



## ***ISO 9001 and Lean Six Sigma Comparison and Optimization of Synergies***



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# ISO9001 and Lean Six Sigma – Objectives and History

- **ISO9001**

- **PROVIDES INFRASTRUCTURE FOR IMPROVING OPERATIONS AND FOCUSING ON CUSTOMER NEEDS AND EXPECTATIONS IN ORDER TO IMPROVE THE CUSTOMER'S SATISFACTION**

- **LEAN SIX SIGMA = LEAN + SIX SIGMA**

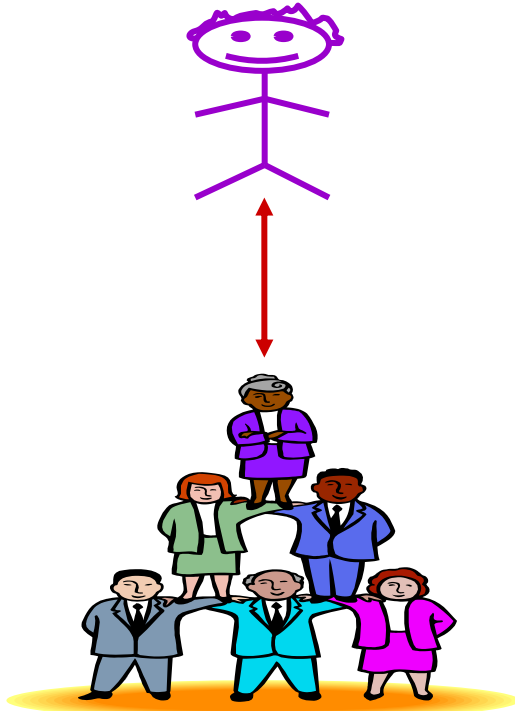
- **LEAN**

- **MINIMIZES/ ELIMINATES WASTE – REDUCES REQUIRED RESOURCES TO CARRY OUT WORK**
- **REDUCTION IN COST**

- **SIX SIGMA**

- **IMPROVES QUALITY OF PRODUCTS / SERVICES AND REDUCES VARIATION**
- **GREAT REDUCTION IN COST**

# Rational Behind Implementing a Quality Management System



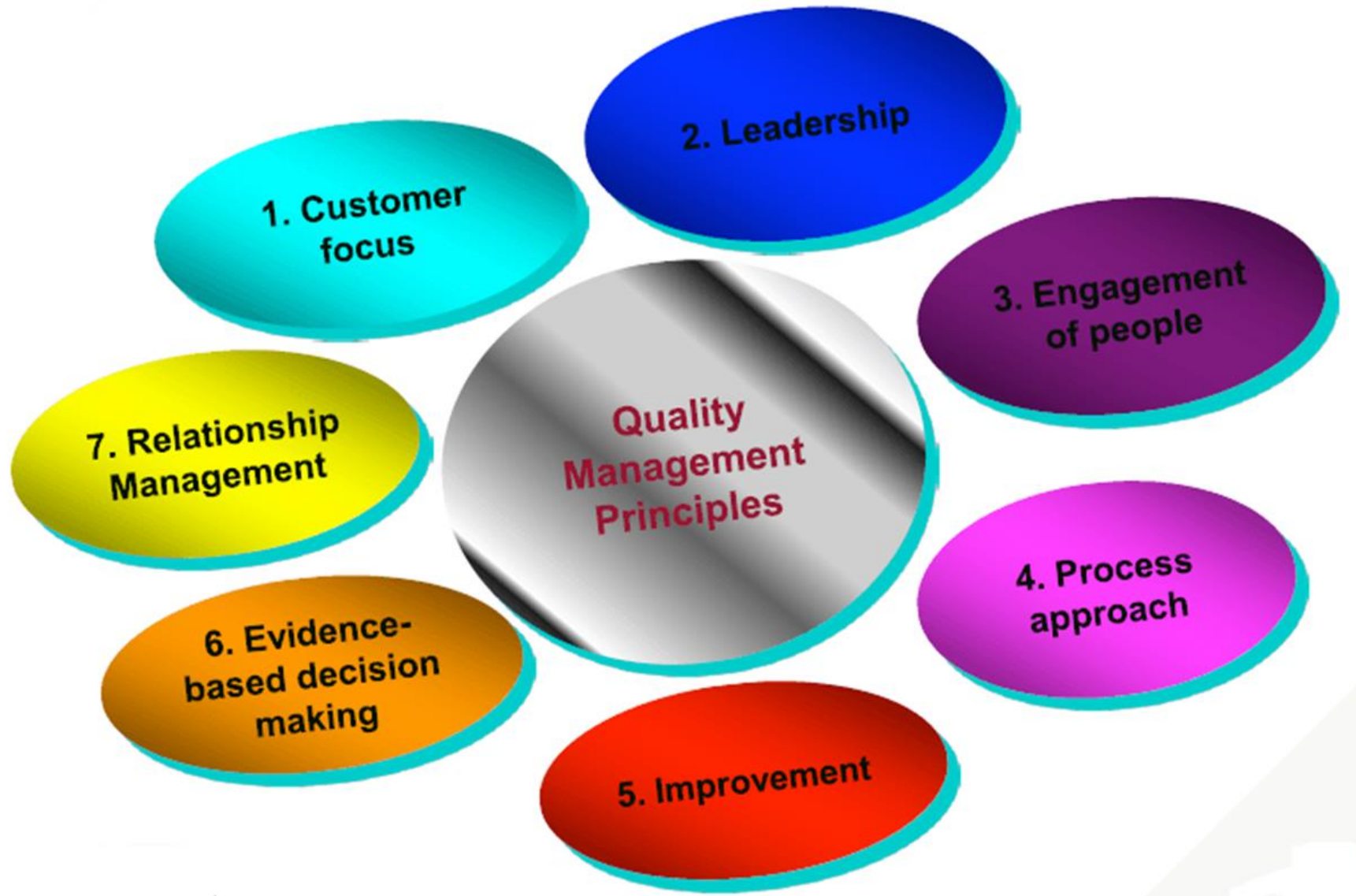
Customers require products that **satisfy their needs and expectations**

