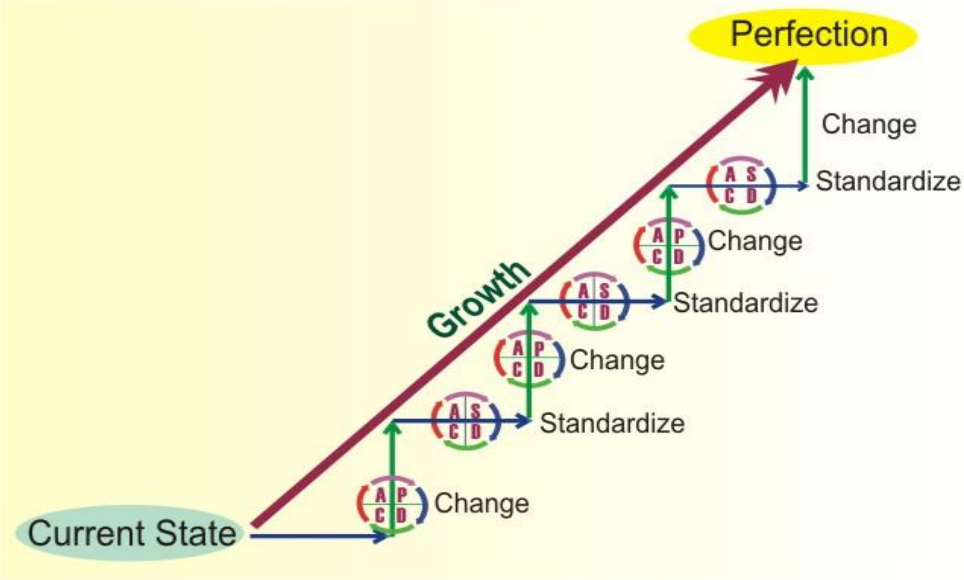
A comprehensive list of projects taken up across all the three units is given later. By the end of four months, each unit has moved up to a higher performance level in terms of both business results, quality of working conditions and environment for employee growth and development.

2.4 Sustainability

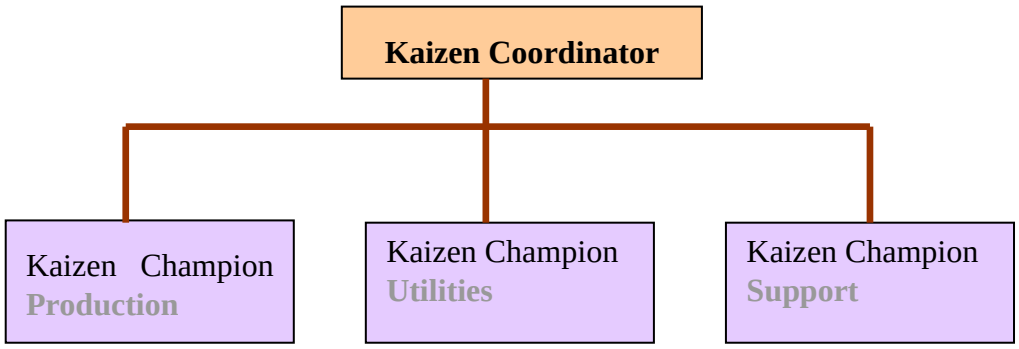
Lean is not a one off improvement initiative. The Toyota Production System which is the bedrock for Lean has been evolving for the past 60 years and sustaining a culture of continuous improvement.

The close of this pilot lean implementation is actually just the beginning of a never ending journey of improvement for the SME which will enable it to meet the challenges and pressures of business environment and keep growing all the time.

Kaizen means continual improvement through a series of improvements and standardization. The initiative started is only at the base level.



Having standardized the improvements made over a three month period, each SME is now ready to move up the improvement ladder. An organization structure was formed at each unit to keep the wheel of improvement rolling upwards.



Each champion is expected to form his/her own cross functional team and take up improvement projects identified already as per PDCA approach leaned during the workshops.

The Kaizen Coordinator will review the status of the projects with the teams and support the champions with any resources required for the projects. Training on lean and kaizen to all the employees down the line as well as reporting to the entrepreneur and top management is also his responsibility.

