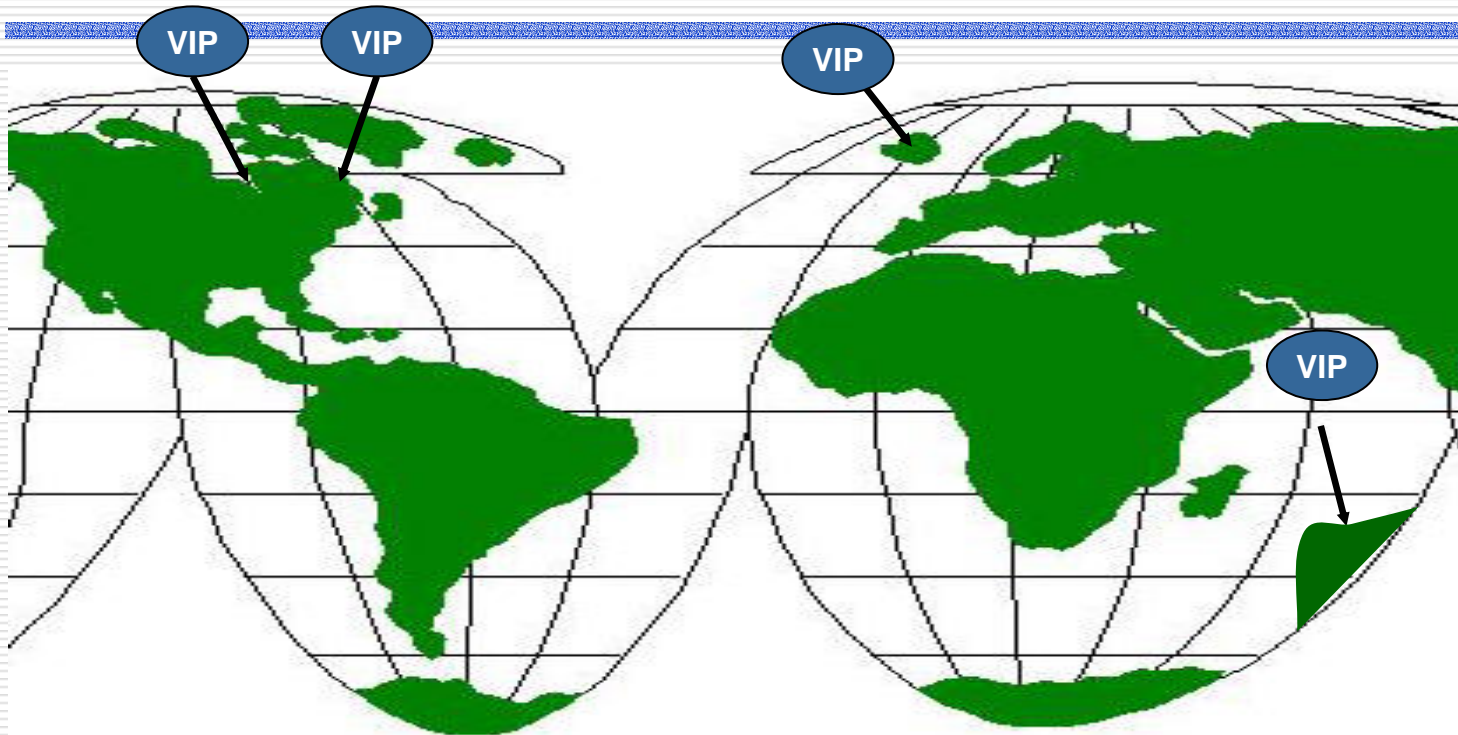


Value Innovation Partners

partnership in value creation



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Boston

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Haverhill, MA 01830
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Who We Are

Value Innovation Partners, Ltd. was founded by a group of business practitioners with offices in Boston, Chicago, Leeds, UK and Melbourne, AU.

Experience

- Professionals with an average of 20 years of industry experience
- Clients in all major business sectors
- Recognized leaders in Lean Enterprise, Lean Supply Chain, ABC Analysis, Pharmacovigilance, Six Sigma, Lean Office and Lean Healthcare

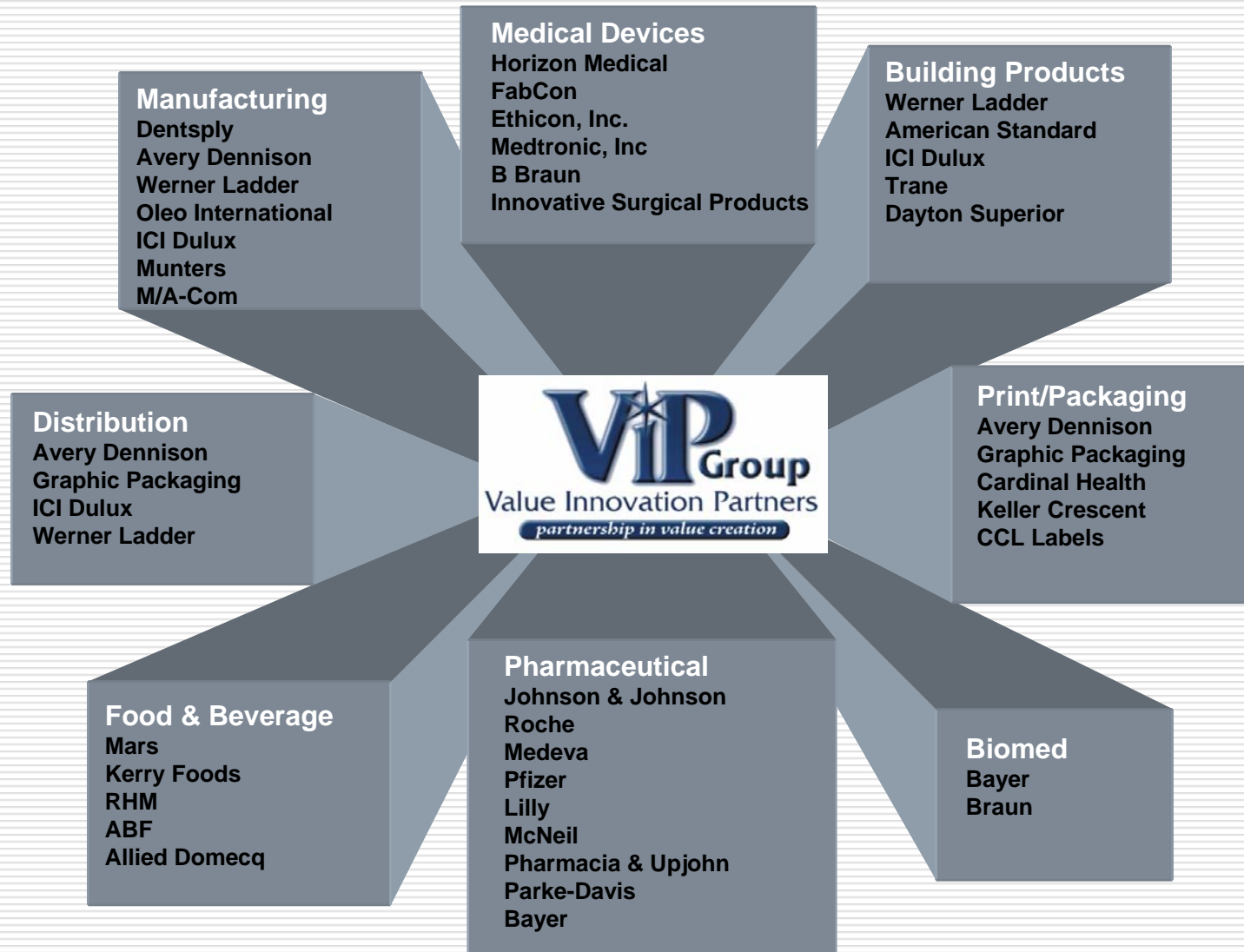
Involvement

- Participate in the analysis and implementation of solutions
- Deliver innovative, hands-on, creative approach
- Establish long-term relationships

Results

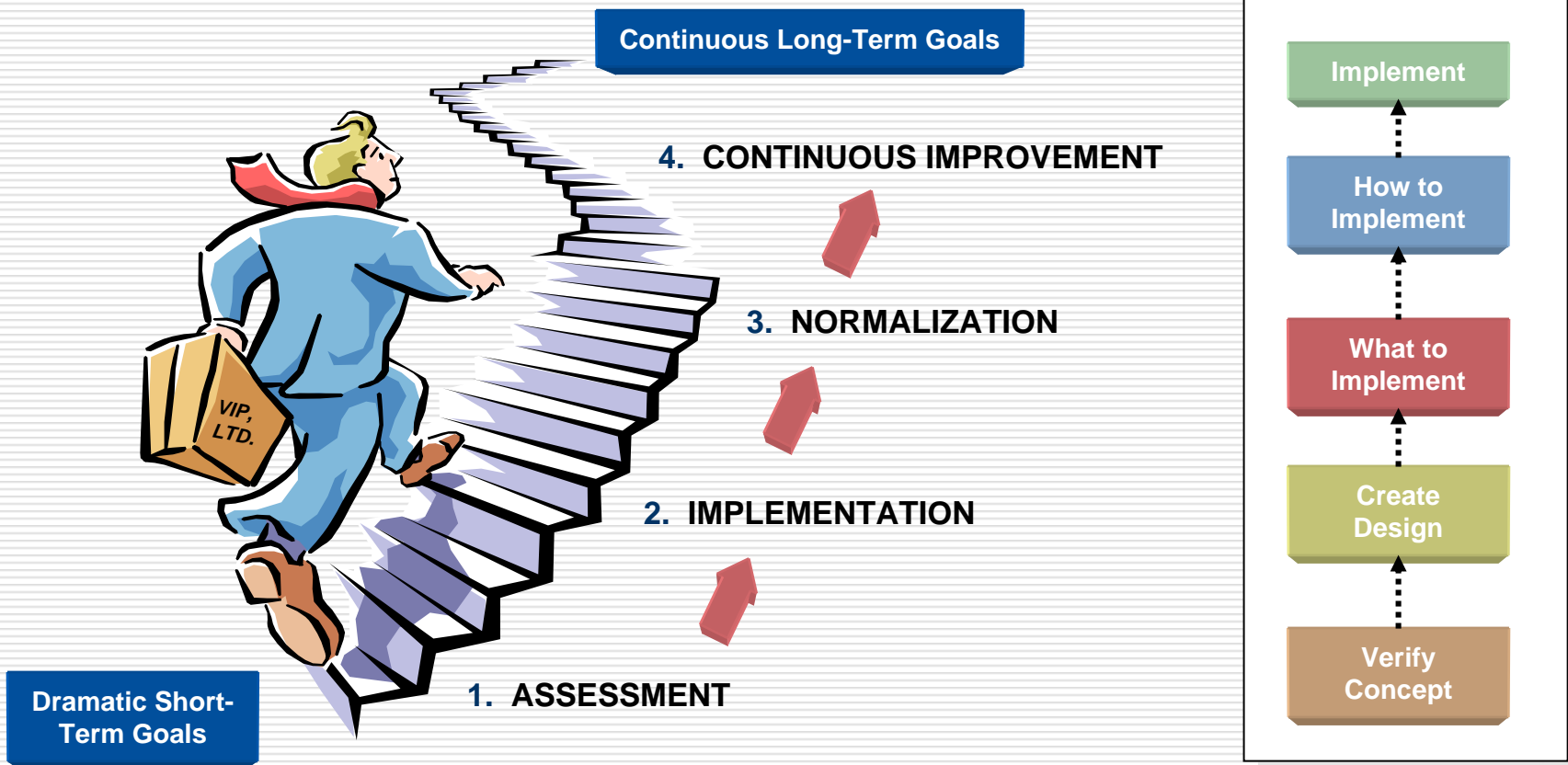
- Quantifiable and sustainable benefits
- Transfer critical skills
- Improve customer satisfaction, working capital, revenue and processes

