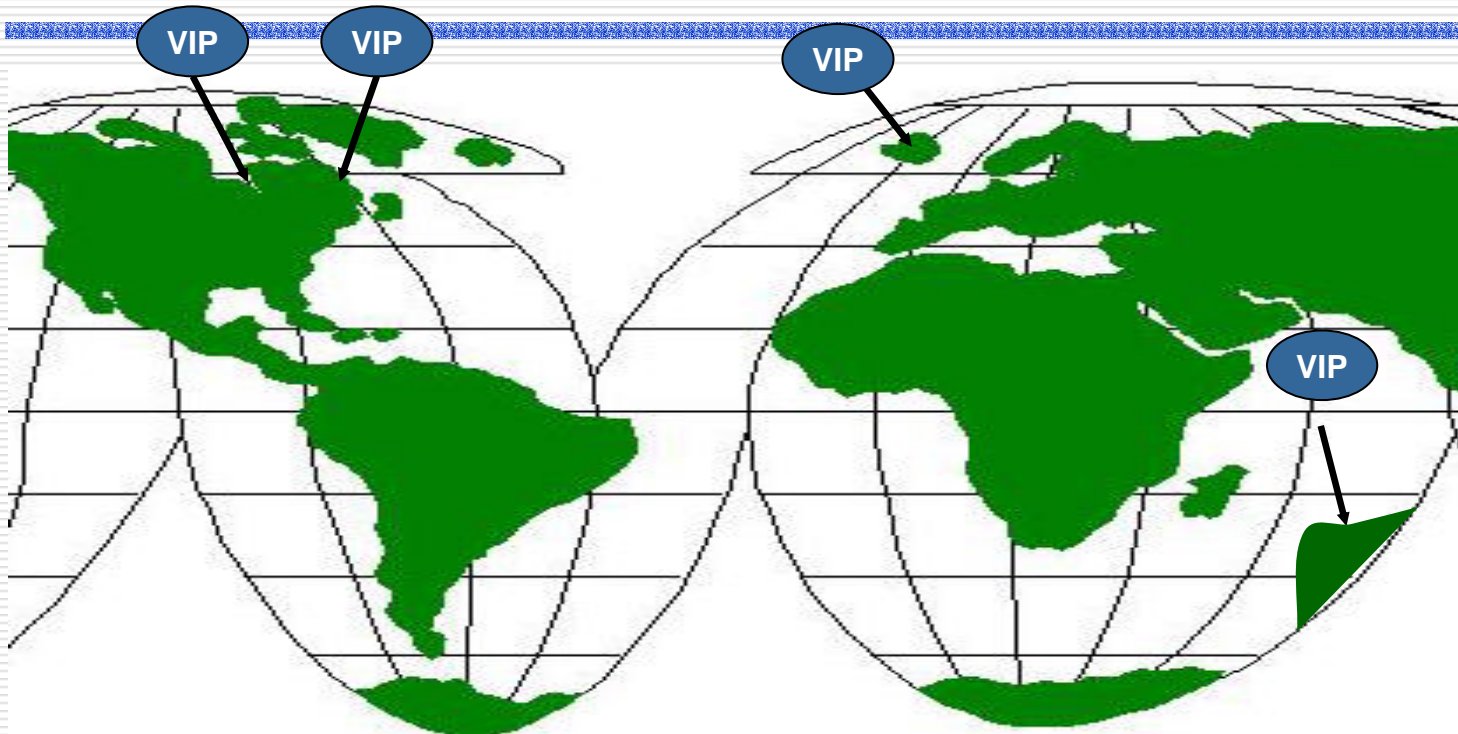


# Value Innovation Partners

*partnership in value creation*



## Chicago

41966 N. US Hwy 45  
Antioch, IL 60002  
001 (847) 395-7076

## Boston

12 Crowell Street  
Haverhill, MA 01830  
001 (978) 372-3469

## Europe

33 Wharfe Grange  
Wetherby  
LS22 6SS UK  
011 44 1 937584617

## Australia

119 Hawthorn Road  
Caulfield Victoria 3161  
011 61 (03) 9523 7955

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# Who We Are

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**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

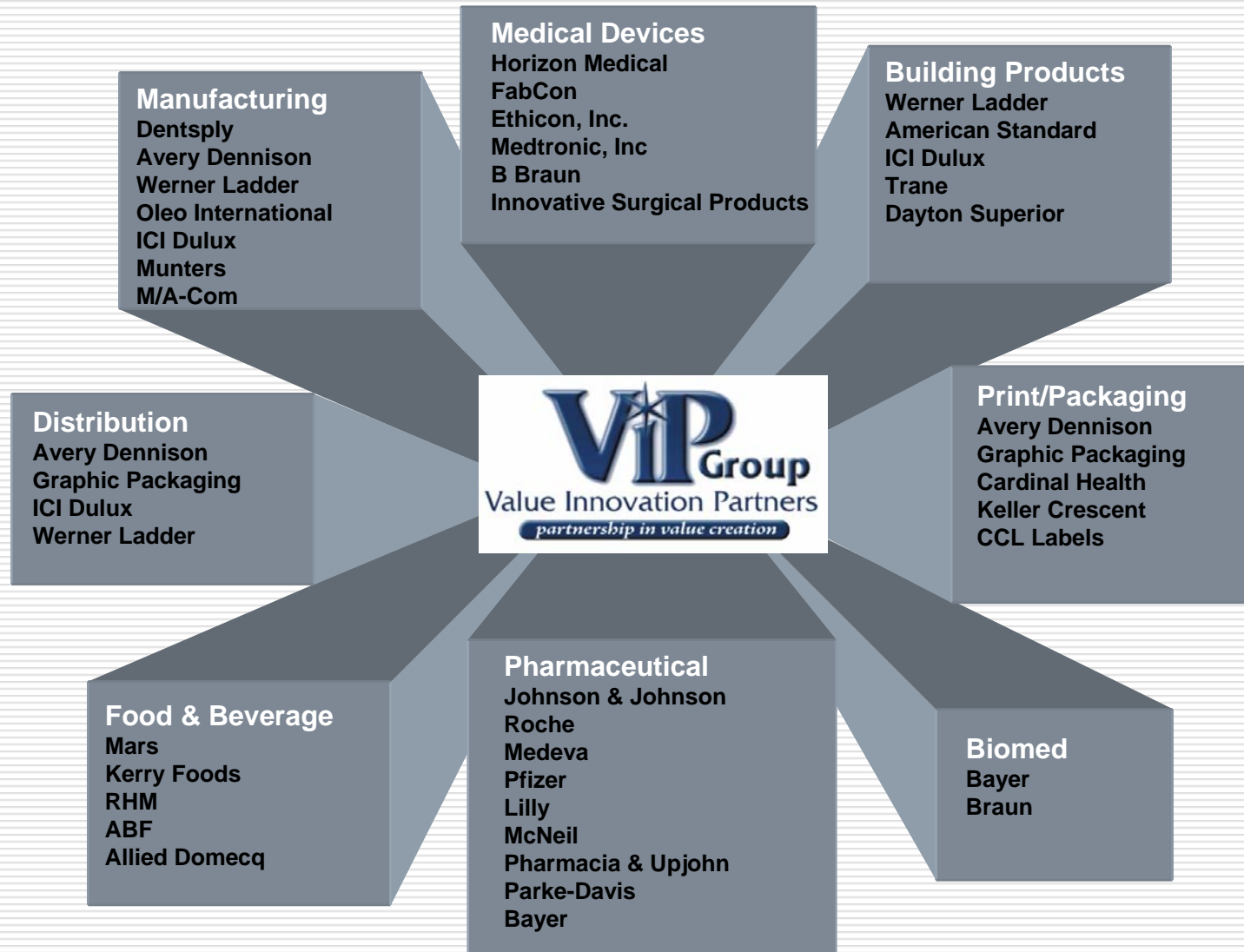
## Involvement

- 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



# Health Care Operations

## Business Side



- Physicians
- Provider Organizations
- Hospitals
- Hospital Depts.
- Insurance Companies
- Nursing Homes
- Home Care Agencies
- Scheduling Appointments.
- Admitting Patients
- Insurance Eligibility
- Insurance Verification
- Billing
- A/R
- Collections/Bad Debt

