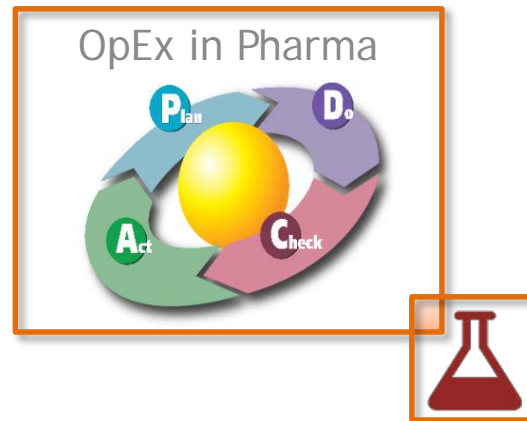


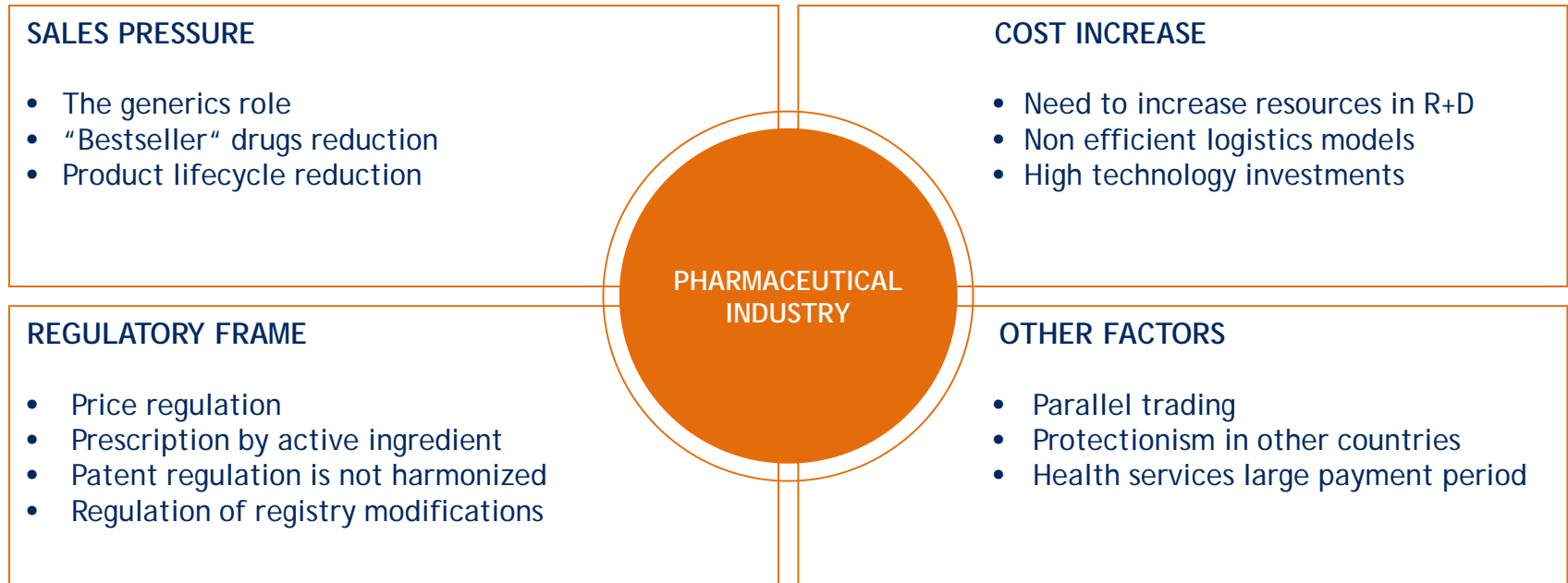
## OPERATIONS MANAGEMENT TEAM: A SCIENTIFIC APPROACH TO PRACTICAL SOLUTIONS





# NEW CHALLENGES IN THE PHARMA INDUSTRY

- The Pharmaceutical industry is under unprecedented pressure to deliver innovative health benefits at affordable costs

