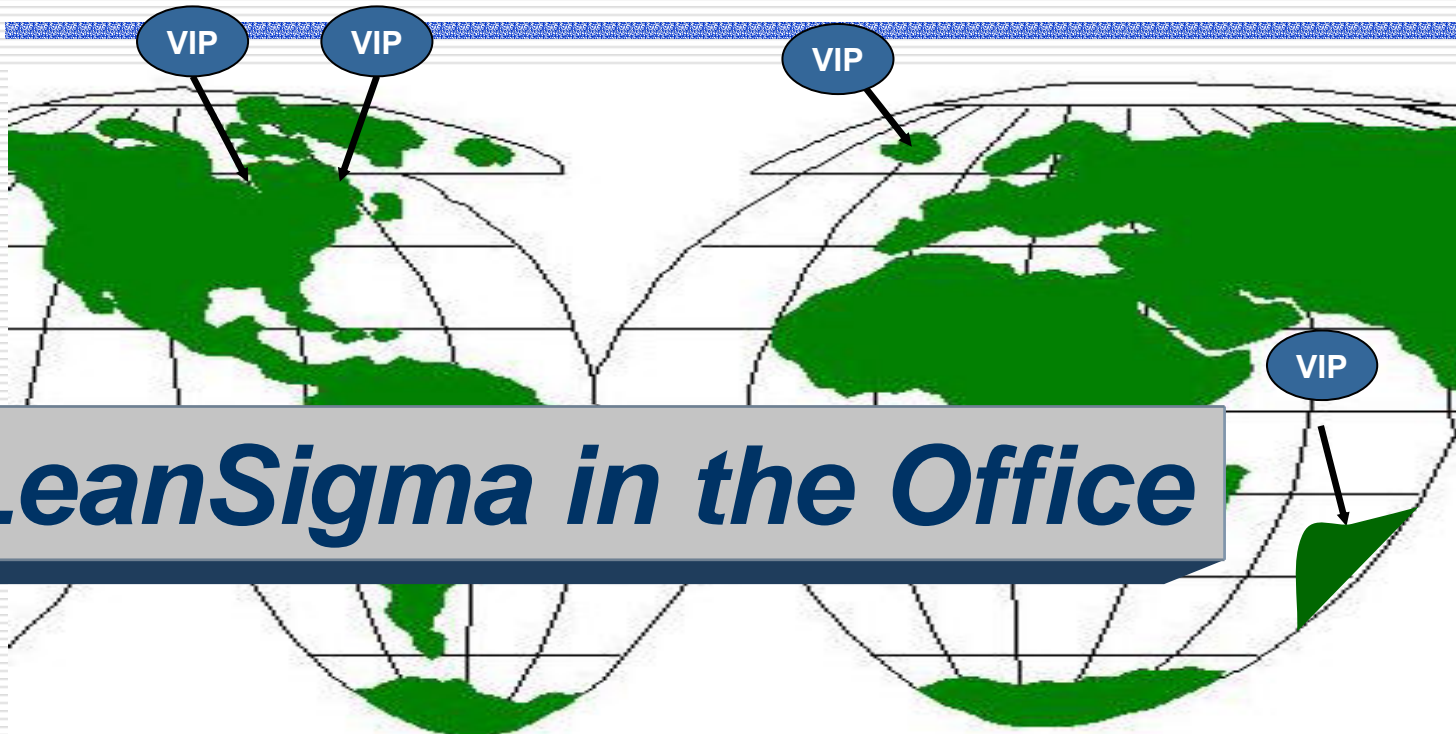


Value Innovation Partners

partnership in value creation



LeanSigma in the Office

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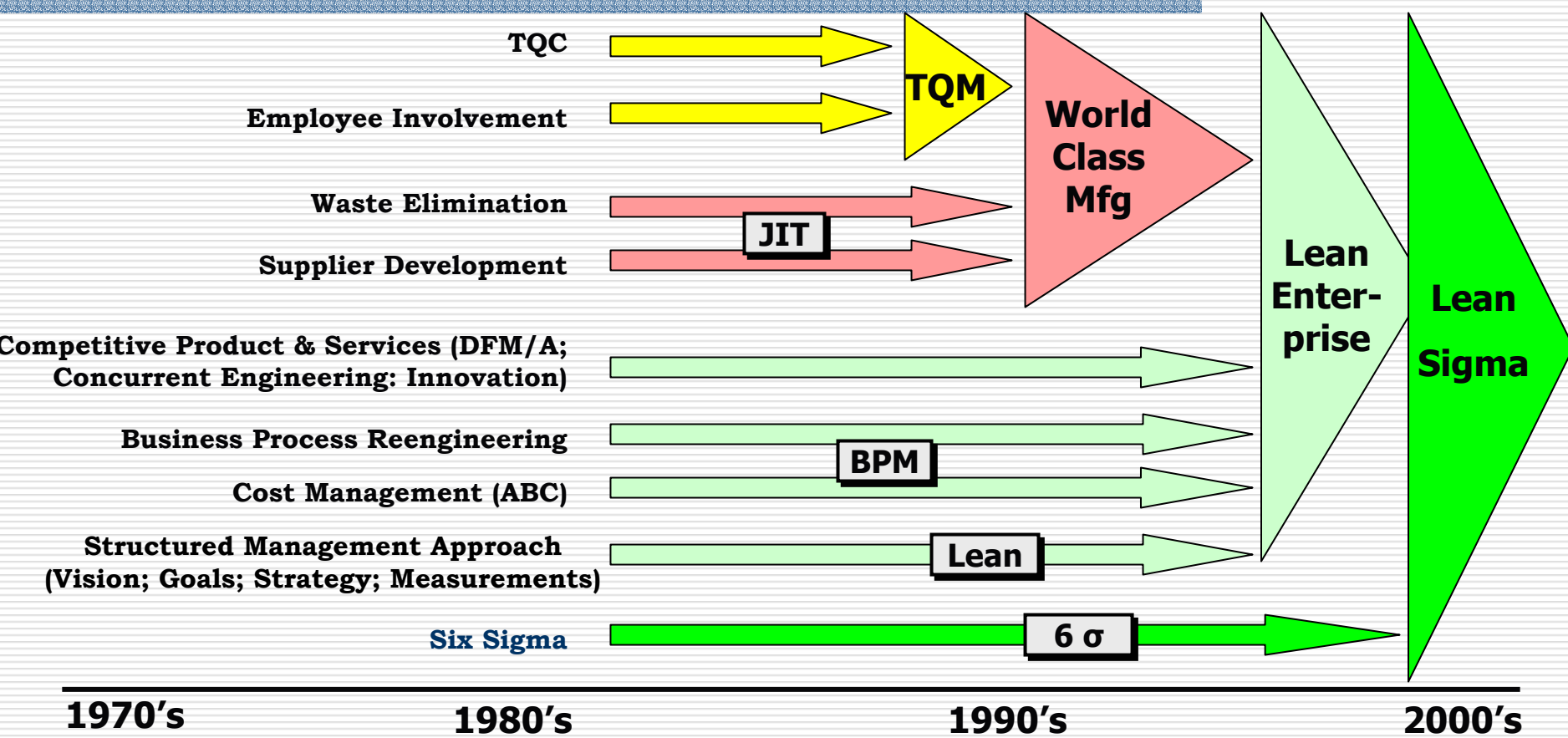
The Agenda



• What is LeanSigma

- Lean
- Six Sigma
- Lean Sigma
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Evolution of Lean Sigma



All efforts are focused on Process Excellence

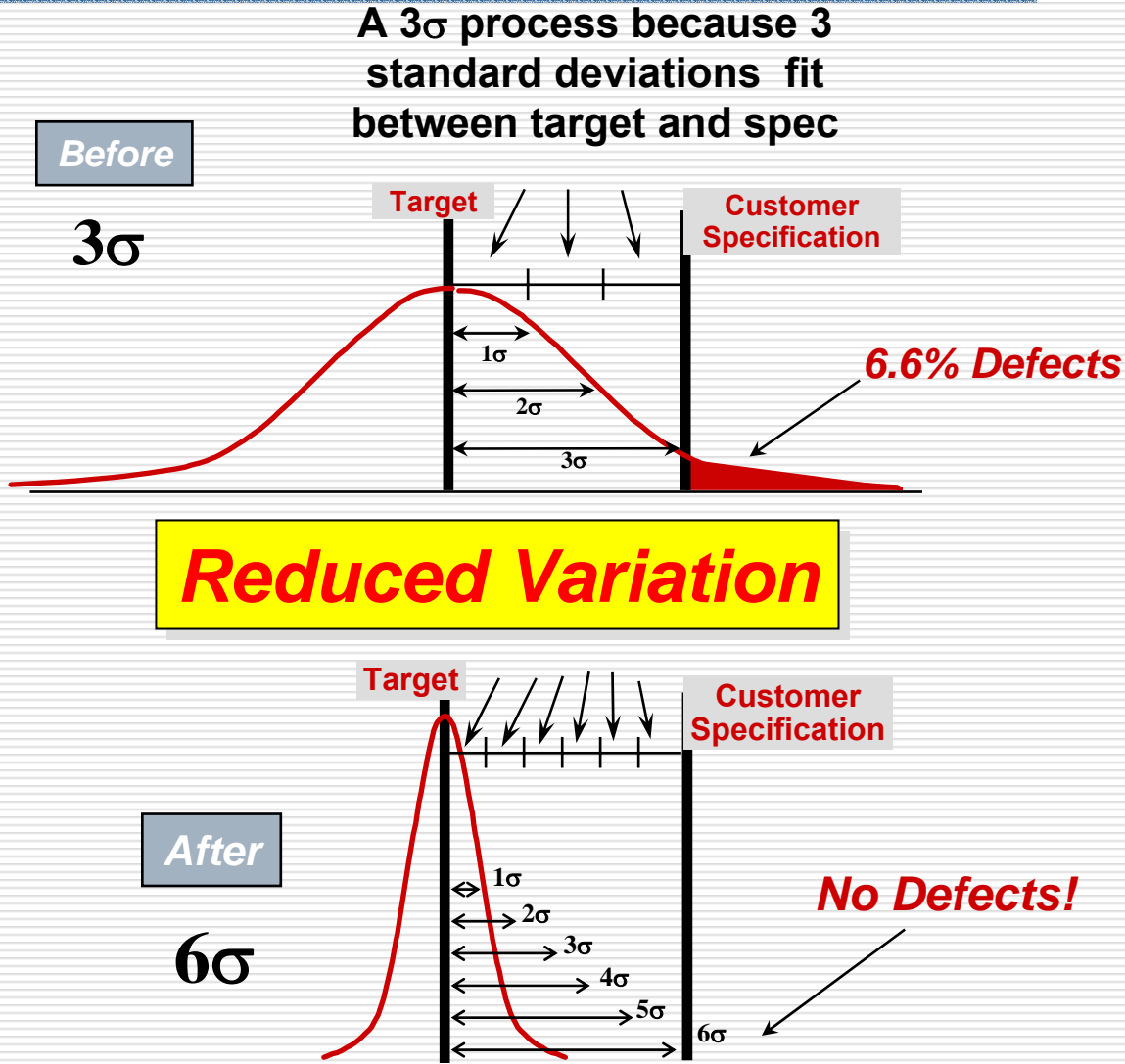
What is Lean Enterprise

A Group of individuals, functions, and sometimes legally separate but operationally synchronized organizations. The value stream defines the Lean Enterprise. The objectives of the Lean Enterprise are to:

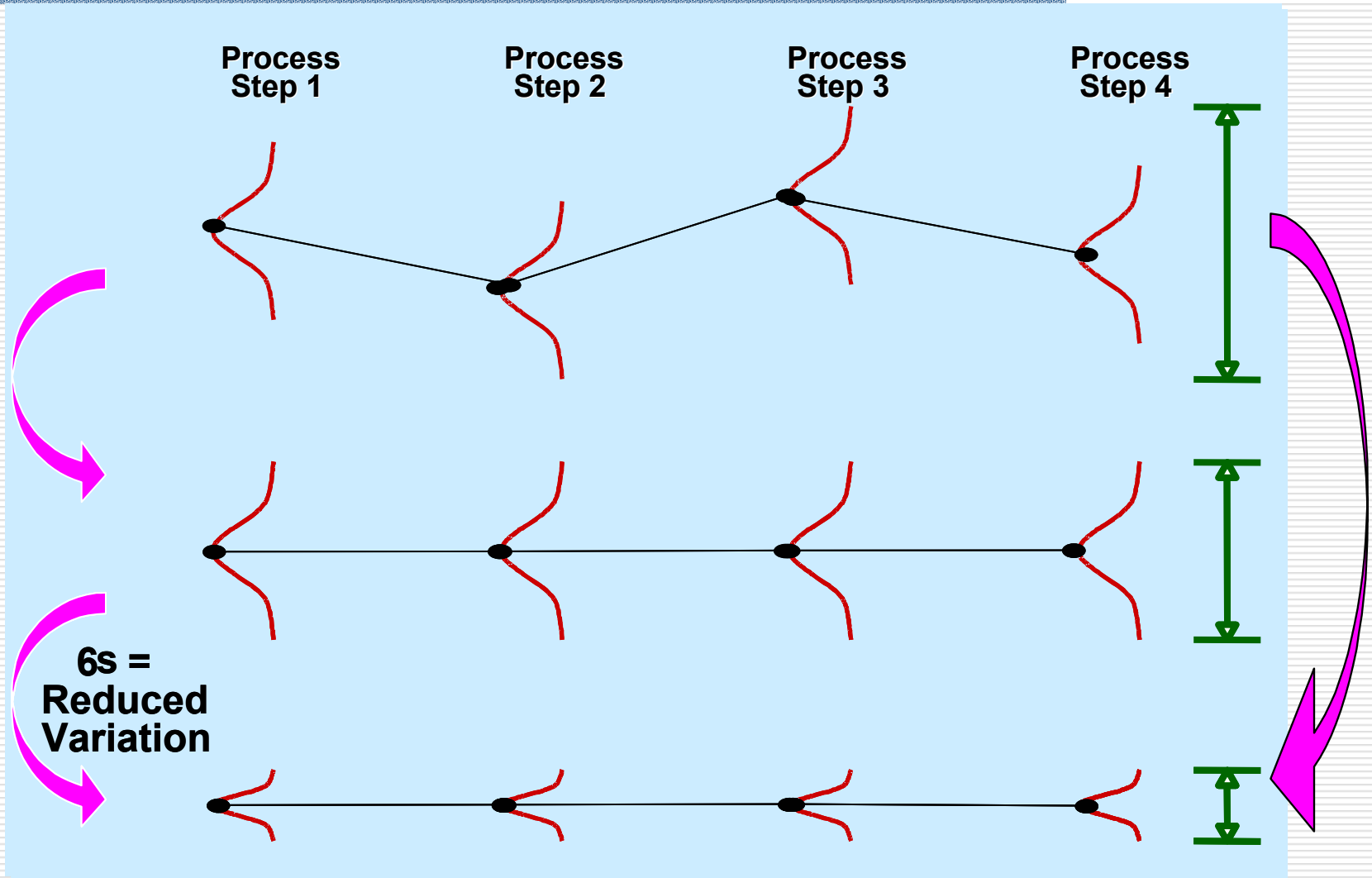
- correctly identify and specify “value to the ultimate customer / consumer” in all its products and services
- analyze and focus the value stream so that it does everything from product development and production to sales and service in a way that activities that do not create value are removed and actions that do create value proceed in a continuous flow as pulled by the customer.