## Clinical Side



- Physicians
- Provider Organizations
- Hospitals
- Hospital Depts.
- Insurance Companies
- Nursing Homes
- Home Care Agencies
- History & Physicals
- Diagnostic Procedures
- Prescriptions
- Medical Records
- Clinical Protocols
- Discharge Planning
- Episodes of Care



## Health Care

# Where the industry is today...

## Current Situation

- **Costs are high and rising**
- **Quality systems have not addressed the root cause only treated the symptoms**
- **Cost reduction efforts have not been successful**
- **HealthCare has become “Zero –Sum’ both for the participants and competitors**
  - **Cost shifting occurring rather than cost reduction**
  - **Focus is on greater bargaining power rather than better care**
  - **Choice and access is restricted**
  - **Courts must settle disputes**
- **Payer incentives drive customer market segmentation**
- **Provider incentives drive a one-stop shop, not specialized quality care.**

**“Between the care we have and the care we could have lies not just a gap but a chasm. The current care systems cannot do the job. Trying harder will not work. Changing the system of care will. Lean is one way to make this happen” *President of Iowa Healthcare Organization***

# Two Goals we see today

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1. **The objective should be to increase value as defined by the Voice of the Customer.**
2. **Focus should be on the form of competition**
  - **Diseases and conditions define the competitive arena**
  - **Payers and providers define the strategies**
  - **Incentives should be on increasing value and true cost reduction**
  - **The customer must have the ultimate choice decision**
  - **Provider information must be visible (scorecard)**

**“Not only is it your fiduciary responsibility to ensure that your enrollees receive high quality care, but it is also smart from a business perspective. Health care fraught with mistakes leads to sicker patients, longer lengths of stay, readmissions and unnecessary added costs. All this also translates into employee absenteeism, reduced productivity and an impaired workforce.”** *Bruce E. Bradley, Director, Health Plan Strategy and Public Policy, General Motors Corp.*

# Some Requirements for Successful Change

1. Engage LeanSigma in the health care industry to drive out waste, improve quality, reduce cost and eliminate variation.
2. Develop and install an inward looking measurement system driven by the Voice of the Customer.
3. Eliminate the restrictions to competition and choice
4. Make information accessible... publicize
5. Price standardization within and across the industry
6. Billing simplification
  - The internal and external process
  - Focus on speed of delivery but not at the cost of quality or compliance

Minnesota first in the nation to have all hospitals provide information to Leapfrog Group.

“The purpose of this partnership is to provide useful relevant information to Minnesotans about the steps Minnesota hospitals are taking to improve safety and quality...Our 100% participation is a result of our strong commitment to have one standard of high quality care regardless of how big the hospital is or what community it is in.” **Bruce Rueben, President, Minnesota Hospital Association**

# Applying LeanSigma In The Health Industry:

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## Three Complimentary Areas of Focus

1. **Health Care Services**

Health care professionals and organizations, i.e. hospitals, doctors, clinics, etc.

2. **Billing, Claims, Payment and Information Services**

Clearinghouses, TPA/insurance companies, Pharmacy Benefit Managers (PBM), information vendors, etc.

3. **Customers** (Expectations, information/measures)

-Employers/sponsors

-Consumers/patients

# Summary:

## Efforts to Drive LeanSigma through the Industry

### #1. Working the Complete Process

- Step 1. Define your Voice of the Customer
- Step 2. Develop health system high level process map of the current state between employers, health plans health care providers and patients.
- Step 3. From the map identify the problem areas, gather data and other information to describe and understand these issues.
- Step 4. Identify desired future state.
- Step 5. Perform a Gap analysis.
- Step 6. Develop your implementation plan
- Step 7. Achieve buy-in and agreement
- Step 8. Implement

### #2. Identify Early Adopters in the Industry

### #3. Support Local Demonstration Projects

- Networking among sites and supportive organizations
- Encourage new demonstration sites

### #4. Conduct Education and Communications

- Glossary of terms
- Communicate success stories
- Hold education sessions/seminars
- Providers want opportunities to share time with manufacturers and LEAN practitioners
- LEAN 101 training
- LeanSigma Training

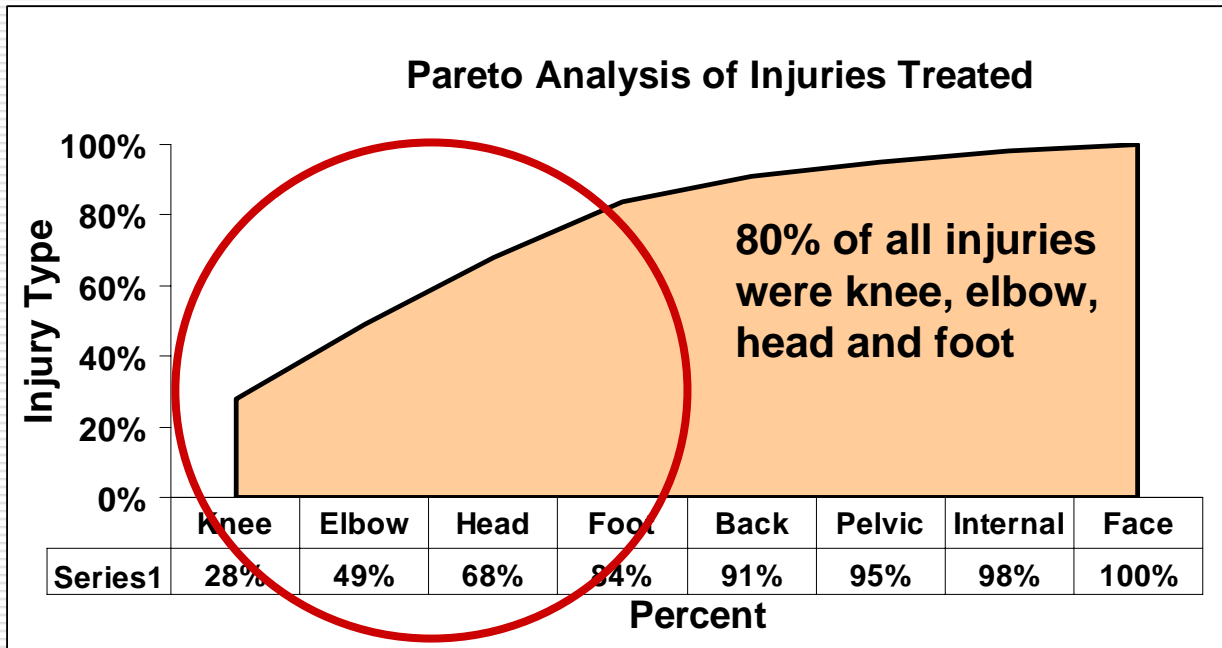
### #5. Develop Customer Expectations and Measures

- QCDS Metrics
- Supply chain integration
- Standards & specifications
- Measurement
- Control the process

**“There are no easy answers** to health-care costs, but education is essential. People need to know how the system works. They need to understand what things cost so they can make intelligent choices. Making intelligent choices won’t necessarily bring down health care costs, but it will take away the blame factor. The way things work now, we’re looking for someone else to blame...Consumers need health-care cost information. Without it, we’ll never make intelligent choices nor truly appreciate what we have.” **David Elbert, Des Moines Register, December 2002**

# 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



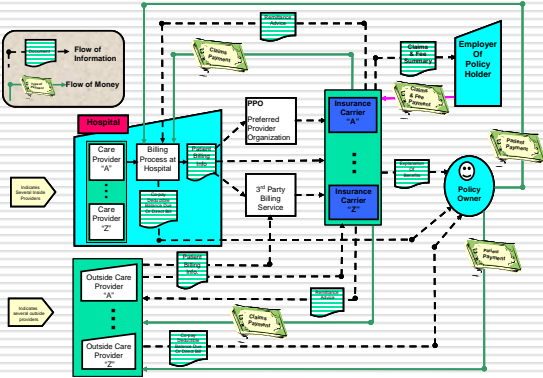
The demand analysis allow the treatment centers to reset stocking levels of treatment carts in line with the demand. Local activities (skate boarding contests) accounted for the increase number of knee, elbow and head trauma treated. Drs and nurses spent less time hunting for the right materials and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



