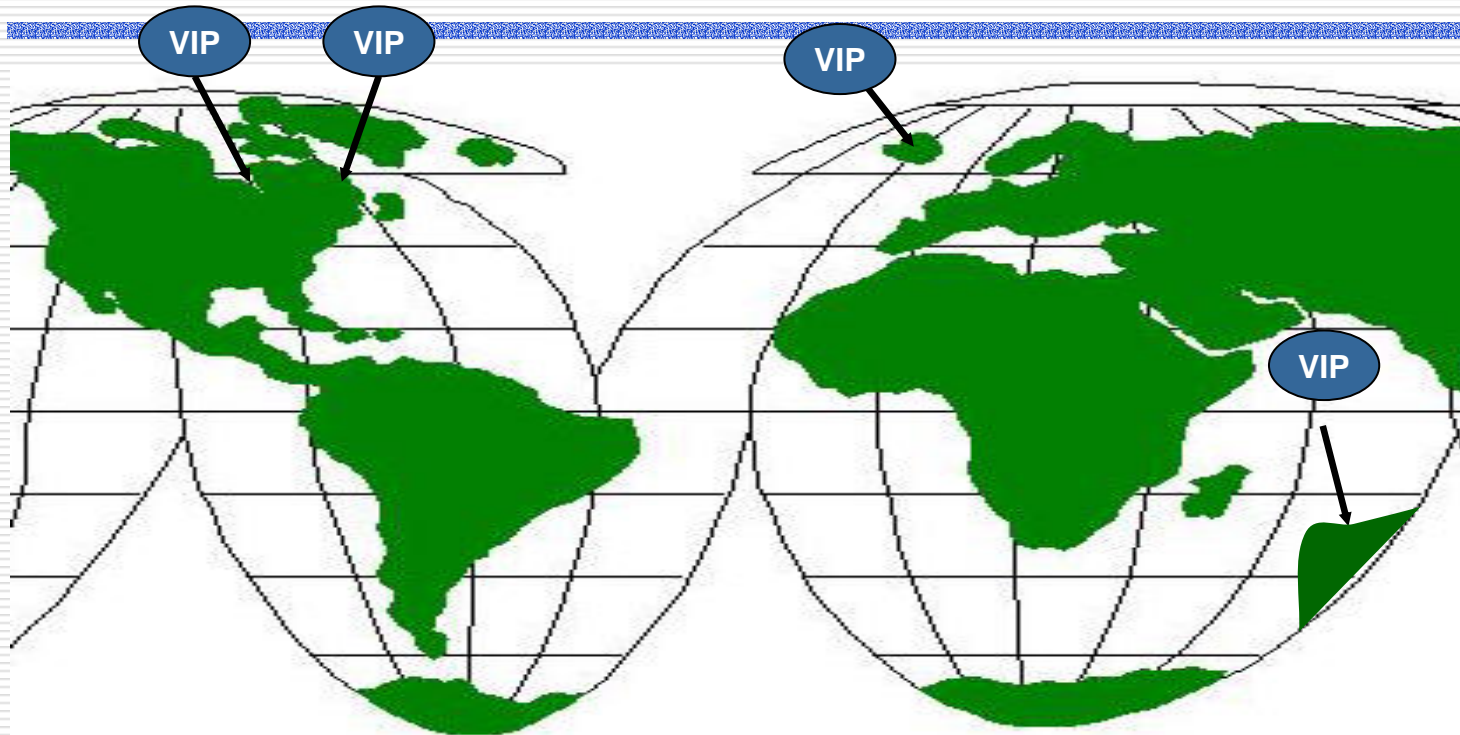


# Value Innovation Partners

*partnership in value creation*



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Caulfield Victoria 3161  
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# Who We Are

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Value Innovation Partners was founded by a group of business practitioners with offices in Boston and Chicago.