Partial Client List



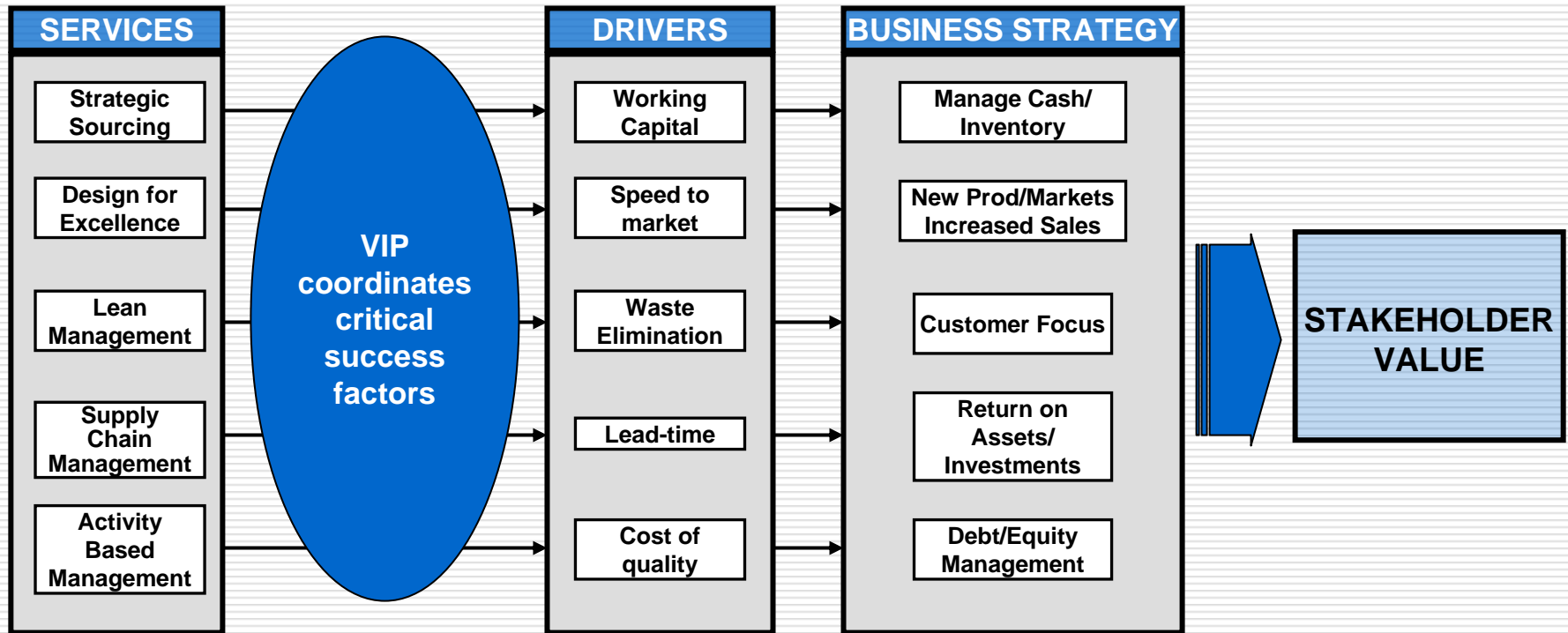
VIP's Proven Methodology

VIP employs a structured 4-step process.
(Benefits realized throughout the process)

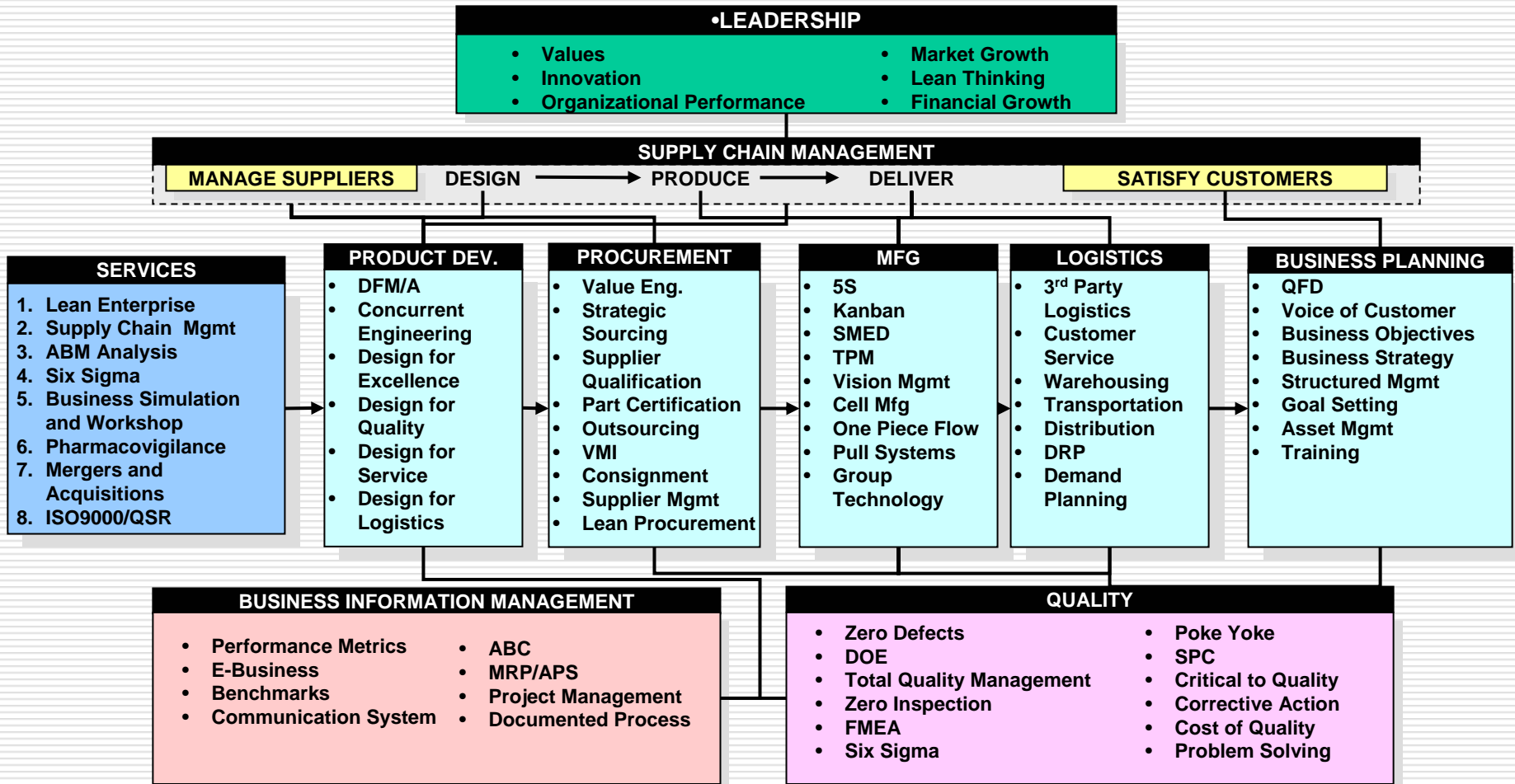


Our Approach:

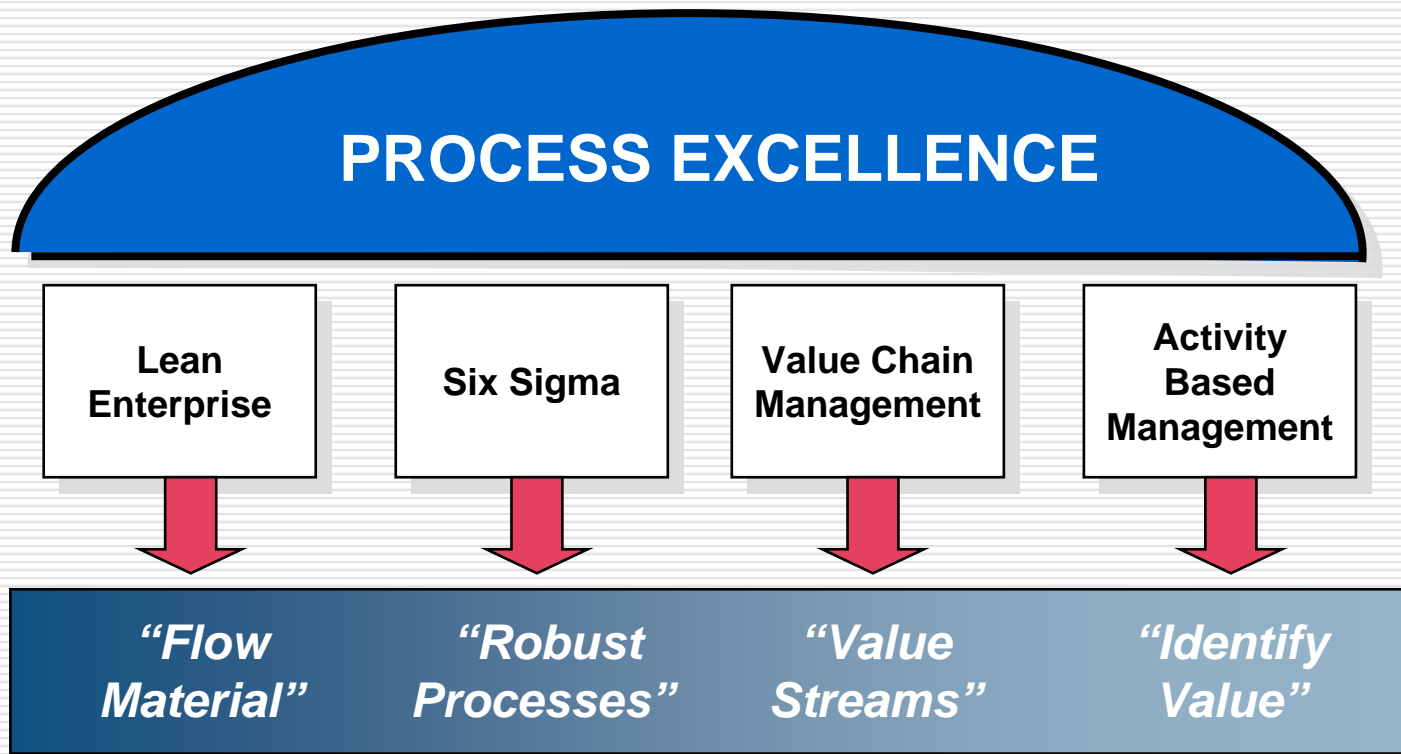
Linking VIP Services with Stakeholder Value