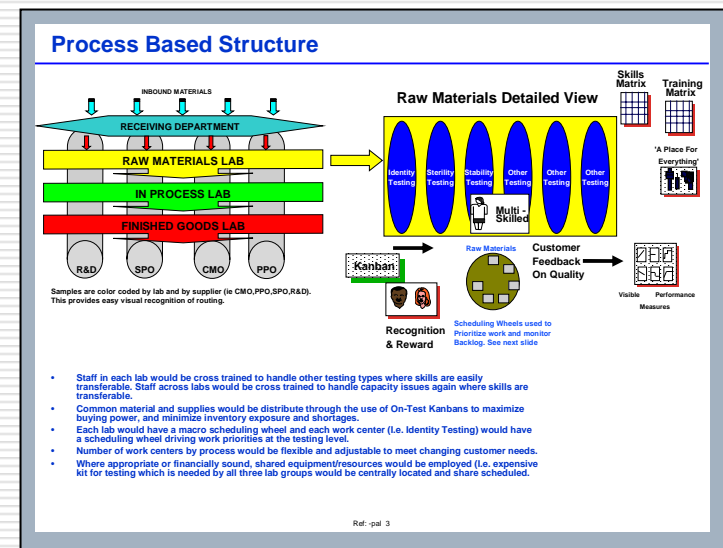
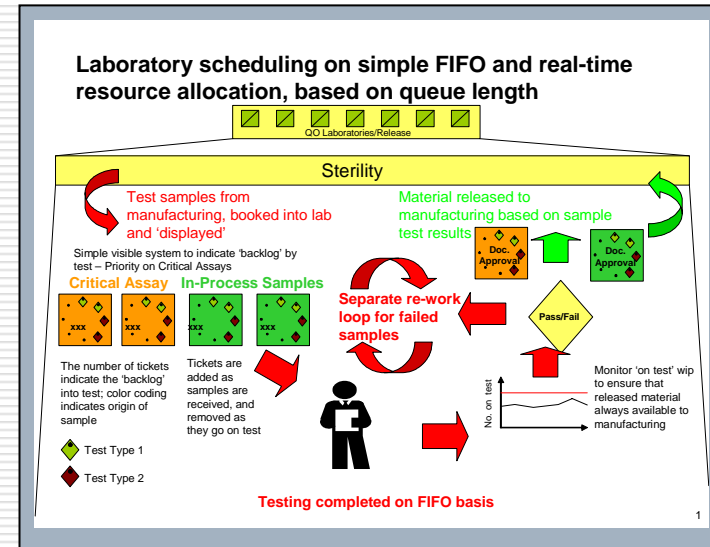
### Sterilization Process

### Key Benefits

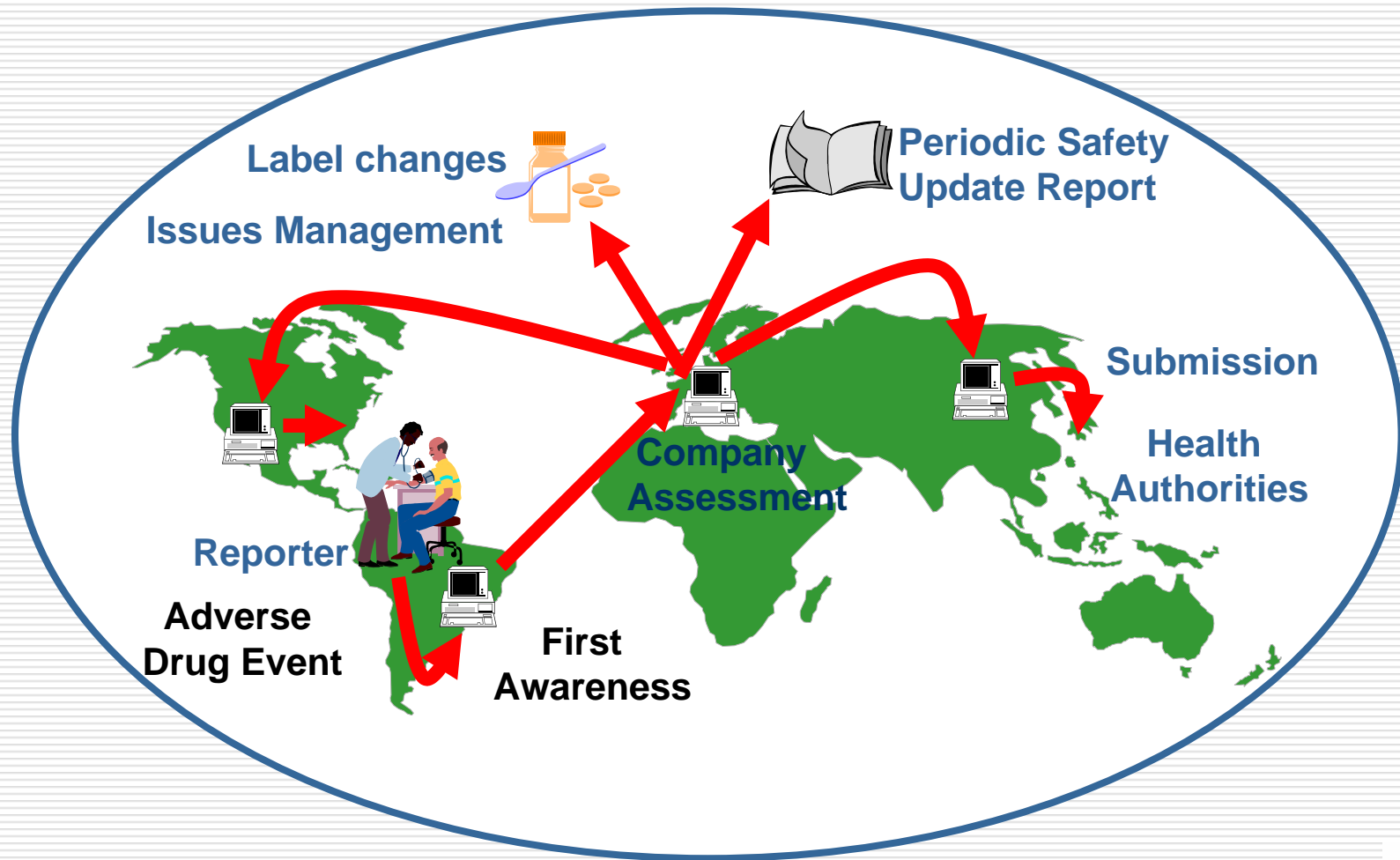
- 89% of process steps were NVA and removed reducing the process time by 65%.
- New process freed up the sterilizer thereby allowing for an additional 2-4 surgeries per day to be done.
- Current sterilizer was not capable of more than 3 cycles per day. However, a new unit would allow for up to 10 cycles/day.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