Lean is focused on reducing waste through increasing speed, reducing process inventory and decreasing process cycle times

What is Six Sigma

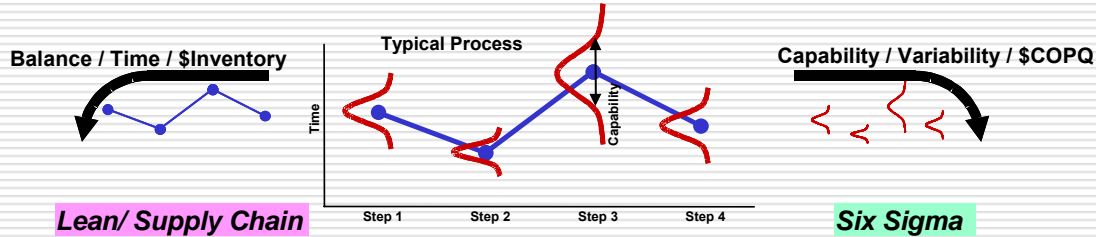


What is Lean Sigma



Lean Sigma “DMAIC” Approach

**Lean Sigma
& Process
Improvement**



Phases

Define

Voice Of the Customer
Value Stream Mapping
Product Family Matrix
Muda Matrix

Deliverables

Select projects within the process

Measure

Cycle Time Measurement
5S, Quick Hits, OTD, LT
Sequence Of Events
Spaghetti Diagram

Quality Basics
Minitab, Basic Graphical Analysis
Z Calc, Capability metrics
Measurement Systems Analysis

Understand current state and potential factors

Analyze

Takt Time Determination
Mixed Model Line Balance
Vendor Managed Inventory

Cause & Effect, FMEA
Statistical Hypothesis Testing

Confirm Vital Few factors

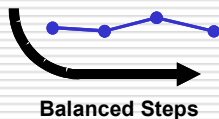
Improve
Control

Heijunka, Kanban, Pull
OMS, Visual Management
Flexing, Daily Rate Planning

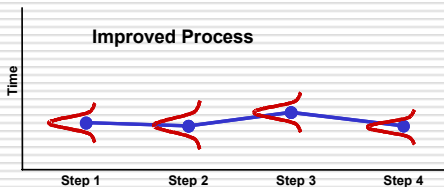
Design Of Experiments, Tolerance
Poka Yoke
SPC, Control Plan

Optimize, Implement Sustain

Improving Balance...
Enhances Process Capabilities



Improving Capabilities...
Enhances Process Balance



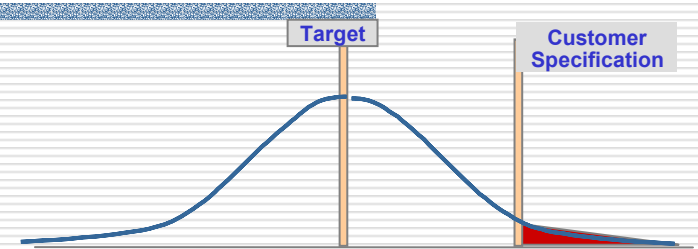
Customer Focused Quality

Potential Benefits

Lean Sigma Potential Results

- **Productivity +20% per year**
- **Lead Time Reduced to a Few Days (75%)**
- **Manufacturing Space Cut in Half**
- **Reduce Overhead and Quality Cost 20% /yr**
- **Inventory Turns +25% Per Year**
- **Little or No Capital Investment**
- **Cycle times at 3 to 4 times “one piece touch time”**

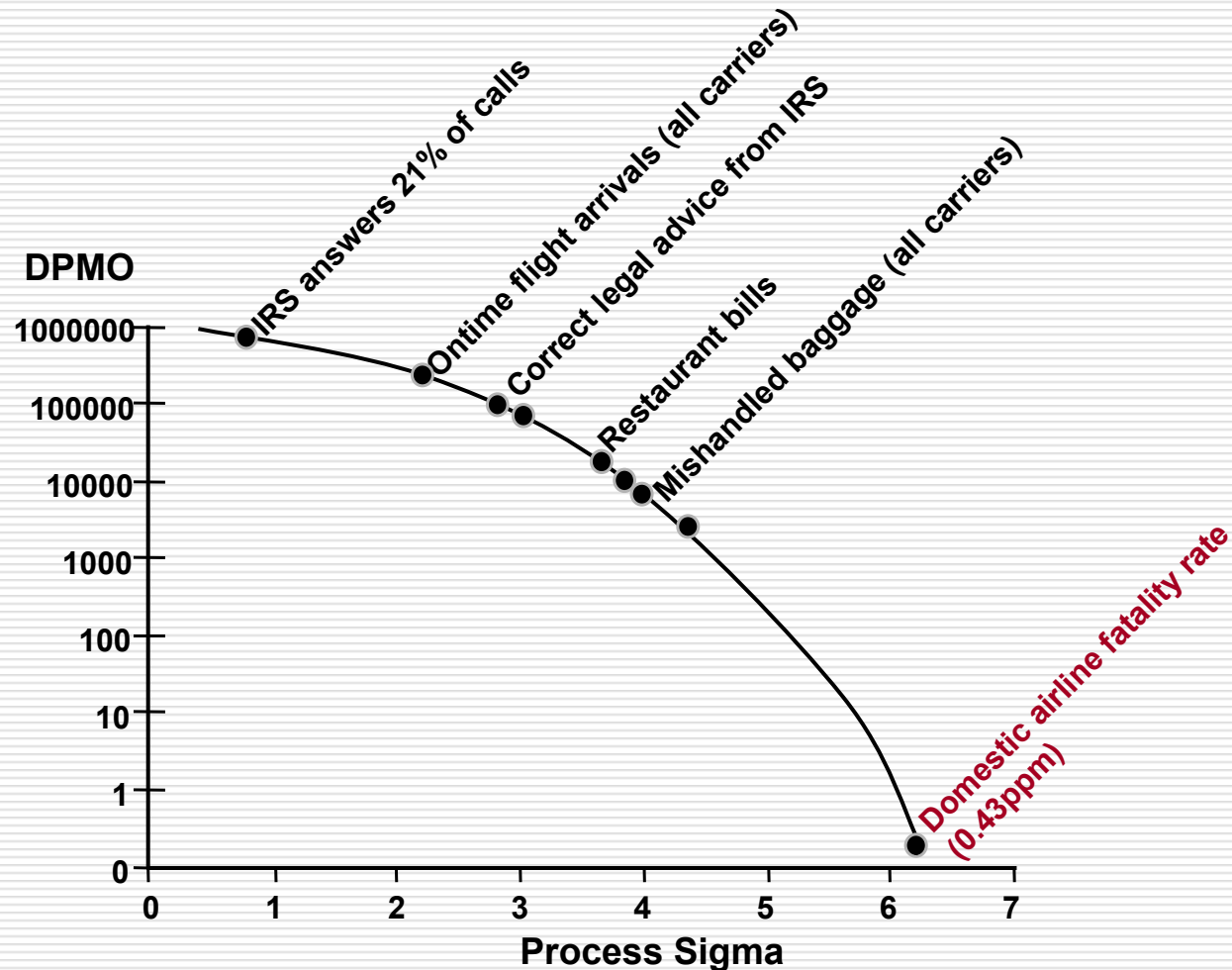
The Lean Sigma Philosophy



- The enemy of **quality** is **variation**
- The enemy of **lean** is **waste**
- Implement **lean** = reduced **variation**
- Implement **Six Sigma** = reduced **waste**
- **Lean** and **Six Sigma** enhance each other

Where are Businesses Today?

Most business processes are around 3σ



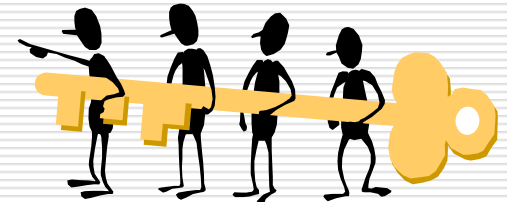
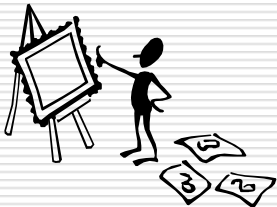
- 99% results in:
 - 20,000 lost articles of mail per hour
 - 5,000 incorrect surgical operations per week
 - 200,000 wrong prescription drugs each year
- Even at 99.9% quality (= 4.6 sigma)
 - 20,000 wrong drug prescriptions per year
 - Two short or long landings at O'Hare airport each day

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Principles of a LeanSigma Office

- Positive, clear communications.
- Ensure “no-blame” culture.
- Work through cross functional teams.
- Staff involvement at every stage.
- Process maps on display for comments.
- Remove non-value added steps, hand-off`s, rework loops.
- Agree design principles with All.
- Fix the root cause not the symptom.
- Ensure solution supports departmental interfaces.
- Incorporate Continuous Improvement



LeanSigma is Achieved Through:

***Simplifying*.....Processes**



***Integrating*.....Across Organizations**



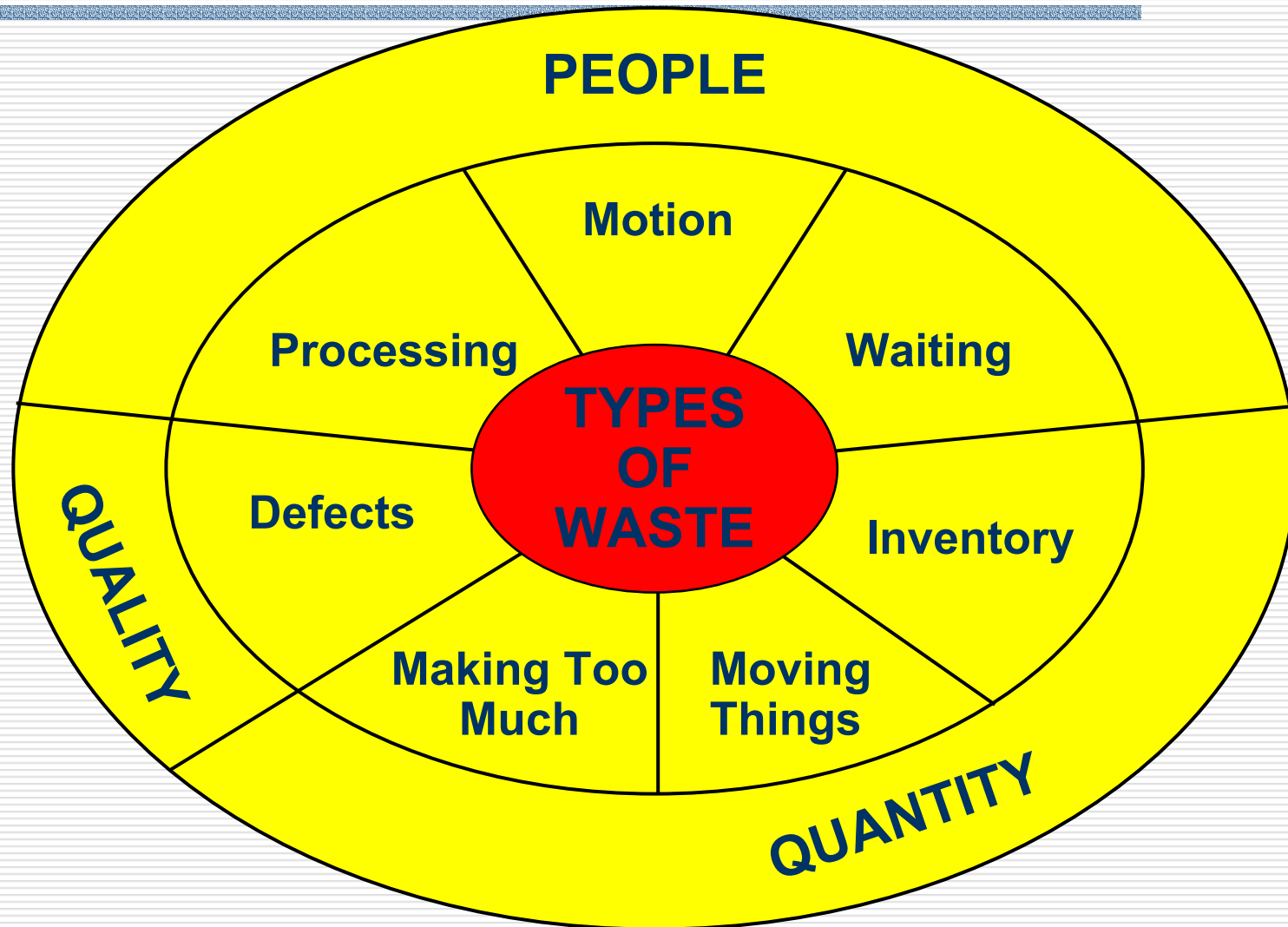
***Automating*..... Utilizing IT functionality and
connectivity**

WASTE or “MUDA”

*... Any resource-consuming activity
that delivers NO value to the customer*

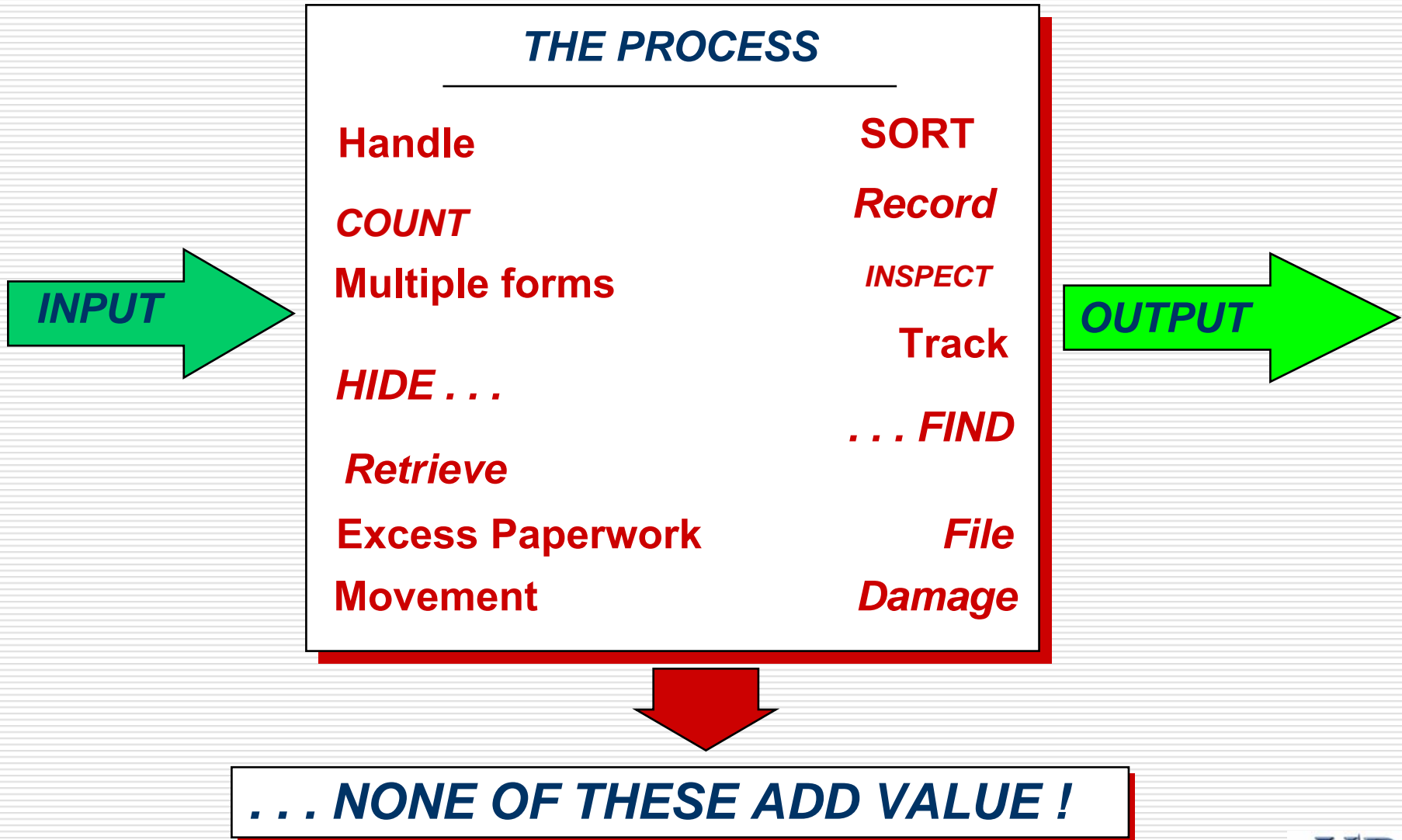
Lean Sigma Means...

Identifying and Eliminating the 7 Wastes



TAIICHI OHNO, ARCHITECT OF THE TOYOTA PRODUCTION SYSTEM

Waste In The Office



The analysis and redesign requires a clear understanding of:

Value Added, Non Value Added, and Sustaining Activities

VA The value related attribute of an activity can only be assessed in the context of the process, never in isolation
–Considering other activities upstream and downstream

Value Added activities are those absolutely necessary to deliver the customer's requirements
–These are colored green on the flowcharts
–They are later re-designed into the new process

NVA

Non Value Added activities are those that are not necessary to deliver the customer's requirements and can be eliminated in the re-design
–These are colored red on the flowcharts



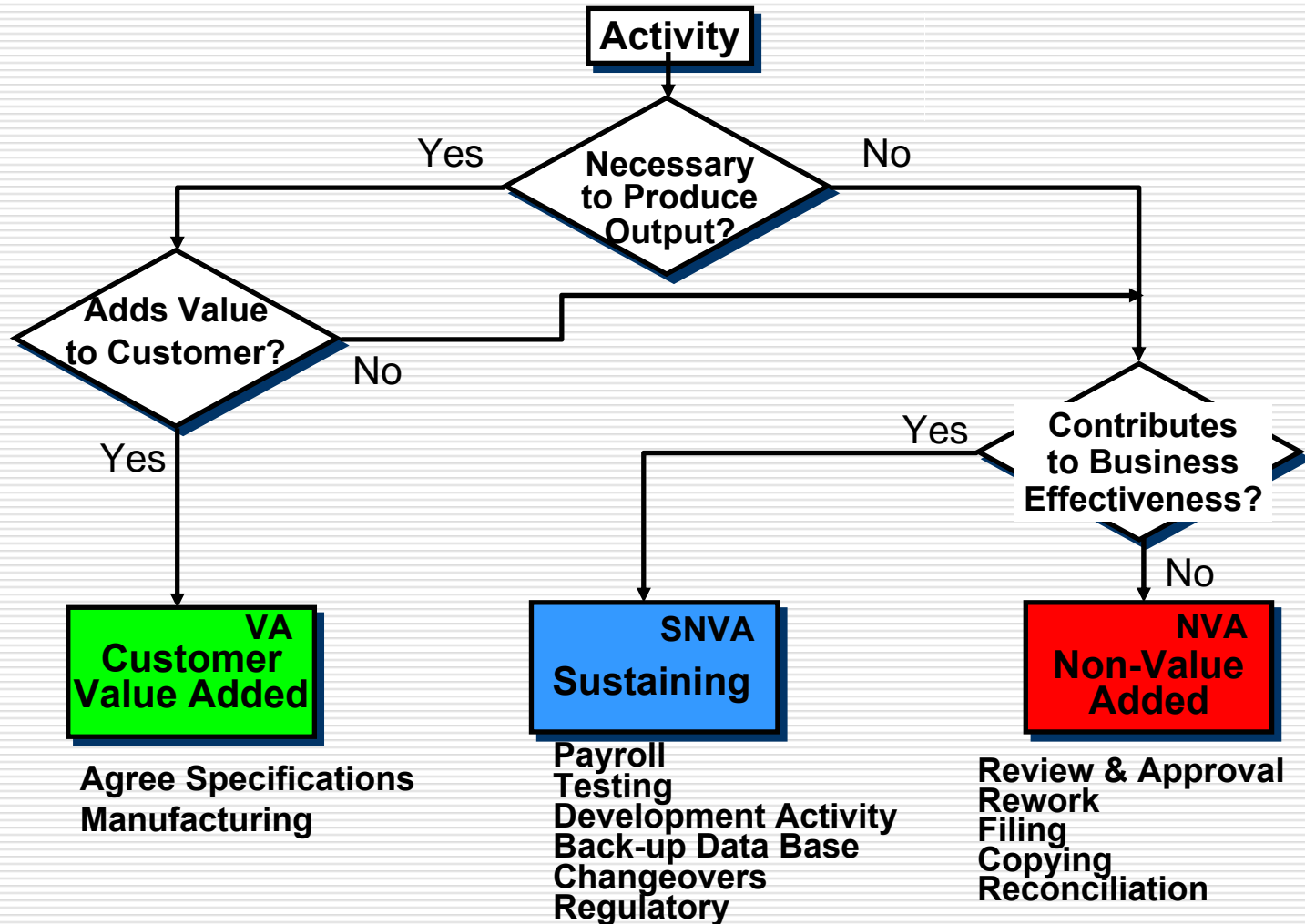
Sustaining activities are those that are not necessary to deliver the customer's requirements but are either:

- absolutely necessary to sustain the business or:
- cannot be eliminated due to known severe constraints (often external)
- These are colored blue on the flowcharts
- They are later re-designed into the new process

Sustaining Activities

Sustaining activities are targeted for gradual elimination during the Continuous Improvement process

How to Determine VA / NVA / SNVA?