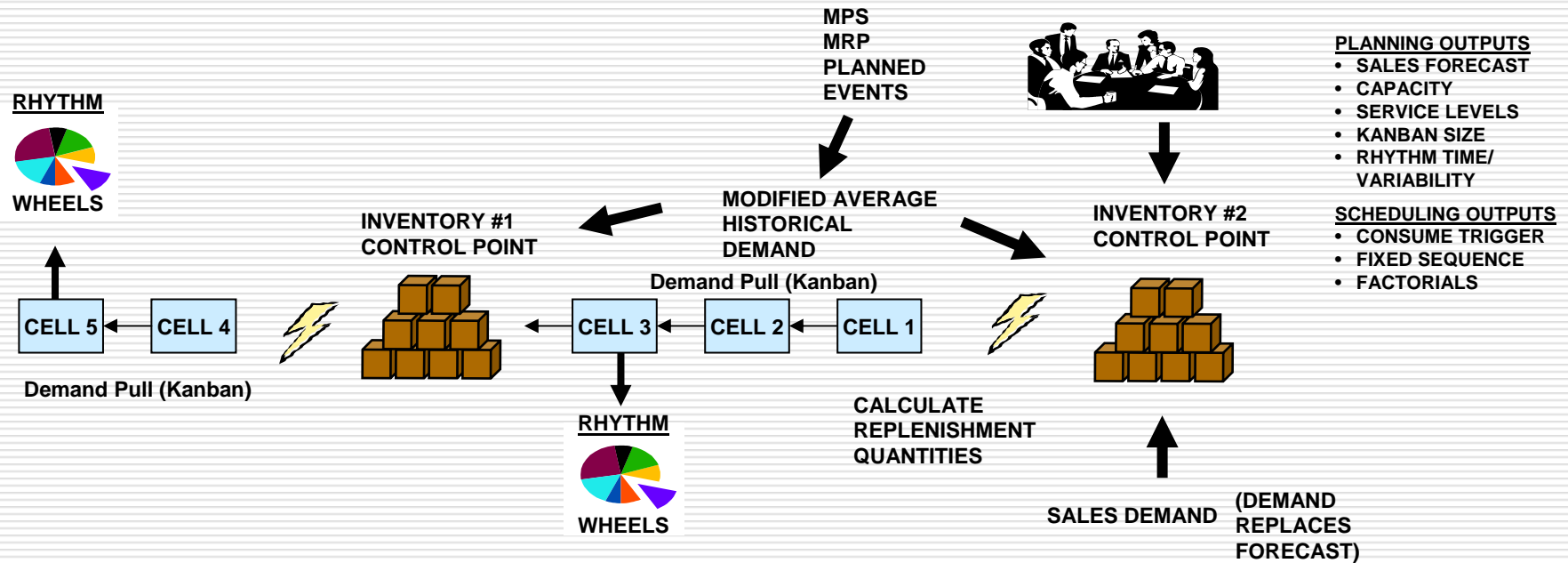
VIP Tools and Techniques



Our Process Excellence Model



VIP Lean Forecasting, Planning, Scheduling, & Manufacturing Concept



FINISHED GOODS REPLENISHMENT

- INVENTORY LEVEL
- CONSUMPTION TRIGGER
- PRODUCTION SCHEDULE

FINISHED GOODS PRODUCTION

- PRODUCTION ORDER REPORT
- MATERIAL CONSUMPTION
- BACKFLUSHING

LEAN PRODUCTION

- PULL
- 5S
- SMED
- LAYOUT
- ONE RIGHT WAY
- STANDARD WORK
- CELLS
- GROUP TECHNOLOGY

PURCHASING

- STRATEGIC SOURCING
- KANBAN
- POSTPONEMENT
- PRODUCTION DEMAND

PERFORMANCE METRICS

- SIX SIGMA
- BALANCED SCORECARD

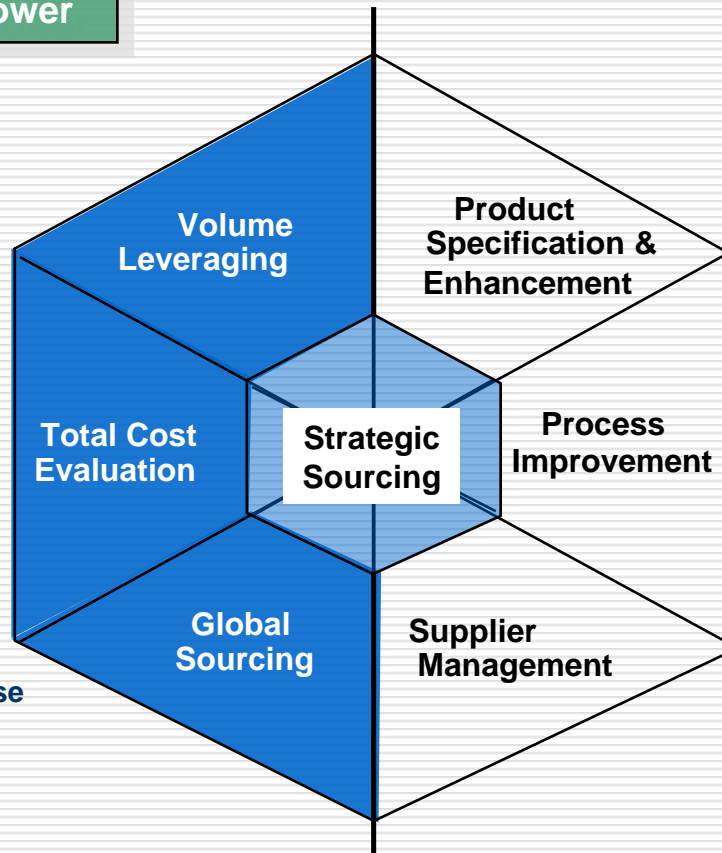
Our Strategic Sourcing Model

Leverage Purchasing Power

- Review supplier base
- Leverage volumes
- Single source
- Bundle commodity categories with same source

- Review “total” costs
- Implement target cost
- Renegotiate costs
- Unbundle pricing

- Expand geographic supply base
- Develop new suppliers (partners)
- Profit from global supply



Create Value

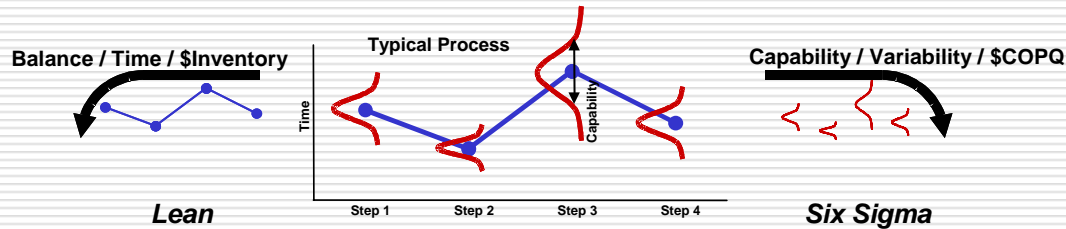
- Value Engineering
- Concurrent Engineering
- Improve product quality
- Part Certification
- Optimize product liability

- Value map
- Share productivity gains
- Integrate logistics
- Supplier qualification

- Develop supplier partnerships
- Integrate supply chain
- Robust make/buy process
- Develop supplier communication process

LeanSigma "DMAIC" Approach

Lean Sigma and 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
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

Cause & Effect, FMEA
Statistical Hypothesis Testing

Confirm Vital Few factors

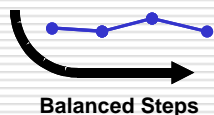
Improve
Control

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



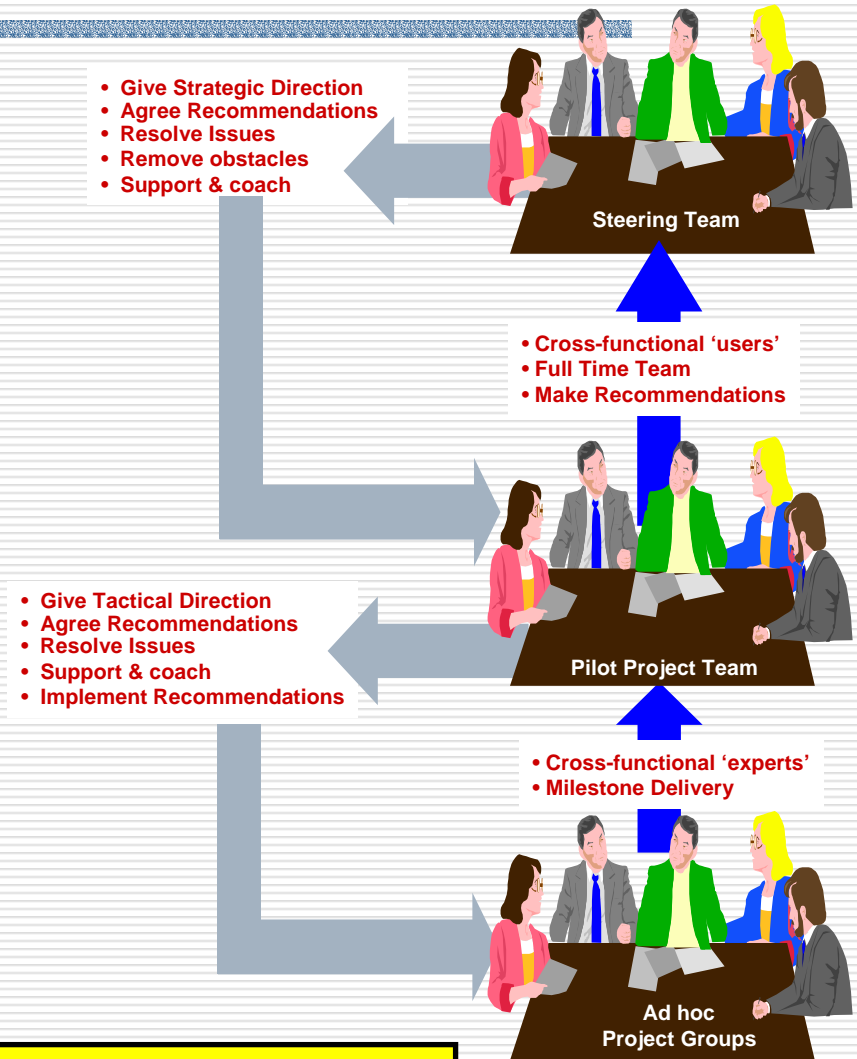
Improving Capabilities...
Enhances Process Balance