Projects have been identified for the next 3 months for each of the units and will be reviewed monthly by the entrepreneurs themselves.

In continuity lies the hope of much bigger improvements to come.

3 Impact of Lean Intervention

An organization can best sustain growth and development through complete involvement of its entire people. Lean lays down a clear path for such sustainable development of SMEs and has a cascading effect by which all the stakeholders within and outside the unit are benefited in some way or the other.

3.1 The Industry

Most initiatives focus on the technologies and facilities for bringing in improvement and this requires investment. Lean is the only intervention which focuses on the organisational systems, work processes, conveying methods and practices. These are common issues faced by every organisation and hence can be shared freely by companies to others. This unique feature enabled **the cluster approach effective as it facilitates cross learning across participating SMEs**.

3.2 Entrepreneurs

The SME sector in pharmaceutical industry has grown phenomenally over the past 10 years and many of the entrepreneurs are fairly young with a long business horizon ahead of them. Through this initiative GTZ has introduced the Lean philosophy to them for the first time and this will be an integral part of their future expansions as well as in new business ventures that they start up. Lean therefore will have a significant long term impact.

3.3 Employees – Managerial and Supervisory

The focus is on individual learning and development which in turn leads to improvement in the process. The lean intervention in this cluster has helped in the development of people who normally would never have got the opportunity. Most employees who work in the SME sector are mainly from a lower middle income strata and have had limited opportunities for education and development.

Award being presented to the most creative team during a workshop

3.4 Workmen

Improvements made for arresting leakages, spillages of hazardous chemical vapours and dispersion of dust in the air have made **day to day working easier and healthier for workmen**. This has been made possible **through taking up**

"strain reduction" projects during the workshops in which the workmen were also an integral part of the teams. The workshop was also a medium for their personal **growth and development** by giving them opportunity to

⇒ Participate in cross functional teams

⇒ Apply their minds and come up with creative ideas to improve their workplace

⇒ Hone their communication skills through formal presentation to a large forum

Team which improved working conditions in drying room – included drying operator and production operator

The entrepreneurs have already pledged to share a part of the gains arising out of the improvements with their employees – both the staff and the workmen. Not only now, but employees who continue to make improvements will be recognized and rewarded during the annual appraisals. Awards were handed to the best teams and specific individual contributions at the end of each workshop.

3.5 The Enterprise

Each of the participating SMEs has benefited significantly in terms of business results within the short span of six months. Qualitative gains include

- Customer Satisfaction through consistent On Time deliveries of quality products. This will help with growth in the business volumes.
- Learning organization consisting of people for whom continuous improvement becomes the way of life
- Employee retention because of better working conditions at the shop floor and better work environment for the staff
- Better compliance with statutory norms on safety, health and environment

COST AND BENEFIT ANALYSIS

⇒ Consultant fees

⇒ 5 days per month of entrepreneur's time

⇒ 35 man-days per month of employee time

⇒ Minor expenses on

.

Unit A

Parameter	Oct '08	Feb '09	Improvement
Production volume (MT)	28	35	25% gain
Throughput time (days)	10.4	4.5	57% reduction in WIP
Yield (kgs)	510	540	6% savings in material loss

Unit B

Parameter	Oct '08	Feb '09	Improvement
Throughput time (days)	32	20	38% reduction
Production volume (MT)	300	480	Potential of 60% increase

Can bring down working capital requirement and associated interest burden by 1/3rd

Unit C

Parameter	Oct '08	Feb '09	Improvement
Production volume (MT)	8	12	Potential of 50% increase

The increase in volume would translate to a 2.5% increase in the bottom line.

All these significant quantitative and qualitative benefits are the outcome of numerous process improvement projects taken up during the lean intervention. A few of these which also illustrate the key concepts and lean techniques used have been presented as case studies at the end of the next chapter on the implementation methodology.

4 Case Studies

A list of projects taken up across all the three units is given below. Various lean tools and techniques were learned by the participants while applying to make improvements in these projects.

About 50 employees across the three participating SMEs were trained during and after the workshops.