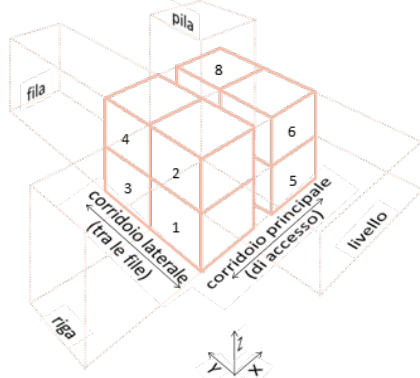


All these factors decrease margins and make pressure on pharma industry profitability



## How to Face Issues

- **Operational Excellence** concerns a set of methods and techniques, whose objective is the continuous improvement of performances towards excellence
- Achieving Operational Excellence is based on the analysis of technical and economic opportunities for improvement and the processes optimization and streamlining
- Operational Excellence projects aim to:
  - Reduction of non-value-added activities and wastes
  - Optimization of accessibility and resource exploitation
  - Improvement due to use of effective information systems
  - Reduction of delays, errors, misunderstandings, and waiting for resources
  - Opportunity for new technologies adoption



Logistics & Supply Chain



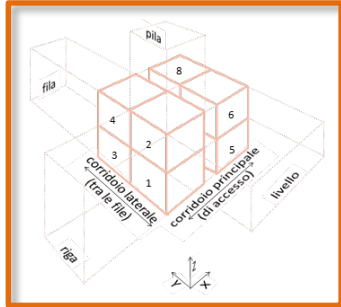
Production & Maintenance



Quality & Processes



## Focus and Improvement opportunities



- High costs of raw materials
- Voluminous conditioning materials and limited spaces
- Waiting times required for analysis of raw materials
- Materials/Products obsolescence
- High costs of wastes management
- Maintenance of the environmental conditions or special regulations

## Standard approaches

### Logistics & SCM

- Re-design of the stocking-area layout aims to minimize material handling cost, but also involves:
  - minimize fixed asset costs
  - increase space occupancy, movement performance, material accessibility
  - guarantee Service level and material availability



Typical projects in Logistics & SCM are:

- Optimization of warehouse structure
- Re-Layout and process analysis
- Stock rationalization and reduction
- Opportunity / feasibility / suitability of automation solutions
- Opportunity / feasibility / suitability of software implementation analysis
- Storage locations and warehouse management
- Distribution network re-design

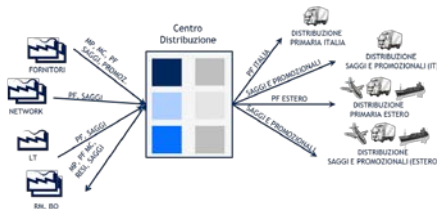
## «Warehouse Management» case example

- Background: Production plant of an Italian leader pharmaceutical company
- Objective: Evaluation of outsourcing logistics providers for Distribution Center management

### Scenarios definition

A

- Identification of warehouse activities
- Identification of KPIs
- Definition of Make or Buy scenarios



### Evaluation of alternatives

B

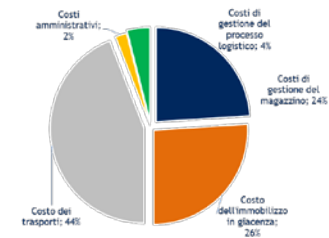
- Estimation of storage area and physical characteristics of the warehouse
- Estimation of handling and storage requirements for the analyzed scenarios
- Analysis of logistics providers available in Italy, capabilities and location