Customer requirements may be **stated, implied or determined**

Through a QMS, organizations are **encouraged** to:

- a. **analyze** customer requirements and transform them into product specifications
- b. **define** the processes through which it will **design and produce** these products so that its customers are **satisfied**
- c. implement **controls** in order to ensure that the **outcome** of these processes is according to **specifications**
- d. **implement** mechanisms for **continual improvement** so that it continually **adjusts** to the ever changing **customer demands** in order to continue to keep them **satisfied** and **even increase** their level satisfaction

# ISO9000: 2015 – Quality Management Principles

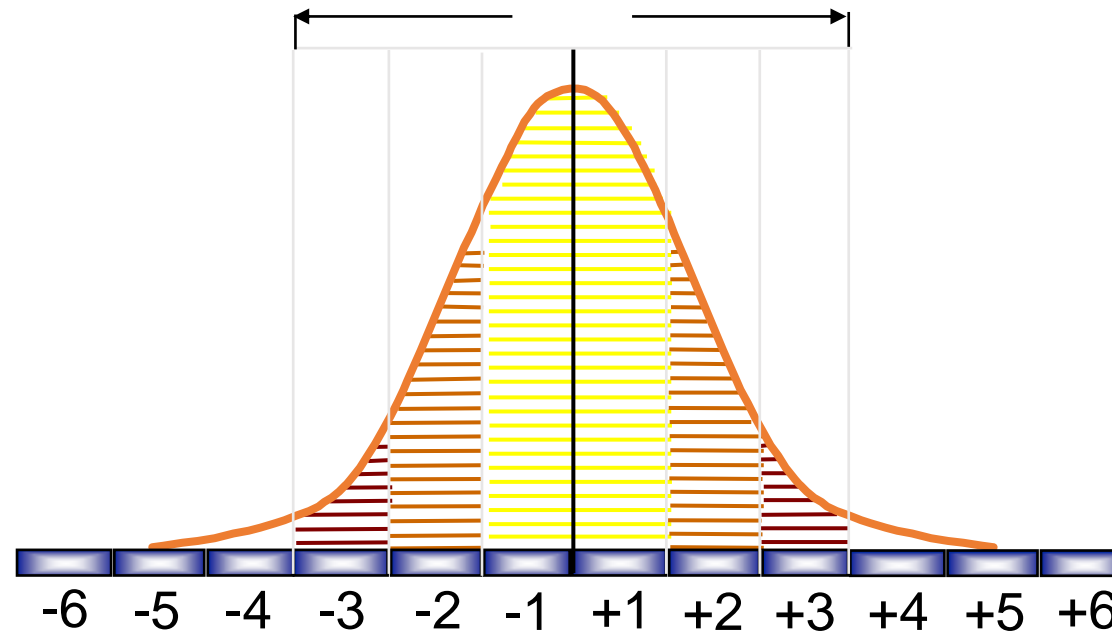


# Lean Principles

- "Toyota Way" (2001)
- Elimination of Waste
- 8 types of Waste
  - Overproduction
  - Overprocessing
  - Waiting/ Delay
  - Rework
  - Motion and Transport
  - Inventory
  - Work in Process
  - Intellect

## Six Sigma Measures the Data Spread

The probability of creating a defect can be estimated and *translated* into a “Sigma” level.

