PHARMAprocess

Innovation Forum in Pharmaceutical Process

OPERATIONAL EXCELLENCE

Advanced methods for operational excellence

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Track 2: OPERATIONS

Advanced methods for operational excellence: INTRODUCTION





Competitiveness has different meanings depending on the country or company:

The developing countries of emerging economies compete exclusively on price

• (make things cheaper)

Intermediate countries compete on quality

• (make things better)

Rich countries compete on innovation

• (make different things)

The only solution is to **INNOVATE** or **TRANSFORM** an institution or a company, to create more recurrent **VALUE** in an increasing way





FROM COMPETITIVENESS TO EXCELLENCE



"CHANGE CAN BE PAINFUL FOR THOSE WHO CLING ONTO THE PAST, BUT WE MUST REMEMBER THAT PROGRESS COMES ABOUT WHEN THE STATUS QUO IS CALLED INTO QUESTION. WHETHER ONE LIKES IT OR NOT, COMPETITION WILL MAKE THOSE WHO DO NOT WANT TO CHANGE DISAPPEAR"



K. Suzaki



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Track 2: OPERATIONS OPERATIONAL EXCELLENCE MEANING





• OPERATIONAL EXCELLENCE: THE BEGINNING



"MAKING PEOPLE, BEFORE MAKING PRODUCTS"

"MATSUSHITA ELECTRIC MAKES PEOPLE...AND WE ALSO MANUFACTURE ELECTRICAL APPLIANCES AND VARIOUS OTHER PRODUCTS"



K. Matsushita on Human Development



OPERATIONAL EXCELLENCE: THE "FOUR REVOLUTIONS"

First revolution "Customer demands have increased significantly"

• From practising PRODUCT-OUT to being MARKET-IN

Second revolution "Market is global and competition is hard"

• From setting prices to cutting costs

Third revolution "Complexity of organisations and social patterns"

• From managing human resources to mobilizing people

Fourth revolution "Change is increasingly faster"

• From maintaining to continuously improve



TQM companies must clearly define who their customers are, know their needs and produce products/services of attractive quality to delight them and go beyond such needs



TQM companies orientate processes and activities to customers, controlling processes and increasing their effectiveness and efficiency by eliminating "losses" and "waste"



TQM companies require the participation of all staff to satisfy customers efficiently, aligning resources and efforts around common objectives and developing and using them to their full potential



CONTINUOUS IMPROVEMENT: S-D-C-A + P-D-C-A





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Track 2: OPERATIONS ADVANCED METHODS FOR OPERATIONAL EXCELLENCE







• TIGHT FLOW: LAYOUT











• MANUFACTURING IN EVER SMALLER LOTS: SMED



Shigeo Shingo breaks the paradigm of small lots:

- If we reduce the references changeover time, reducing the lot size is no big deal
- The limit on reducing the changeover time is only in our imagination
 - Only will and following the method are needed







• EFFICIENT PLANNING: PULL



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- Level and mix production to prevent demand fluctuations affecting the system and so avoid overacting
- Create information flows at "ground level" with many "bits" of information at short intervals
- Let the market "pull" the production

Small quantities...



...with low costs



• JIDOKA

"People assure quality in their work posts and make problems to light immediately...

...and machines have to do the same"





ΤΟΥΟΤΑ

Automation with a human touch



STANDARDS •









CONTINUOUS IMPROVEMENT: S-D-C-A + P-D-C-A





Track 2: OPERATIONS ADVANCED METHODS FOR OPERATIONAL EXCELLENCE CASE STUDY 1: DIAGNOSIS AND REDUCTION OF LEAD TIME





CASE PRESENTATION

Area

Implementation of a Lean Production System in the new Bioflash product family to reduce the Lead Time to the customer, increasing the process flexibility and reducing the amount of work in process, and the amount of obsoletes