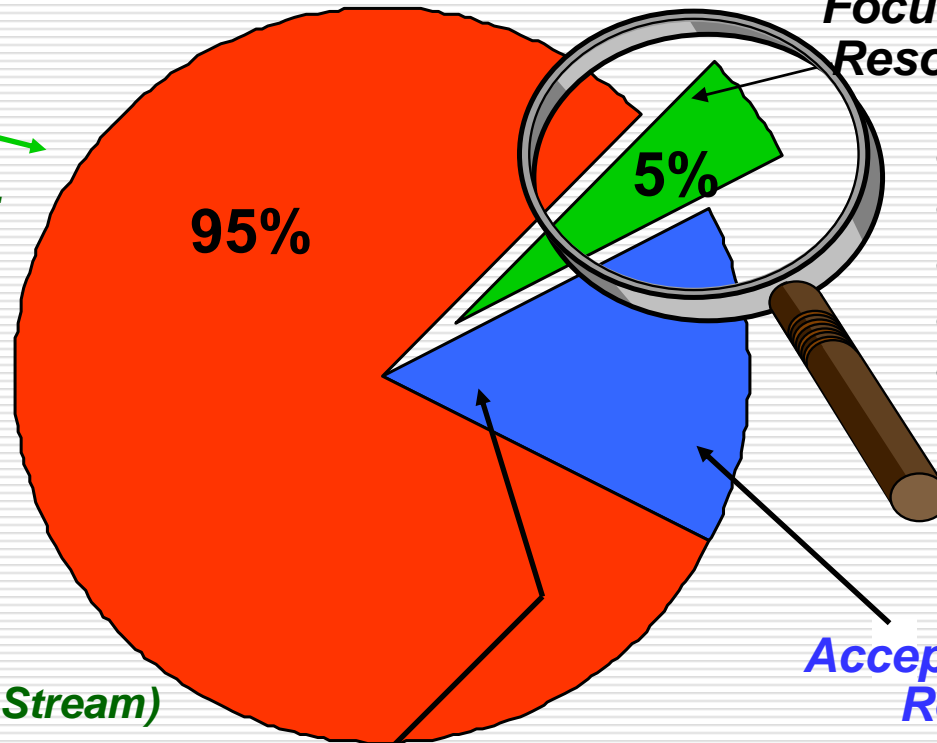
Approaches to Improvement

LEAN SIGMA APPROACH

*Focus on the 95%
Non-Value Added
Resources Through . . .*

- *Total Quality Control*
- *Total Waste Elimination*
- *Enforced Problem Solving*
- *Total Involvement*
- *Process Focus (Value Stream)*

*Challenge/Reduce the Need for
Imposed Quality Requirements*



TRADITIONAL APPROACH

*Focus on Value Added
Resources through . . .*

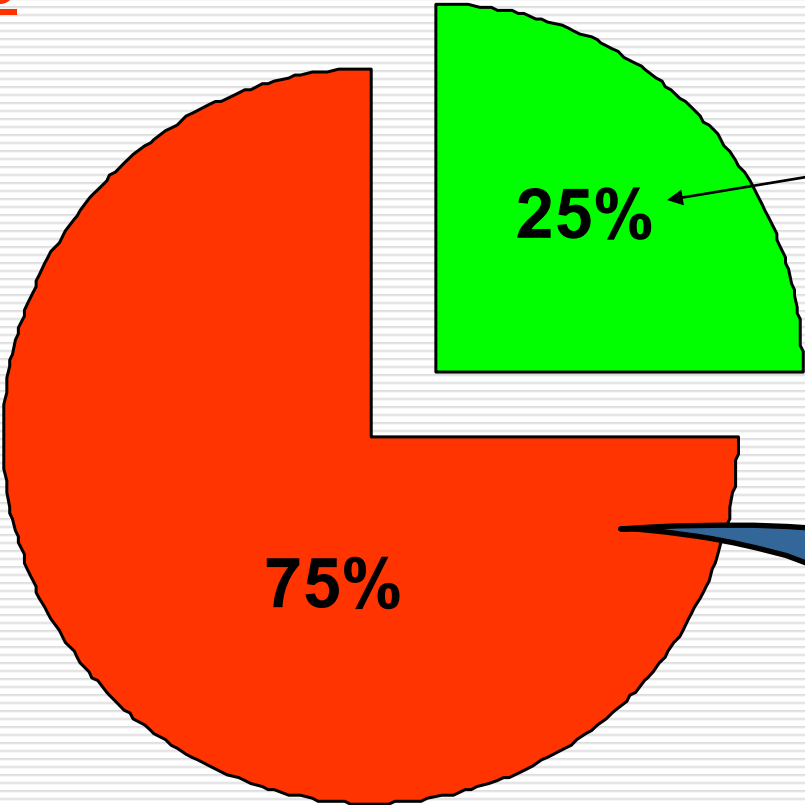
- *Time Study*
- *Work Study*
- *Piecework*
- *Utilization*
- *Automation*

*Accept Imposed Quality
Requirements*

Lead Time Analysis ... Office Processes

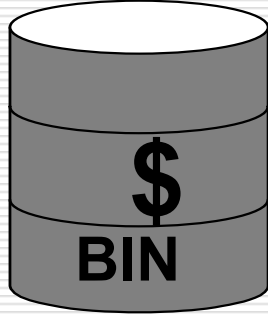
NON-VALUE ADD

- Recording
- Sorting
- Counting
- Filing
- Retrieving
- Corrections
- Reconciliation
- Copying
- Tracking
- Etc
- Stocking/restocking



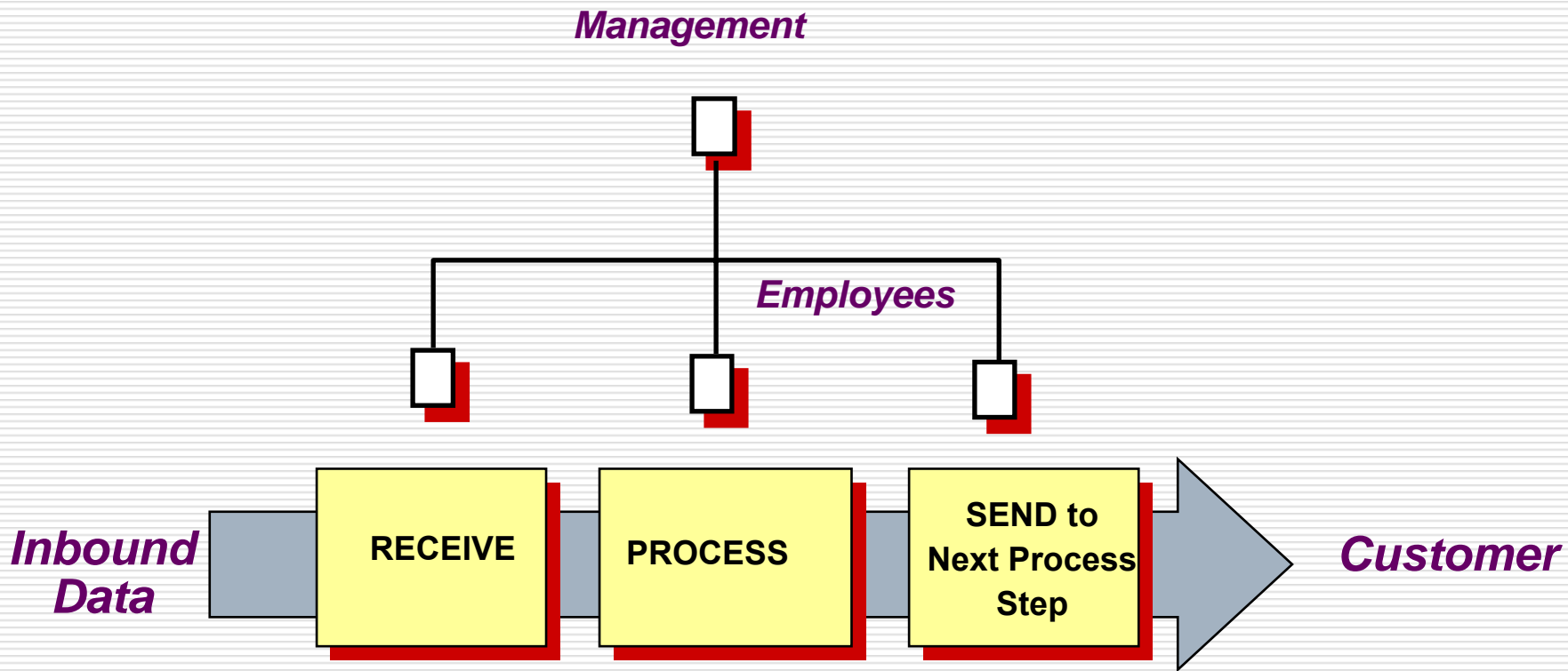
VALUE ADD

- Purpose

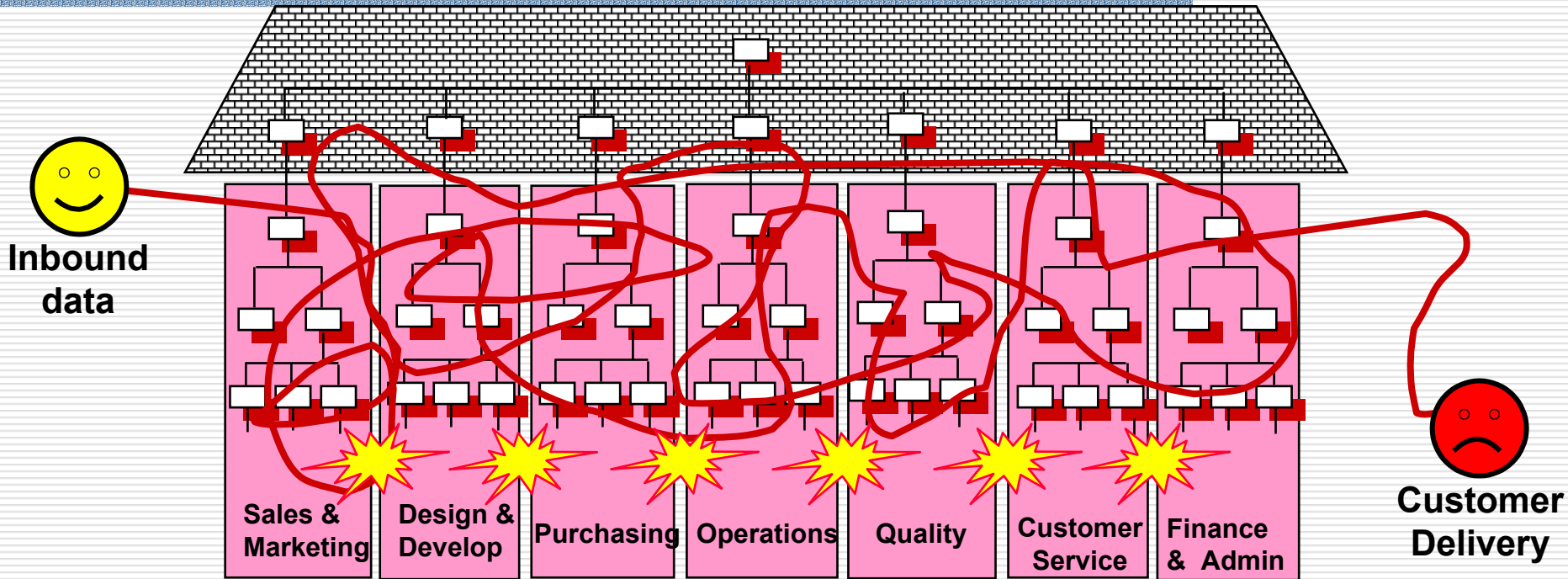


TYPICALLY . . . 75% PLUS OF LEAD TIMES ARE NON-VALUE ADDED

Basically, we've taken a simple process . . .



... & Complicated it!



Inbound data

Customer Delivery

Sales & Marketing

Design & Develop

Purchasing

Operations

Quality

Customer Service

Finance & Admin

FUNCTIONAL MEASURES

- Finance Related
- Efficiencies
- Utilization
- Variances

DEPARTMENTAL BARRIERS

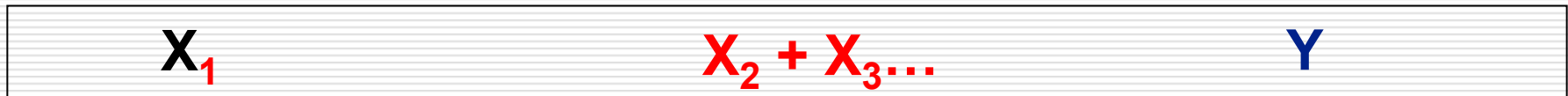
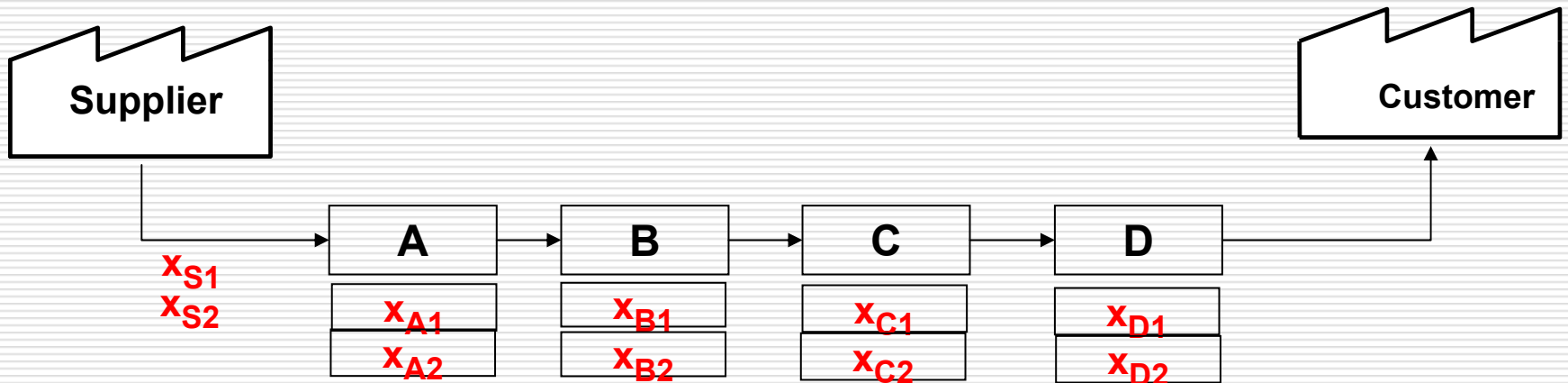
- Bureaucracy
- Delays

SYSTEMS BARRIERS

- Island of Autonomy
- Aligned to Functions

Important Concepts About Processes....

Lean Sigma uses the VSM (Value Stream Map) format of process flowcharts.