S.No.	Project	Concept
1	Reduce inconsistency in reaction	Differential Diagnosis
2	Reduce cycle time in Carbon Filtration	Eliminate MUDA
3	Reduce Drying time in tray drier	Eliminate MUDA, MURI and MURA
4	Autonomous maintenance for boiler pump	Jishu Hozen
5	Effective space usage -engineering stores	5S
6	Improve column distillation performance	Supervisory Walk
7	Streamline ETP to match plant capacity	Flow manufacturing
8	Zero powder dispersion in drying room	5 WHY analysis
9	Reduce movement of material – drying room	Flow layout
10	Reduce bottleneck process cycle time	Line balancing
11	Zero error in reaction stages	Poka yoke
12	Zero spillage during storage and handling	5 Why analysis
13	Zero wastage of product during processing	Problem solving
14	Improve cleaning process for tray dryer	Workstation arrangement
15	Reduce changeover time in tray dryer	SMED
16	Reduce centrifuge unloading time	Workstation design
17	Zero error in solvent storage, handling	Visual management
18	Reduce testing time in laboratory	5S and layout
19	Increase availability of utilities	TPM
20	Production scheduling as per flow	Flow manufacturing

A few of the key projects illustrating different lean concepts are now detailed as case studies.

4.1 Reduce inconsistency in Reaction Cycle time

Problem Definition

57 hrs

Widely varying from 46 to 73 hours

- Production volume: 28 MT/month
- High Work In Progress – lead time 10 days
- Uncertainty in delivery
- Idle processes

Observations & Analysis

Problem solving technique used – **Differential Diagnosis**

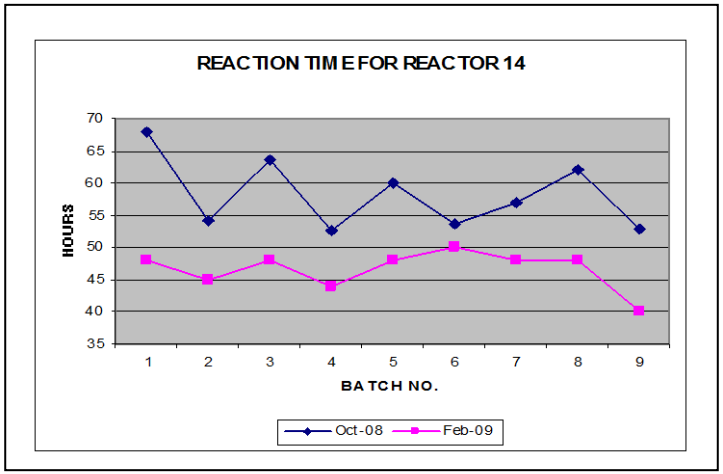
Observations: Batch record data for the 5 reactors

Hypothesis: As the same reactor can give reaction in less time also, then the defect is not due to reactor but due to variation in operations.

Root cause identified: Variation in temperature outside the specified range. Once temperature drops, it takes at least couple of hours to return to required level. Current method - manual steam control through valve at each reactor based on periodic temperature observation by operator.

Actions

- Recalibration of sensors & display units
- Cleaning of thermo well by removing the sludge
- Improved method of steam control to reactor
- Process chart prepared
- Visual management system for monitoring of parameters put in place.



