OPERATIONS MANAGEMENT TEAM

TorVergata UNIVERSITY OF ROME SPIN-OFF

OPERATIONS MANAGEMENT TEAM:

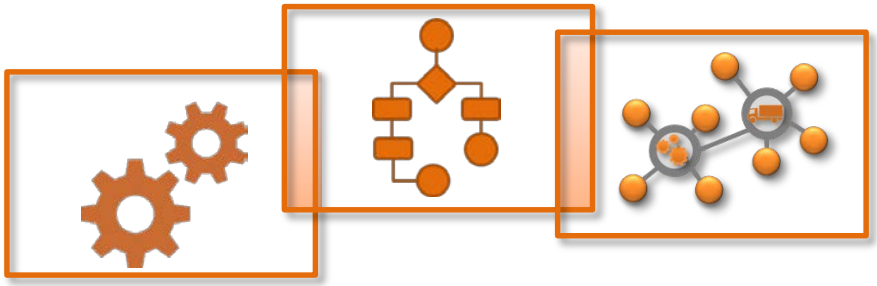
A SCIENTIFIC APPROACH TO PRACTICAL SOLUTIONS

Operations Management Team

- OM Team is a spin-off of the **Enterprise Engineering Department of "Tor Vergata" University of Rome,** founded in 2010.
- It collects the wide expertise of the Operations Management research group, and inherits the experiences of collaboration with companies gained over the years.

Consulting areas

- **Production and Operations**
- **Business Processes**
- **Supply Chain**



Our profile

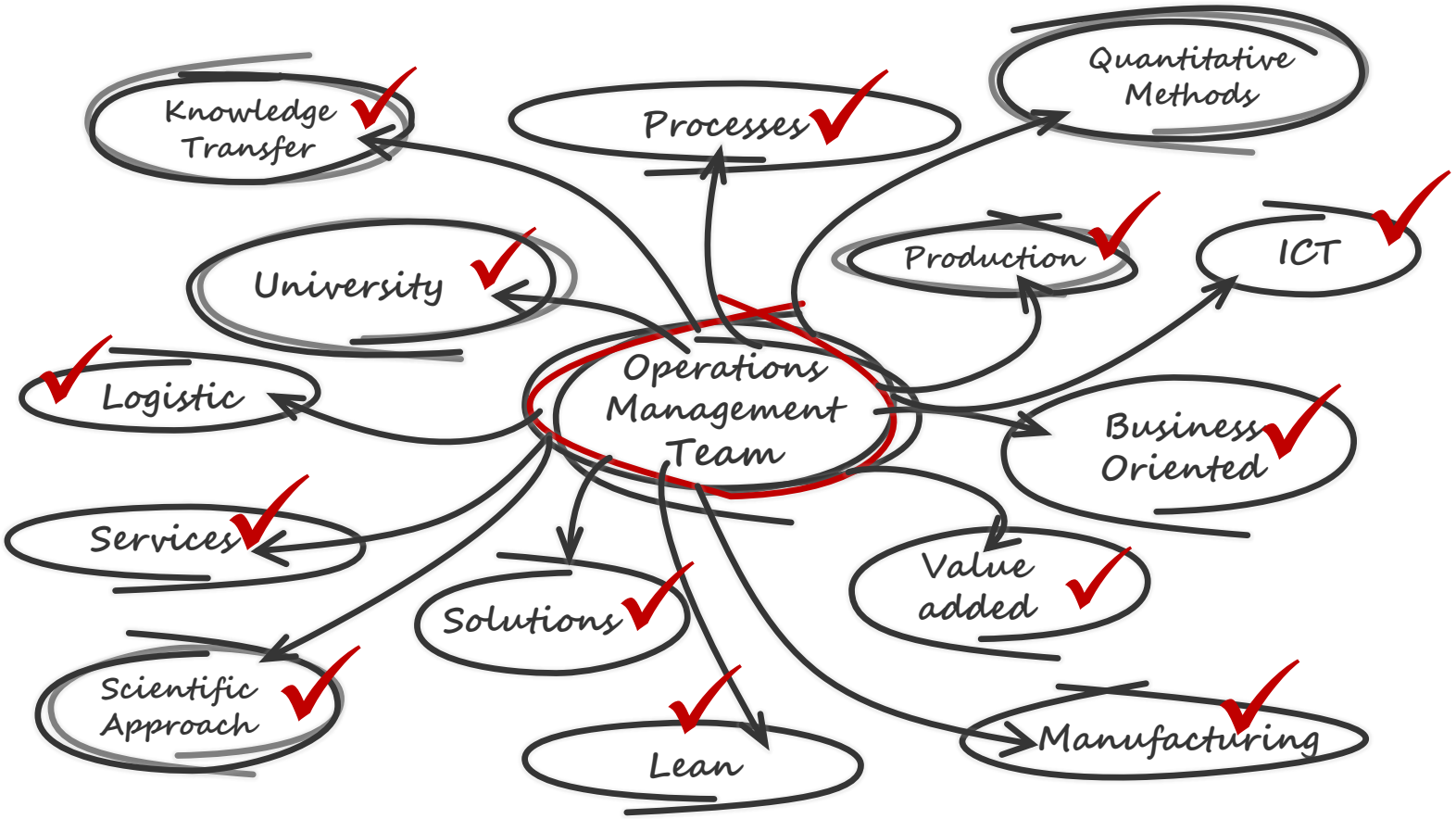
Vision — Lead companies to reach excellence through a continuous research for concrete and innovative solutions