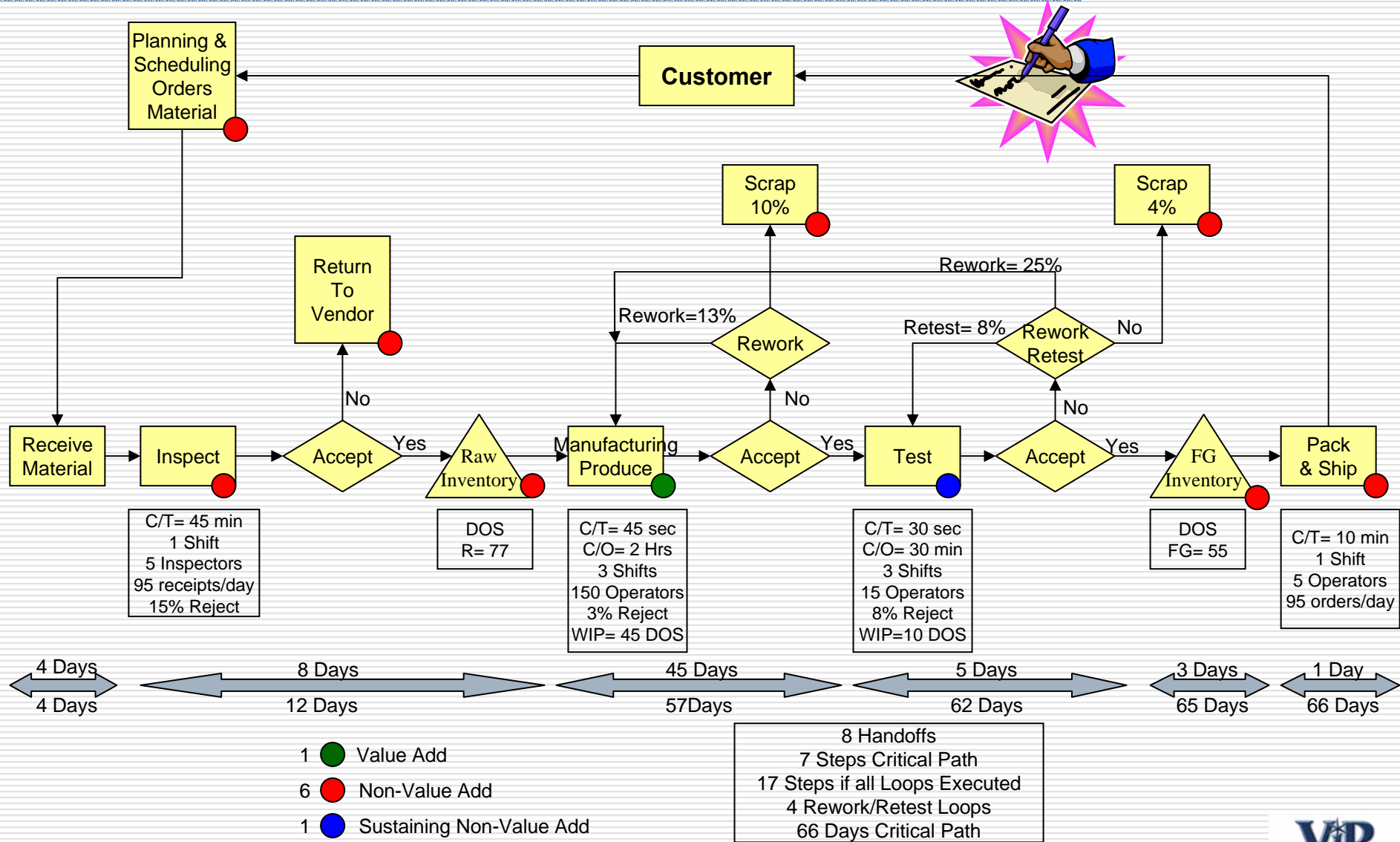
SIPOC =

S = Suppliers
I = Inputs
P = Processes
O = Outputs
C = Customers

- What is your Y?
- What are the possible x's?
- How does it flow?

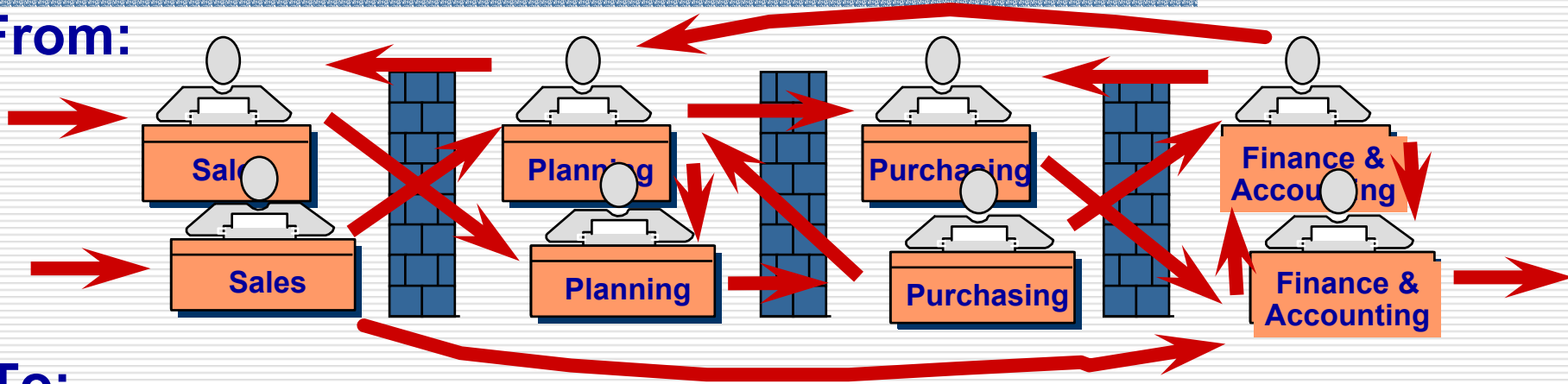
VSM the Process "E2E"

...Depicting the process as it is done today

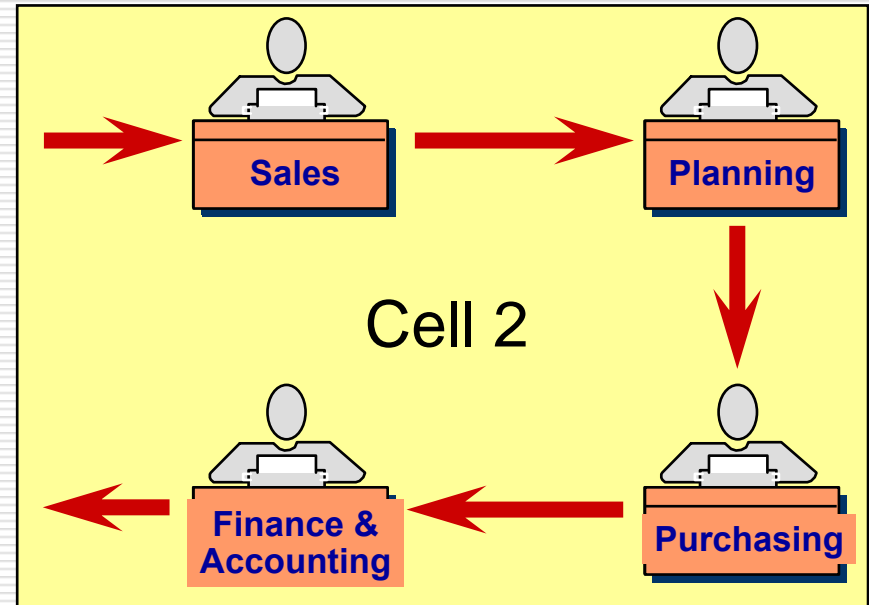
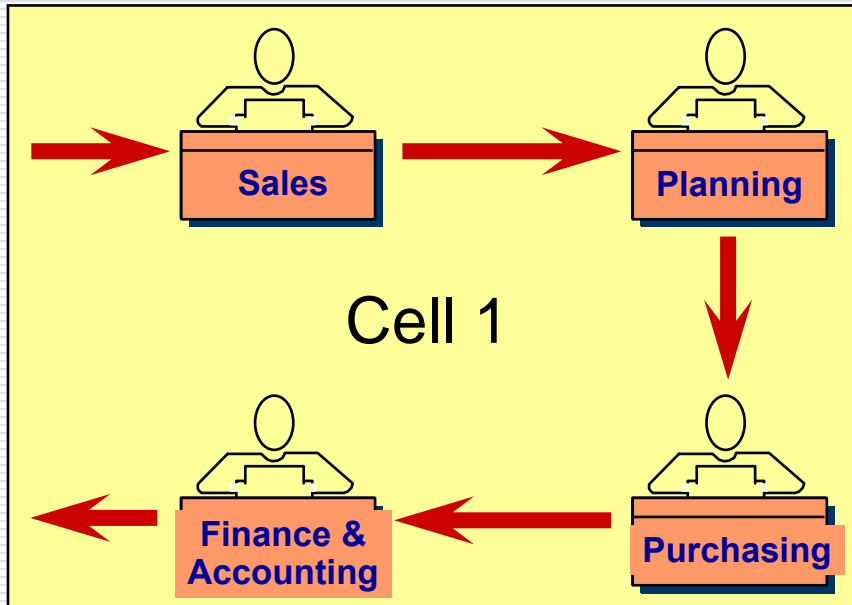


Customer Order Process Opportunities

From:



To:



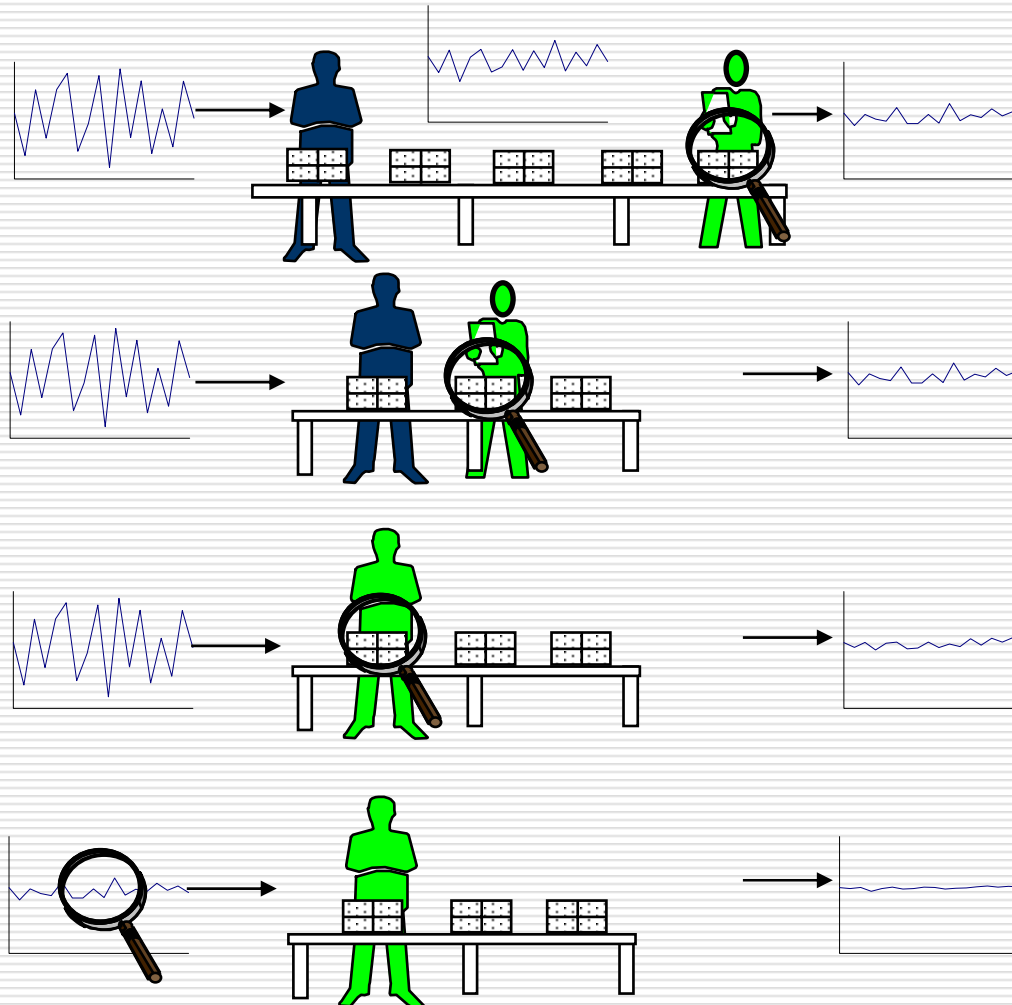


**QUALITY^{x1} IS OUR
BUSYNESS**

Everyone must have... ...ownership of quality

Towards Lean 'Inspection'

Type of 'inspection'



End

Successive

Self

Source

How many F's are there?



FINISHED FILES ARE THE RESULT OF YEARS OF SCIENTIFIC STUDY COMBINED WITH THE EXPERIENCE OF MANY YEARS.

The Quality Dilemma

You are now inspectors of the office process of creating invoices. Count the number of basketball passes the team in the white shirts make. Each pass is a poor quality invoice.

How many
bad invoices
were caught?

Did you
see the
Defect?

**Ball
Passing
Video**

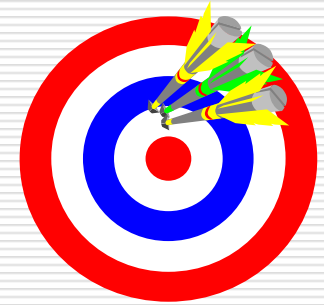
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Strategy Deployment requires a disciplined approach and a robust management system

- Structured Management
- Communications Program
- Voice of the Customer (VOC)
- Lean System for Managing
- Deployment Strategy
- Culture Change
- Reward and Recognition
- Metrics



The Agenda

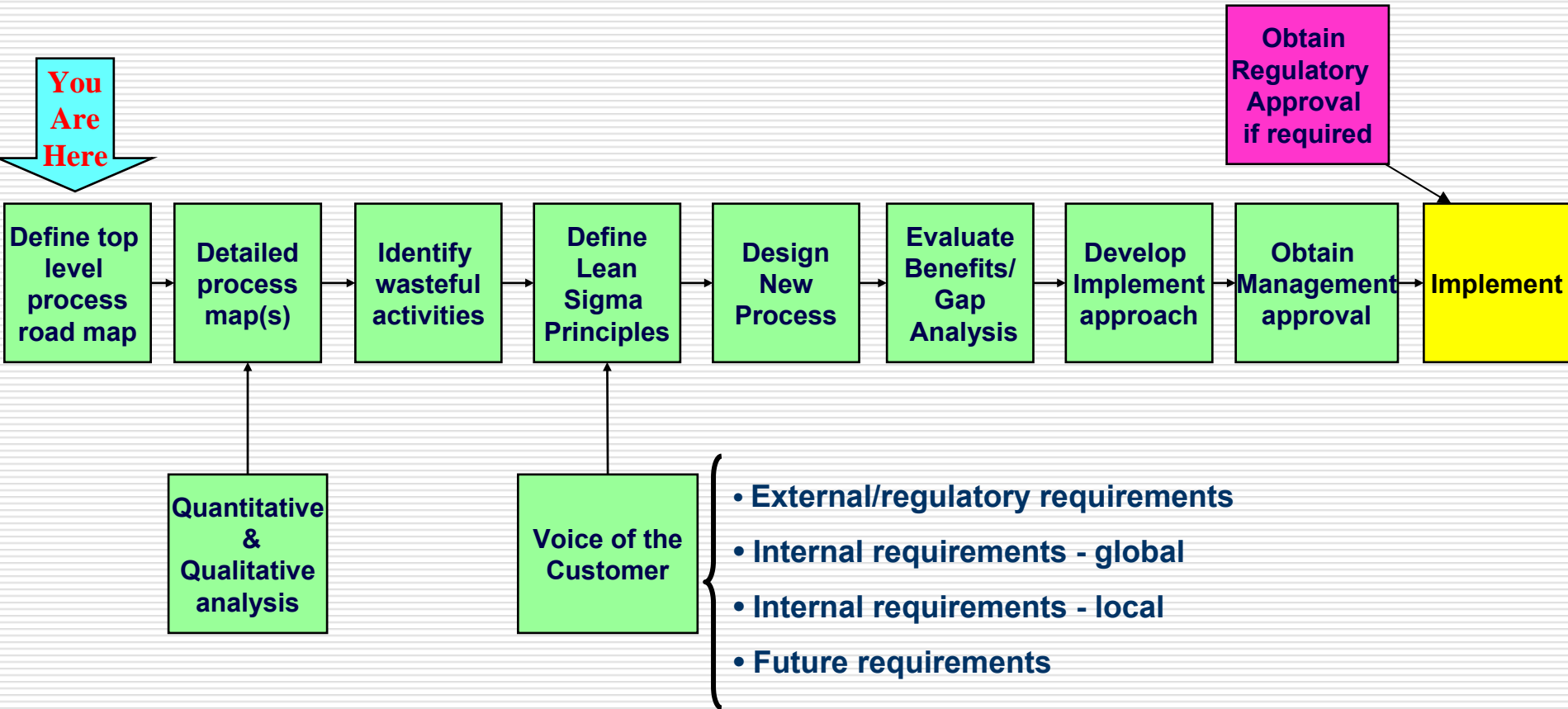
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Methodology

Use a disciplined methodology to achieve consistency and sustainability

A clear, structured, step by step process



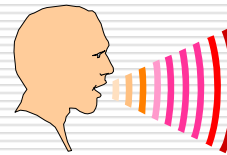
Communication Programs are a key ingredient to any change process



- **Distribute communication through a variety of media and communications channels**

Communicate !
Communicate !
Communicate !
Communicate !