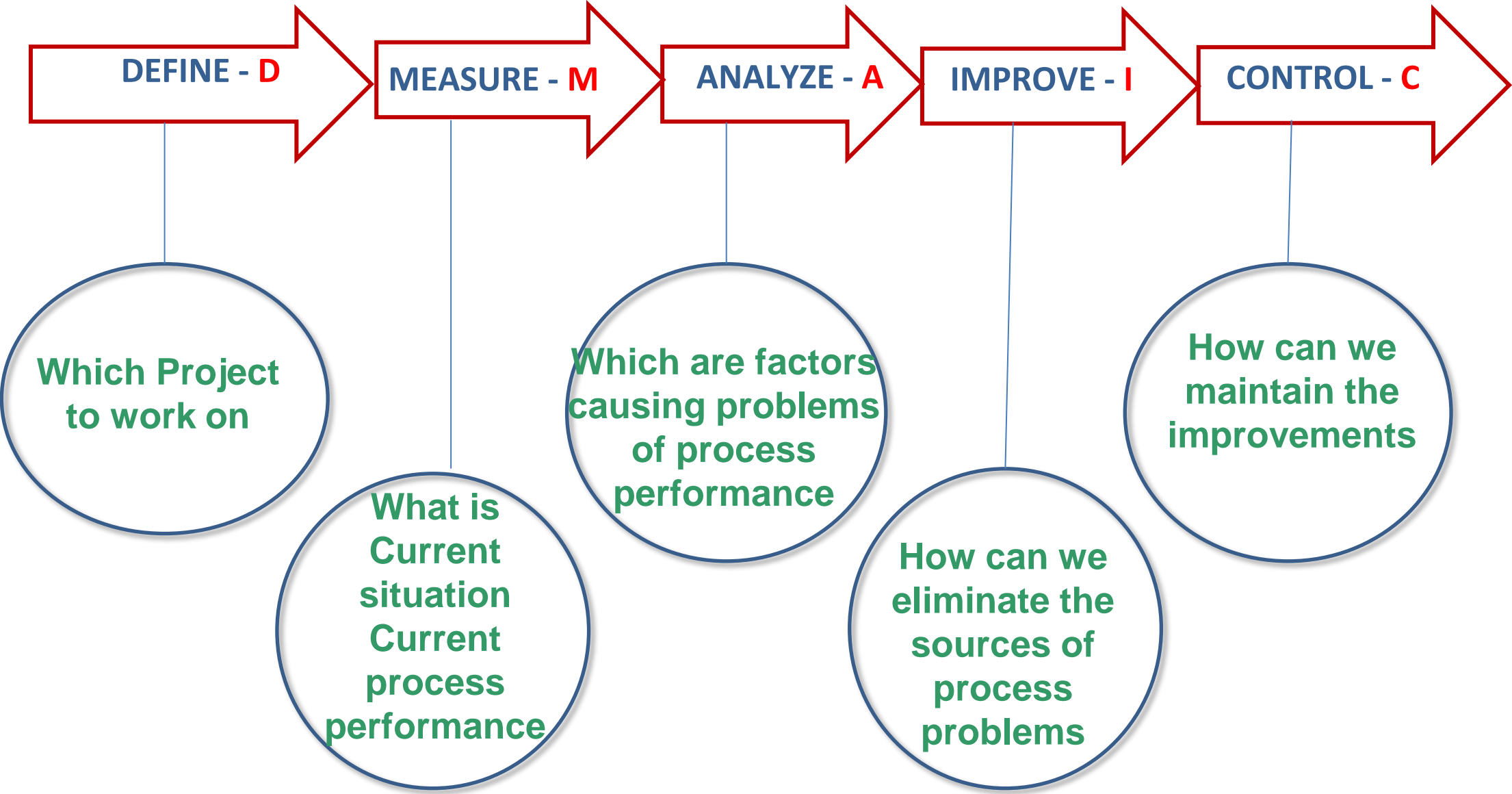


The higher the sigma level, the better the performance. Six Sigma refers to a process having 6 Standard Deviations between the average of the process center and the closest specification limit or service level

## Objective: 6 $\sigma$ , 3.4 defects per million opportunities (DPMO)

Process sigma – $\sigma$	Defects per million opportunities-DPMO	Yield
1	697,672	30.2328%
2	308,537	69.1463%
3	66,807	93.3193%
4	6,210	99.3790%
5	233	99.97670%
6	3.4	99.99966%

# DMAIC





<b>ISO9001 &amp; LSS MAIN SIMILARITIES</b>	<b>LEAN SIX SIGMA</b>	<b>ISO9001</b>
<b>BASIS FOR METHODOLOGY</b>	<b>PLAN-DO-CHECK-ACT</b>	<b>PLAN-DO-CHECK-ACT</b>
<b>INITIAL INVESTMENT</b>	<b>NECESSARY</b>	<b>NECESSARY</b>
<b>EXTERNAL CONSULTANT</b>	<b>USUALLY NEEDED (INITIALLY)</b>	<b>USUALLY NEEDED (FOR DEVELOPMENT)</b>
<b>STAFF INVOLVEMENT</b>	<b>NECESSARY</b>	<b>NECESSARY</b>
<b>MANAGEMENT COMMITTMENT</b>	<b>NECESSARY</b>	<b>NECESSARY</b>