## 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, and Due Diligence pre- Mergers and Acquisitions

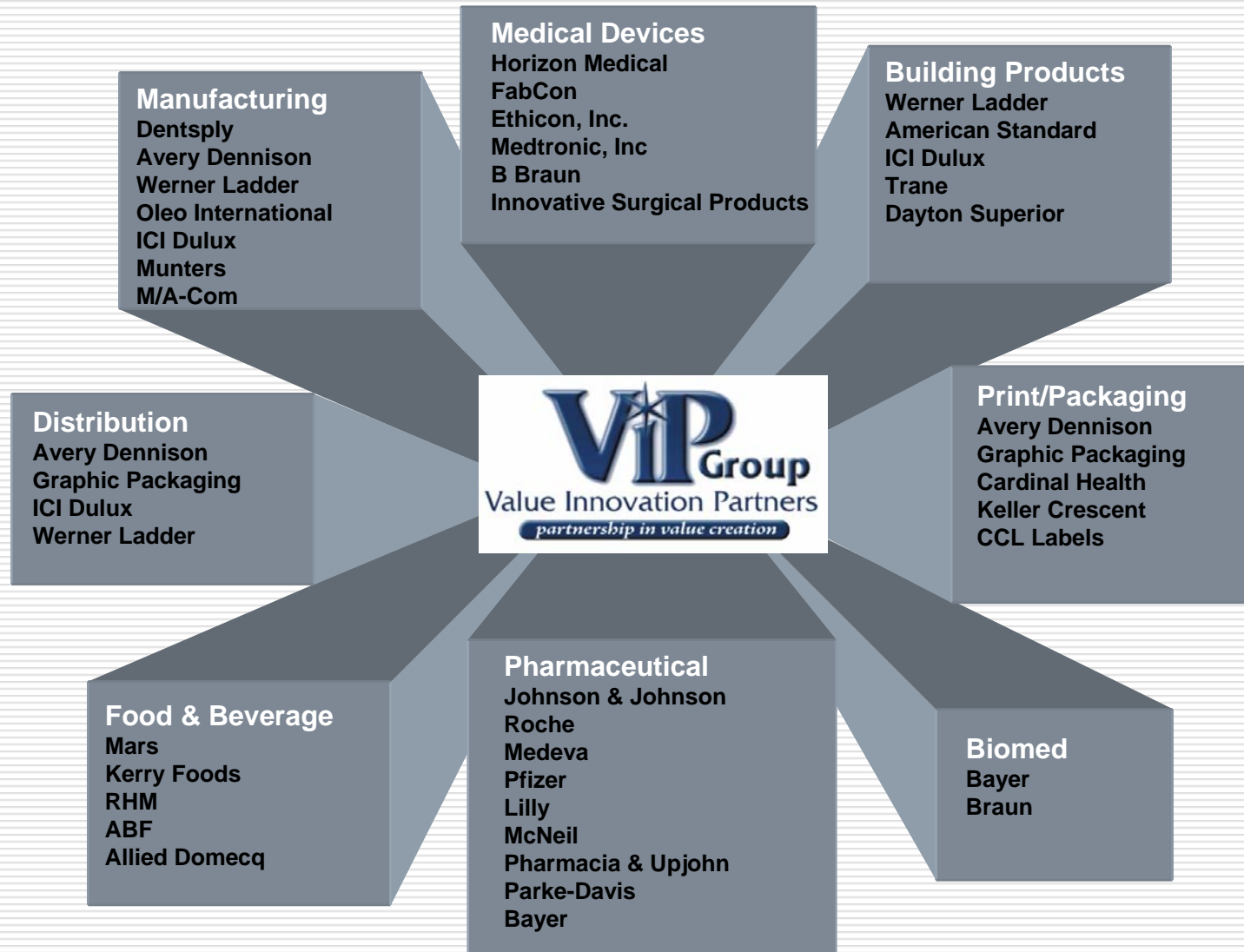
## Involvement

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

## Results

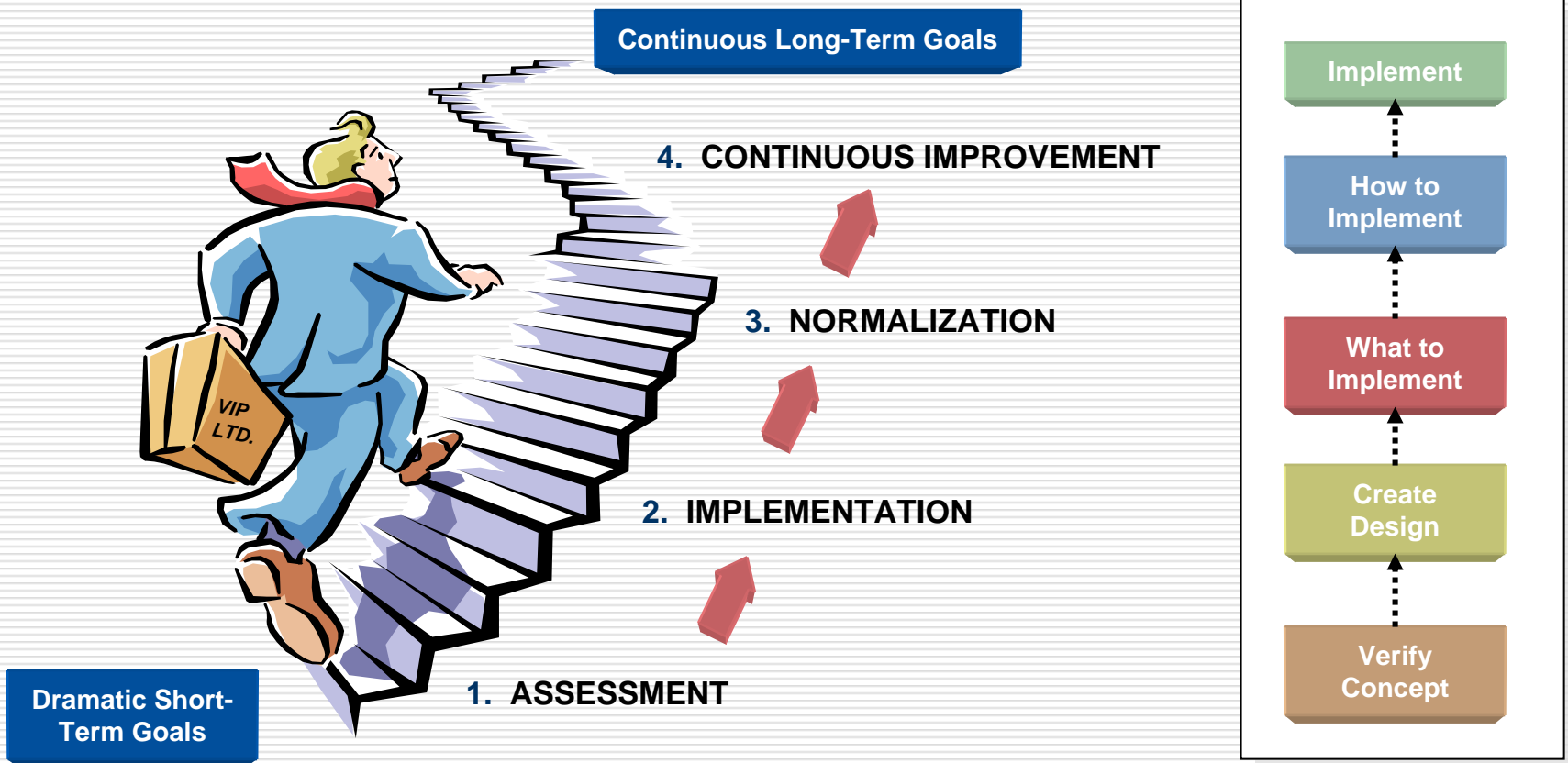
- Quantifiable and sustainable benefits
- Transfer critical skills
- Improve customer satisfaction, working capital, revenue and processes