- **Publications**
 - Newsletters, magazines
 - Memos, bulletins, handbooks, manuals
- **Formal presentations**
 - Meetings, conferences
 - Training
- **Video, film, audio, computer**
- **In-person informal socializing**
- **Email**
- **Voice Mail**
- **One-on-one meetings**
- **Town Hall meetings**

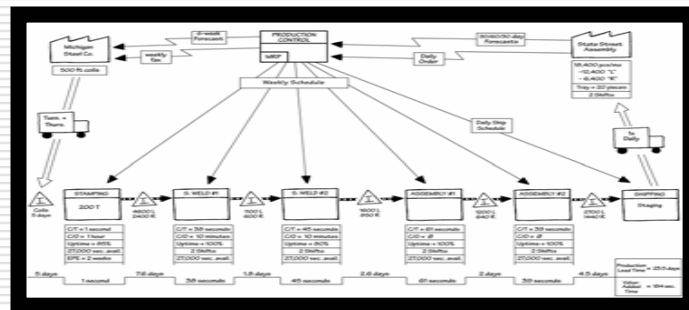
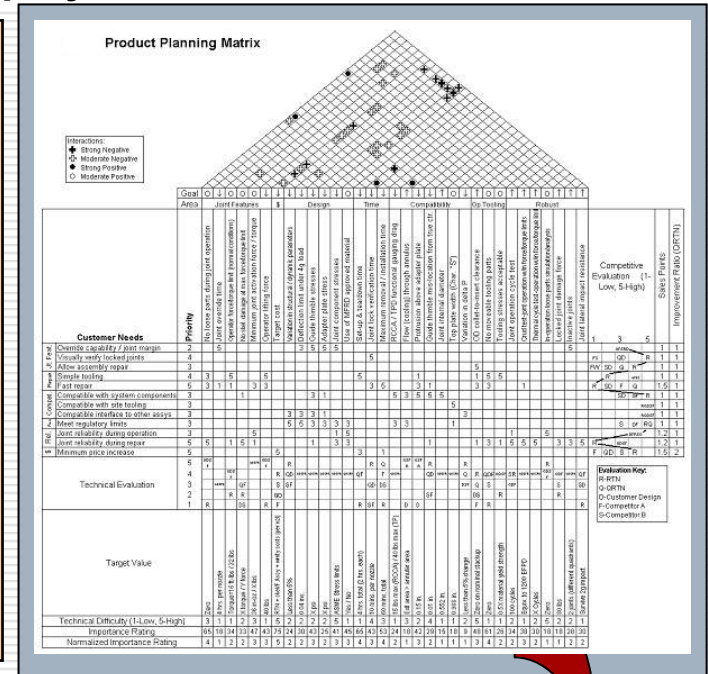


Voice of Customer is a necessary first step in DMAIC along with Value Stream Mapping

Quality Function Deployment



- What do they need?
- When do they need it?
- How do you know if they received it?
- What will they want?
- What do they want it to do?



Value Stream Map

Lean System for Managing is the glue that makes it work today and tomorrow



A Statement of Responsibility

A Long Term Aim (e.g. To improve significantly our business processes through radically reduced waste and time)

***Quantification of the Goal
in the Short/Medium Term (Reduce invoice errors by 50% by mid-2004)***

***How Resources will be exerted to
achieve the Goal or Aim (Operations Strategy)***

***Those Actions which are fundamental
to the success of the Goal (Reduce cycle time)
... i.e. MUST be achieved***

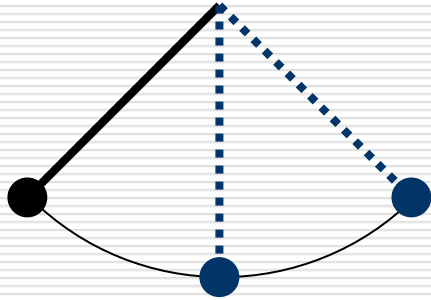
***Anything that is going to stop you from
meeting the CSF's (e.g. another department's resistance)***

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Possible Approaches to Deployment

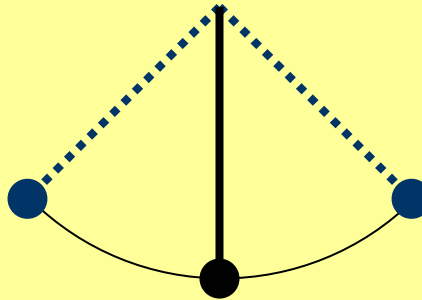


Autonomy

Business independence and self-deployment

Pros: Local owners, some zealots, low stress

Cons: No focus, minimal bottom line impact. No common language or talent pool. Wasted efforts, re-inventing of the wheel. Incorrect applications.

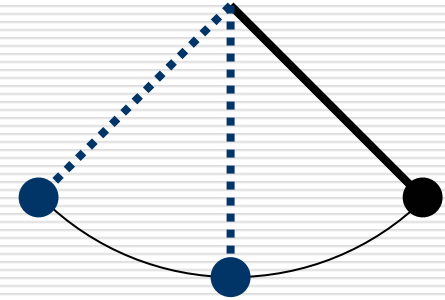


Process Focus

Value stream process map, data driven methodology selection

Pros: Customer focused, consistent across the business, can be applied anywhere, has bottom line impact, relies upon lean and proper six sigma

Con: A bit more bureaucratic for lean and upfront homework before projects



Mandate

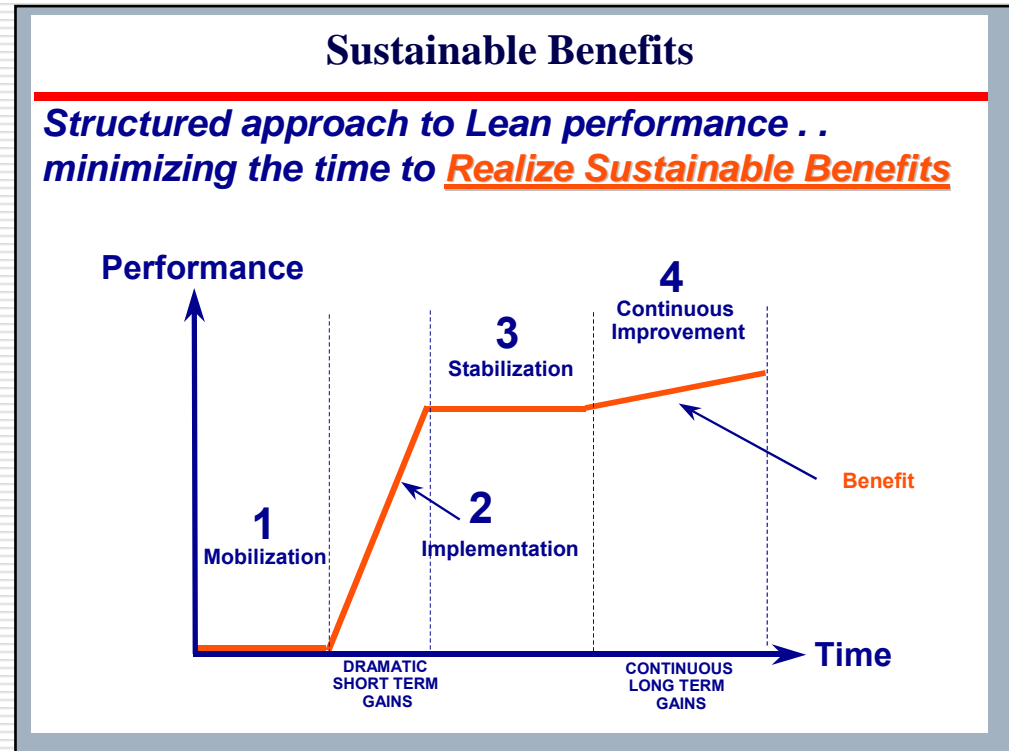
Corporate edict, deployment focus

Pros: Quick to the bottom line, full participation

Cons: No real ownership or sustainability. Many “weak” projects and implementations. Used for a “ticket punch” not for its power.

Deployment Strategy must be easy to follow, consistent and repeatable

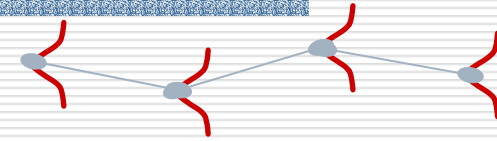
- Pick Pilot & Implement
- Stabilize Process
- Rollout to Other Areas
- Measure Results
- Adjust Process As Needed / Determined By Metrics



A structured process provides your team(s) with formal training along with responsibility and ownership, thereby ensuring program success and continuation.

Tactical Strategy needs to be visual, structured and process oriented

1) Identify target processes through Value Stream Mapping and VOC



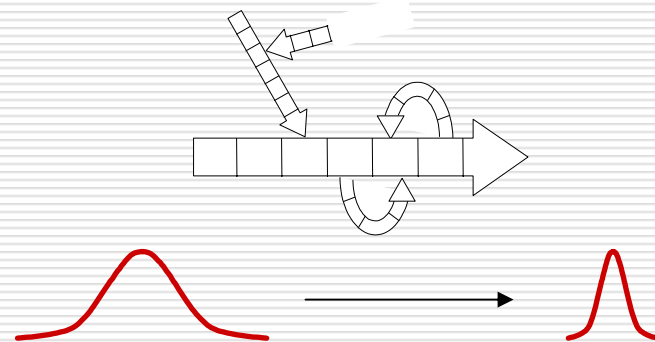
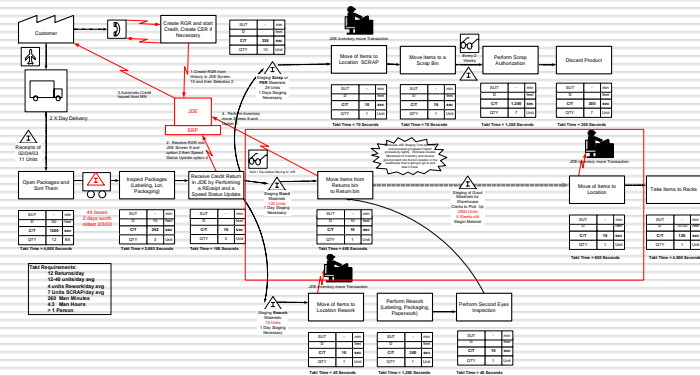
2) Value Stream Process Map

3) Customer & current metrics

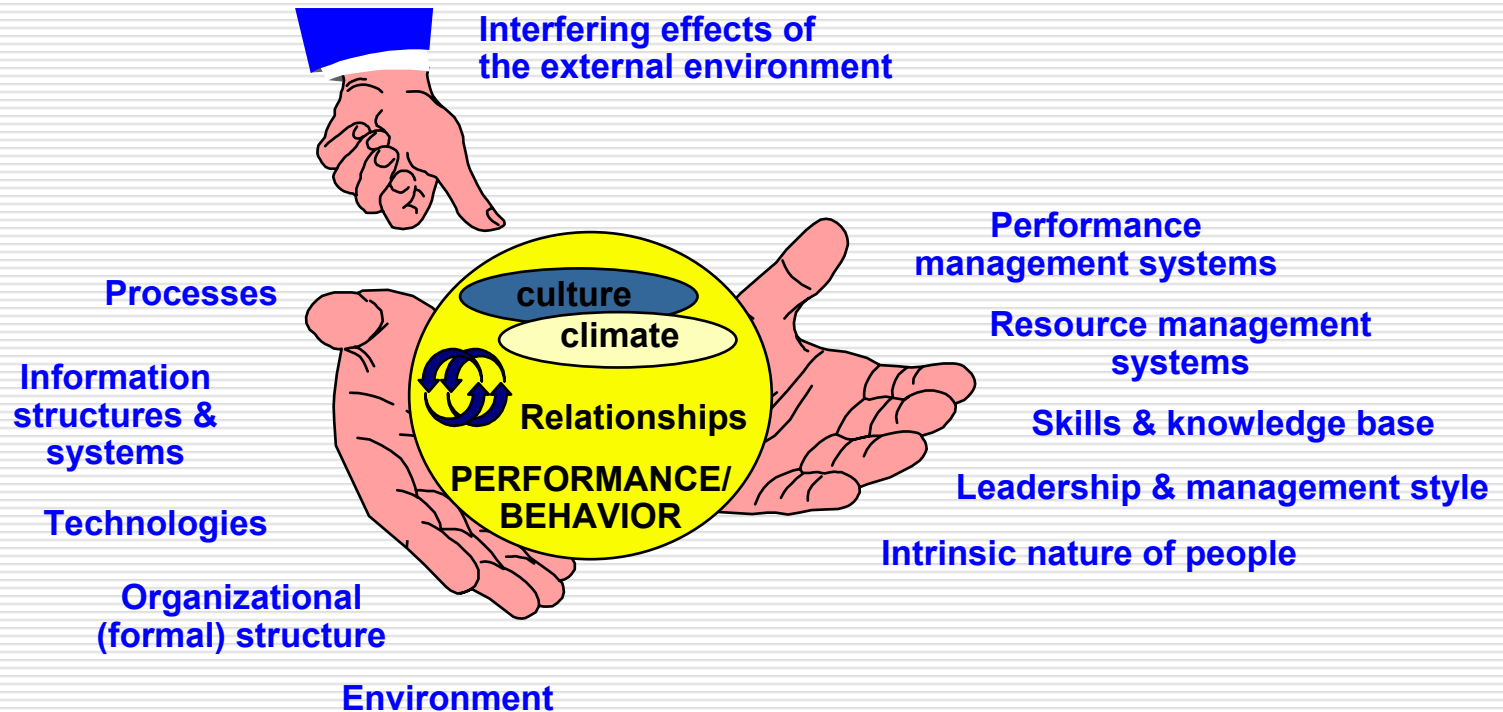
4) Prioritize attack projects and methods

- Lean → waste, cycle time, flow, basic quality, office space
- 6s → the tough quality issues

Current State Credit Returns Value Stream Map



Understanding the environment and influencing factors will assist implementation of the change



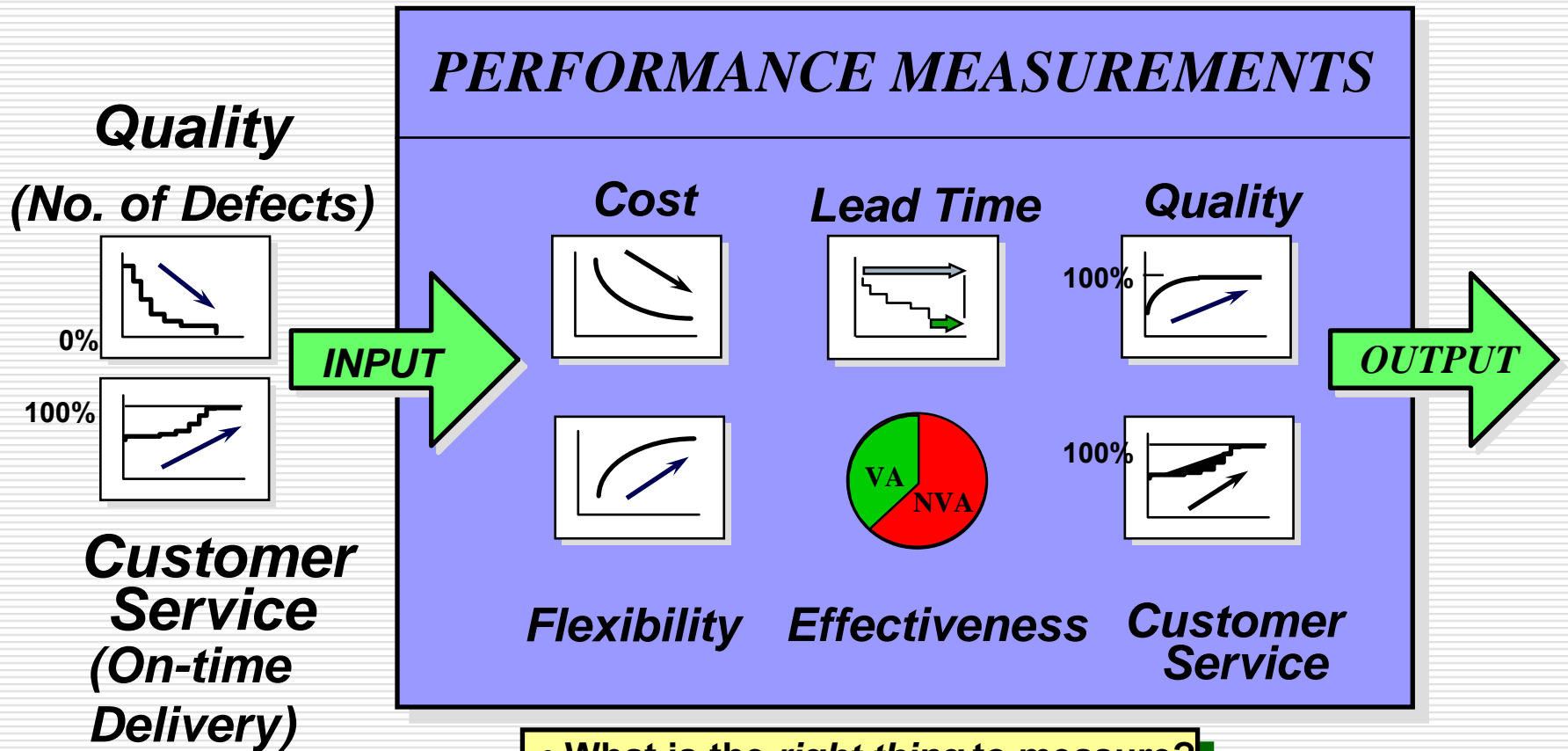
- Mutual dependencies between various influencers
- Change in one influencer will require change from one or more of the others
- Change agents need to be aware of interfering effects of external environment
- Take cognizance of organization culture, climate and internal relationships

Critical Success Factors

- Voice of Customer
- Compliance
- Measures
- Senior Management Commitment
- Middle Management
- Skill Matrix
- Culture Change