Mission — Spread a scientific methodological approach to help companies achieving their goals

Goal — Create a network between companies and the academic world in order to exploit the synergies and develop innovative solutions

An original approach

The strength of our working methodology relies in the Team's **specialist skills** that concern the ability to apply methods, approaches and techniques from **Operations Management** to Industrial Engineering and Management.

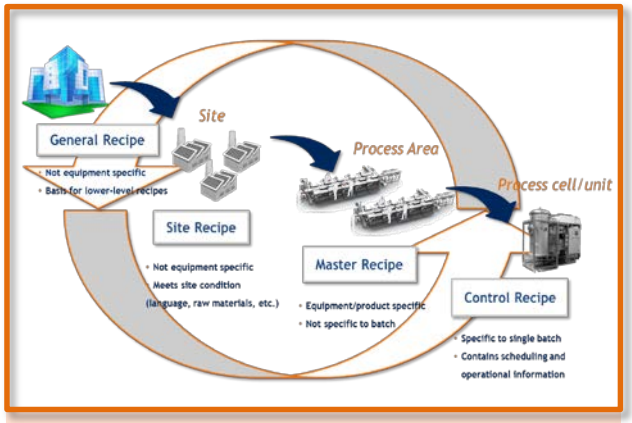


Our proposal for the sector

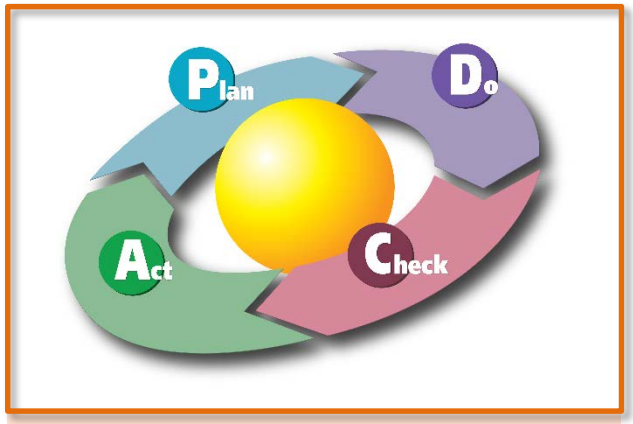
- Provide reference, guidance, and support to pharmaceutical operations managers in selecting the most appropriate solutions for the identification and completion of the objectives of their manufacturing operations
- Provide operations management with a robust basis for understanding how compliance and continual improvement/innovation can be achieved simultaneously
- Define a common language and provide guidance for performance measurement, benchmarking, and improvement
- Identify new performance improvement tools, clarifying what is applicable and what is not, for pharmaceutical