# 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



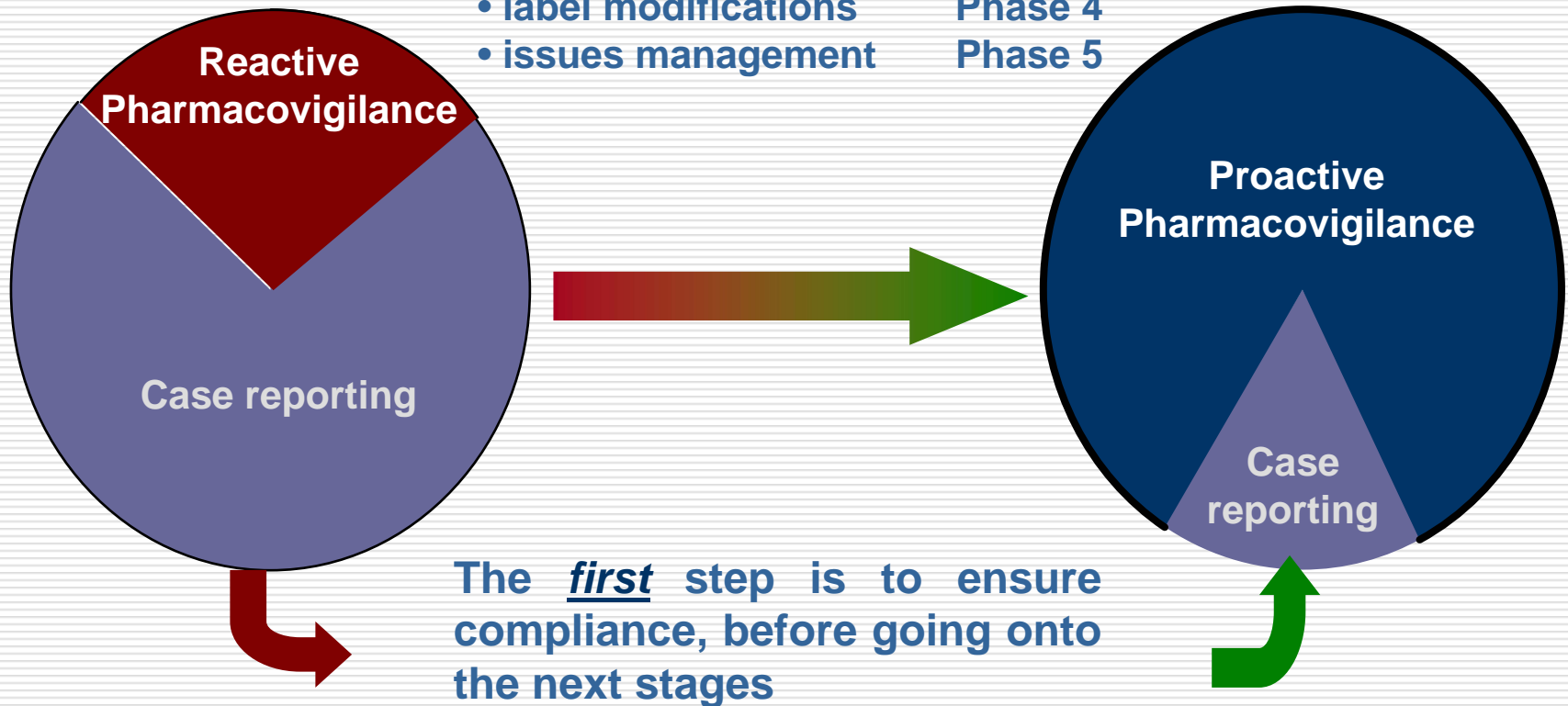
# Global Drug Safety Perspective



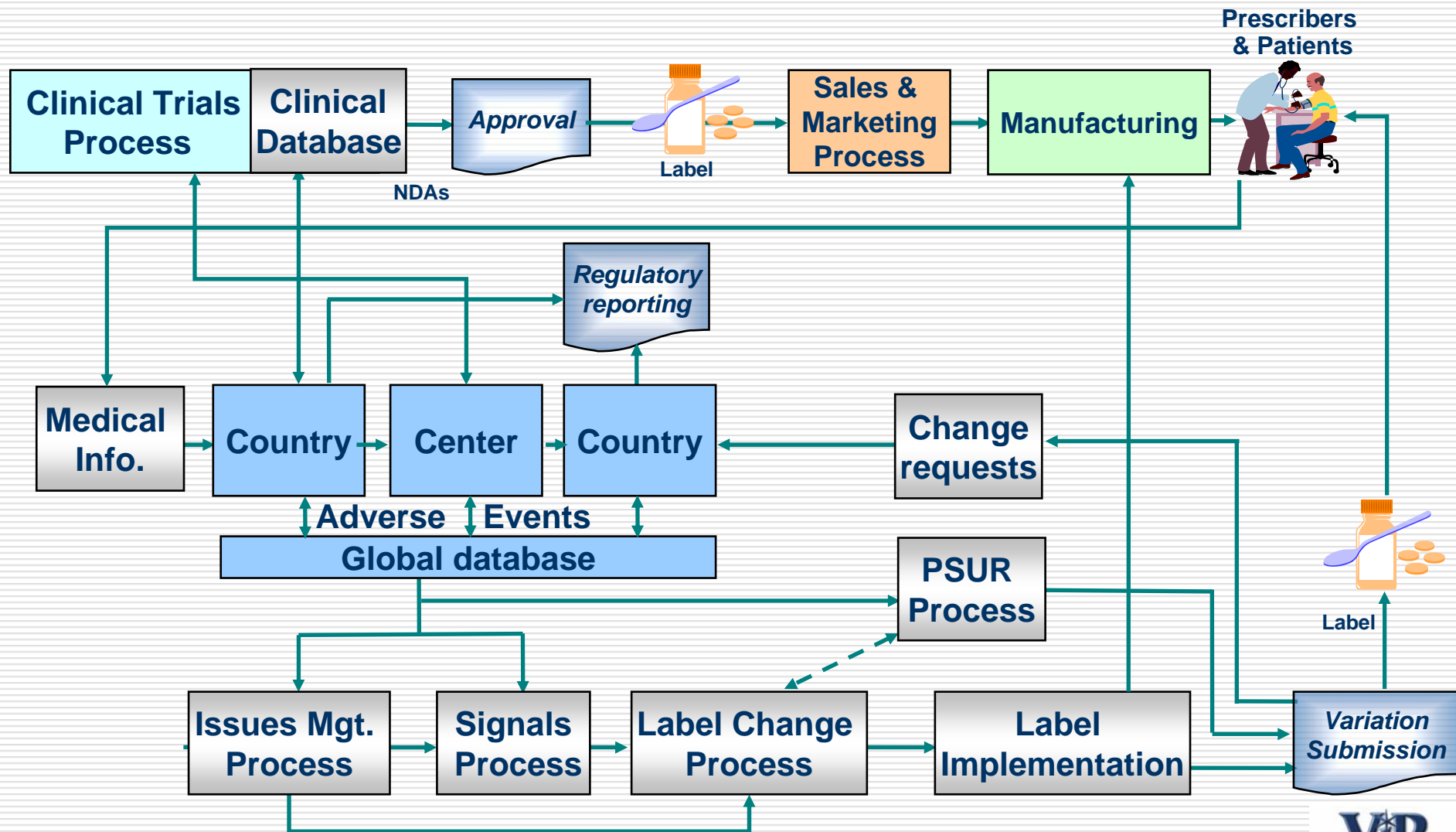
# The Objective

## 5 Stages to Lean Pharmacovigilance

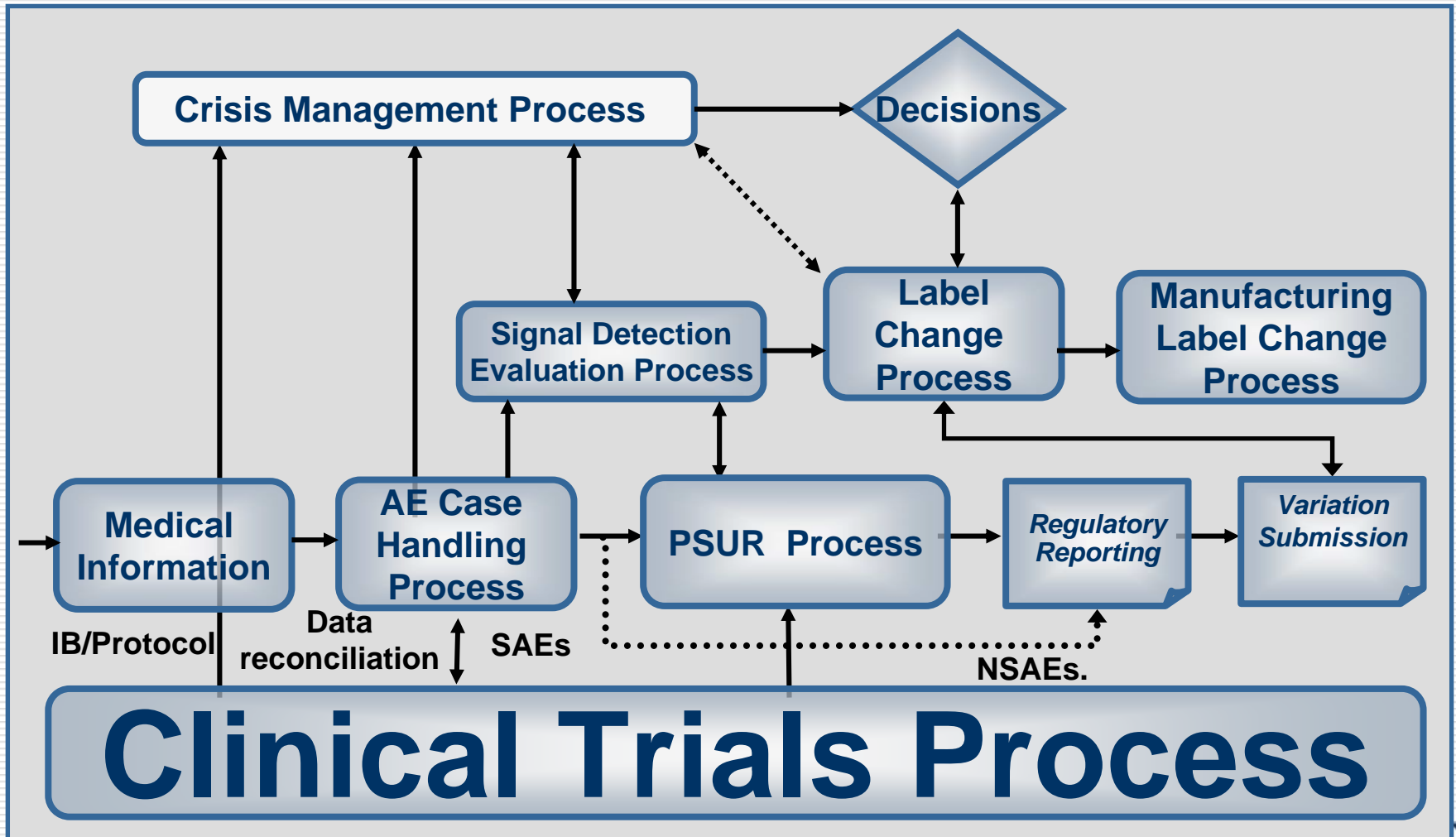
- case reporting Phase 1
- signal detection Phase 2
- periodic reports Phase 3
- label modifications Phase 4
- issues management Phase 5