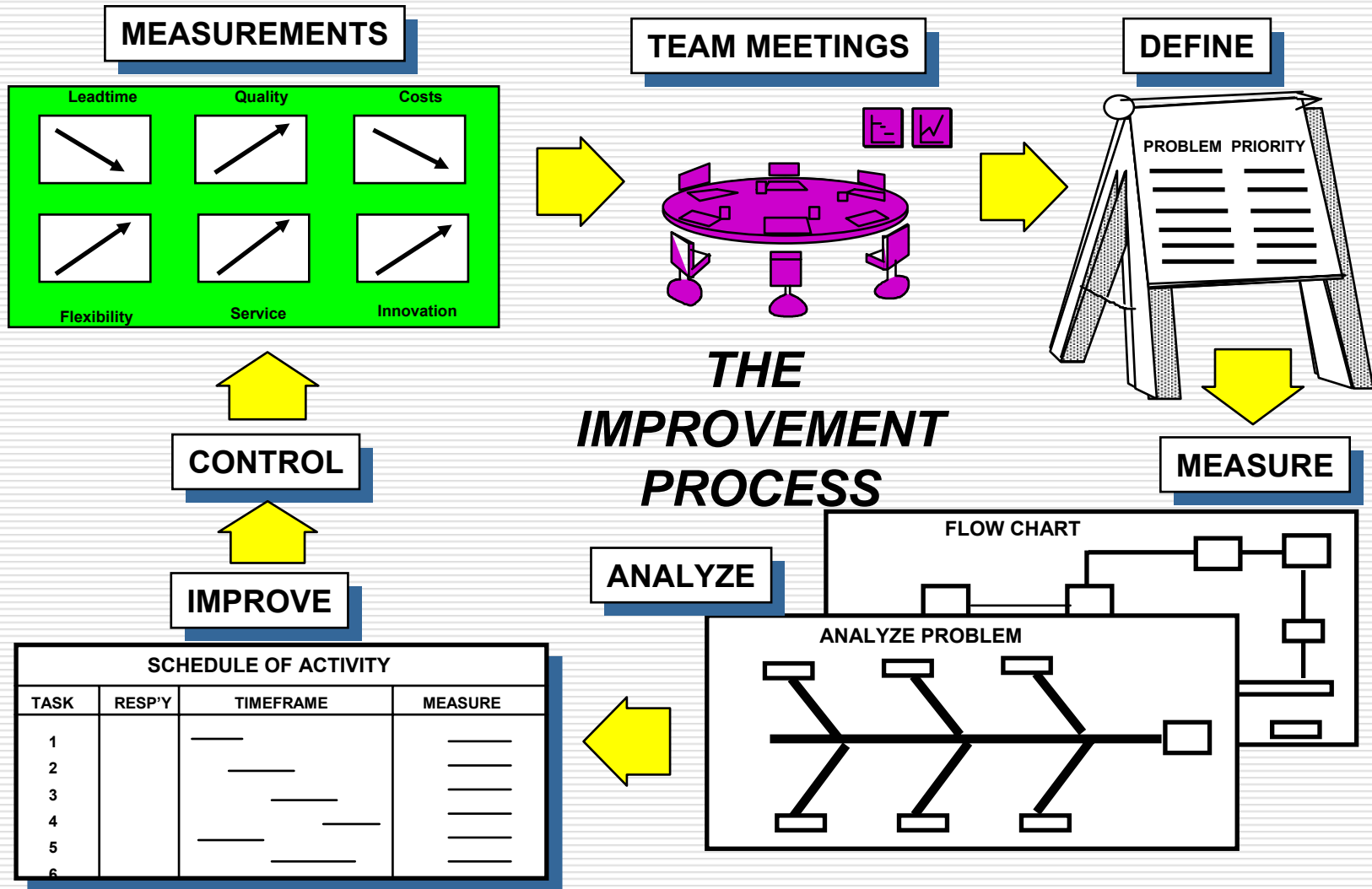
LeanSigma Performance Measurements

... Apply to all the Supply Chain & Business Processes



- What is the *right thing* to measure?
- Set the *Target Goals* to strive for
- Make measures *visible*.

Measures should be integral to the Continuous Improvement Process



Senior Management and Team Structure

- Senior Management efforts across the Company including:
 - **Communication Strategy**
 - **Reward and Recognition systems**
 - **Goal Alignment**
 - **Project over-site management**
 - **Prioritization**
 - **Process Alignment**
 - **Collaborative environment**
 - **Scorecard/Dashboard**
 - **Roles & Responsibilities**

Keep all informed through a "LeanSigma Project" Folder on a shared drive

- Give Strategic Direction
- Agree Recommendations
- Resolve Issues
- Remove obstacles
- Support & coach



- Cross-functional 'users'
- Full Time Team
- Make Recommendations



- Give Tactical Direction
- Agree Recommendations
- Resolve Issues
- Support & coach
- Implement Recommendations

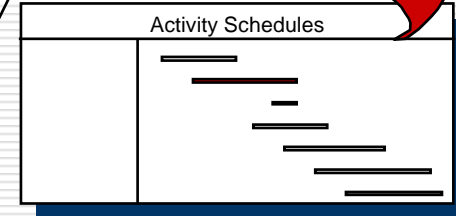
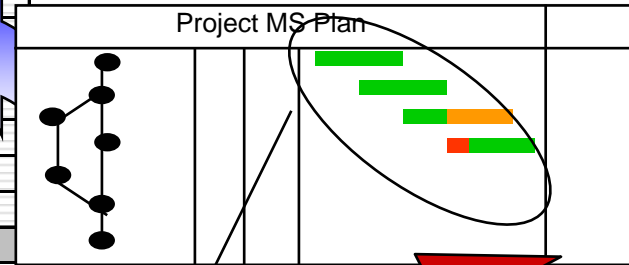


- Cross-functional 'experts'
- Milestone Delivery

Project Management Style

- Project plan is visible to all
- Milestones are fixed
- Ownership is clearly defined
- Steps to success are realistic and achievable
- Traffic light system identifies tracking

Visible Project Management

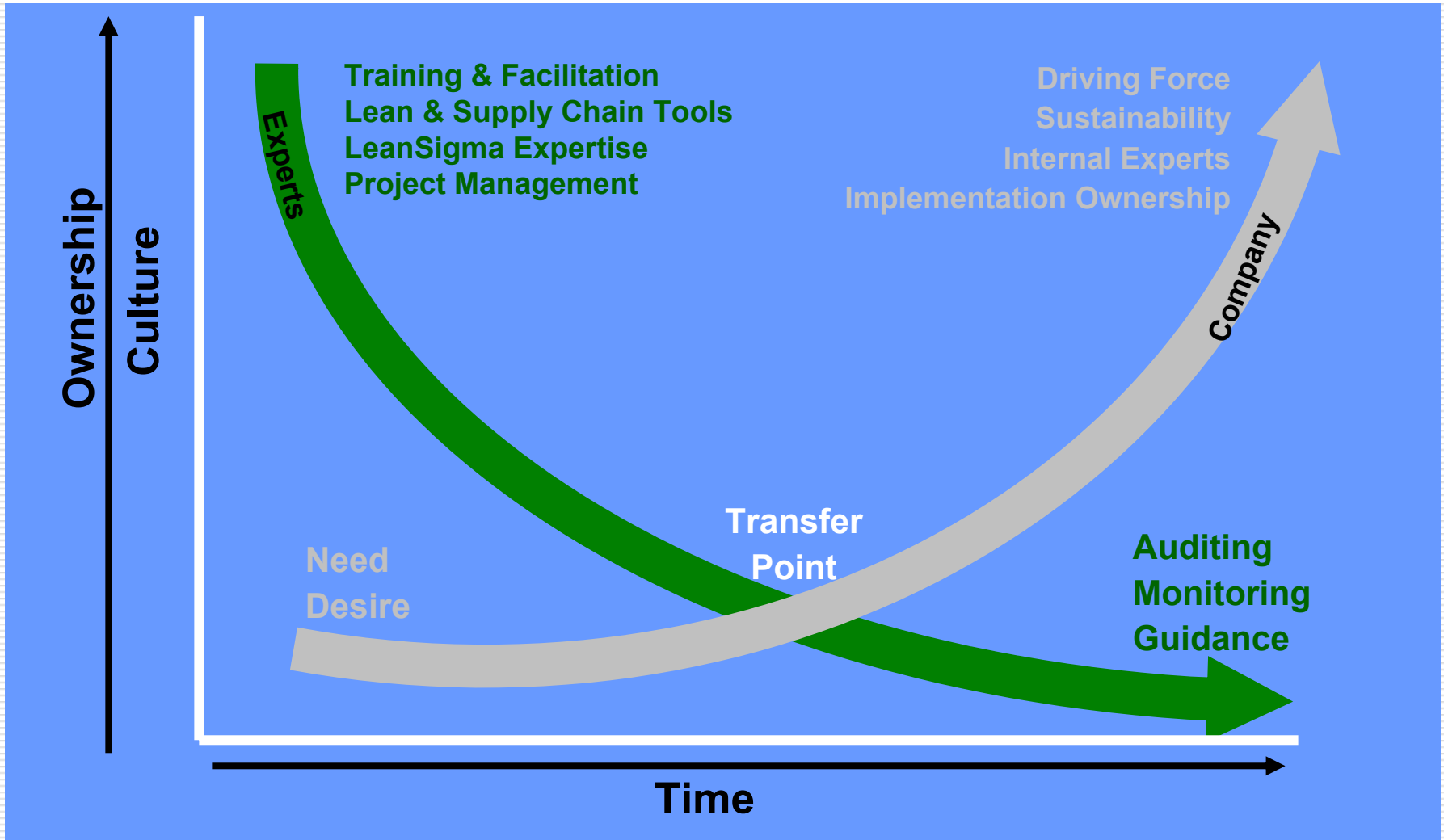


Traffic Light Measure
 Red = off schedule
 Amber = recovery plan
 Green = on schedule

Lean Project Support												
Rev -	Your Company Owner	Your Company MASTER PROJECT PLAN	5/9	5/16	5/23	5/30	6/6	6/13	6/20	6/27	7/4	7/11
1		When the Team has been agreed to	Green	Green	1	2	3	4	5	6	7	8
2		When the Design Principles has been accepted	Green	Green	Green							
3		When Lean Business Simulation Workshop is Complete			Green	Green						
4		When the curent process is Value Stream Mapped			Green	Green	Yellow	Grey	Grey	Grey	Grey	Grey
5		When the future state map is agreed							Grey	Grey	Grey	Grey
6		When the implementaiton plan is agreed							Grey	Grey	Grey	Grey
7		When the Skills Matrix is designed							Grey	Grey	Grey	Grey
8		When the staff has been trained							Grey	Grey	Grey	Grey
9		When the Continuous Improvement plan is implemented							Grey	Grey	Grey	Grey
		On Schedule	Green									
		Off Schedule, recovery plans in place	Yellow									
		Off Schedule, recovery plans not yet in place	Red									
		Shutdown	Pink									
		Scheduled work	Grey									



Experts Role in Facilitating LeanSigma



The Agenda

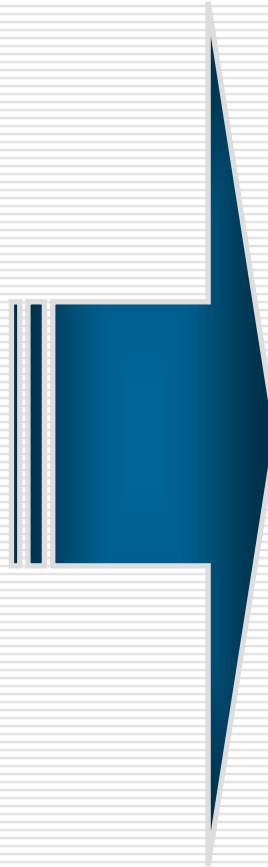
- **What is LeanSigma**
 - Lean
 - Six Sigma
 - Lean Sigma
- **Designing LeanSigma for the Office**
 - Strategy
 - Methodology
 - Deployment
- **Case Studies**
 - Issues
 - Methods
 - Results
- **Questions and Answers**



Typical Change Efforts & Benefits Realized

Change Initiatives

- Lean Pharmacovigilance
- Pull Replenishment Systems
 - Kanbans
- Schedule Optimization Programs
- Vendor Managed Inventory Programs
- Right First Time
- Cellular Manufacturing
- Business Process Redesign
- Value Stream Mapping
- Lean System For Managing
 - Change Management
 - Team-working/Teambuilding
 - Supervisory/Management Training
- Strategic Sourcing
 - Supplier Certification
 - Supplier Negotiation/Selection
- SMED, 5S, OOE,Poka Yoke (Error Proofing)

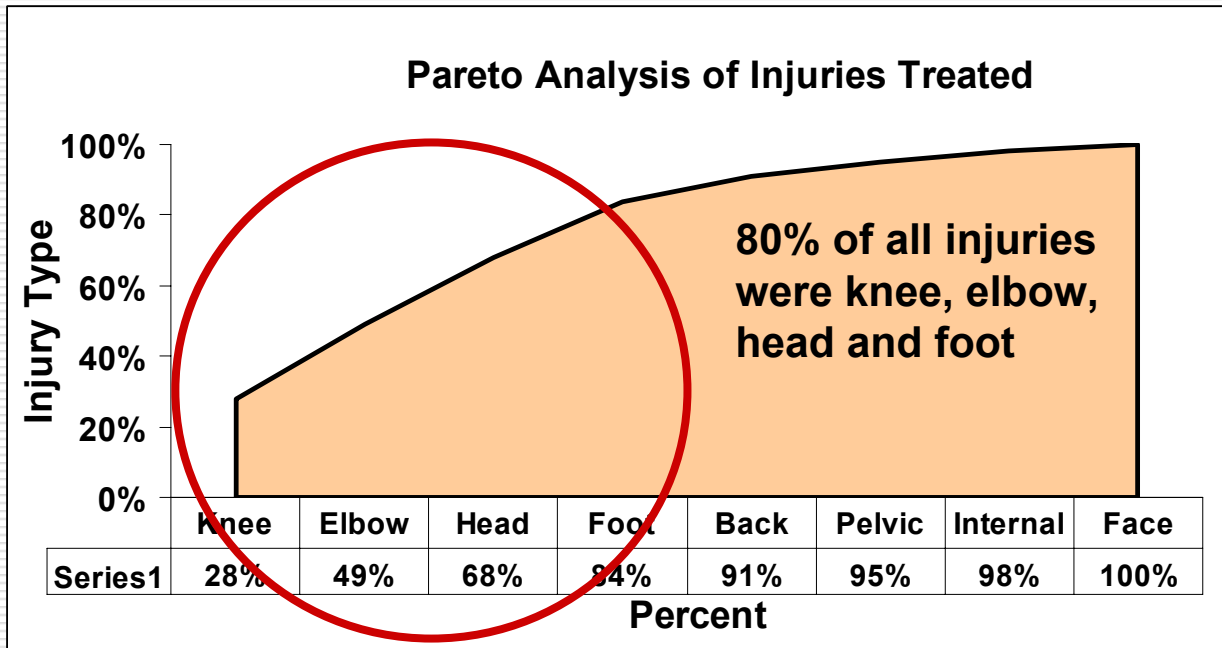


Client Benefits Realized

- Average 98% compliance, improve capacity by 105% and removed all NVA steps
- \$10.4M run rate reduction in operating expenses
- Inventory reduction of 50 - 80%
- Space reduction of 30 - 60%
- Adherence to schedule of 90 - 100%
- Improvement in OTD to 96% average
- Reduce time to changeover from hours/days to minutes, additional capacity of 5 - 25%, improve safety by 50%, reduce scrap by 30 - 50%
- Improved quality by 30 - 50%
- 100% achievable metrics through goal alignment
- Supplier partnerships providing no loss of production time due to shortages, poor quality or late shipments
- Reduction in NVAA by 50 - 80% and hand - offs by 30 - 50%
- Decreased distance traveled by 60 - 80%
- Increase productivity by 5 - 40%
- Improve moral by a factor of at least 2
- Identification of bottlenecks and problem areas
- Improve regulatory compliance to 98% average
- Skills and training matrices provide for solid, cross - functional teams capable of handling volume surges

Lean Healthcare in Action

\$20 Million Emergency Room Management Group



Key Benefits

- Labor and Over-time reduced 5%
- Maintained compliance and quality
- \$250k annual operating expense reduction



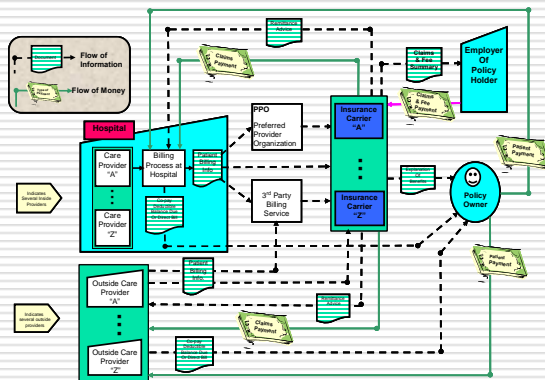
The demand analysis allow the treatment centers to reset stocking levels of treatment carts in line with the demand. Local activities (skate boarding contests) accounted for the increase number of knee, elbow and head trauma treated. Drs and nurses spent less time hunting for the right materials and implements.