<b>DECISION MAKING</b>	<b>BASED ON MEASURABLE CRITERIA</b>	<b>BASED ON MEASURABLE CRITERIA</b>
<b>TRAINING</b>	<b>NECESSARY</b>	<b>NECESSARY</b>
<b>FOCUS ON NEEDS OF CUSTOMERS AND OTHER STAKEHOLDERS</b>	<b>GUIDING PRINCIPLE</b>	<b>GUIDING PRINCIPLE</b>

<b>ISO9001 &amp; LSS MAIN SIMILARITIES</b>	<b>LEAN SIX SIGMA</b>	<b>ISO9001</b>
<b>PROCES APPROACH</b>	<b>IMPROVEMENT OF PROCESSES DEFECT REDUCTION AND LESS VARIATION</b>	<b>PROCESS APPROACH OF AN ORGANIZATION – A SYSTEM OF INTERACTING PROCESSES</b>
<b>PREVENTION INSTEAD OF FIREFIGHTING</b>	<b>ELIMINATION/ REDUCTION OF DEFECTS IN PRODUCTS/ SERVICES</b>	<b>CORRECTIVE AND PREVENTIVE MECHANISMS IMPLEMENTED</b>
<b>RISK MANAGEMENT</b>	<b>FMEA TOOL</b>	<b>A REQUIREMENT OF ISO9000:2015</b>
<b>ESTABLISHMENT OF QUALITY IMPROVEMENT CULTURE</b>	<b>INSTATED</b>	<b>INSTATED</b>
<b>VITAL SUCCESS FACTORS</b>	<b>MANAGEMENT COMMITTMENT, STAFF INVOLVEMENT, TRAINING, INVESTMENT</b>	<b>MANAGEMENT COMMITTMENT, STAFF INVOLVEMENT, TRAINING, INVESTMENT</b>