# Partial Client List



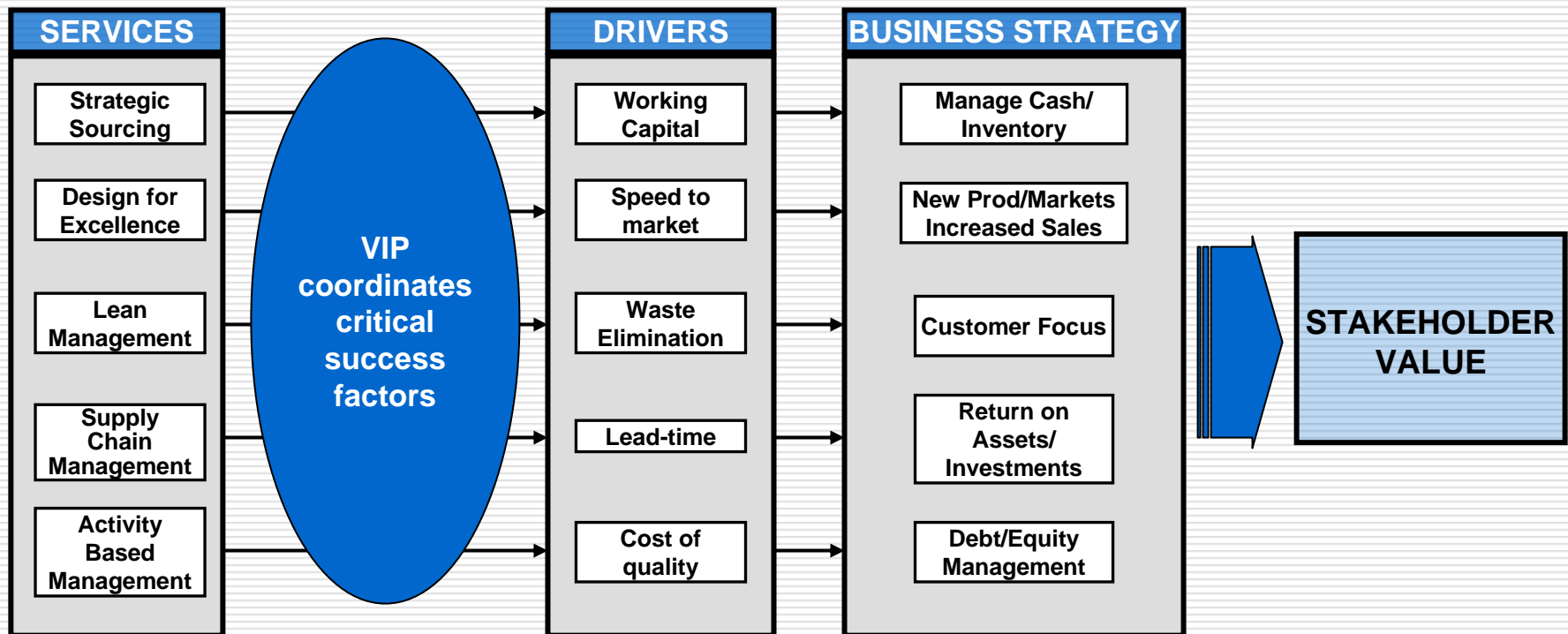
# VIP's Proven Methodology

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

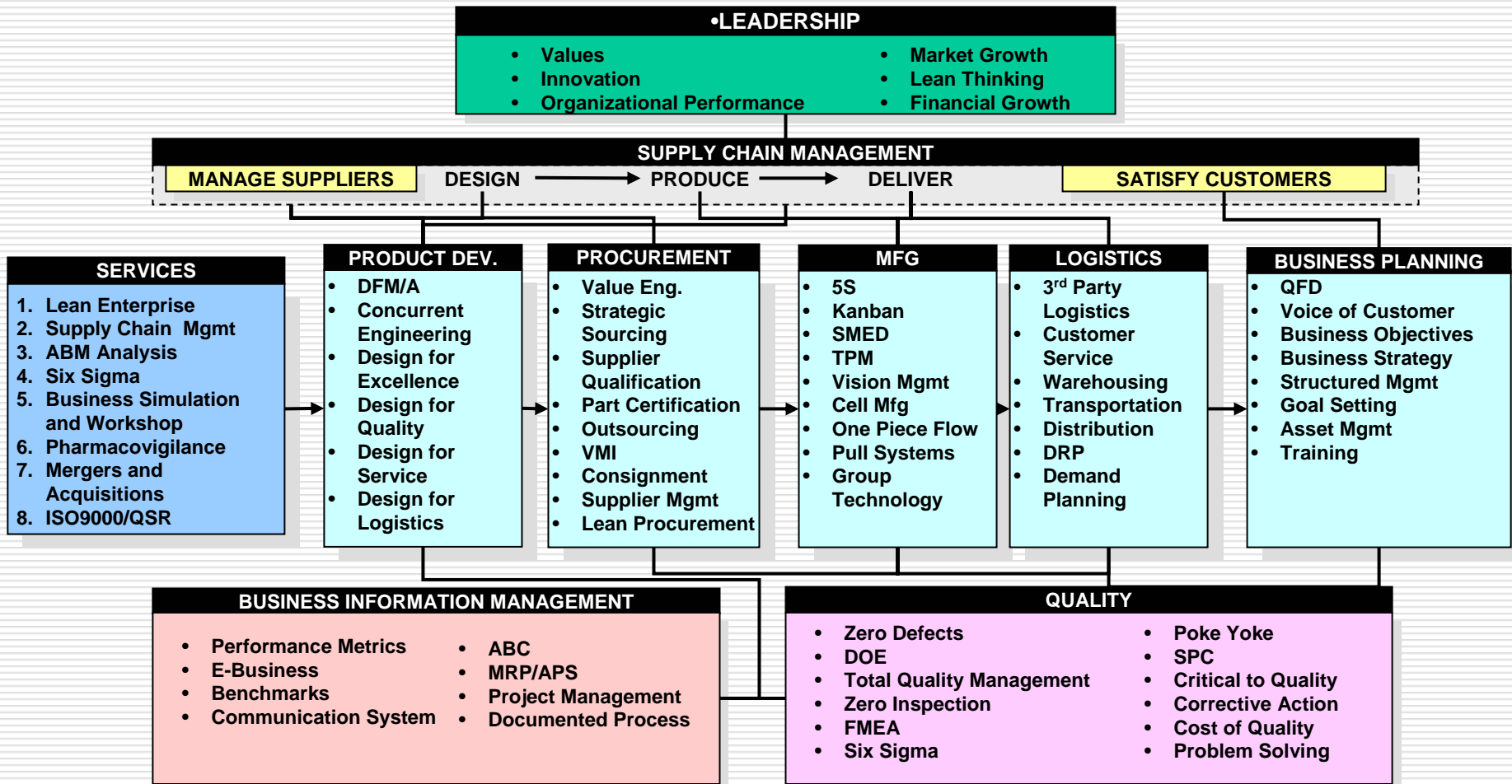


# Our Approach:

## *Linking VIP Services with Stakeholder Value*