Customer Focused Quality

Senior Management Participation Model

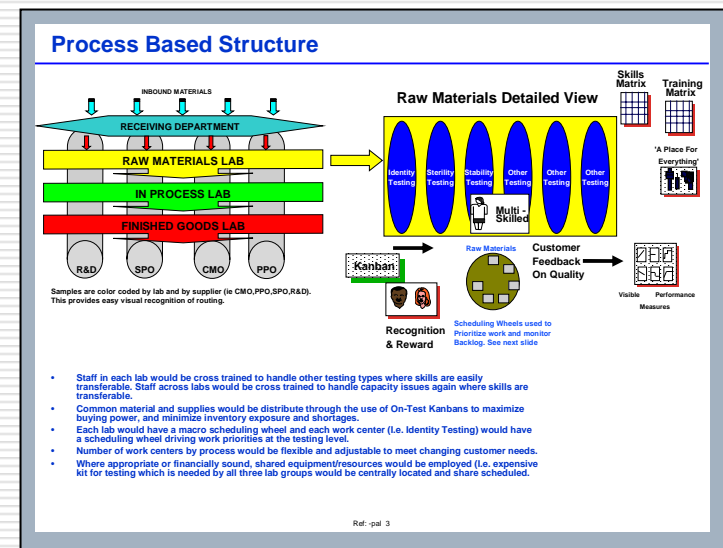
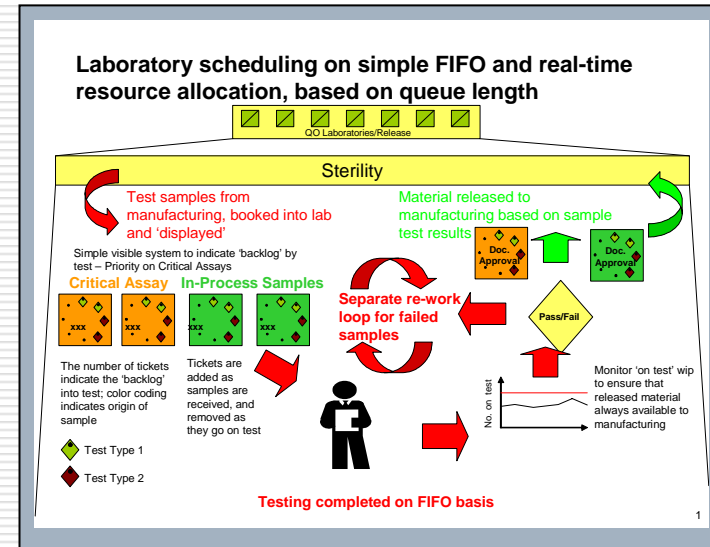
- Senior Management efforts across the Company including:
 - **Communication Strategy**
 - **Reward and Recognition systems**
 - **Goal Alignment**
 - **Project over-site management**
 - **Prioritization**
 - **Process Alignment**
 - **Collaborative environment**
 - **Scorecard/Dashboard**
 - **Roles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



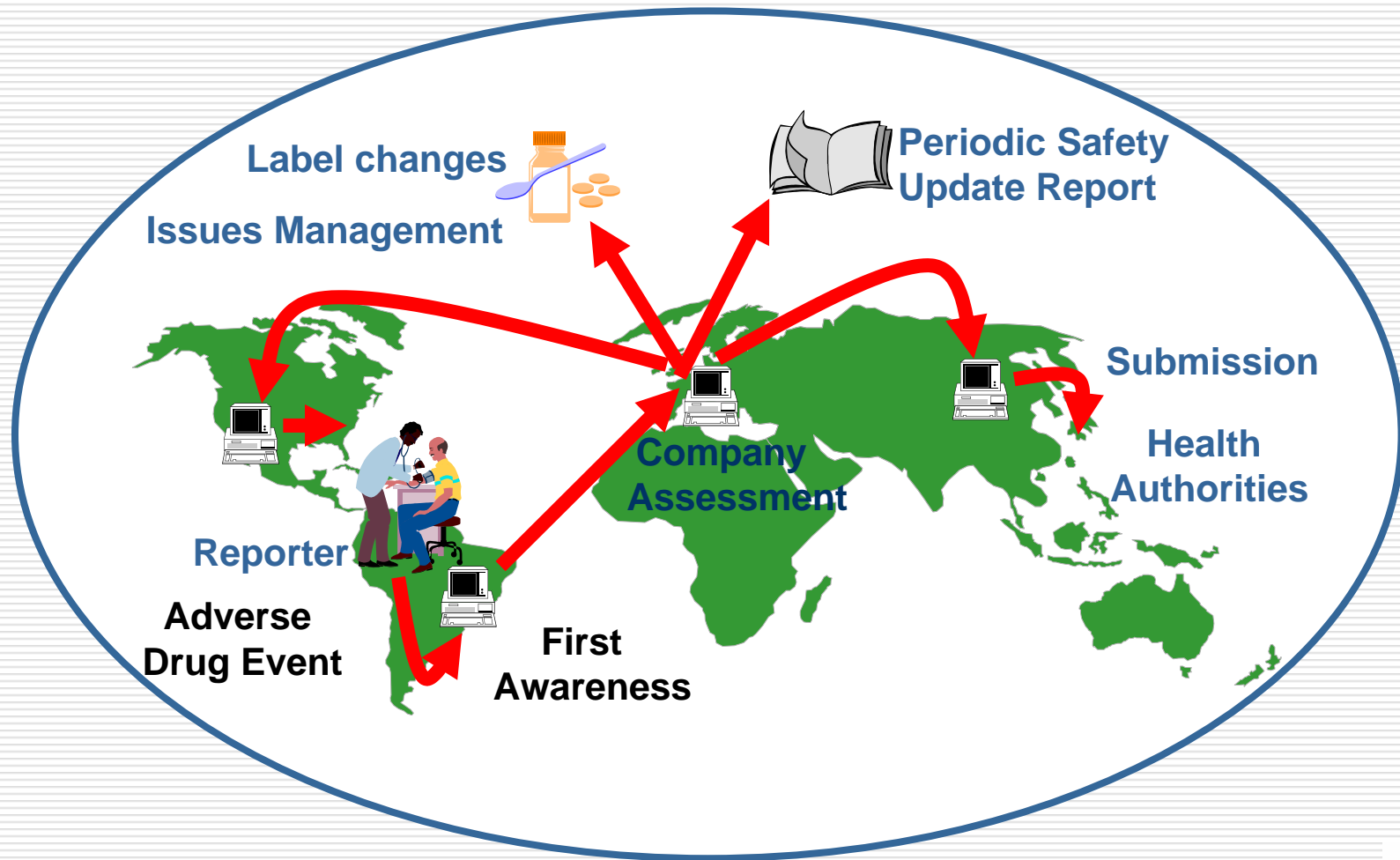
Keep all informed through a "Lean Project" Folder on a shared drive

Life Sciences Expertise

- **Pharmacovigilance**
 - Compliance
 - PSURS
 - Signaling
- **Laboratory redesign**
 - Layout and Process Flow
 - LIMS/GLP
 - Virtual
 - Scheduling
 - Testing requirements
- **Documentation design and redesign**
- **SOP/GMP/cGMP/GLP**
 - Reviews
 - Audits
 - Redesigns
- **Manufacturing Floor**
 - Lean concepts
 - 5S, SMED, TPM, etal
 - Batch record redesign
 - PIMS
- **Supply Chain**
 - Procurement
 - Raws and components
 - Testing and inspection
 - Distribution and Logistics
- **Utilities Optimization**
- **Sales & Marketing**
 - Bid Process