Results

44 hrs

Volume: 33 MT/month

Lead time = 4.5 days

Balanced processes

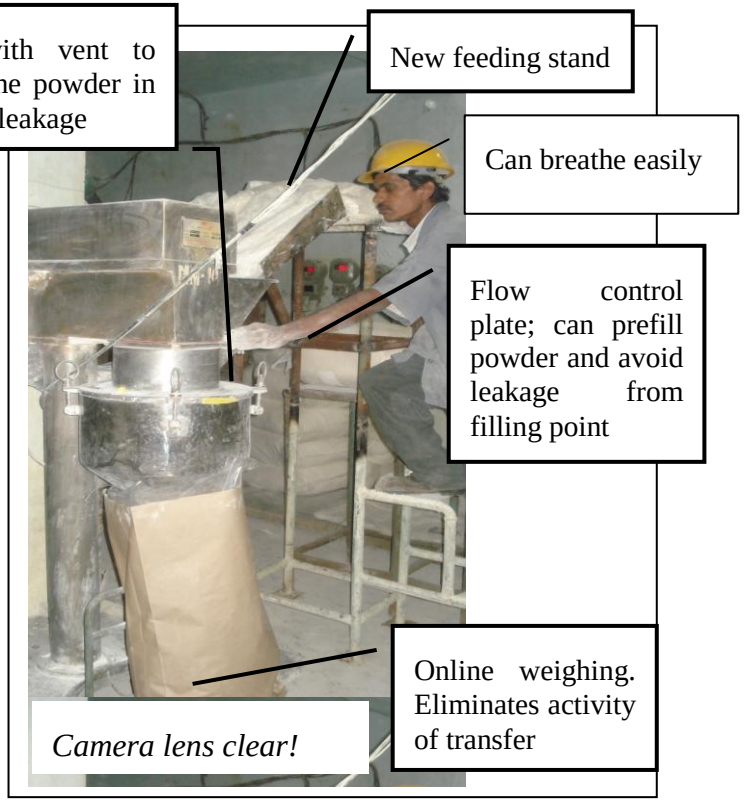
On time delivery

Variation in time reduced by 50% across 5 reactors

4.2 Improve working conditions in Drying Room

Atmosphere in room full of fine powder particles – *camera lens coated as well*

Powder spillage during manual transfer at the time of weightment.



- Operators are able to work comfortably without irritation.
- Material loss is minimized
- Long term health hazards to workmen minimized

4.3 Reduction in Cycle Time of Bottleneck Process through Line Balancing

Problem definition

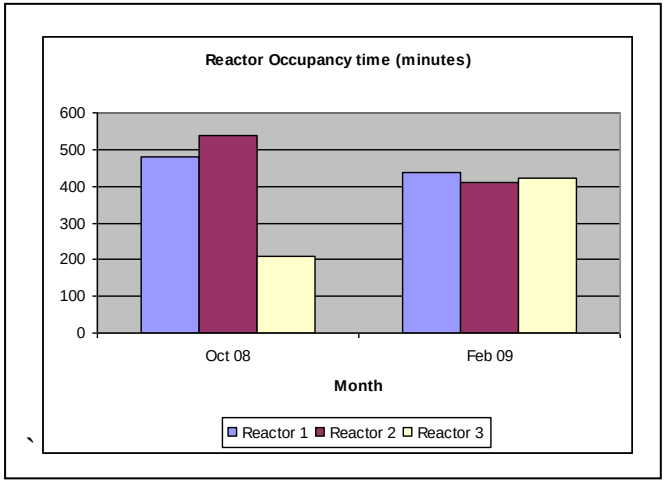
3 stage process' 2nd stage Distillation has highest cycle time of 540 minutes per batch. Limits production capacity to 2.6 batches per day

Customer wants 3 batches per day minimum

Distillation Monitoring Board

Batch No.	1st hour	2nd hour	3rd hour	4th hour	5th hour	6th hour	Total time (minutes)	Total quantity (liters)
Target	350	225	225	150	100	0	300	1050
1	480	220	225	127	93		315	1145
2	345	235	234	122	90	21	310	1047
3	345	215	200	135	80	90	410	1065
4	340	221	225	150	120	153	400	1209