# VIP Tools and Techniques



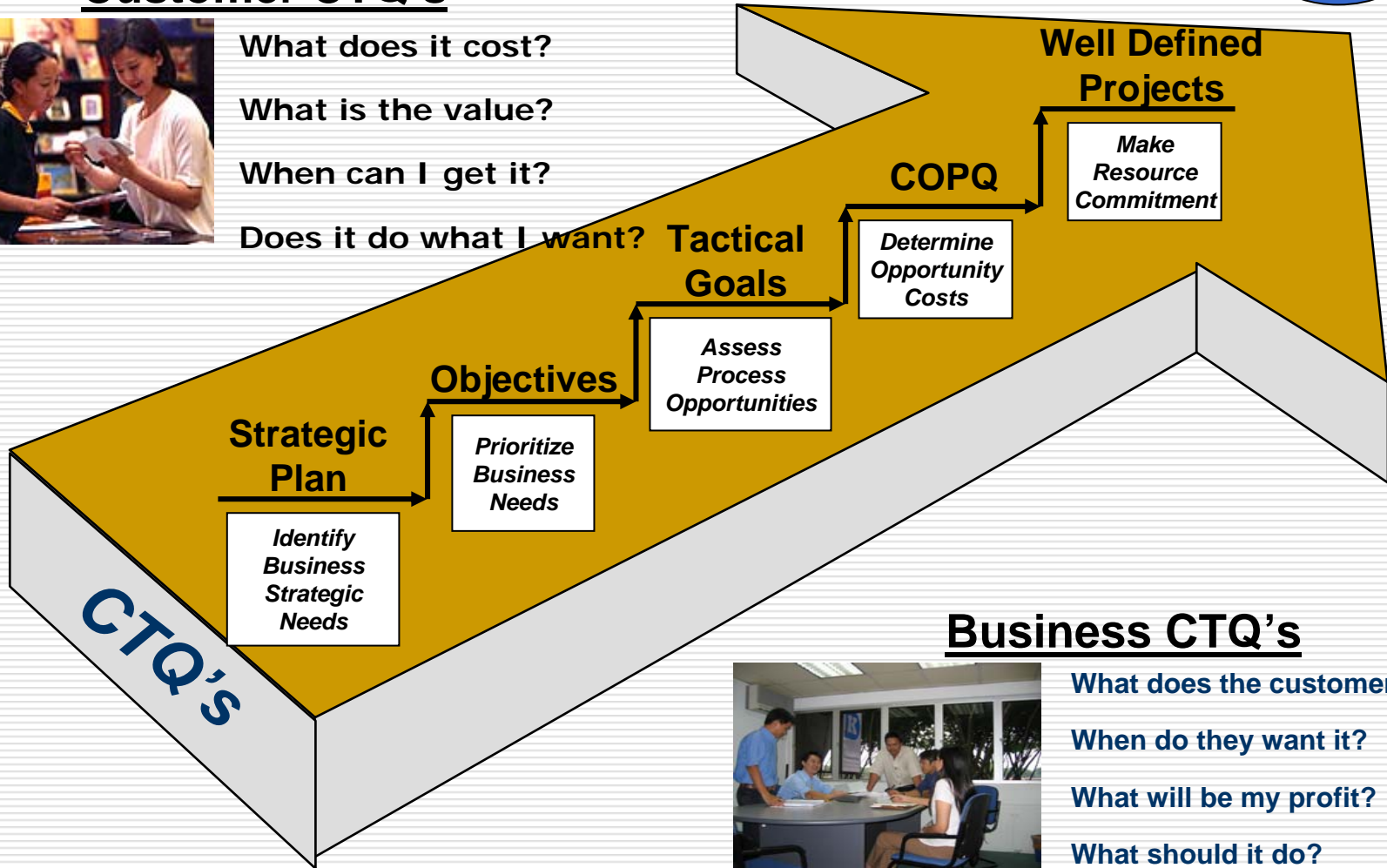
# Align Service and Value Across the Enterprise

Shareholder value  
Profits  
VOC

## Customer CTQ's



- What does it cost?
- What is the value?
- When can I get it?
- Does it do what I want?