Focus

Benchmarking



Standardization



Operational Excellence

Pharma Industrial Efficiency Benchmark

What is it

- Promoted together with Spanish consulting firm **ManageArt**
- Dedicated **exclusively** to **pharmaceutical** companies
- Analysis focused on the **single plant**, rather than on the whole company
- Anonymized comparison with over **600 indicators** structured in **21 KPI**, scalable per **size**, **pharmaceutical forms**, etc.
- Participation of **more than 30** pharmaceutical plants among Spain, Portugal, Italy, Germany, Switzerland, and Austria

Benefits

- The tool provides an effective aid for the management of data collection and allows a detailed and reliable **comparison** among different companies, furthering the identification of **improvement areas** and accurate **corrective actions**, quantifiable in terms of potential **savings**

UPSTREAM LOGISTICS	PRODUCTION	QUALITY CONTROL	DOWNSTREAM LOGISTICS
1. OTIF - Suppliers 2. Inventory	3. Productivity 4. OEE 5. Wasted material 6. Overall indirect cost 7. WIP 8. Production cycle time	9. Quality area cost and productivity 10. Release cycle time 11. Production quality index 12. RFT	13. Inventory 14. OTIF - Clients 15. Industrial logistics cost 16. Distribution cost

INDUSTRIAL AREA
17. Clients complaints 18. Accidents 19. Absenteeism 20. Obsolescence 21. Total conversions cost per unit

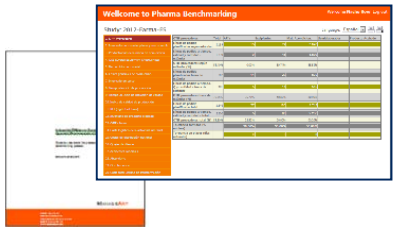
Pharma Industrial Efficiency Benchmark: a success case

«Industrial Efficiency Benchmark» case example

- **Background:** Production plant of a world leader pharmaceutical company
- **Objective:** Detection and quantification of improvement opportunities of the industrial efficiency

Data gathering — A

- Web access to pharmaceutical benchmarking users
- Support in data gathering phase
- On-site workshop to validate and verify data reliability
- Follow-up list of items to review
- Check and end of data gathering phase

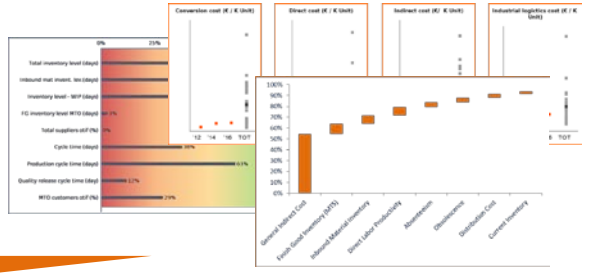


Data analysis — B

- Comparative analysis
- Information sanitization to ensure confidentiality
- Data segmentation (pharmaceutical form, business dimension, distribution channel, etc.)

Final presentation — C

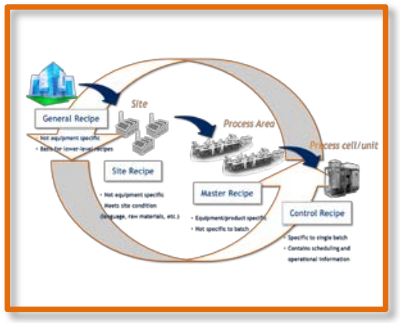
- Meeting with top management to present conclusions and deliver a absolutely confidential and tailor-made final report
- Potential improvement identification for the company
- Discussion about priorities and identification of specific action plans



- **Achievements**
  - Standardization of industrial process indicators
  - Positioning of the company with respect to all the participants
  - Identification of «best in class» companies
  - Identification of improvement opportunities and action plan definition in order to reduce the gaps