Variabile	Scenario 1	Scenario 3	Scenario 9	Scenario 11
Area Magazzino (mq)	20.000	15.000	17.000	10.000
Dimensioni pianta (m)	180x111	150x100	170x100	111x90
# posti pallet (pp)	23.708	17.602	15.704	9.974
# posti pallet HVAC (pp)	12.632	11.392	7.568	5.696
# baie di carico	10	8	10	8
# FTE	14 (-31%)	13 (-38%)	12 (-42%)	11 (-48%)

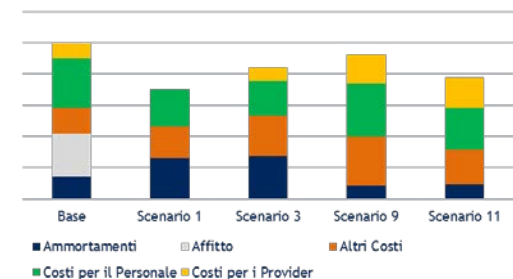
### Evaluation of affordability

C

- Business Plan with economic-financial alternatives of Make or Buy
- Sensitivity analysis
- SWOT Analysis
- Logistics provider's short-list



Struttura Costi 2030





## Focus and Improvement opportunities



- Low efficiency of the production lines due to idling, minor stops and reduced speed
- High complexity due to several presentations/formats and thus setup
- High maintenance costs to ensure maximum availability of the production lines



## Standard approaches

### Lean Manufacturing & Six Sigma

- LEAN implementation lead to:
  - Increase manpower performance
  - Increase equipment reliability
  - Avoid equipment / parts defect
  - Reduce of set-up time, batch size and costs
  - Reduce failure and maintenance costs
  - Optimize overall efficiency and spare-parts management
  - Maximize efficiency, lean culture and intuitive organization
  - Eliminate wastes

JIDOKA

#### Production Resource Management

*Build-in quality* approach to reach automation in order to increase production quality and improve process control



SMED

#### Set-up management

Set-up time reduction and rationalization of activities for production execution



5S

#### Floor shop management

Improvement of working area organization following a structured method, which provides waste elimination, equipment rationalization and visual management



TPM

#### Maintenance management

Training activities in order to allow autonomous maintenance, improving prompt diagnosis of equipment malfunctioning and failures



## «Maintenance Management» case example

- Background: Production plant of a world leader pharmaceutical company
- Objective: Maintenance Planning, implementing TPM

### Criticality Analysis

A

- Equipment classification and FMECA Analysis

Costi diretti di manutenzione (TIME & MATERIAL)	Durata indisponibilità	Impatto sull'ambiente	Impatto sulla sicurezza	Valore G
-	-	-	-	1
Fino a 1 KE	-	-	-	2
Fino a 5 KE	-	-	-	3
Fino a 10 KE	-	-	-	4
10 < x < 20 KE	Fino a 60 min	-	-	5
20 < x < 30 KE	Fino a 240 min	-	-	6
30 < x < 50 KE	Fino a 900 min	-	-	7
> 50 KE	Fino a 1440 min	-	-	8
-	> 1440 min	SI	-	9
-	> 2880 min	-	SI	10

### Definition of action plans

B

- Definition of Preventive Maintenance Plans

Progetto: LATINA		Unità (dec)	
NUM. PREVENZIONE PREVENTIVA	07,20	Operazioni (dec)	
NUM. PREVENZIONE PREVENTIVA	2,50	Manutenzione (dec)	
Totale	30,00		
Tipo intervento		Operazioni (dec)	
VERIFICA LISTINO	0,67	Operazioni (dec)	
SOSTITUZIONE	6,00	Manutenzione (dec)	
CONTROLO LIVELLO E LUBRIFICAZIONE	0,17		
INSERIMENTO STRUMENTALE	2,50		
VERIFICA VERBA	5,83		
CONTROLO DI BATTERIA	0,50		
IDENTIFICAZIONE/REPERIZIONE	0,17		
CONTROLO DI PUNDEABILITÀ	3,17		
PIRELLA	8,00		
Totale	30,00		
A Cura		Operazioni (dec)	
Operatore	25,20	Operazioni (dec)	
Manutentore	6,67	Manutenzione (dec)	
Totale	30,00		
Specializzatore		Operazioni (dec)	
MECCANICO	6,50	Operazioni (dec)	
OPERATORE	25,20	Operazioni (dec)	
ELETTROICO	0,30	Operazioni (dec)	
Totale	30,00		
Specialista (eventuale)		Operazioni (dec)	
MAN. ASSISTOCIATA	30,00	Operazioni (dec)	
Totale	30,00		