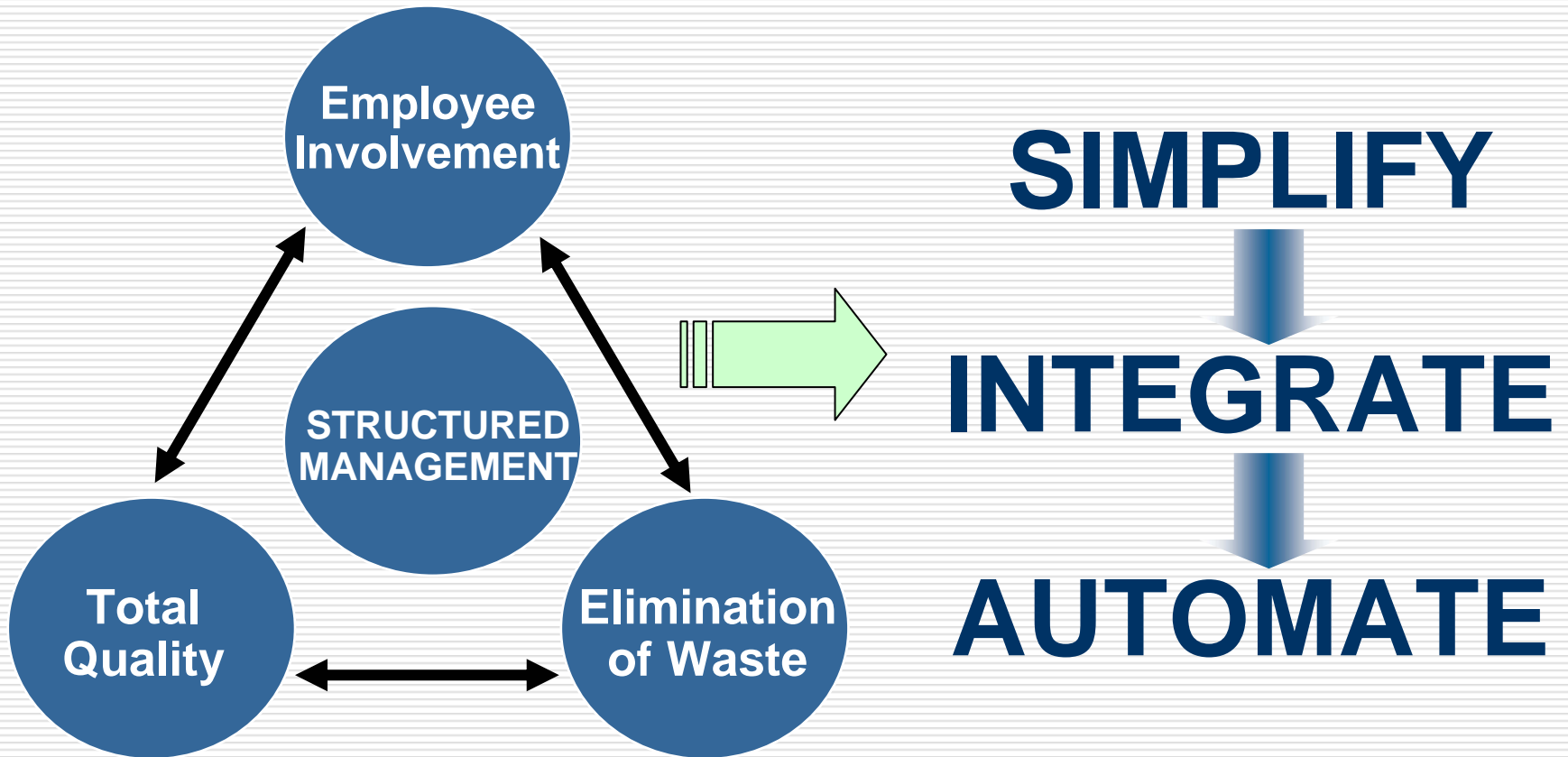


## Business CTQ's

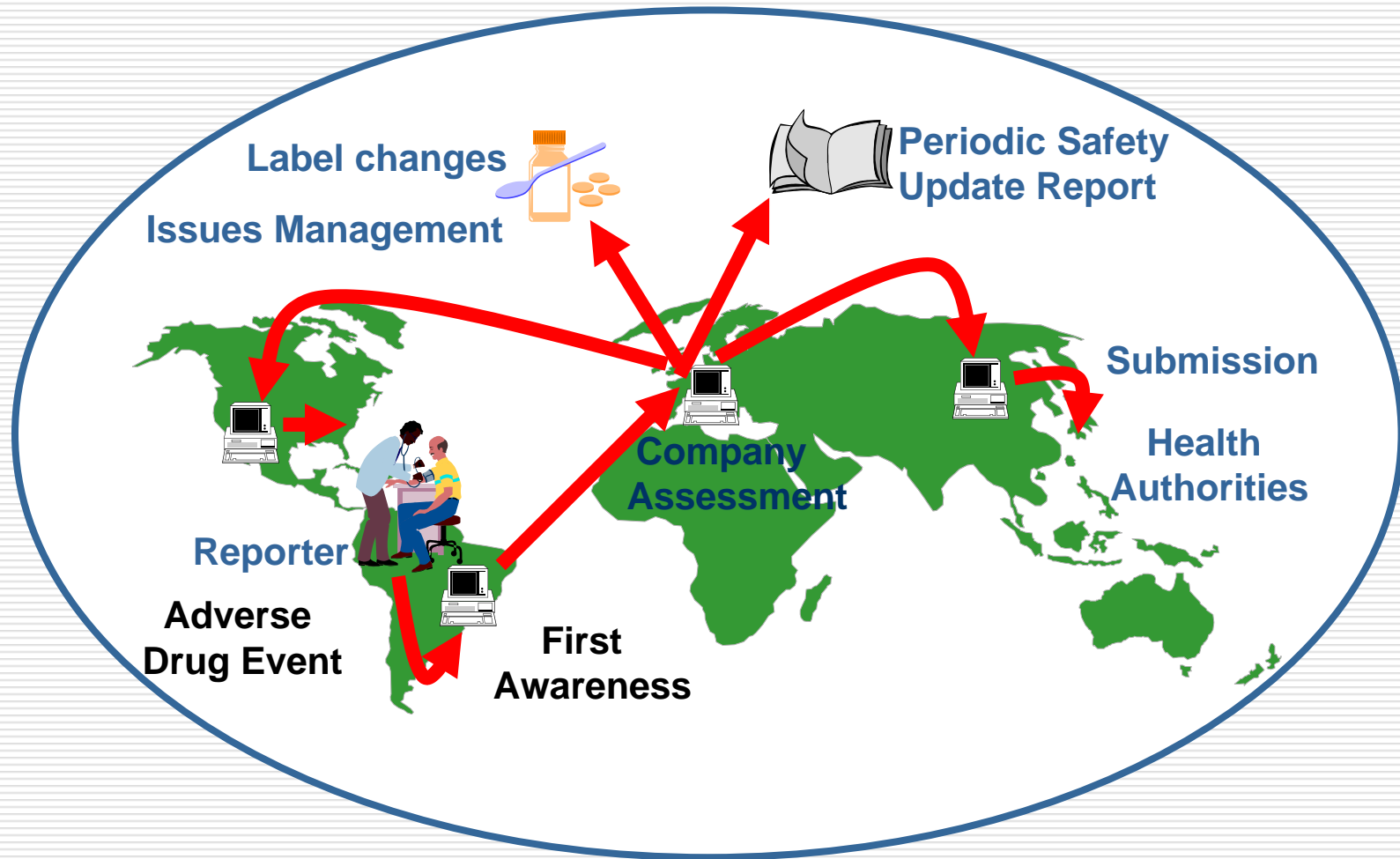


- What does the customer want?
- When do they want it?
- What will be my profit?
- What should it do?

# Application of Lean Constructs



# Global Drug Safety Perspective



# Lean Principles for the Adverse Events Case Handling Process

## PROCESS

- Efficient and streamlined
- Simple and visible
- Harmonized across departments & functions
- Right first time approach
- Agreed business rules to support controls

## STANDARDS

- Consistent
- Simple and readable
- Understood by all

## PERFORMANCE MEASUREMENT

- Focused (thoroughness, integrity, time)
- Simple and visible
- Aligned targets, reward and recognition

## ORGANIZATIONAL STRUCTURE

- Process aligned
- Aligned priorities, roles and responsibilities
- Communication, co-operation, co-ordination and empowerment

## PHARMAOVIGILANCE

- Proactive
- Communication internally and externally
- Best methods used
- Involvement of local subsidiary as required
- Signals detected/evaluated

## SYSTEMS

- One global database
- Transparent 'end to end' tracking
- Reduction of duplication of entry
- Supports local needs as well