# VIP has Pharmacovigilance Expertise



# Our Methodology addresses all Safety issues across the entire business



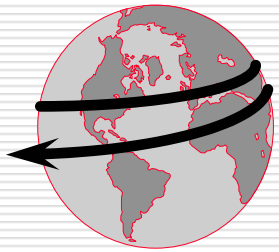
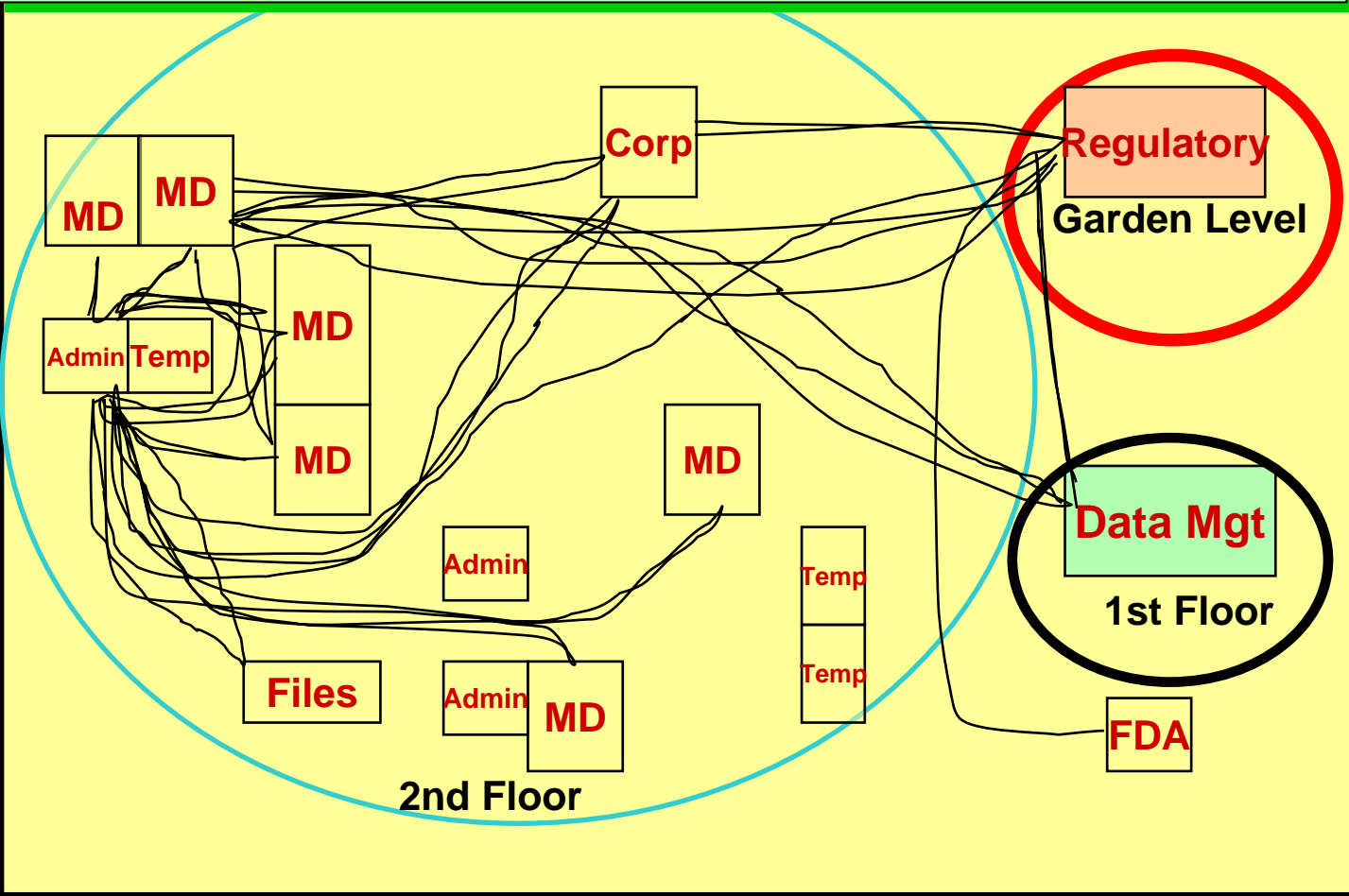
# Example Pharmacovigilance... AS-IS Map



	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

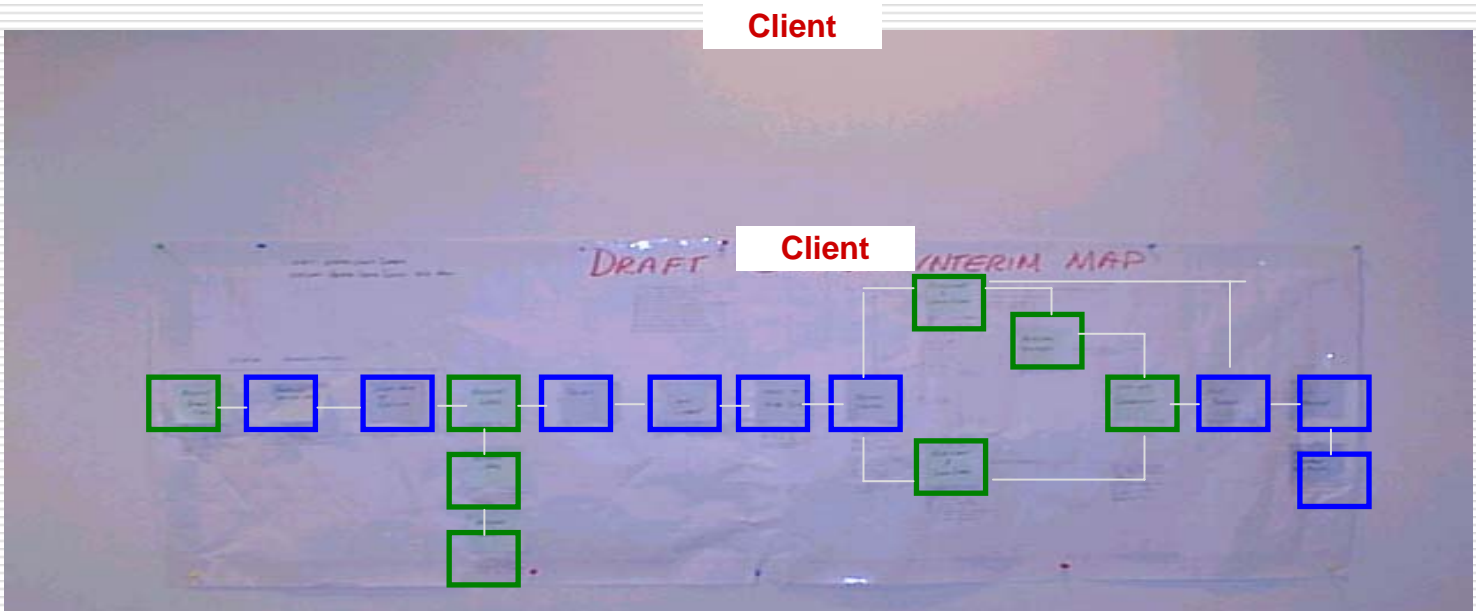
The current layout leads to a case travelling about 1/2 mile from case receipt to submission