### Editing of maintenance procedures

C

- Procedures for Preventive and Autonomous Maintenance

DESCRIZIONE ATTIVITÀ	MISURA DEL PASSO DELLA CATENA
	
<p>Operazione da eseguire:</p> <ul style="list-style-type: none"> <li>• Sostituire le viti del catene, ove questo sia presente.</li> </ul> <p>IN CASO DI CATENA ACCESSIBILE ESEGUIRE LE ATTIVITÀ QUI SOTTO:</p> <ol style="list-style-type: none"> <li>1. Verificare che la catena sia sottoposta ad un'usura ammissibile suggerita dal costruttore.</li> <li>2. Misurare n° 10 maglie con il calibro.</li> <li>3. Verificare che l'allungamento riscontrato sul totale delle maglie misurate sia minore del 2%. In caso contrario sostituire la catena.</li> </ol> <p>IN CASO DI CATENA DIFFICILMENTE ACCESSIBILE:</p> <ol style="list-style-type: none"> <li>4. Individuare la falsa maglia ed aprirla con l'utilizzo delle pinze appropriate.</li> <li>5. Mettere in tensione la catena su un piano di lavoro.</li> <li>6. Misurare n° 10 maglie con il calibro.</li> <li>7. Verificare che l'allungamento riscontrato sul totale delle maglie misurate sia minore del 2%. In caso contrario sostituire la catena.</li> <li>8. Rimontare la catena.</li> </ol>	

## Achievements

- Maintenance criticalities identification
- Increased plant Up-time
- Improvement of production plant stability and quality



## Focus and Improvement opportunities

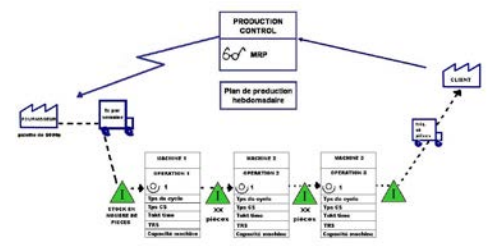


- Very high release cycle-time
- Complicated processes difficult to manage and to be monitored
- Unclear procedures and sometimes redundant
- Inefficient documental structure and incomplete information flows
- Analytical activities aimed to emergencies handling and out of control
- Frequent deviations and inadequate monitoring/mitigation system

## Standard approaches

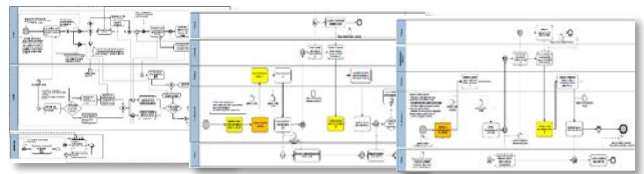
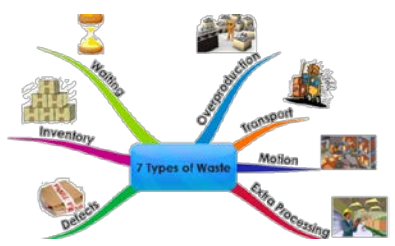
### BPM & Process Improvement

- BPM techniques allow to:
  - Analyze utilized resources in order to balance workloads
  - Improve efficiency in the information exchange and in documental structure
  - Identify improvement opportunities to reduce the lead-time