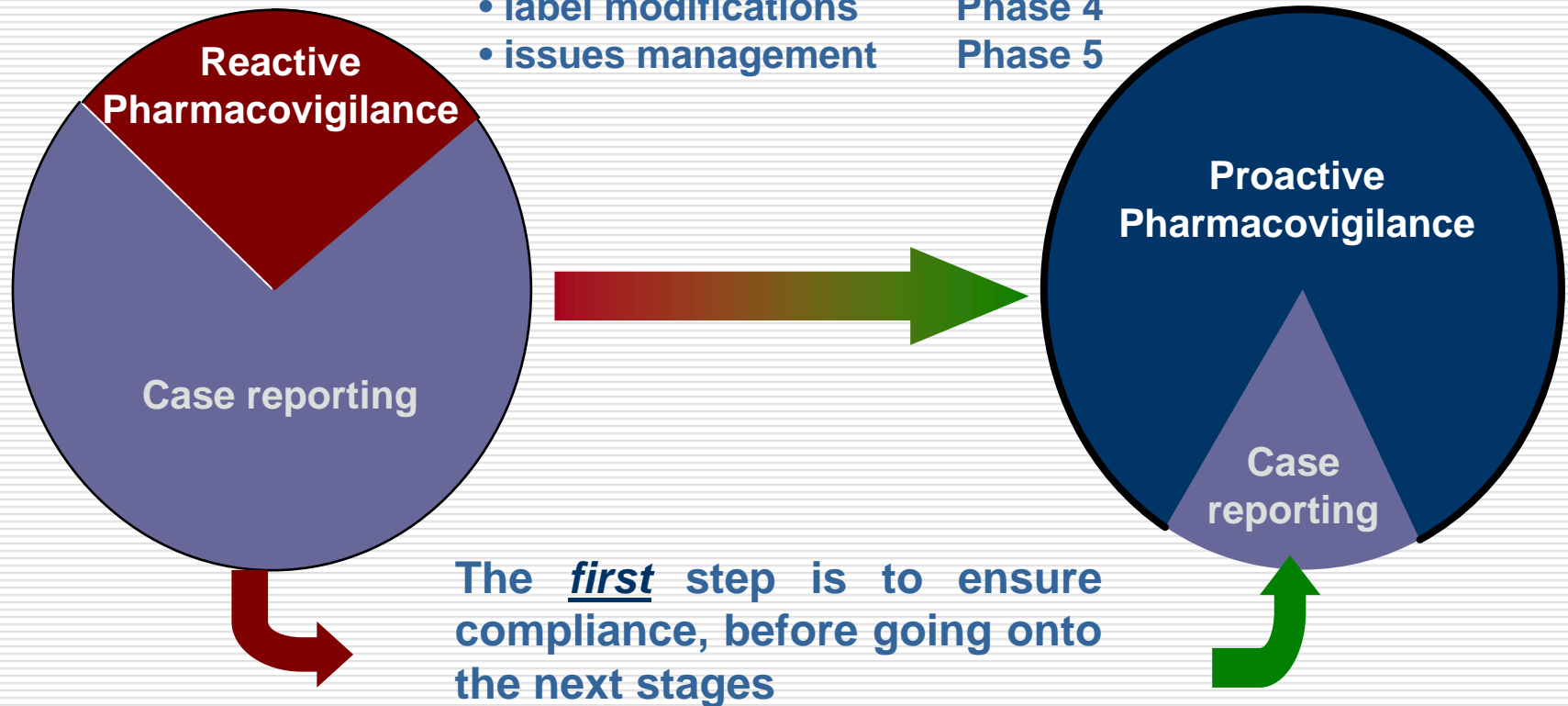
Global Drug Safety Perspective



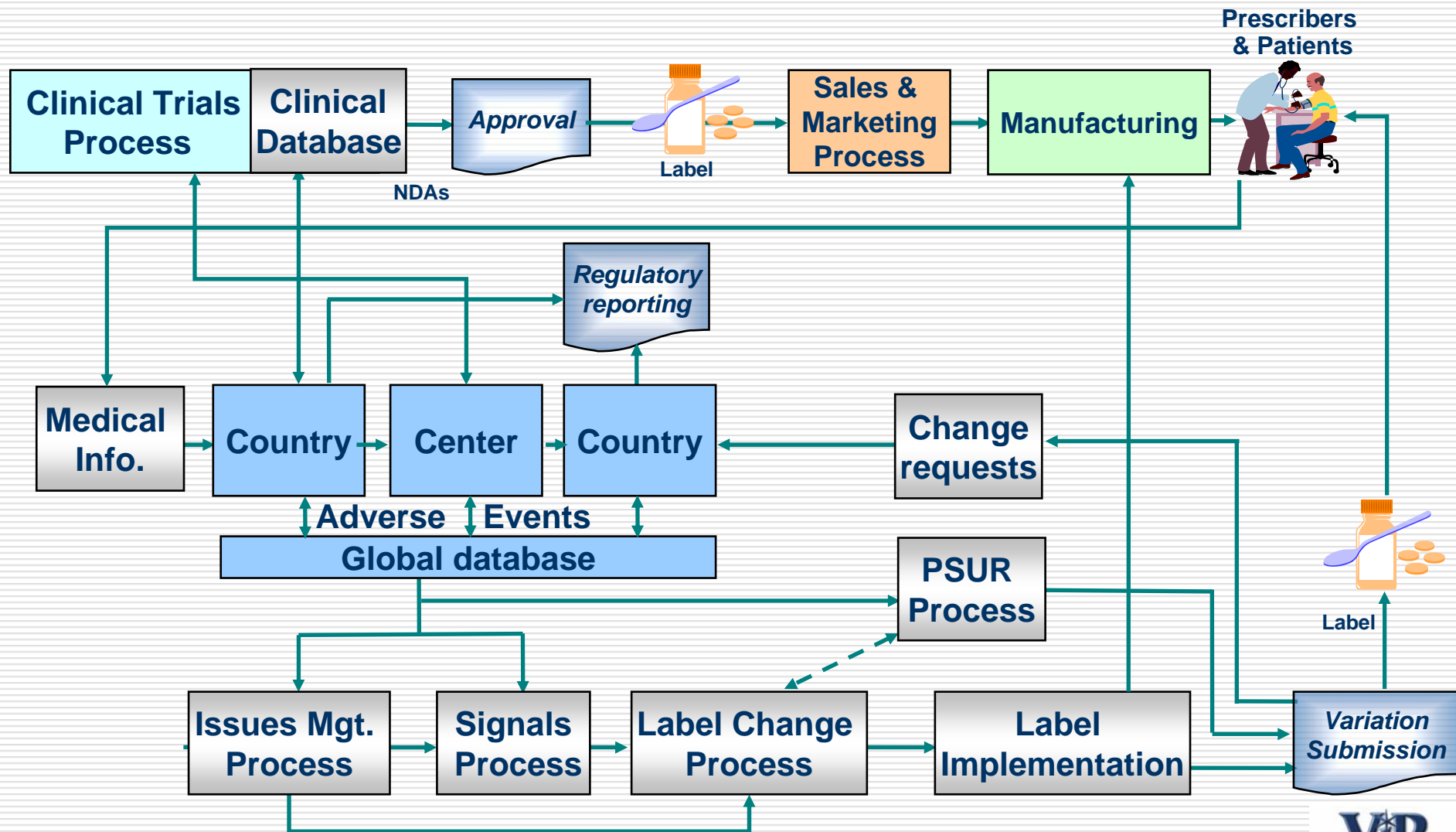
The Objective

5 Stages to Lean Pharmacovigilance

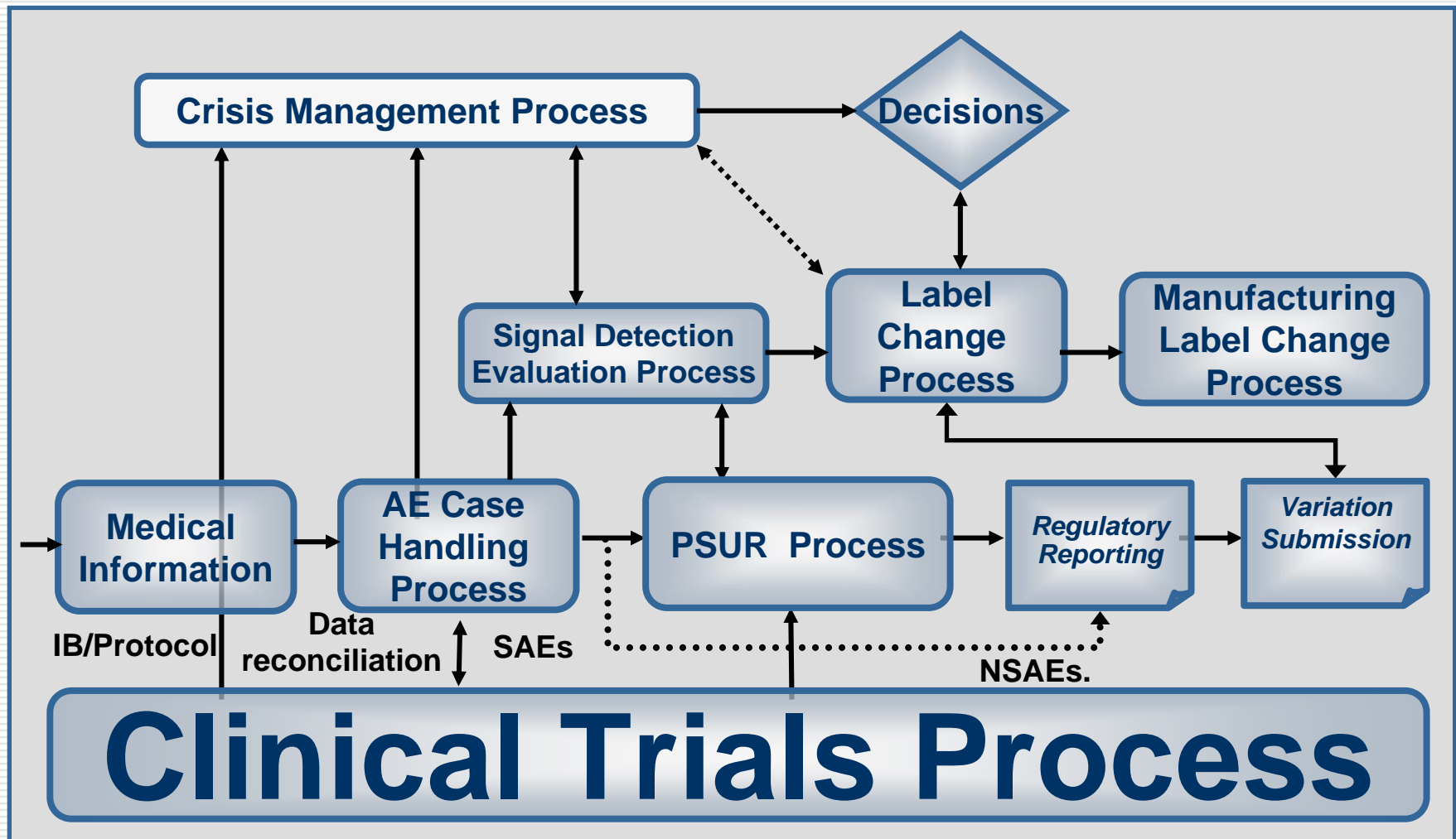
- case reporting Phase 1
- signal detection Phase 2
- periodic reports Phase 3
- label modifications Phase 4
- issues management Phase 5



VIP has Pharmacovigilance Expertise



Our Methodology addresses all Safety issues across the entire business



Example Pharmacovigilance...

AS-IS Map

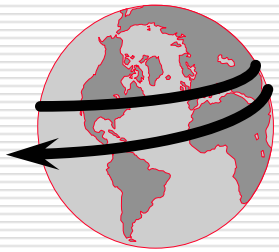
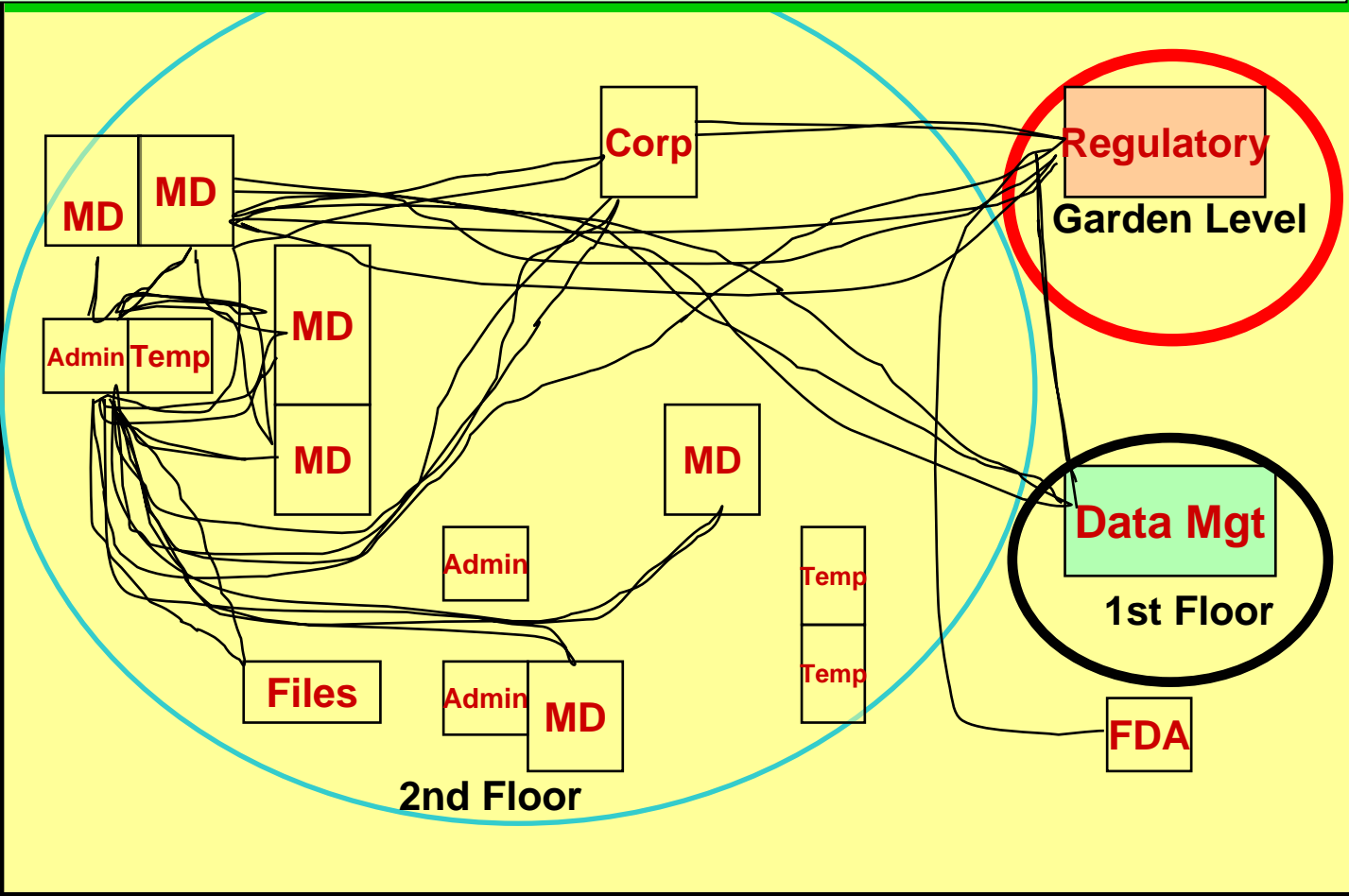