Standard ISA-88/95

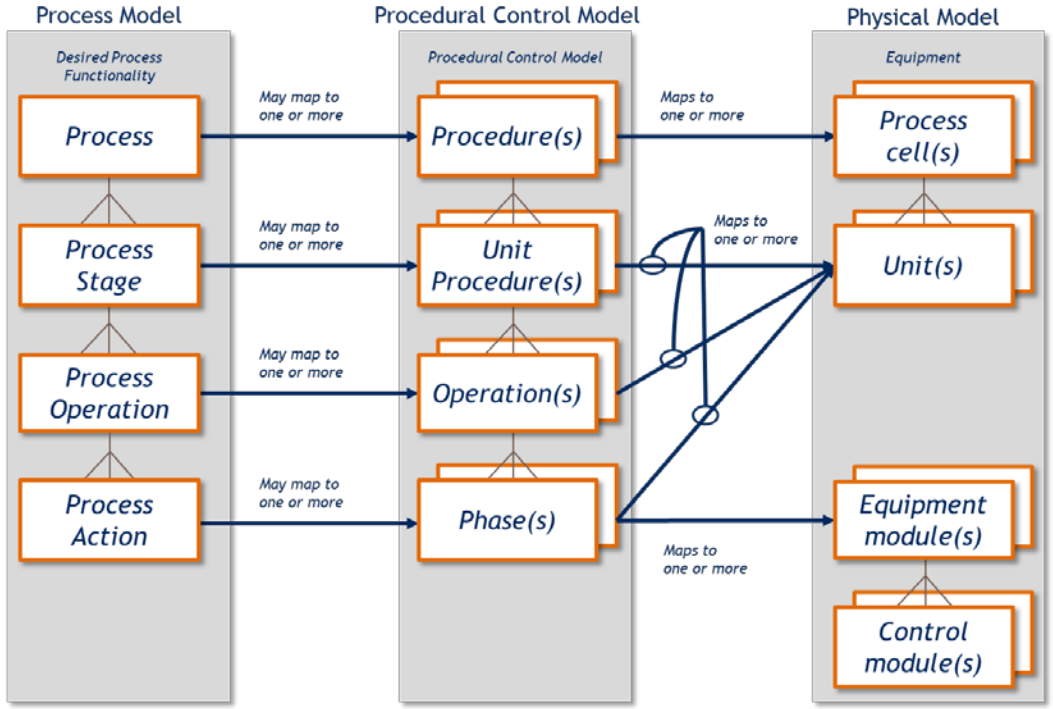
What is it



- Reference standards in **batch automation and control**
- ISA-88 standard provides guideline to efficiently **manage the development, transformation and execution** of industrial batch-recipes
- ISA-95 standard provides guideline to efficiently **define and manage information exchange** between business and manufacturing control systems

Benefits

- Increase batch-to-batch consistency
- Ease Investigation process
- Reduction time for site specific validation
- Reduction of time-to-market
- Standardization of processes and systems
- Increase of Project success Rate
- Reduces Integration costs due to standard format
- Eases proceduralization of workflows / SOPs



Standard ISA-88/95: a success case

«ISA-88 assessment & compliance» case example

- **Background:** Production plant of a world leader pharmaceutical company
- **Objective:** ISA-88 assessment and definition of a road map for the improvement

Data gathering

A

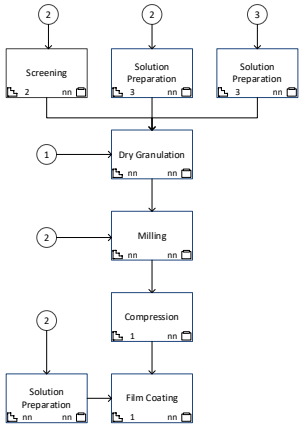
- Data gathering for the analysis of the AS-IS process

Quality Attributes	Applicable in Consumer
Appearance / Aspect	x
Odor	x
Color	x
Analytical test results, active	x
Analytical test results, preservative	
Analytical test results, solvent	
Identification	
Microbial Limits / Microbiological purity	
pH	
Preservative Effectiveness	
Viscosity	
Volume in container	
Clarity	
Density	
Drop point	
Drop point on bulk	