### Lean Lab

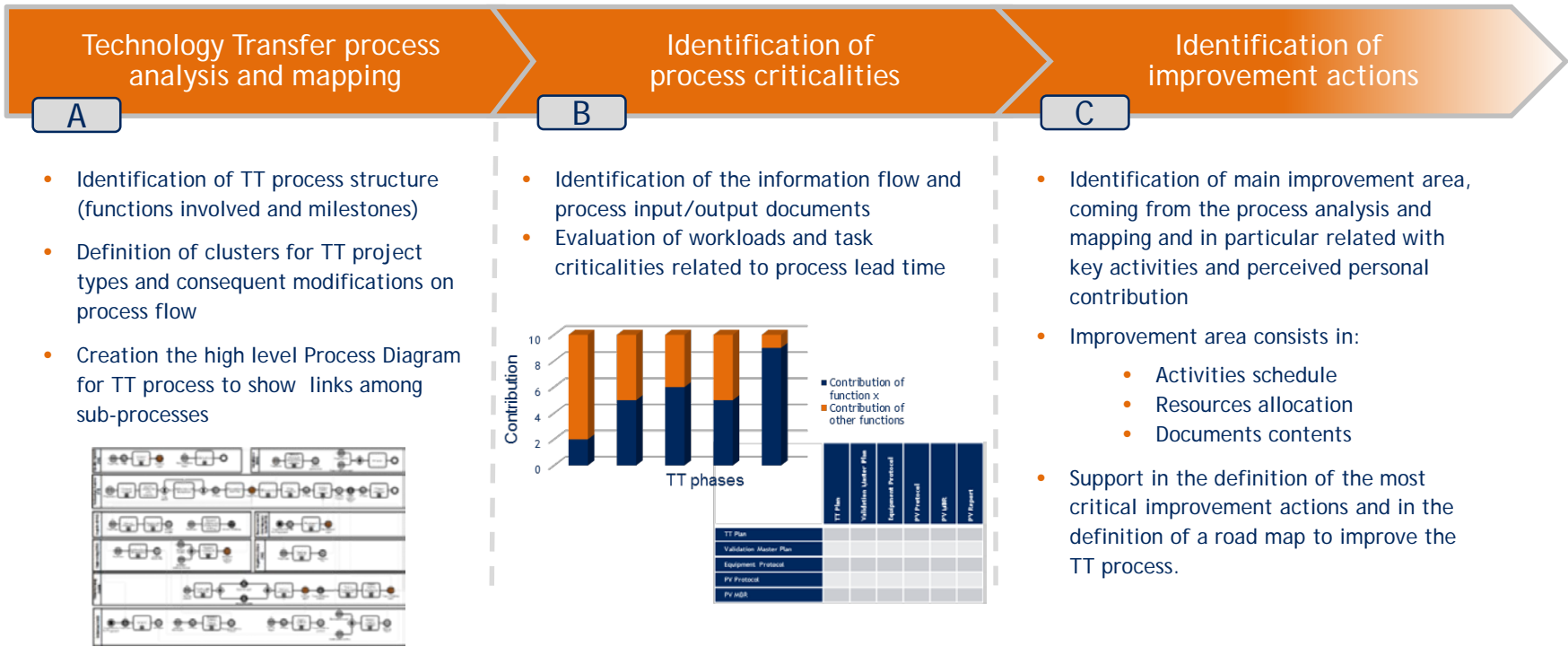
- Lean Lab allows laboratory activities to:
  - Ensure to reduce process losses with leaner flows of people and materials
  - Focus on activities with higher added value, those analytical ones





## «Optimization of NPI process» case example

- **Background:** Production plant of a world leader pharmaceutical company
- **Objective:** Support to analysis and improvement of technology transfer process



### Achievements

- RACI matrix, Business Process diagram, Document Criticality matrix
- Definition of road map to improve the TT process

## REFERENCES

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