- 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

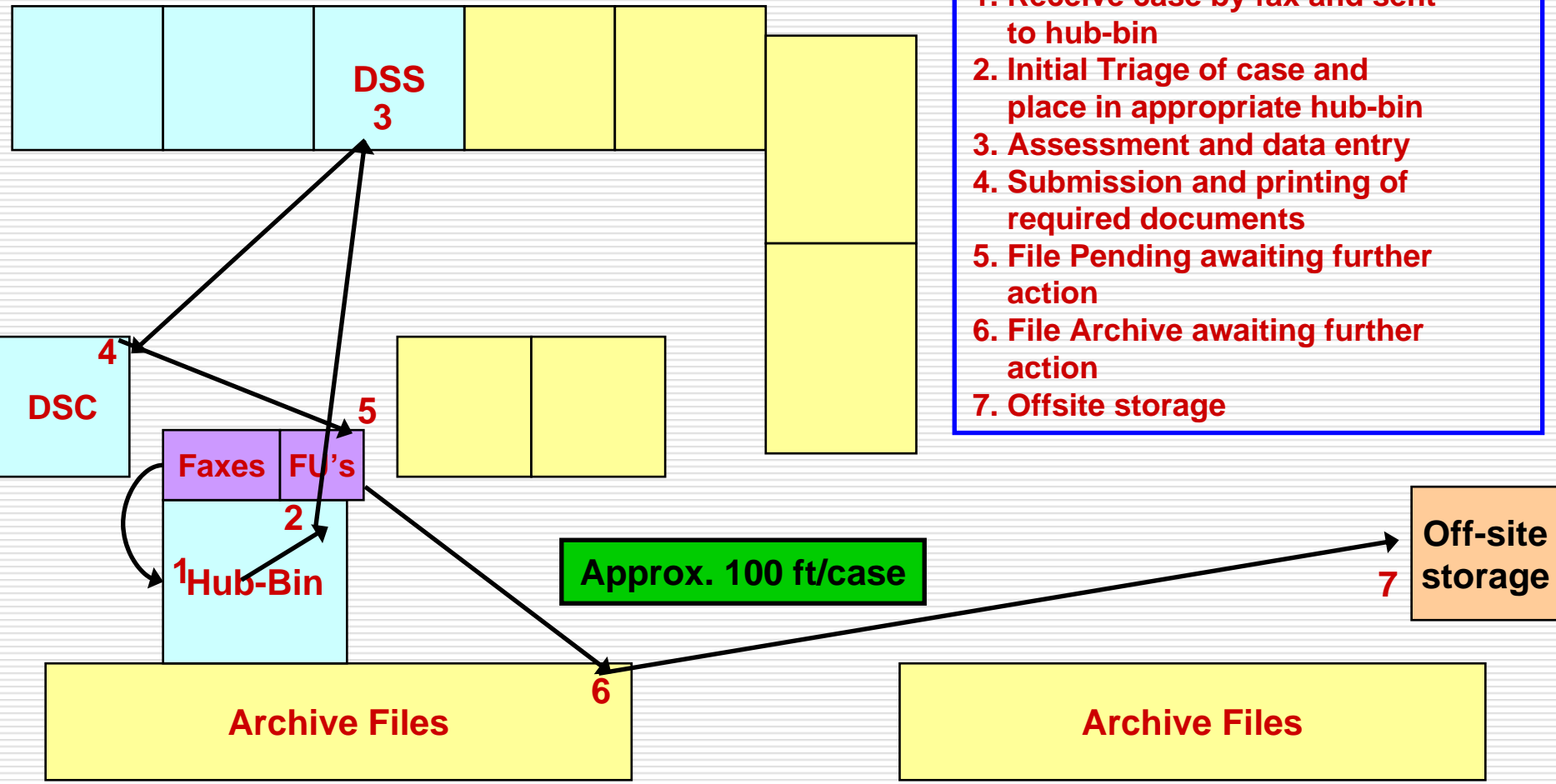


	Process Steps	QC Steps	Reg Steps	S&DS Steps	Total Steps	Error Loops, F/U's & Cosuspect	Total Steps	NVA	VA	SNVA
All	17	0	0	0	17	0	17	0	8	9