	Process Steps	QC Steps	Reg Steps	S&DS Steps	Total Steps	Error Loops, F/U's & Cosuspect	Total Steps	Report Type	Process structure
US-CT	47	11	29	0	87	17	104	15 day IND	Parallel
Non US-CT	35	11	22	0	68	9	77	15 day IND	Parallel
Non US-Spont	32	13	21	19	85	45	130	15 day NDA	Parallel
US-Spont	79	12	21	19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

Example Pharmacovigilance...

AS-IS Flow Diagram

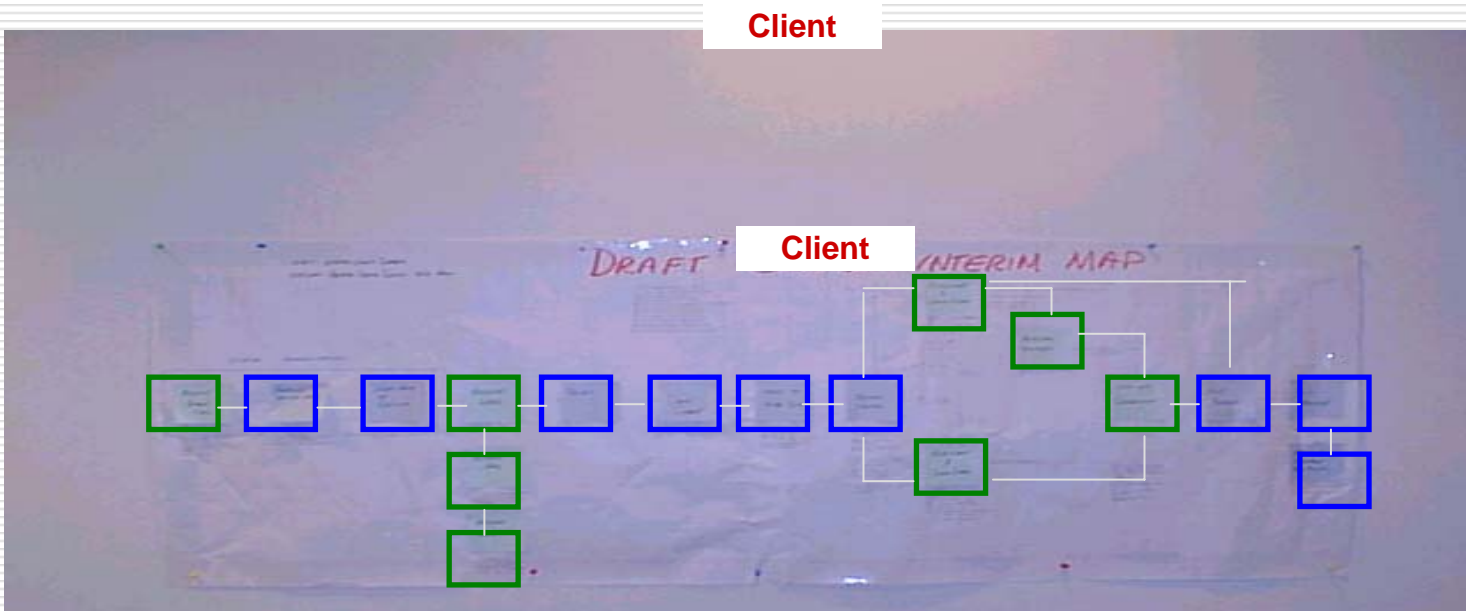
The current layout leads to a case travelling about 1/2 mile from case receipt to submission



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

Example Pharmacovigilance... Redesigned Process Map

Actual SAE redesigned process

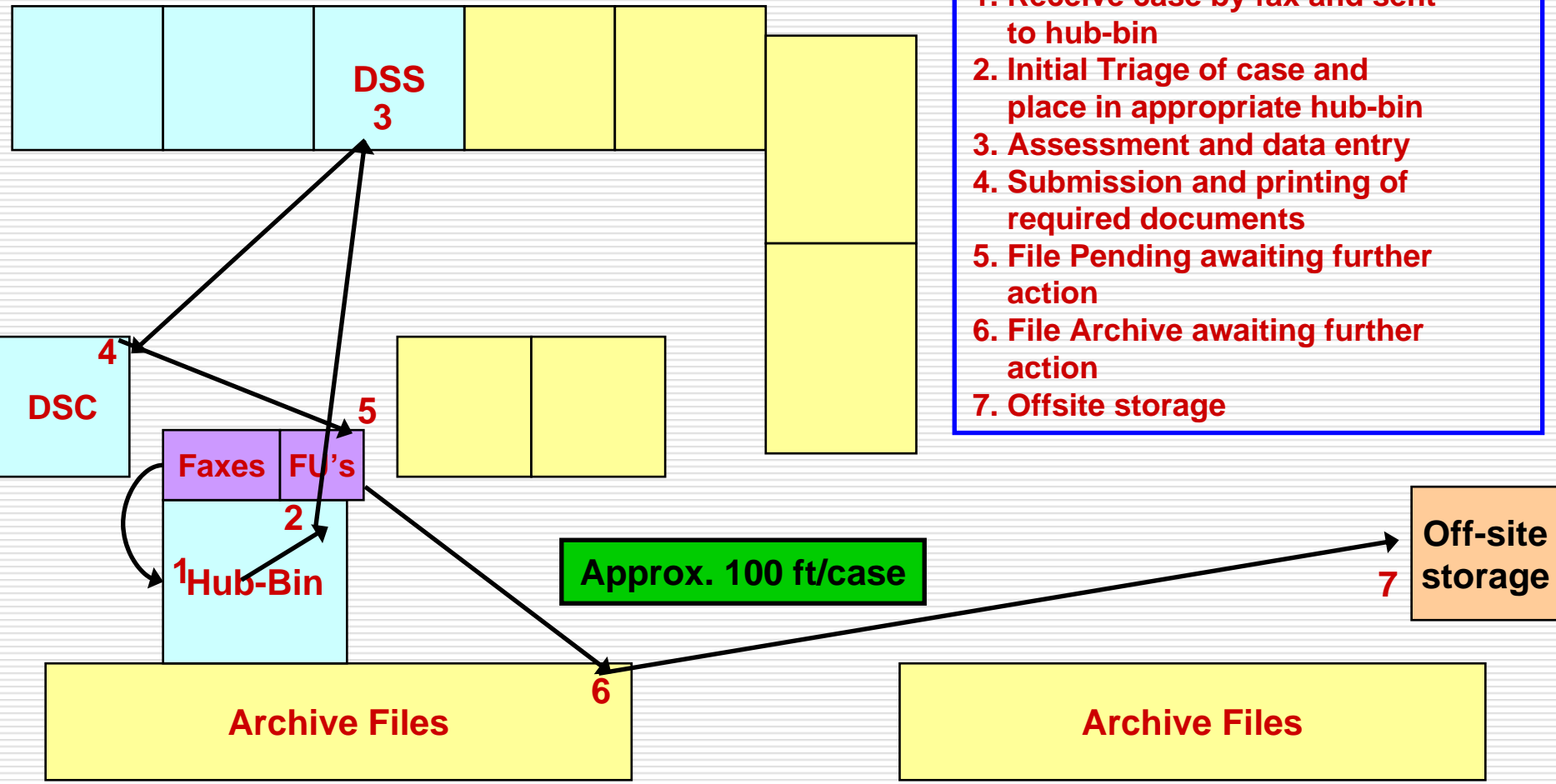


	Process Steps	QC Steps	Reg Steps	S&DS Steps	Total Steps	Error Loops, F/U's & Cosuspect	Total Steps	NVA	VA	SNVA
All	17	0	0	0	17	0	17	0	8	9