Lean Healthcare through... ...“Value Stream Mapping”

\$350 Million Hospital Group

- The issue : could only get 2 knee operations per day accomplished.
- Perceived constraints: Drs blamed the nursing staff, Nursing staff blamed Administration and Administration blamed the Drs. and Nurses.
- **Actual constraint found through VSM: Sterilizer could only process 2 cycles per day.**

Current State Map



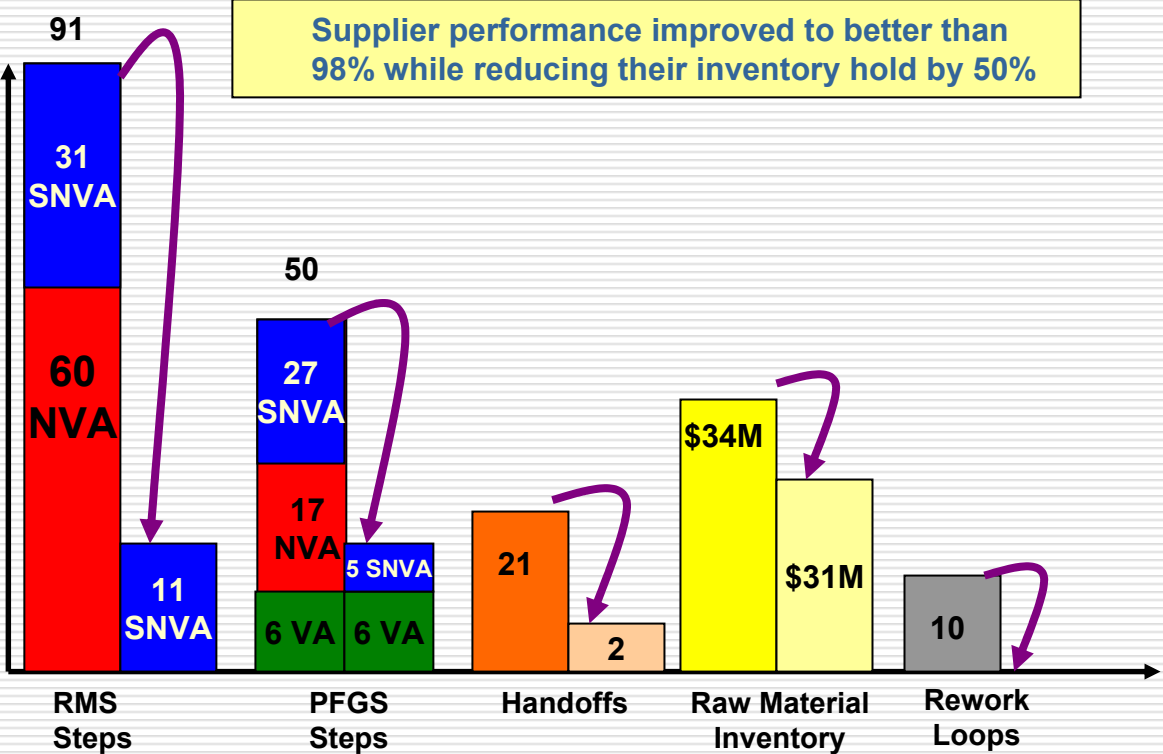
Sterilization Process

Key Benefits

- 89% of process steps were NVA and removed reducing the process time by 65%.
- New process freed up the sterilizer thereby allowing for an additional 2-4 surgeries per day to be done.
- Current sterilizer was not capable of more than 3 cycles per day. However, a new unit would allow for up to 10 cycles/day. The Hospital purchased a new unit and was able to perform 2-4 more surgeries per day. The new unit was paid for within 3 months.
- Cost per procedure was reduced 8%.

Lean Procurement Utilizing LeanSigma

\$1.2 B Medical Device Operation
(a division of J & J)

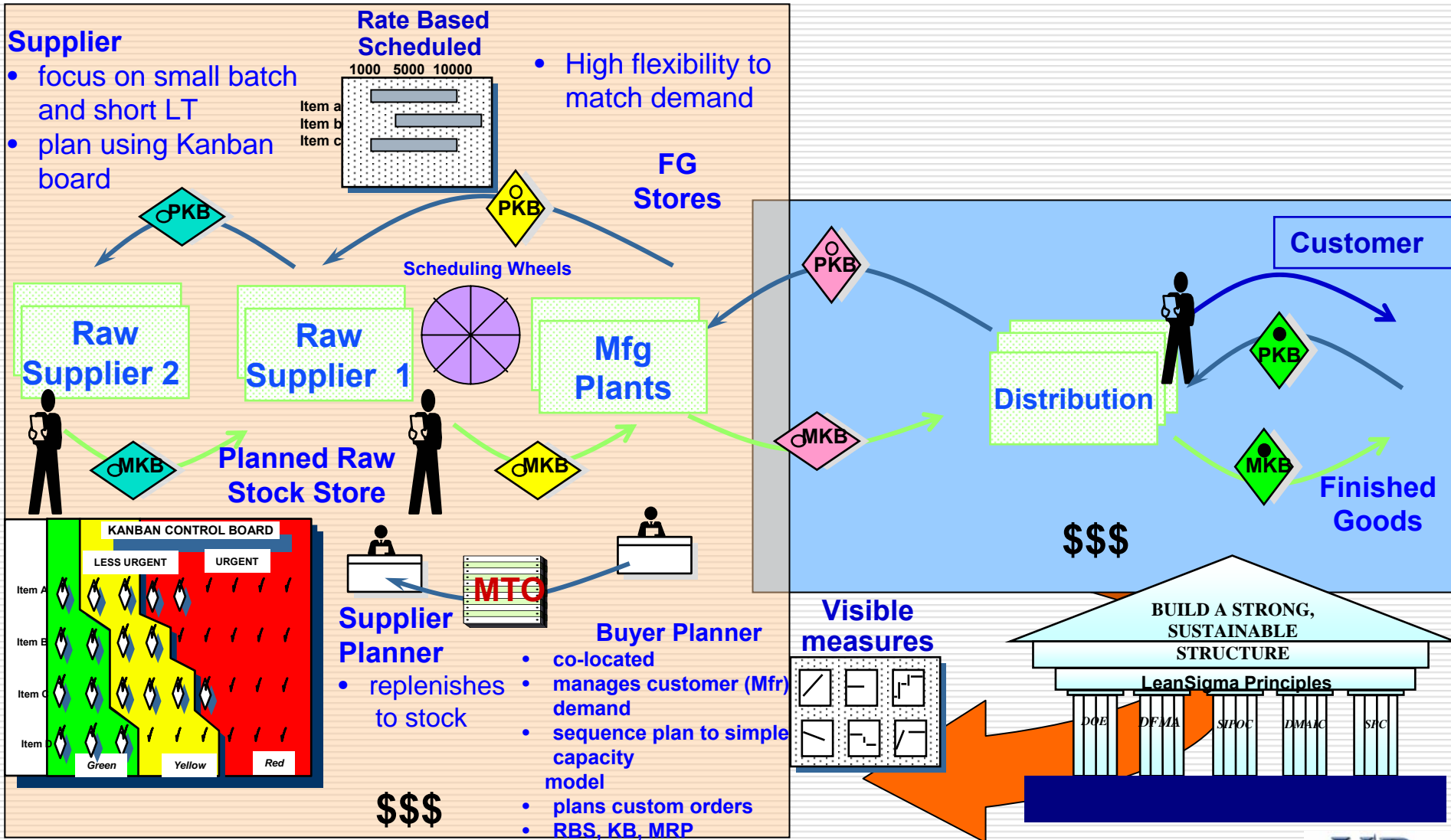


Defect:
Process and tolerance variability
DMAIC Project:
Lean out the Supply Network, reduce Supplier parts variability and install a pull replenishment model



Procurement lead-time was reduced from 4-5 weeks down to 1 day

Lean Procurement Model for Success



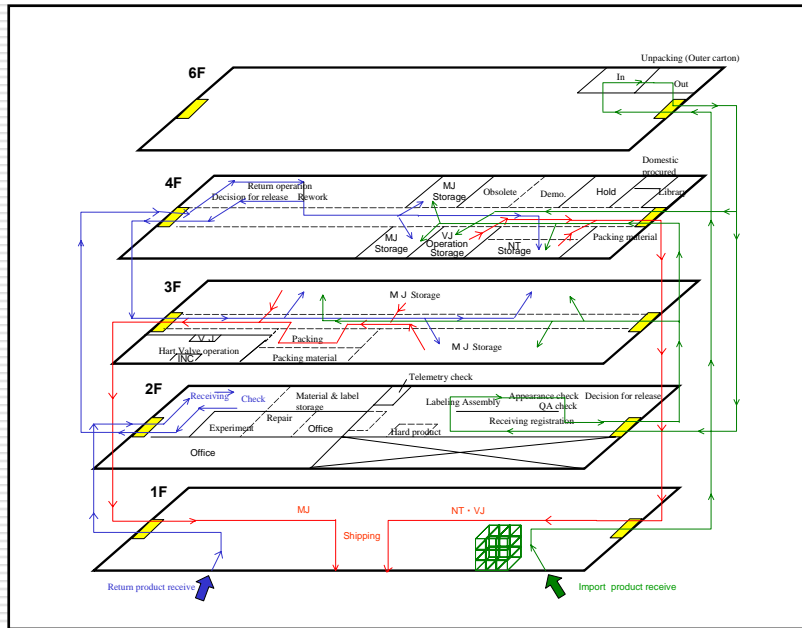
LeanSigma Distribution Example

Japan Distribution Center for a \$40B Medical Device Company

Defect: Process and compliance variability

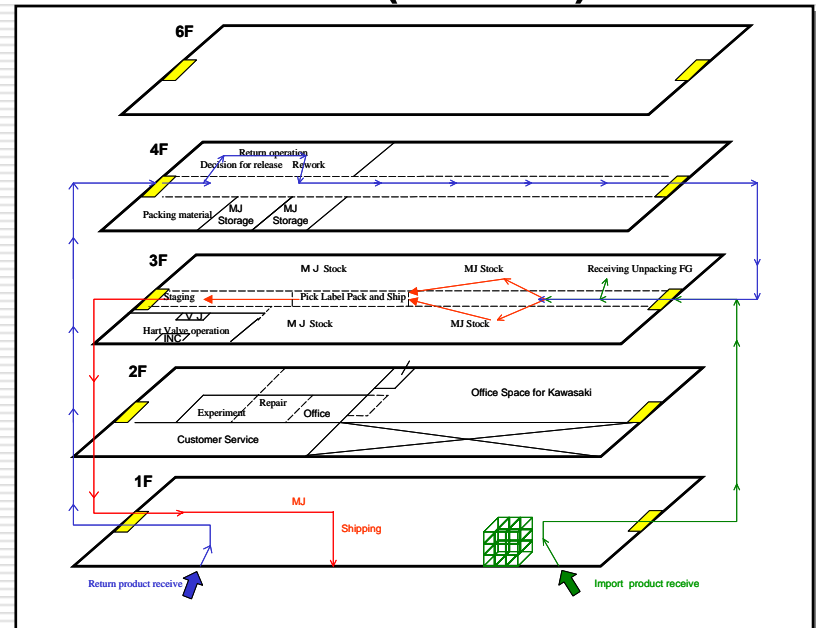
DMAIC Project: Lean out the Distribution Center

Before



**13 days lead time, 5 floors
38 FTEs**

After (4Q ' 04)



**2 days lead time, 3 floors, 18 FTEs
\$1M savings, + office space**

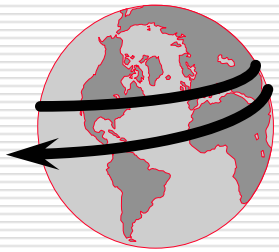
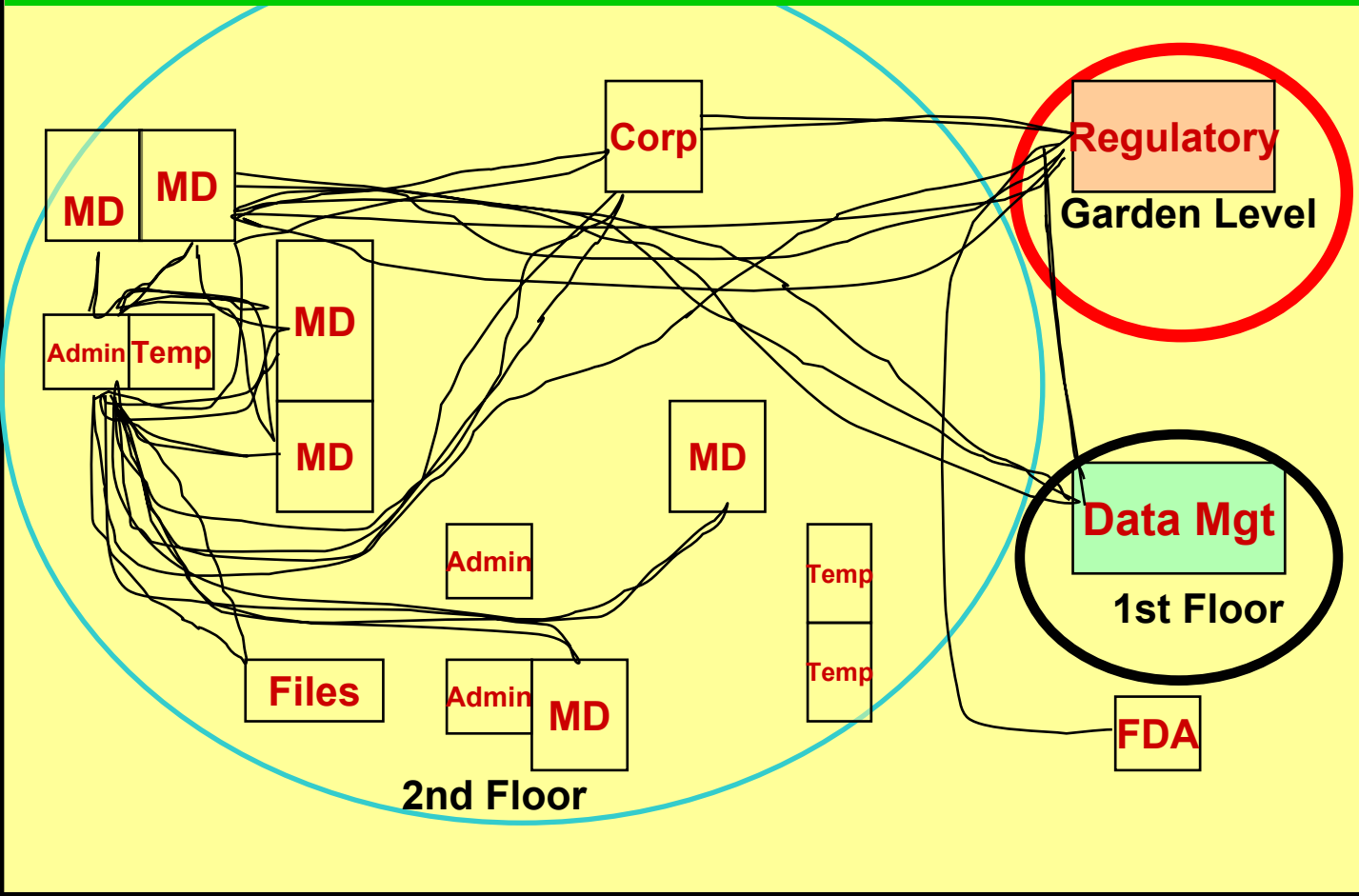
Example 2- Pharmacovigilance... As-is Map



	Process Steps	QC Steps	Reg Steps	S&DS Steps	Total Steps	Error Loops, F/U's & Cosuspect	Total Steps	Report Type	Process structure
US-CT	47	11	29	0	87	17	104	15 day IND	Parallel
Non US-CT	35	11	22	0	68	9	77	15 day IND	Parallel
Non US-Spont	32	13	21	19	85	45	130	15 day NDA	Parallel
US-Spont	79	12	21	19	131	35	166	Spont	Sequential
									477

Example 2a - Pharmacovigilance... As-is Flow Diagram

While, the current layout leads to a case travelling about 1/2 mile from case receipt to submission

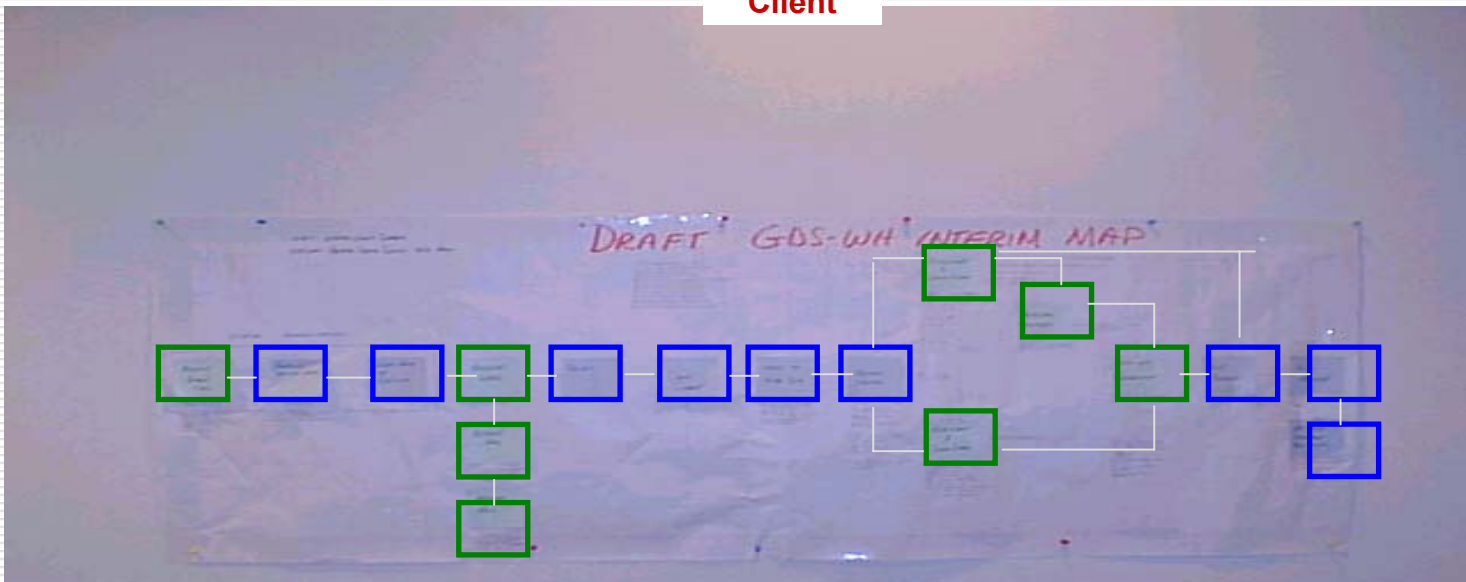


- 4560 cases times .5 miles/case = 2780 miles traveled/year.
- The distances result in increases in:
 - lead times
 - batching
 - process delays