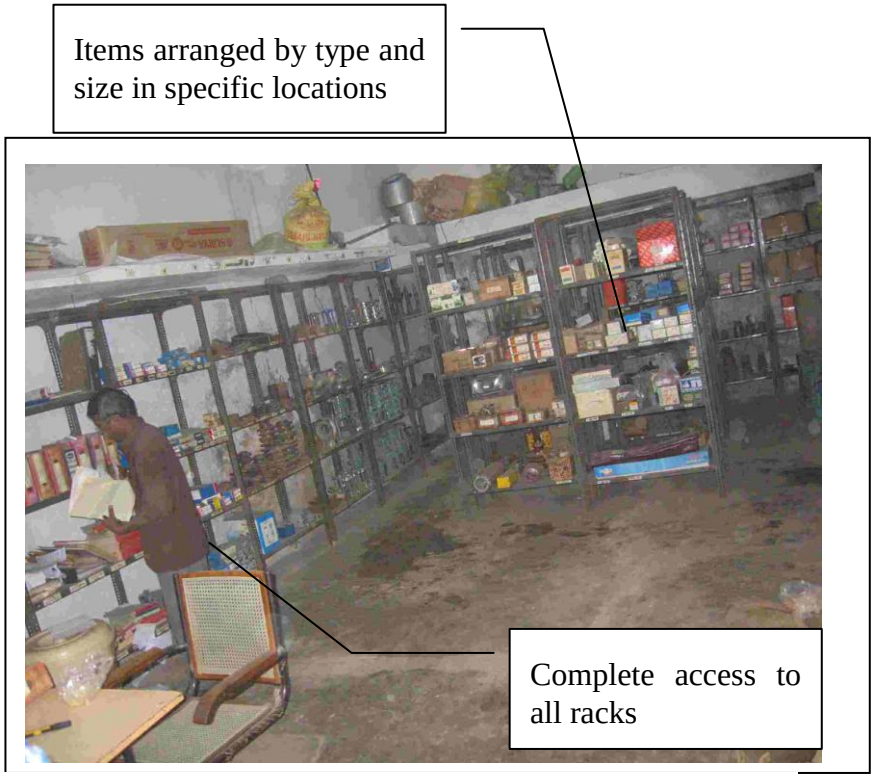
- Excess water found in organic layer, also excess water filled in previous stage
- Steam problem leading to slower distillation rate in one batch
- Cycle time of next process only 150 minutes



- Made level indicator more visible to operator and shifted water flow control valve next to it to enable filling of correct quantity of water
- Careful separation of water in Organic Layer
- Reduced waiting time between Ist and IInd MDC Layer by starting the distillation immediately after getting Ist MDC Layer from previous stage
- Reduced distillation time by preheating of R 115 by hot water
- Established new practice of transferring mass to next stage reactor and completing balance steps of water addition and maintenance there

Line balanced amongst three reactors – highest cycle time < 450 minutes = production volume of 3.3 batches

4.4 Improving storage, handling and issue practices in stores using 5S



50% of stores space is free as compared to earlier position of no space to store new items. Visual control on inventory and issue without searching is now possible.

4.5 Reducing production throughput time using flow manufacturing concept

Problem definition

The product is made through a complex process route involving 10 reactor processes, 8 intermediate drying operations, 11 centrifuging stages and 5 filtration stages and the average throughput time for a batch is about 32 days. It is also a very high value product and working capital requirement is huge due to the work in progress inventories built up due to the extended lead time.

Major Observations

- No fixed reactors or centrifuges have been assigned to each stage
- After stage 3, material from 2 batches is mixed. Hence one batch at least has to wait for Stage 4 by design
- There is huge variation in the reactor occupancy times for different stages from a low of 22 hours to a high of 56 hours per batch
- There are 2 tray dryers that are common to all stages. The trays have to be cleaned before reuse if the stage changes. Changeover time is very high

Countermeasures

- Reactors fixed for each stage based on occupancy; some stages combined into same reactor to increase reactor occupancy.
- Centrifuges fixed based on reactor locations
- Initial batch size increased so that single batch can flow from Stage 3 to Stage 4
- Dryer changeover time – unloading, cleaning of trays reduced through kaizen
- Production schedule made for an entire order of and actual flow monitored against this.

Results

Lead time has reduced from 32 days in Oct 08 to 20 days in Feb-09, a 38% reduction

5 Glossary of Lean Terms

Muda – Japanese word for waste

Muri – Japanese word meaning physical strain or mental stress

Mura – Japanese word for inconsistency or variation

Gemba – real place of work or place where value addition occurs

5S – a Japanese concept for workplace organization and improvement, the 5 Ss being

1S – Seiri or Sort – sort out and discard unnecessary items

2S – Seiton or Segregate – arrange all required items systematically

3S – Seiso or shine – clean up the workplace and keep it clean

4S – Seiketsu or standardize – maintain and monitor first 3S's

5S – Shitsuke or Sustain – follow the rules to keep the workplace right