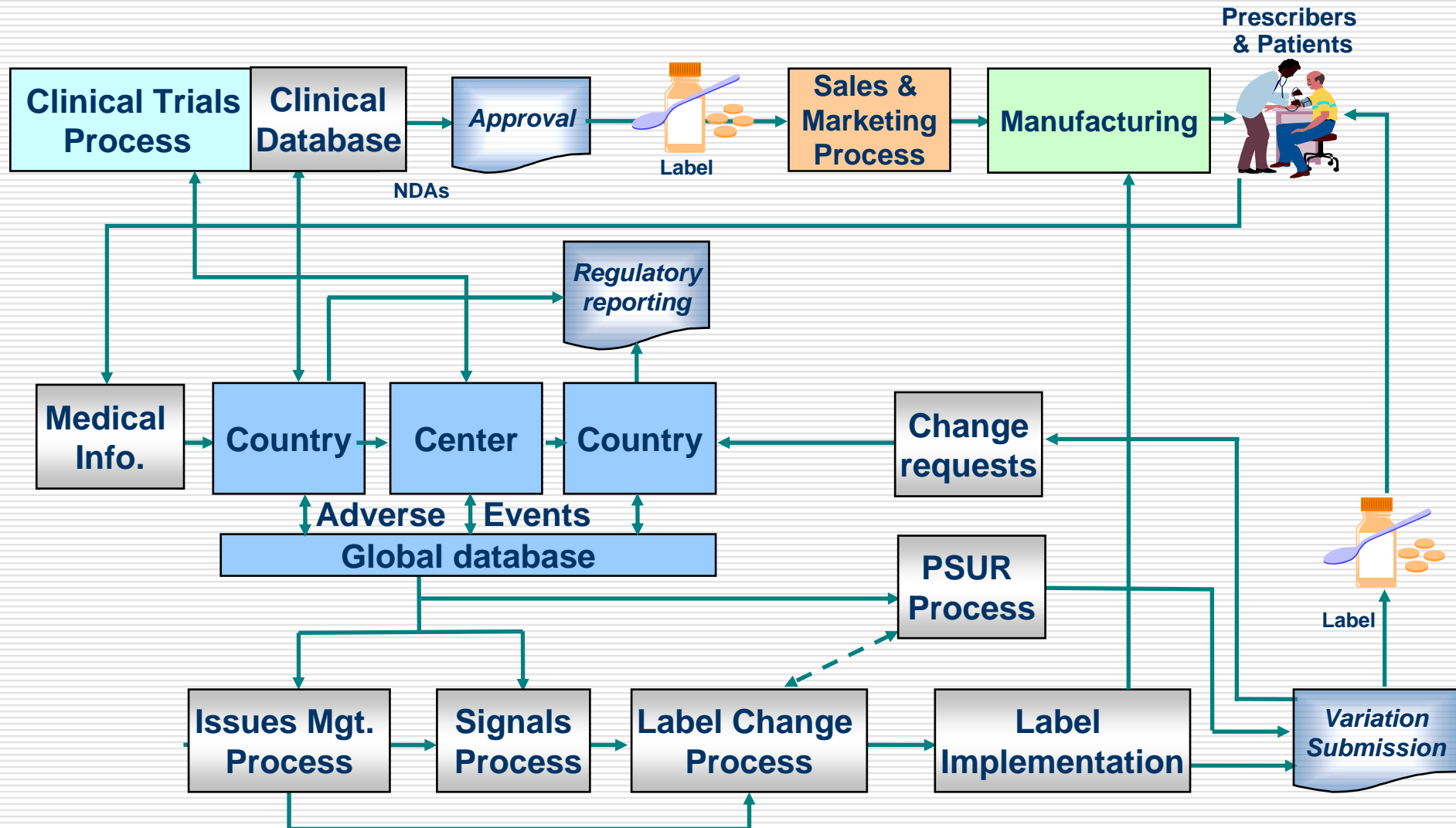
## PEOPLE

- Correct number and skill level

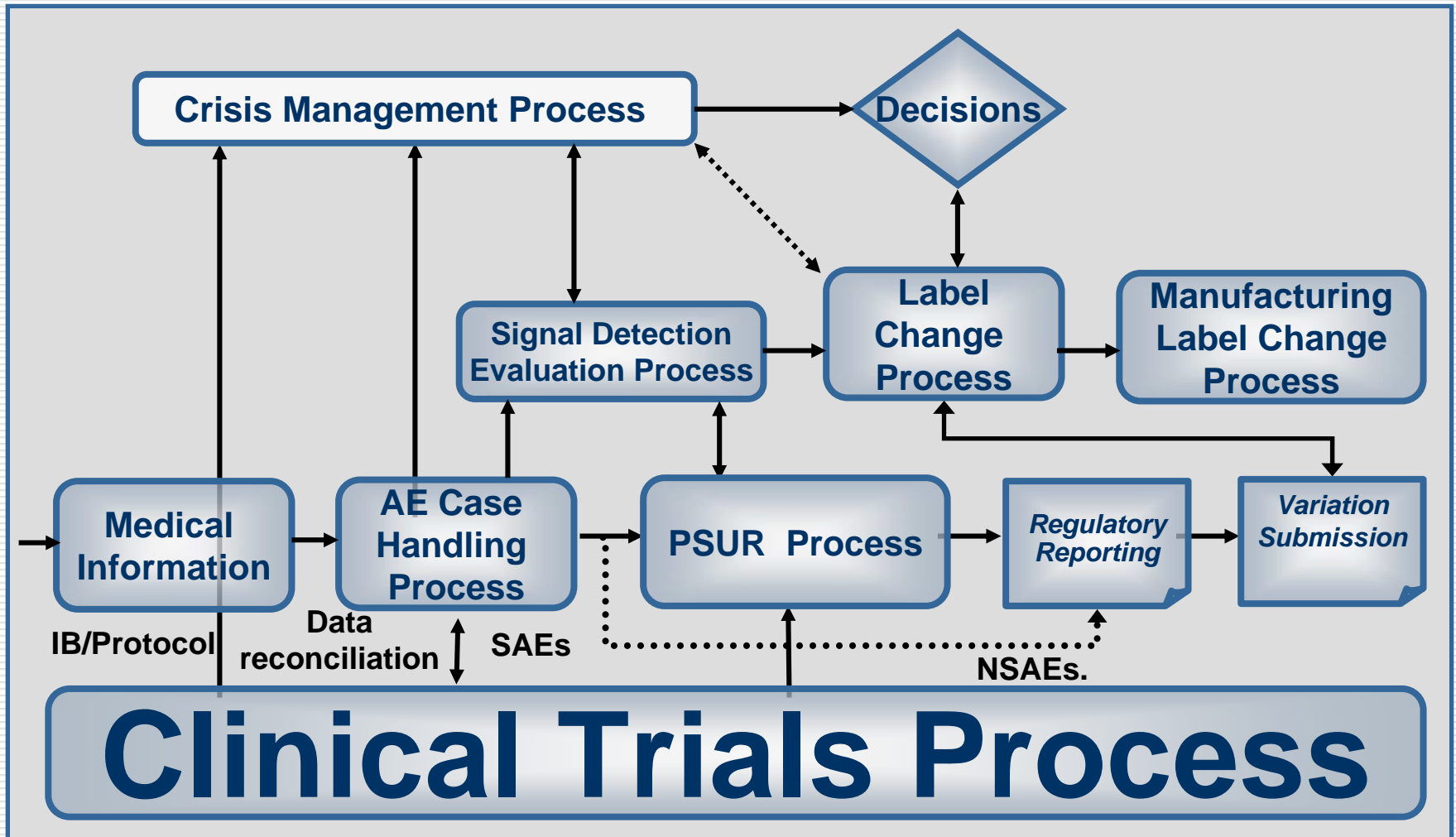
## EXTERNAL

- Compliance
- Quality assessments
- Gain Regulators confidence