Example 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

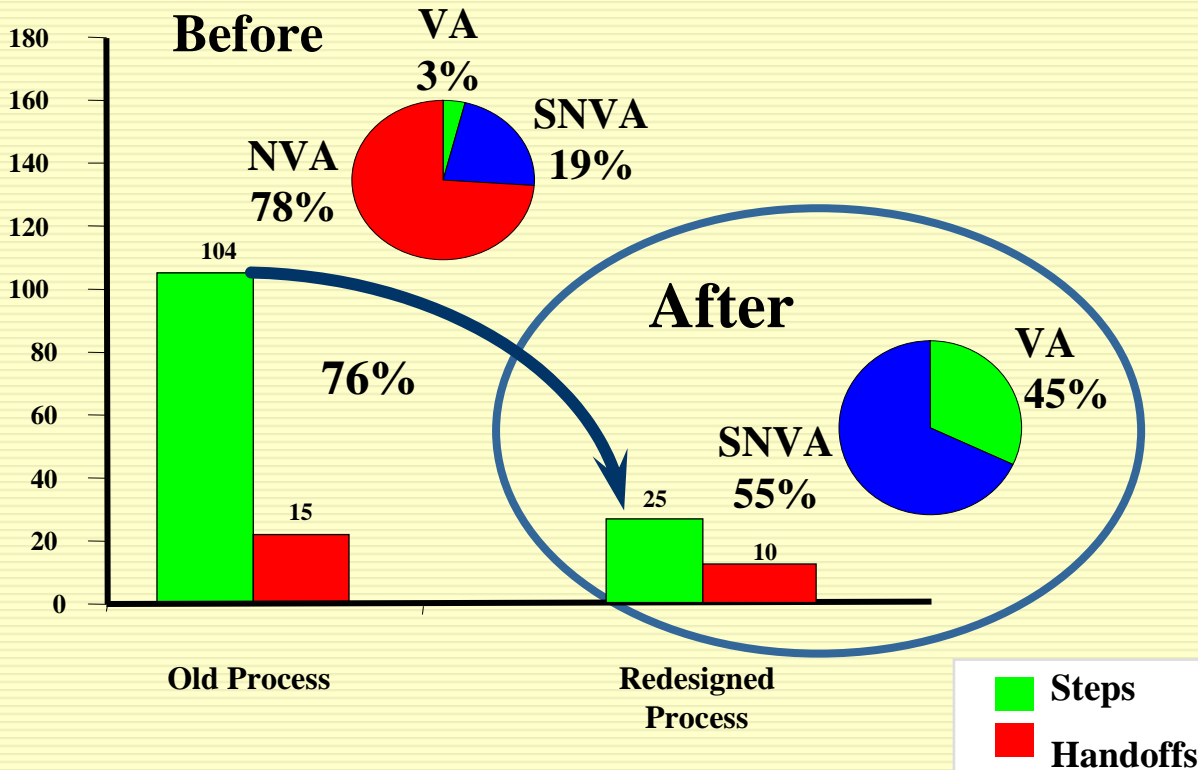


Lean Office in Action

\$4.8 B Pharmaceutical/Biotech/Chemical Operation

Source:
Client Process Maps
includes rework loops

Number of process steps and hand-offs

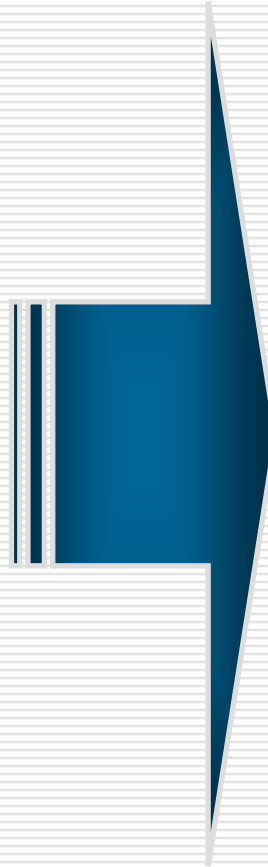


- Case travel distance was reduced by 96% from 1/2 mile to 100ft.
- All NVA steps were removed (400+)
- **Global compliance improved from 30% to better than 99%**
- Case processing time was reduced from 21 days to 11
- Internally generated documents were reduced from 32 to 1
- Improved productivity by 105% with existing staff
- Reduced process steps from 477 to 17
- Internal Regulatory and Compliance Departments approved and endorsed changes

Typical Change Efforts and 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

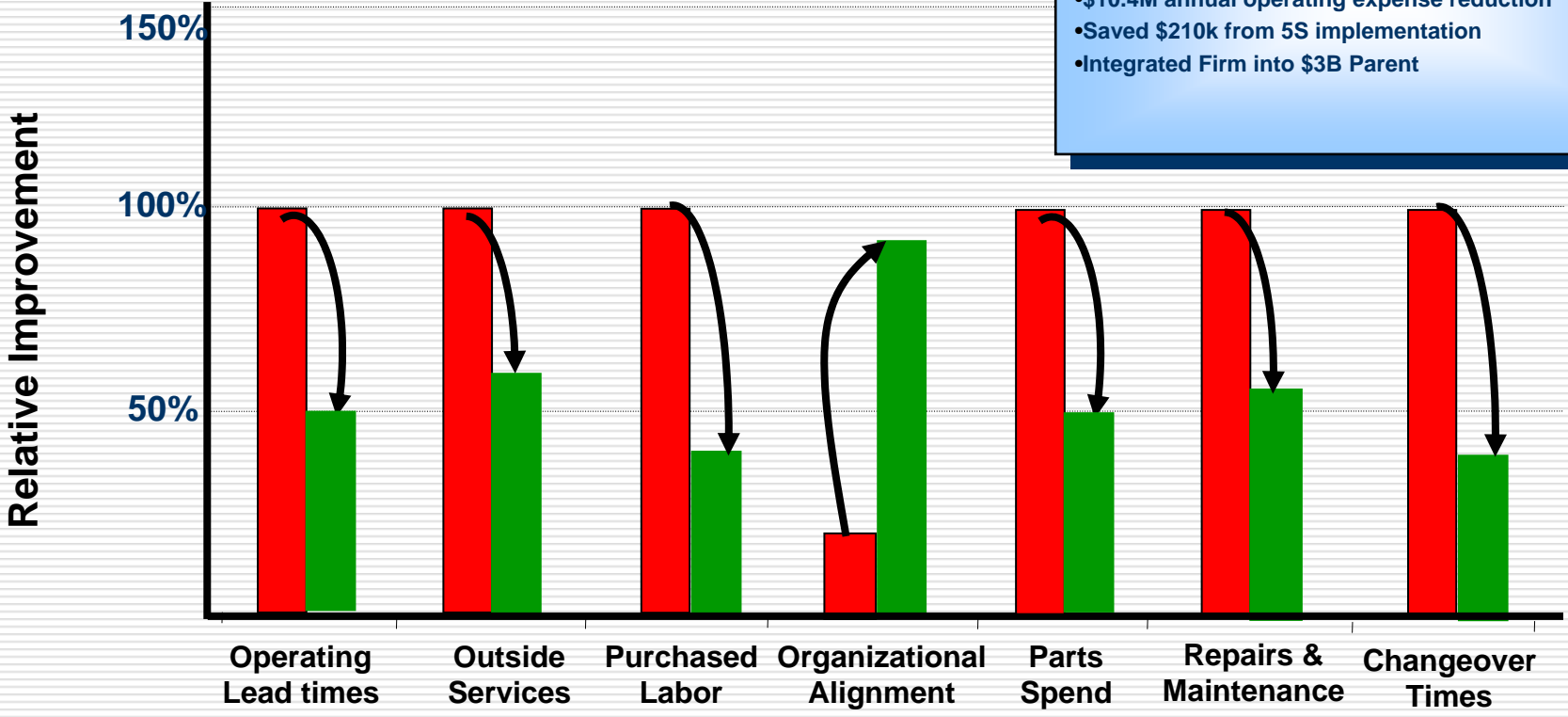
- Average 98% compliance, improve capacity by 105% and removed all NVA steps
- \$10.4M run rate reduction in operating expenses
- Inventory reduction of 50-80%
- Space reduction of 30-60%
- Adherence to schedule of 90-100%
- Improvement in OTD to 96% average
- Reduce time to changeover from hours/days 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 Enterprise in Action

\$.5 Billion Pharmaceutical/Chemical/Packaging Operation

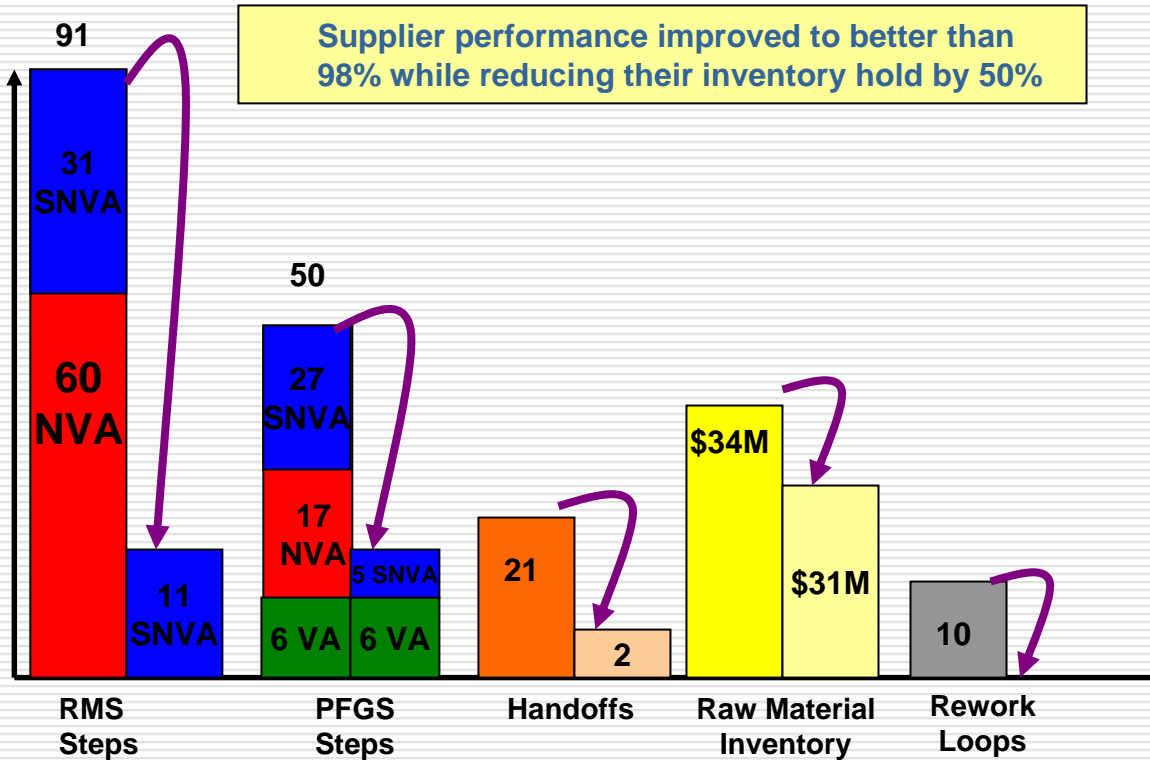
Key Benefits

- Lead-time from 49 days to 3 days in sourcing
- Labor and Over-time reduced \$6M
- Maintained 98% OTD and 100% quality
- \$10.4M annual operating expense reduction
- Saved \$210k from 5S implementation
- Integrated Firm into \$3B Parent