<b>ISO9001 &amp; LSS MAIN DIFFERENCES</b>	<b>LEAN SIX SIGMA</b>	<b>ISO9001</b>
<b>SCOPE OF IMPLEMENTATION (USUALLY INITIALLY)</b>	<b>SPECIFIC PROCESS (PROCESSES)</b>	<b>SPECIFIC FUNCTION/ DEPARTMENT OF ORGANIZATION</b>
<b>MAIN OBJECTIVE</b>	<b>SATISFACTION OF CUSTOMERS AND OTHER STAKEHOLDERS AND QUICK REDUCTION OF COST MAYBE SUPPLIER REQUIREMENT</b>	<b>SATISFACTION OF CUSTOMERS AND OTHER STAKEHOLDERS AND LONGER TERM REDUCTION OF COST</b>
<b>MAJOR ROLES ASSIGNED</b>	<b>GB, GB, BB, MBB</b>	<b>MR</b>
<b>CERTIFICATION</b>	<b>STANDARD DEVELOPED</b>	<b>USALLY A MUST</b>

<b>ISO9001 &amp; LSS MAIN DIFFERENCES</b>	<b>LEAN SIX SIGMA</b>	<b>ISO9001</b>
<b>PROCESS APPROACH</b>	<b>EMPHASIS ON PROCESS IMPROVEMENT (IMPROVEMENT OF EFFECTIVENESS AND EFFICIENCY)</b>	<b>EMPHASIS ON PROCESS STANDARDIZATION</b>  <b>SYSTEMS APPROACH</b>  <b>MECHANISMS FOR IMPROVEMENT OF THE QMS REQUIRED</b>  <b>PROCESS IMPROVEMENT MECHANISM REQUIRED (AS PART OF A SYSTEM OF INTERRELATED PROCESSES)</b>
<b>METHODOLOGY</b>	<b>DMAIC AND TOOLS</b>	<b>A SYSTEM OF SPECIFICATIONS/ MECHANISMS REQUIRED</b>
<b>INITIAL INVESTMENT (DEPENDING ON SCOPE)</b>	<b>USUALLY LESS</b>	

<b>ISO9001 &amp; LSS MAIN DIFFERENCES</b>	<b>LEAN SIX SIGMA</b>	<b>ISO9001</b>
<b>IMPROVEMENT TOOLS</b>	<b>GREAT VARIETY OF QUANTITATIVE AND QUALITATIVE TOOLS</b>	<b>IMPROVEMENT MECHANISMS</b>
<b>GREATEST TIME CONSUMPTION</b>	<b>COLLECTION AND ANALYSIS OF INFORMATION AND DATA</b>	<b>DEVELOPMENT OF PROCESSES</b>
<b>STAFF INVOLVEMENT</b>	<b>INITIALLY LESS (SMALLER SCOPE)</b>	<b>GREATER DUE TO SCOPE</b>
<b>TRAINING</b>	<b>MORE FOR INPUT TO PROCESS IMPROVEMENT SPECIALIZED FOR TOOLS, MORE QUANTITATIVE</b>	<b>MORE TO BUILD QUALITY CULTURE AND IMPLEMENTATION</b>
<b>SW TOOLS NEEDED</b>	<b>NEED TOOLS TO ANALYZE DATA</b>	<b>LESS NEED FOR DATA ANALYSIS SIMPLE DOCUMENTATION SW</b>

<b>ISO9001 &amp; LSS MAIN DIFFERENCES</b>	<b>LEAN SIX SIGMA</b>	<b>ISO9001</b>
<b>IMPLEMENTATION</b>	<b>MORE WIDESPREAD IN USA</b>	<b>MORE WIDESPREAD IN USA IN EUROPE</b>
<b>MARKETING TOOL</b>	<b>COMPETITIVE ADVANTAGE BY INVESTORS</b>	<b>COMPETITIVE ADVANTAGE BY CUSTOMERS</b>
<b>REALIZATION OF COST BENEFIT</b>	<b>EARLIER</b>	<b>LONGER TERM</b>
<b>CONDITIONS FOR SUCCESS</b>	<b>EXTENSIVE TRAINING OF MORE STAFF</b>	<b>USUALLY GREATER INVESTMENT (DEPENDING ON SCOPE) COMMITMENT FROM MORE STAFF</b>