# VIP has Pharmacovigilance Expertise

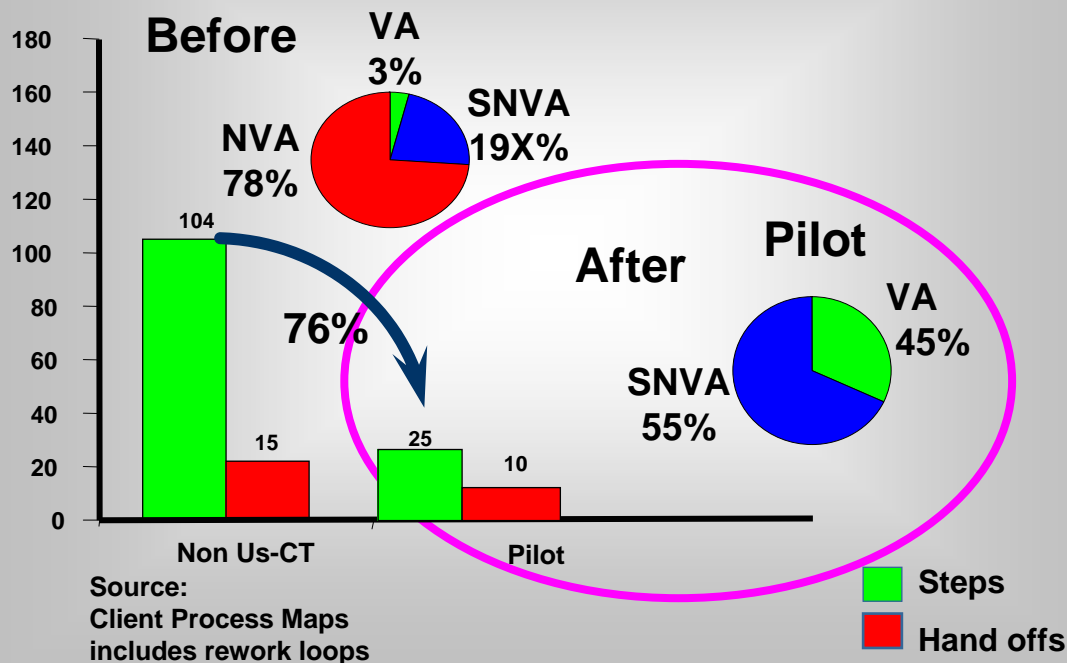


# Our Methodology addresses all Safety issues



# A Case Study: Simplifying the case handling process resulted in improved lead-times/ compliance, fewer steps and less hand off's