# 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

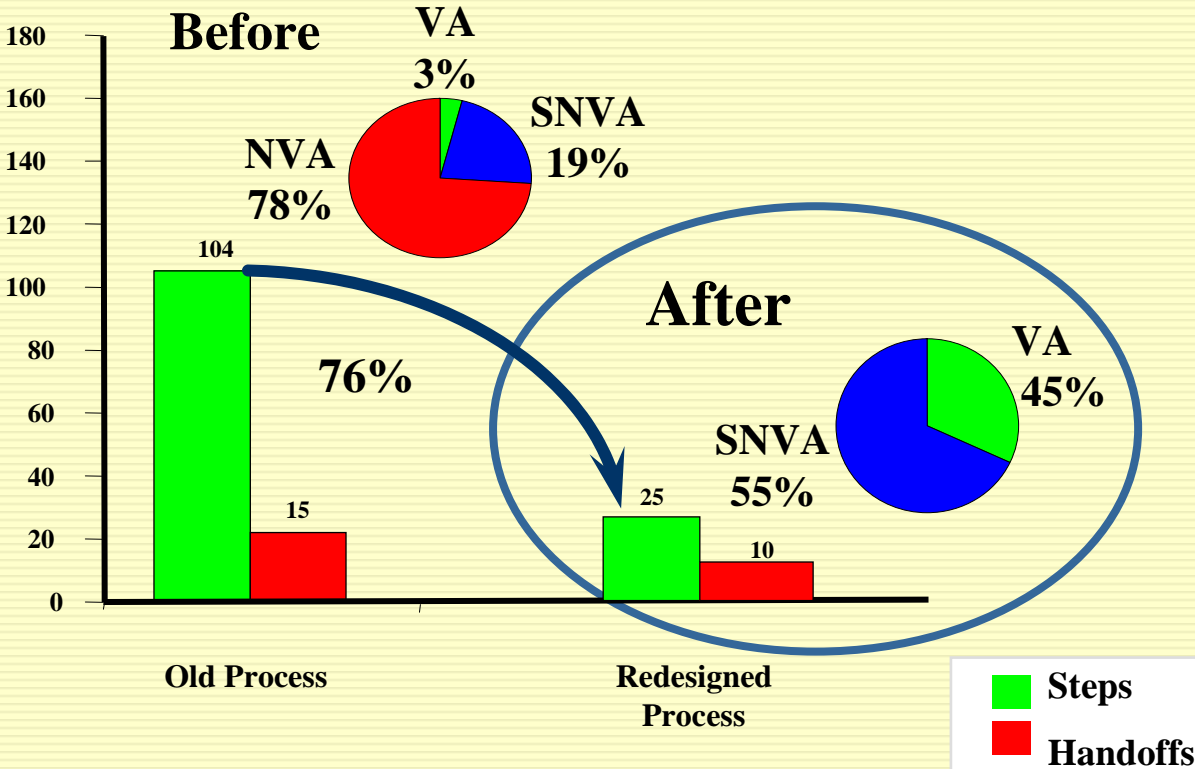


# Lean Office in Action

\$4.8 B Pharmaceutical/Biotech/Chemical Operation

Source:  
Client Process Maps  
includes rework loops

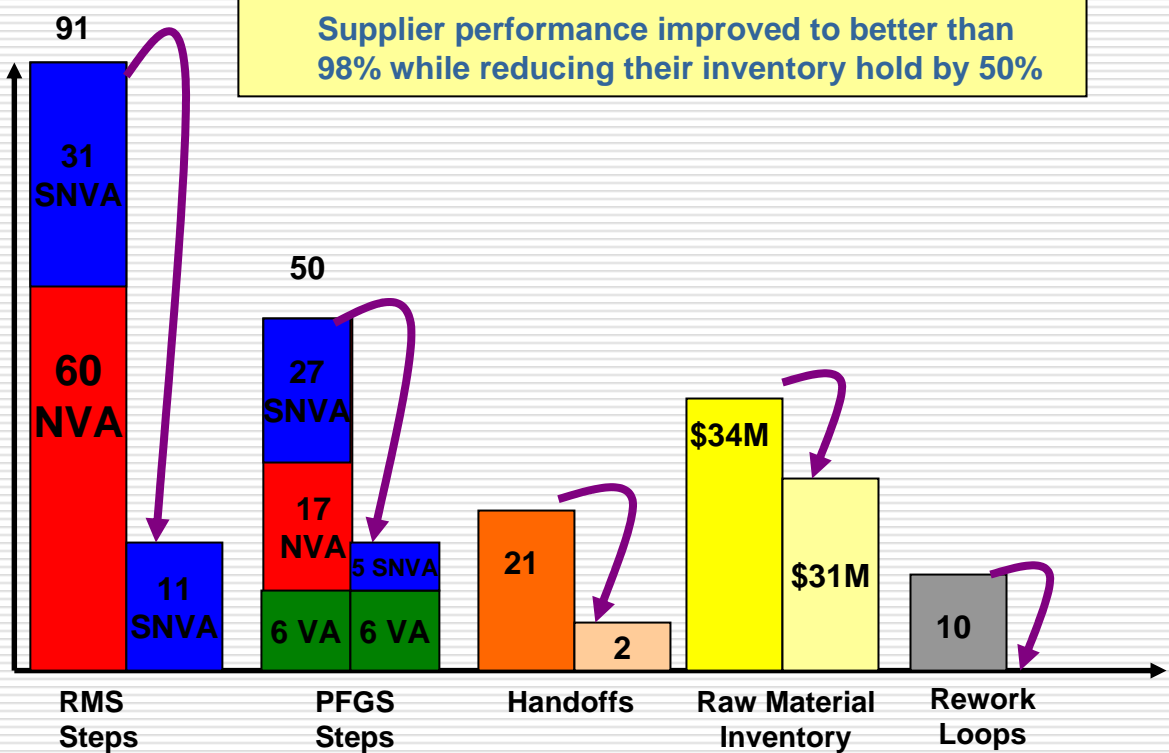
## Number of process steps and hand-offs



- 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

# Lean Procurement Utilizing LeanSigma

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

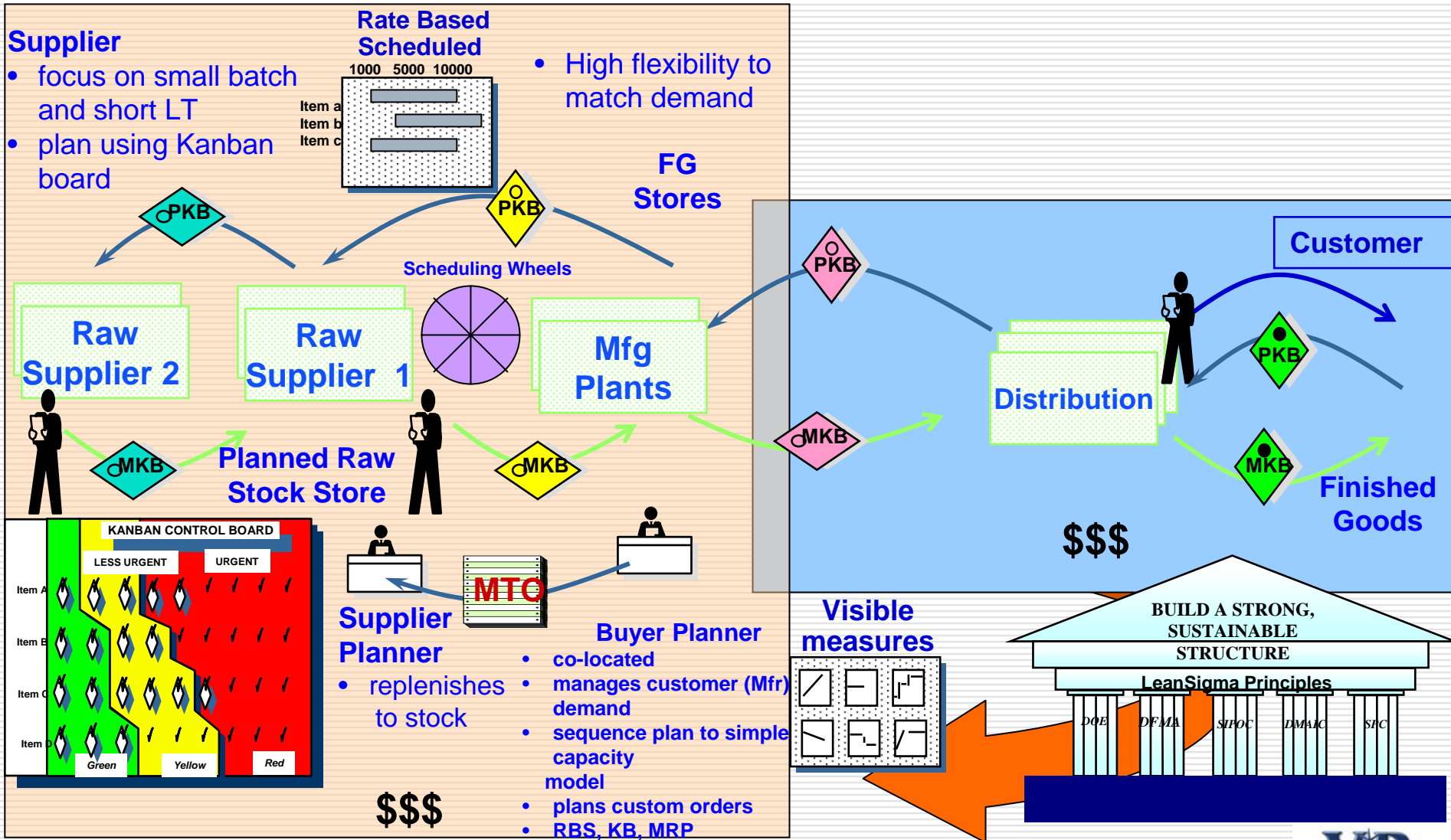


**Defect:**  
Process and tolerance variability  
**DMAIC Project:**  
Lean out the Supply Network, reduce Supplier parts variability and install a pull replenishment model