**ADVANTAGES OF ISO9001  
OVER LSS**

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OVER ISO9001**

**IMMEDIATE COMPETITIVE ADVANTAGE**

**SPECIFIC METHODOLOGY  
AND TOOLBOX TO ASSIST IN  
IDENTIFYING AND PROVING  
SOURCES OF PROBLEMS  
AND IN DECISION MAKING**

**INFRASTRUCTURE BASIS FOR IMPLEMENTING IN THE  
WHOLE ORGANIZATION**

**EASIER TO IMPLEMENT FOR  
A QUICK RETURN**

**INDEPENDENT ASSESSMENT – PROVIDES  
CONFIDENCE TO CUSTOMER**

**IF CUSTOMER REQUIREMENT, EASIER TO OBTAIN  
MANAGEMENT’S COMMITMENT TO PROVIDE  
RESOURCES**

**IMMEDIATE MEASURES  
PROVIDE MANAGEMENT  
INFORMATION AND  
CONFIDENCE IN ORDER TO  
EXPAND SCOPE**

**ADVANTAGES OF ISO9001  
OVER LSS**

**ADVANTAGES OF LSS  
OVER ISO9001**

**MORE STAFF INVOLVEMENT – FOSTERING QUALITY CULTURE**

**CROSS FUNCTIONAL APPROACH TO PROCESS**

**INSTALLS INFRASTRUCTURE WHICH ASSISTS IN IMPLEMENTING ADDITIONAL STANDARDS (14001, 18000 ETC)**

**SHORTER TIME AND COST FOR A “PILOT” TRIAL IMPLEMENTATION**

**EXTERNAL ASSESSMENT AND INTERNAL AUDIT ARE PRESSURES FOR TIMELY AND EFFECTIVE IMPLEMENTATION**

**MEASURES EFFICIENCY IN ADDITION TO EFFECTIVENESS**

**NO NEED TO SPECIALIZED SW**

**DATA ANALYSIS NEEDS SW**



## **ISO9001 & LSS SYNERGIES**

**LSS OFFERS TO ISO9001 SPECIFIC PROCESS IMPROVEMENT METHODOLOGY**

**LSS OFFERS TO ISO9001 TOOLS FOR DECISION MAKING BASED ON OBJECTIVE/  
MEASURABLE DATA**

**LSS OFFERS TO ISO9001 TOOLS FOR PRIORITIZING IMPROVEMENT PROJECTS**

**LSS OFFERS TO ISO9001 TOOLS FOR MANAGING RISKS AND IDENTIFYING  
OPPORTUNITIES**

**LSS CAN ENCOURAGE CHANGE AND QUALITY CULTURE**

**BOTH METHODOLOGIES FOCUS ON THE NEEDS OF THE CUSTOMER**

**BOTH METHODOLOGIES DEAL WITH PROCESSES**

## **ISO9001 & LSS SYNERGIES**

**IMPLEMENTING ISO9001 INCORPORATES DOCUMENTING THE “AS IS” PROCESSES WHICH ARE THE BASE LINE FOR PROCESS IMPROVEMENT THROUGH LSS**

**IMPLEMENTING LSS REQUIRES MANAGEMENT’S COMMITMENT (RESOURCES, IMPLEMENTATION) AND ISO9001 REQUIRES THAT MANAGEMENT DEMONSTRATES COMMITMENT**

**LSS IMPLEMENTATION REQUIRES STAFF INVOLVEMENT AT ALL LEVELS – INCLUDING MANAGEMENT, AS ISO9001**

# IMPLEMENTATION STRATEGY

## SENARIOS

- **FIRST ISO9001 AND AFTER STABILIZATION, LSS FOR IMPROVEMENT**
- **FIRST LSS FOR IMPROVEMENT AND THEN STANDARDIZATION AND CERTIFICATION TO ISO9001**

## SEVERAL CRITERIA – E.G.

- **IMMEDIATE REQUIREMENT FOR CERTIFICATION TO ISO9001–  
COMPETITIVE ADVANTAGE/ CUSTOMER REQUIREMENT**
- **INVESTOR’S REQUIREMENT FOR COST REDUCTION**
- **IMMEDIATE NEED FOR COST REDUCTION/ CUSTOMER SATISFACTION**

# ISO9001 & LEAN SIX SIGMA TOOLS

COMPLEMENT EACH OTHER