Process Elements definition

B

- Design and definition of Visio stencils for the standard Process Elements



Road Map definition

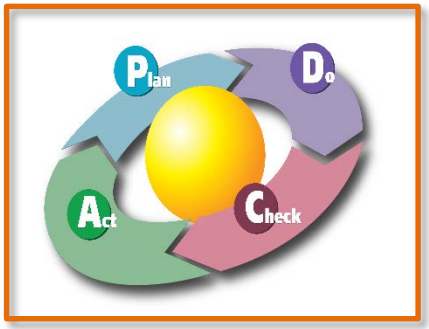
C

- Gap analysis and definition of improvement road map

- **Achievement**
  - Standardization of New Product Introduction process
  - Improvement of knowledge sharing

Operational Excellence in Pharma Industry

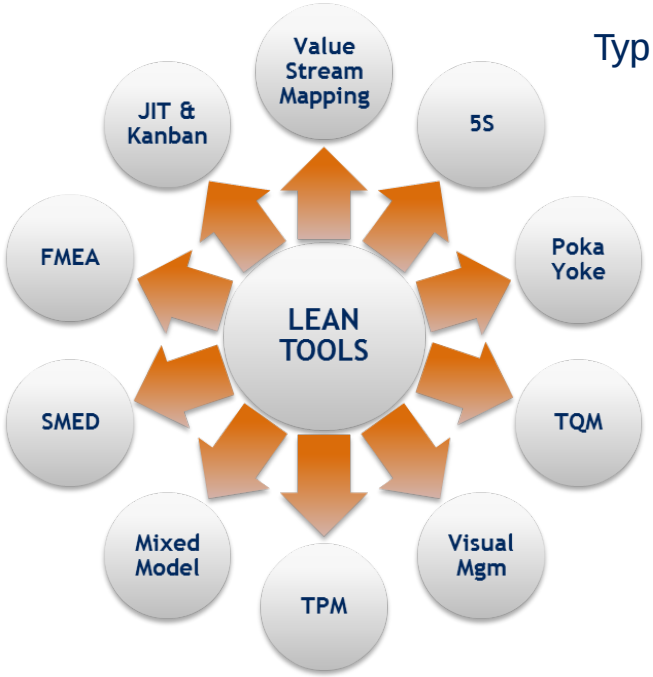
What is it



- **Operational Excellence** concerns a set of methods and techniques for improvement by which organizations are lead to excellence through continuous improvement
- The goal is to **reduce non-value-added activities and eliminate wastes,** including actions aimed to decrease failures and breakdowns, reduce scrap and defects, and increase performance

Areas of interest

- **Production**
- **Maintenance**
- **Warehouse**
- **Supply Chain**
- **Quality**
- **Process**



Typical projects in Operational Excellence:

- Lean Manufacturing & Six Sigma
- Maintenance Management
- Warehouse optimization
- Re-Layout and process analysis
- Inventory Management
- Support to design of storage points and warehouses
- Supply Chain Management
- Re-Design of business procedures

Operational Excellence in Pharma Industry: a success case

«Maintenance Management» case example

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

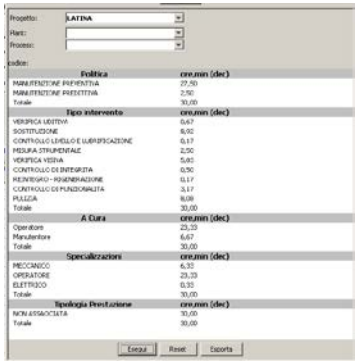
A — Criticality Analysis

- 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 K€	-	-	-	2
Fino a 5 K€	-	-	-	3
Fino a 10 K€	-	-	-	4
10 < x < 20 K€	Fino a 60 min	-	-	5
20 < x < 30 K€	Fino a 240 min	-	-	6
30 < x < 50 K€	Fino a 600 min	-	-	7
> 50 K€	Fino a 1440 min	-	-	9
-	> 1440 min	Si	-	9
-	> 2880 min	-	Si	10

B — Definition of action plans

- Definition of Preventive Maintenance Plans



C — Editing of maintenance procedures

- Procedures for Preventive and Autonomous Maintenance

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

Our Customers

OM Team provides services to several companies in different sectors, especially in **Pharma**:

References

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