Example 2b - Pharmacovigilance... Redesigned Process Map

Actual redesigned process

Client



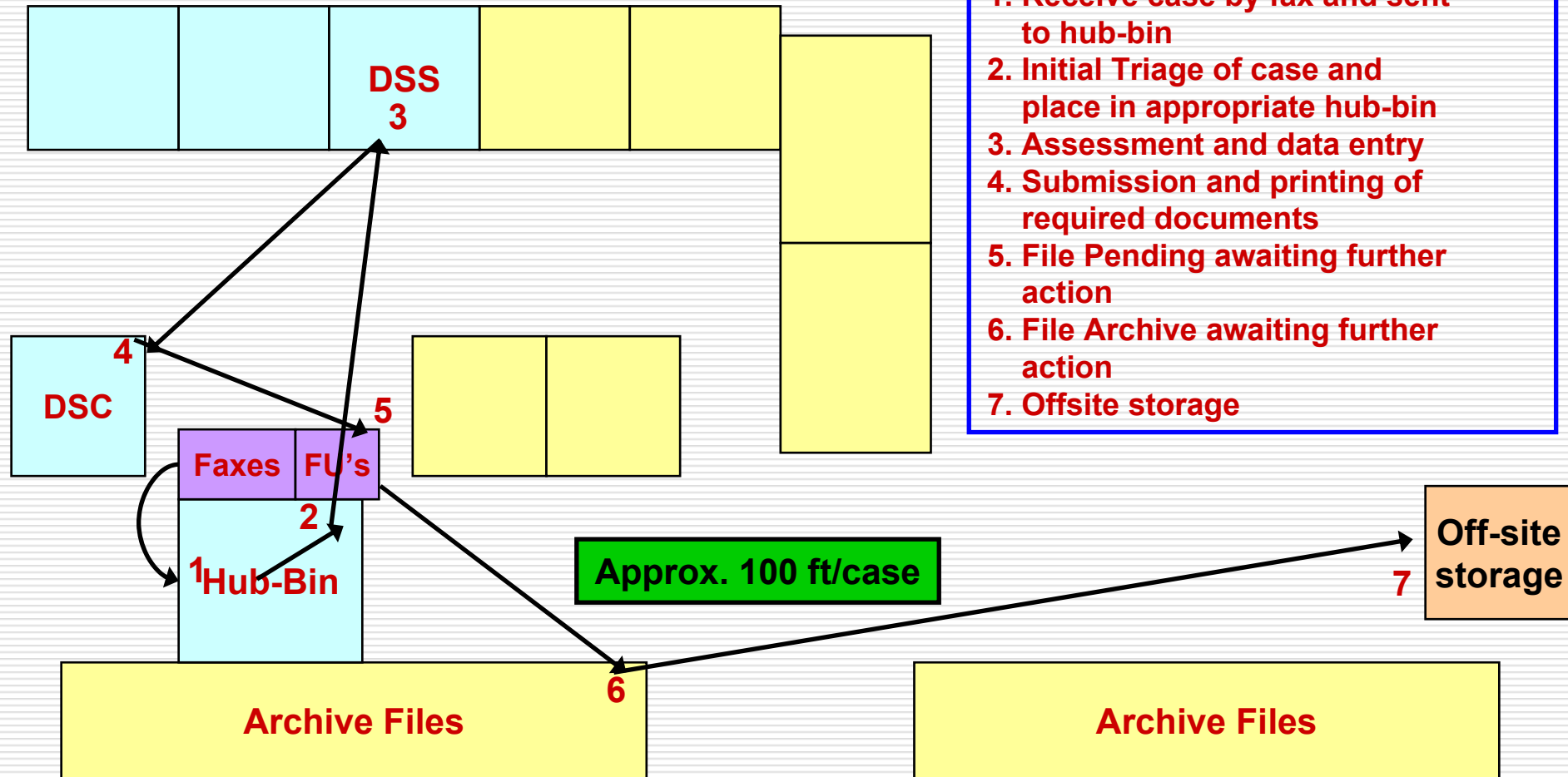
	Process Steps	QC Steps	Reg Steps	S&DS Steps	Total Steps	Error Loops, F/U's & Cosuspect	Total Steps	NVA	VA	SNVA
All	17	0	0	0	17	0	17	0	8	9

Example 2c - Pharmacovigilance... Redesigned Flow Diagram

Distance traveled reduced by 96%

Serious Case Path Sequence

1. Receive case by fax and sent to hub-bin
2. Initial Triage of case and place in appropriate hub-bin
3. Assessment and data entry
4. Submission and printing of required documents
5. File Pending awaiting further action
6. File Archive awaiting further action
7. Offsite storage

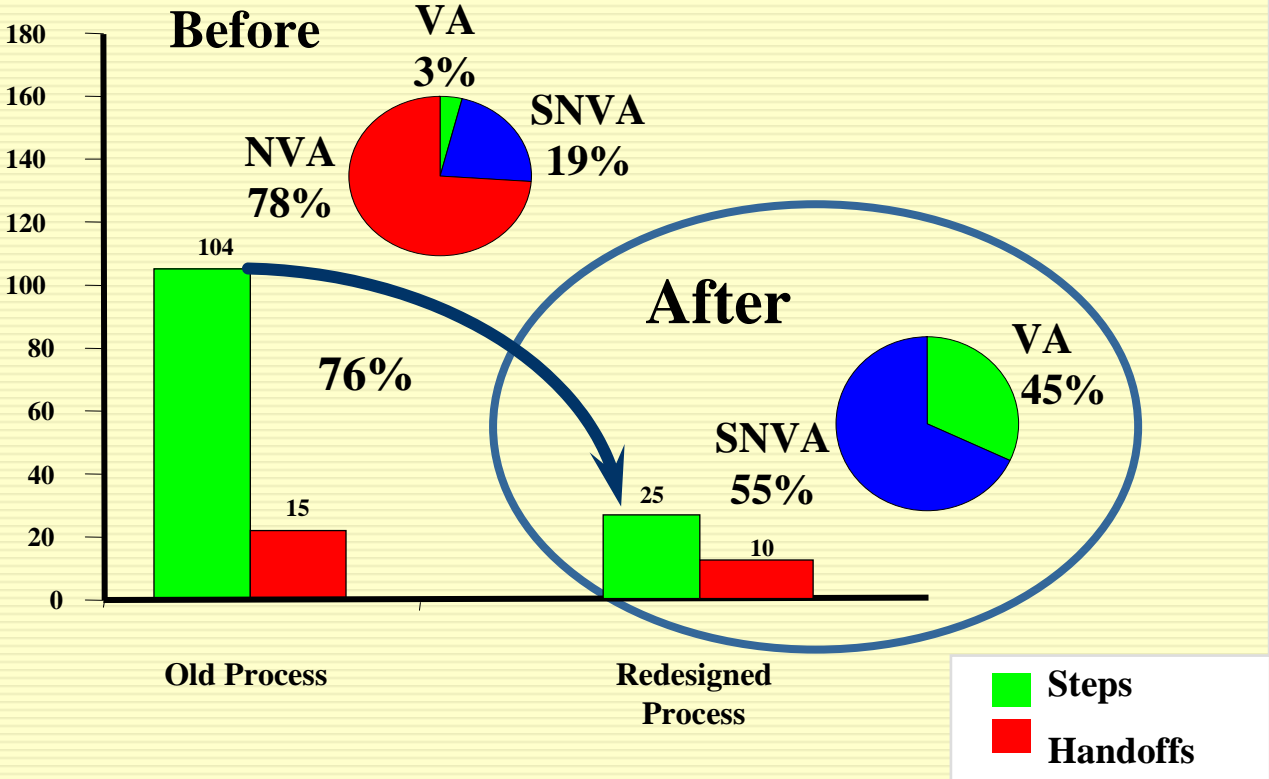


Lean Office in Action

\$4.8 B Pharmaceutical/Biotech/Chemical Operation

Source:
Client Process Maps
includes rework loops

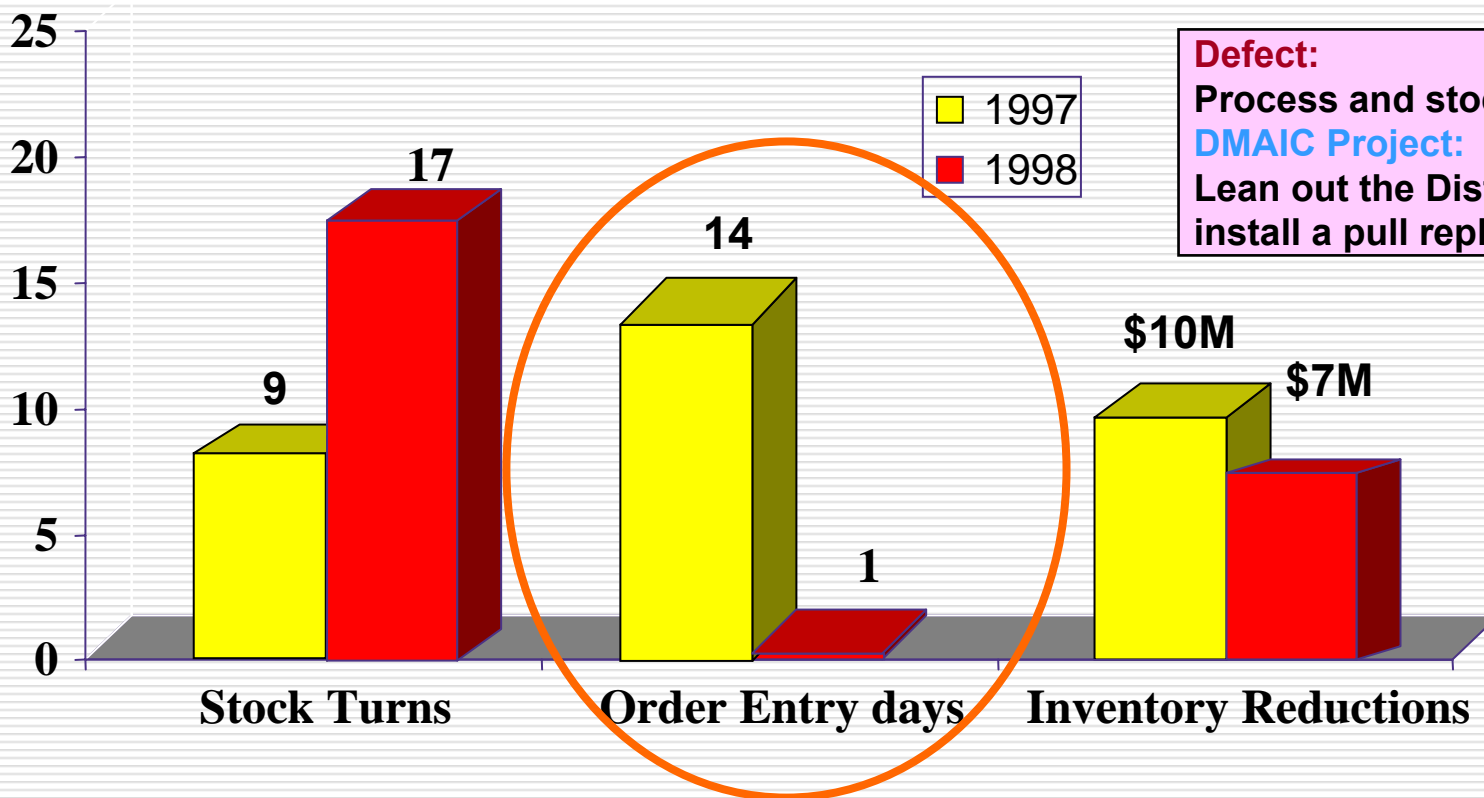
Number of process steps and hand-offs



- Case travel distance was reduced by 96% from 1/2 mile to 100ft.
- All NVA steps were removed (400+)
- Global compliance improved from 30% to better than 97% pa
- Case processing time was reduced from 21 days to 11
- Internally generated documents were reduced from 32 to 1
- Improved productivity by 105% with existing staff
- Reduced process steps from 477 to 17

LeanSigma in Production

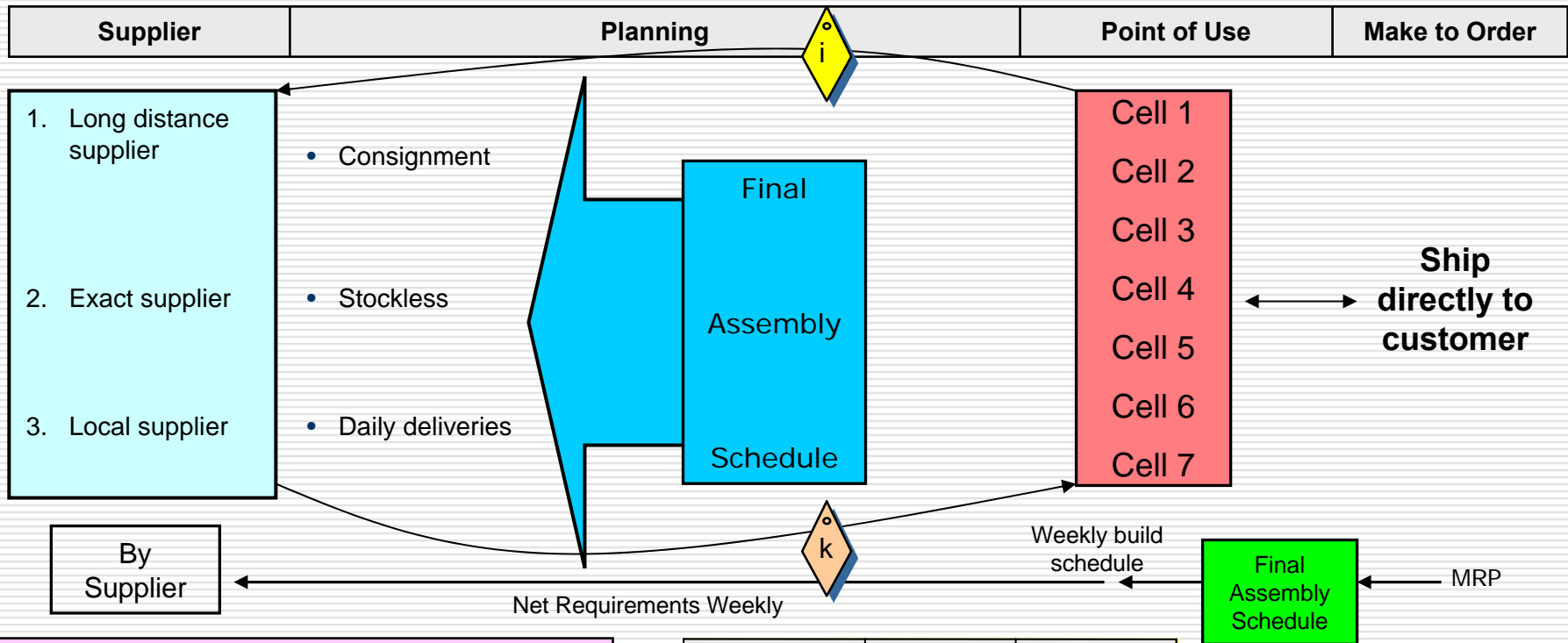
\$150 M, \$90M & \$60M Office/Building Supply Plants



- Stock turns on product for a CNC went from 3 to 49
- Order Entry errors reduce from 48/month (1.2 per order) to less than 1/month
- VMI program allowed plant to acquire \$6M of new business previously out of their reach
- Visible daily cell metrics reduced production errors by over 60% and Lead-time by 20%/order

LeanSigma Supply Chain in Action

\$150M Medical Device Operation, (a division of J & J)



Defect:

Process and tolerance variability

DMAIC Project:

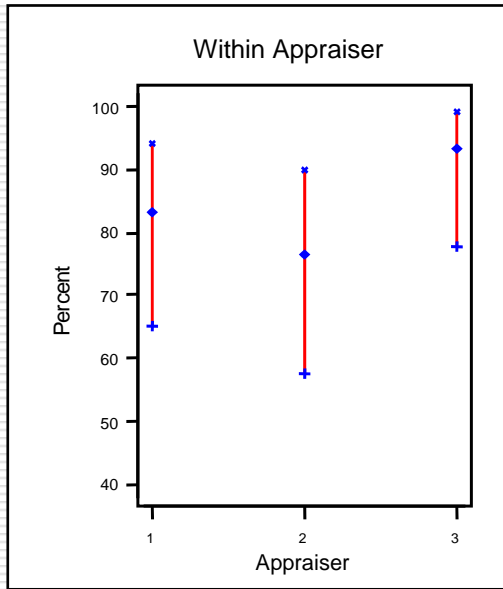
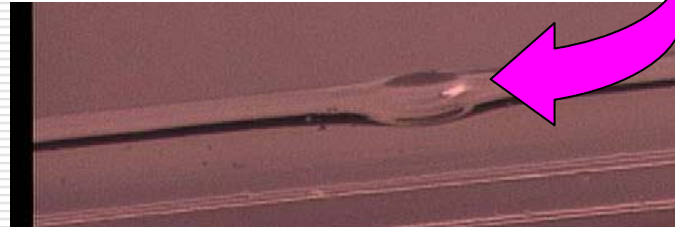
Lean out the Supply and Distribution Network, utilized component model and reduce supplier parts variability

Item	Start	To Date
WIP Inventory	\$1.4M	\$643K
Turns	4.8	12
Supplier L/T	7 day	1 day
Total L/T	67 days	4 days
Whse Space	100 pallets	43 pallets

Warehouse
Manufacturing
Procurement
Suppliers

Supply LeanSigma

Defect: \$150K scrap, 31% yield, polyurethane tubing “gels”
DMAIC Project: Supplier capability project



- **The Eureka!**
- **Bad Gage R&R... only 7 out of 10 judged correctly**
- **Supplier investing in automated video inspection**
- **DOEs can now be run... optimizing extrusion process**

The Agenda

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