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

# Lean Procurement Model for Success



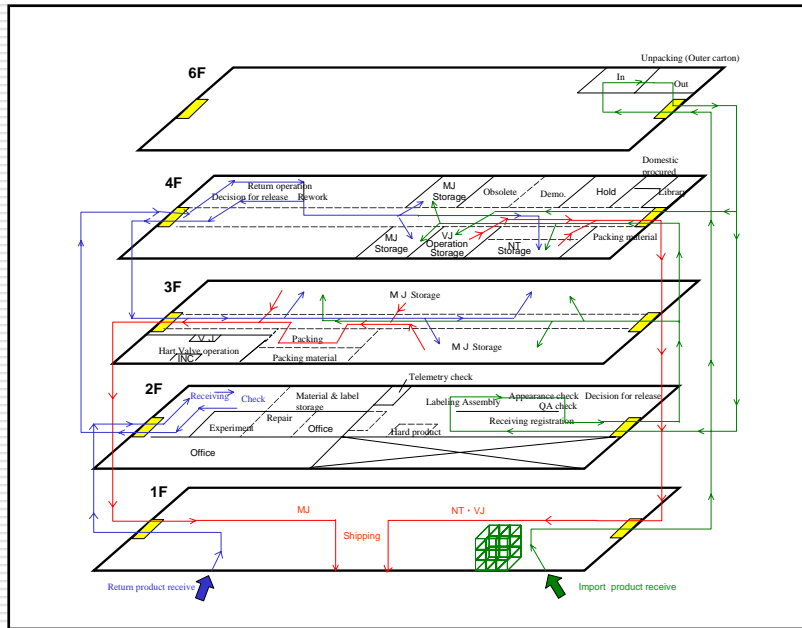
# LeanSigma... Supply Chain Example

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

**Defect:** Process and compliance variability

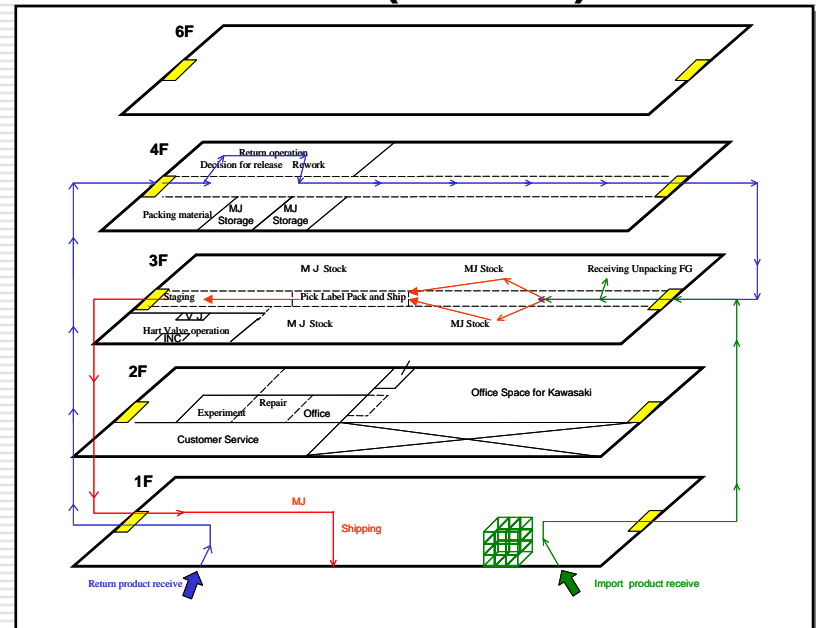
**DMAIC Project:** Lean out the Distribution Center

### Before



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

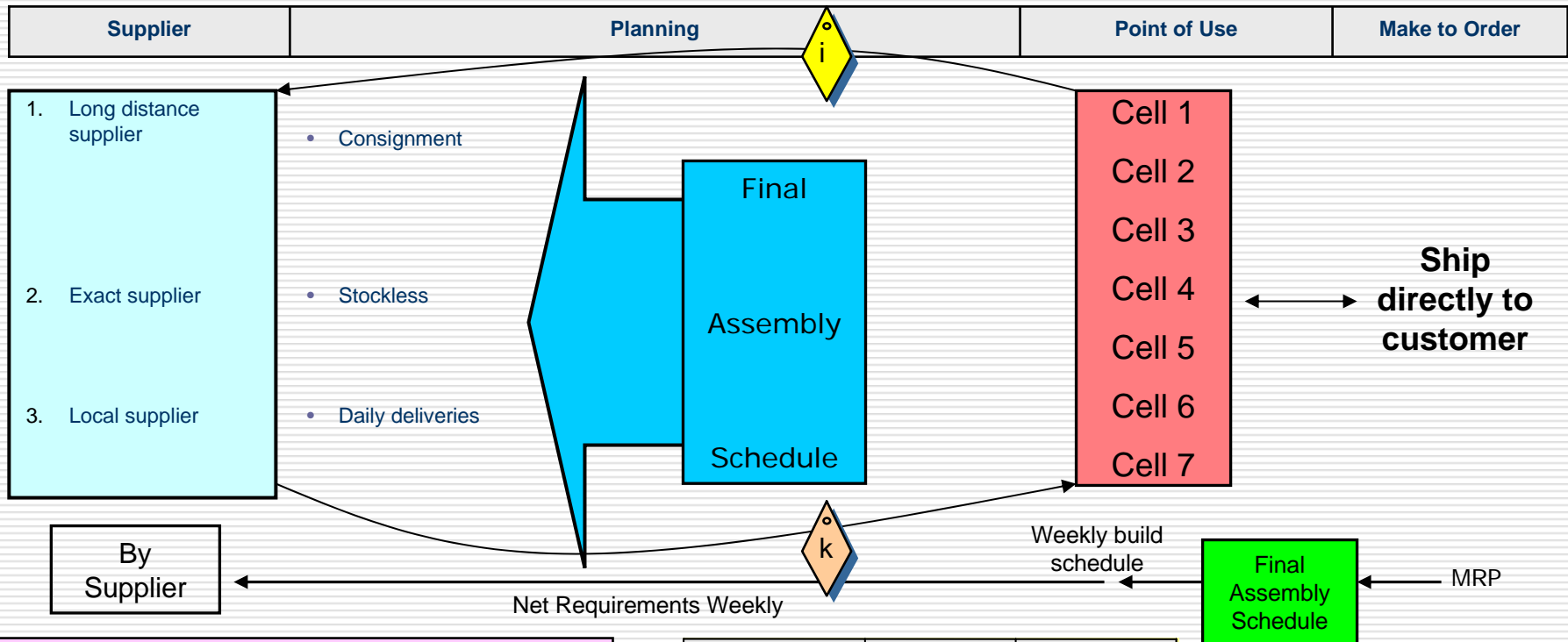
### After (4Q '04)



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

# LeanSigma Supply Chain in Action

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

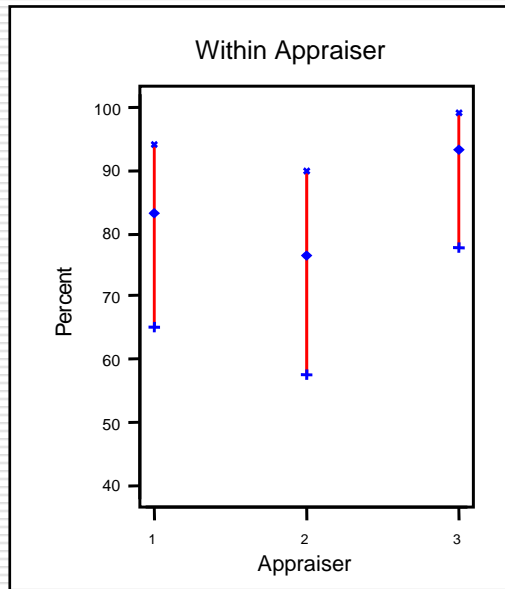
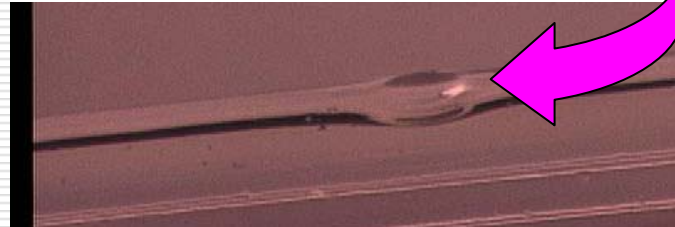


**Defect:**  
 Process and tolerance variability  
**DMAIC Project:**  
 Lean out the Supply and Distribution Network, utilized component model and reduce supplier parts variability

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 VIPGroup

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