Current Situation

- Lead Time: 75 days from order to customer
- Obsoletes: 1.7% of total stock

Aims

- Lead Time reduction
- Increase the ability to react quickly to market changes
- Reduce manufacturing costs (Waste, WIP and Obsoletes)

Improvement Process

The improved process has the following stages:

- Diagram the current value chain (VSM)
- Design the desired value chain
- Establish a Detailed Improvement Plan
- Implement the new Flow of Materials
- Implement the new Flow of Information

Obtained Results

- Lead Time: 20 days (-73,3%)
- Production Cost Savings: -10%

- WIP Reduction: -40%
- Complete elimination of obsolete product

22



• INITIAL VSM: ANALYSIS OF THE VALUE CHAIN





- B) Supermarkets for Raw Materials from first process. Recalculation of stock from Planning Point, and KANBAN card to first process to start production
- C) Intermediate delivers to final process in the same order by FIFO tail, and assembly is made of the Final Kit maintaining the order entry

D) Label printing productions are stored in FIFO tails, ready to be used in final process

E) Cartridge assembly, labelling, fitting and delivery when finished (OF by FIFO tail)



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Track 2: OPERATIONS ADVANCED METHODS FOR OPERATIONAL EXCELLENCE CASE STUDY 2: KAIZEN CYCLES IN AUTONOMOUS MANAGEMENT UNITS





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CASE PRESENTATION

Area

Implementation of Kaizen Management Cycles in chemical and pharmacy plants of a multinational company organized around Autonomous Management Modules. The aim is to involve everyone in losses identification and analysis of problems to increase OEE in plants

Current Situation

- No regular meetings in the MGA's
- No Problem Solving methods
- Overall average O.E.E.: 55%

Aims

- Implement daily and weekly Kaizen cycles
- Involve everyone in problem solving
- Increase O.E.E. at least 10% overall

Improvement Process

The improvement process has the following stages:

- Analysis of initial situation
- Design cycles and associated tools
- · Choose and implement in a pilot area
- Introduce the new model to Management
- Extend to other lines and MGA's

- **Obtained Results**
- Lines with Kaizen cycles: 22 (of all kinds)
- People involved in Kaizen: 80% of the staff
- Average number of problems analyzed by MGA in a year: 120 (acute and chronic)
- Overall O.E.E. increase in MGA's: 15%



4	Planned Time				Programmed stops
C	Planned Time				
5	Available Time				Breakdowns, Changeovers, Machine Starts, Lack of Materials, Lack of Operators, Others
G	Time Standard Sp	Time Standard Speed			Little (Micro) stoppages Speed reduction
Π,	Effective Time				Defects and Reprocesses
FE					
		Quantif.	Non Q.	Quantifiable	
	Unexpected			d Plann	be



• EXAMPLE: SOLIDS 3 MGA



INDICATORS

	January	June	December
OEE Evolution	40%	48%	55%
Availability Evolution	50%	63%	69%
Performance Evolution	82%	83%	83%
Quality Evolution	97%	97%	99%





• ANALYSIS OF PROBLEMS

ACUTE PROBLEMS \rightarrow SCRA

 39 analysis made in 50 days, with 143 completed corrective actions by the Team

CHRONIC PROBLEMS \rightarrow CEDAC

- AIM: reduce the cleaning and changeover time from 11,7 hours to 10 hours
- RESULT: in week 11 cleaning and change of reference real-time is 8 hours





- LESSONS LEARNED AND RECOMMENDATIONS
- Distinguish and attack acute and chronic problems in a different way
- The need to permanently look for information
- There are problems that depend on external factors and we need help to deal with them
- The importance of "Gemba" to analyze causes
- Write observations and gather evidence to deal with problems
- Have an appropriate training before starting the project
- Strengthen joint actions among Kaizen teams: synergies
- Respect the "rules" and follow the methodology
- The involvement of everyone \rightarrow INFORMATION \neq INVOLVEMENT



• RECIPE FOR SUCCESS



Recipe for success

Method

Passion and conviction



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