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

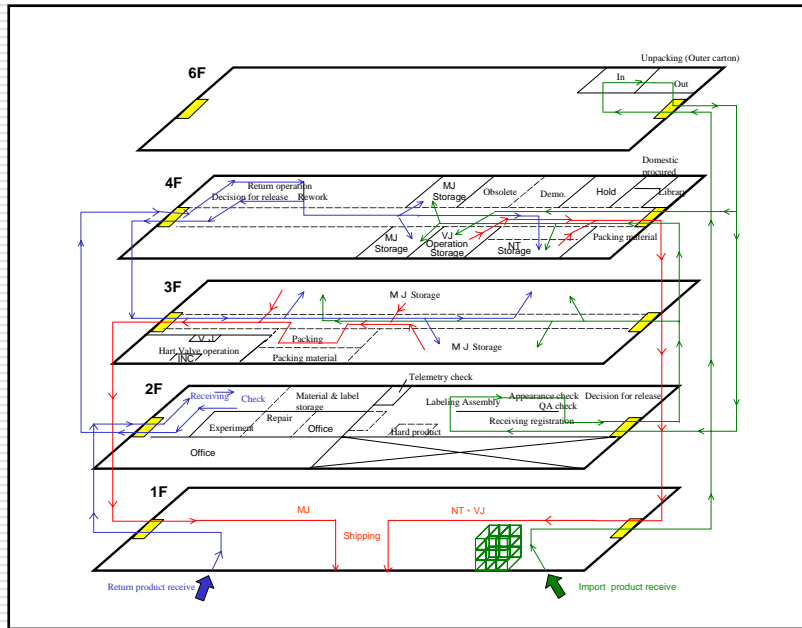
LeanSigma Supply Chain Example

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

Defect: Process and compliance variability

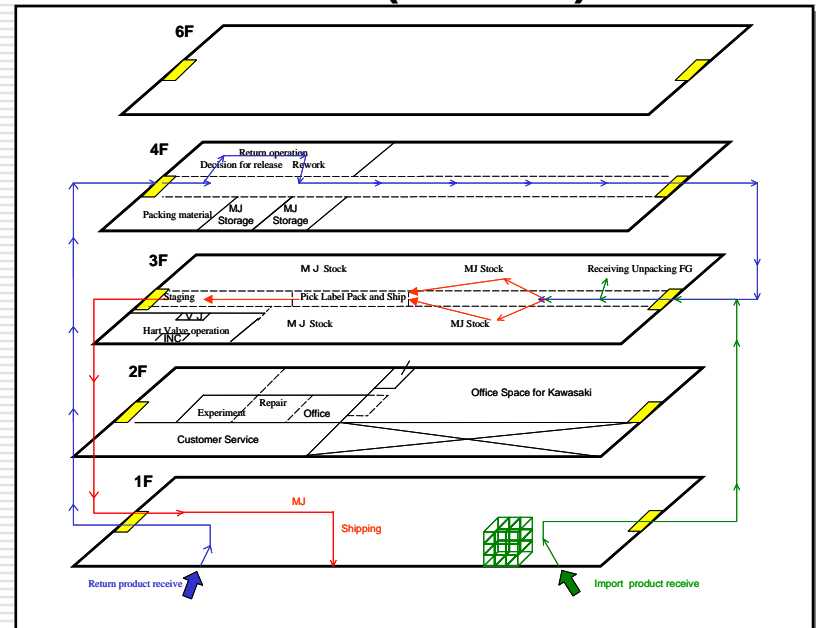
DMAIC Project: Lean out the Distribution Center

Before



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

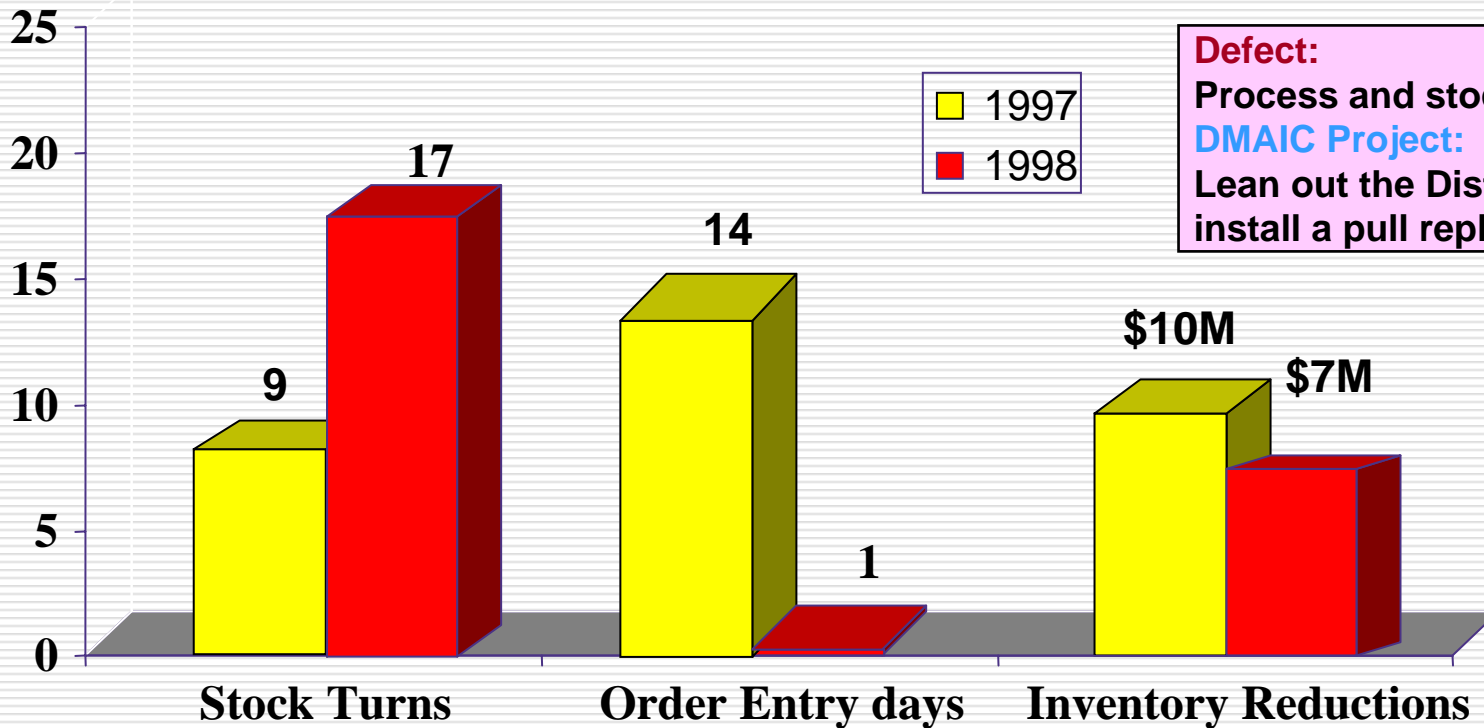
After (4Q '04)



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

LeanSigma in the Supply Chain

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

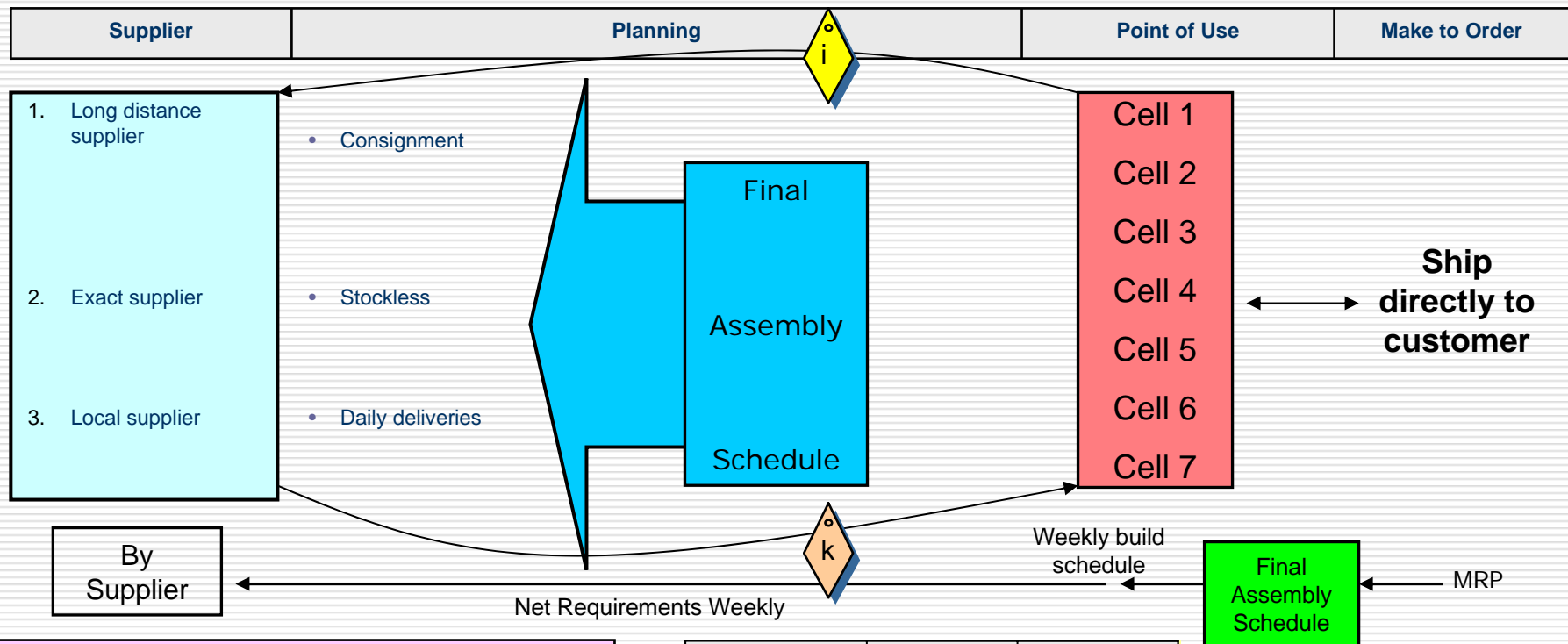


Defect:
Process and stocking level variability
DMAIC Project:
Lean out the Distribution Network and install a pull replenishment model

- 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

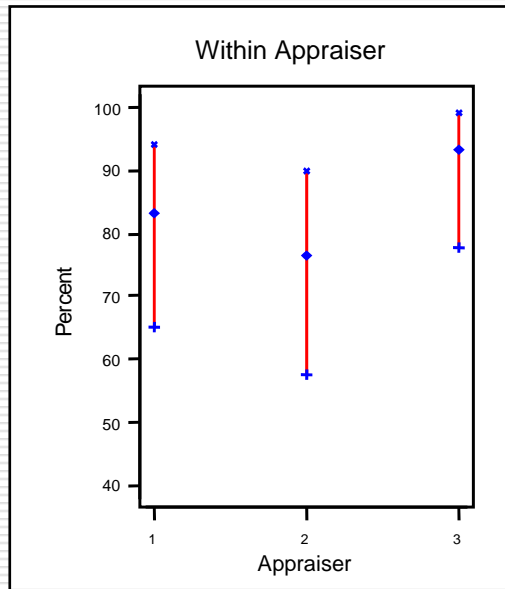
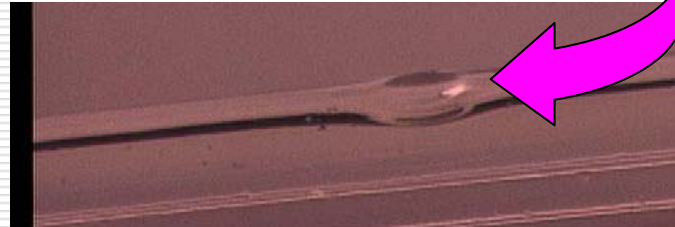
DMAIC Project:

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

LeanSigma Example in the Supply Chain

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**

Why Use Value Innovation Partners

- ✓ **Technical Expertise**
- ✓ **Leverage Other Company Experience**
- ✓ **Avert Pit Falls**
- ✓ **Provide Early Benefits**
- ✓ **Provide Methodology/Techniques**
- ✓ **Project Management**
- ✓ **Outside Resources (benchmarking/technical)**
- ✓ **Creativity/Analytical Skills**