Number of process steps and hand-offs

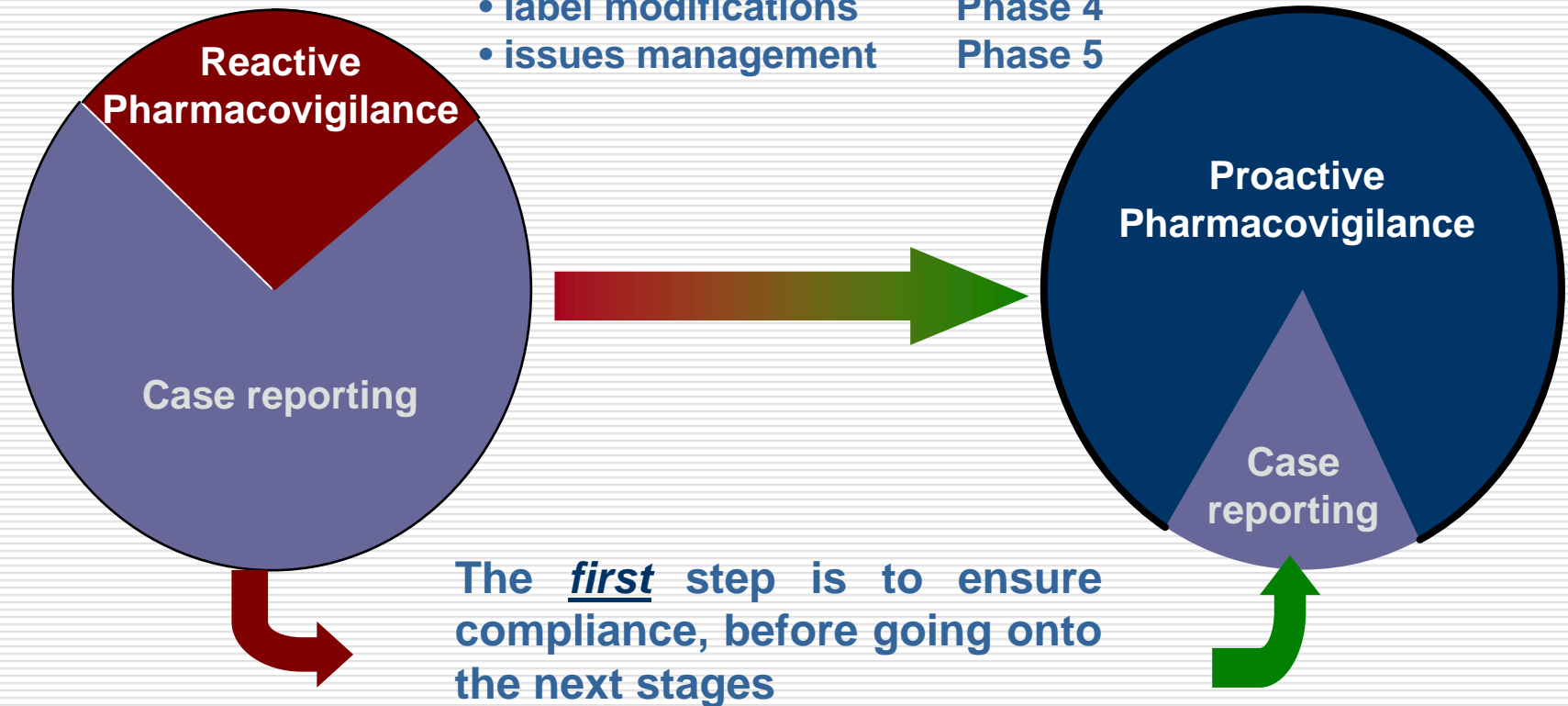


- Case travel distance was reduced by 96% from 1/2 mile to 100 ft.
- All NVA steps were removed
- Compliance improved from 30% globally to +97%
- AE 15 day reportable case processing time was reduced from 21 days to 11.

# The Objective

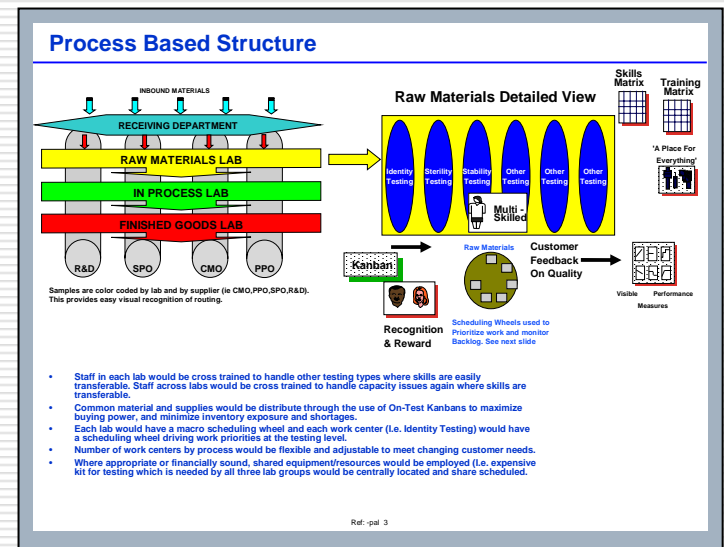
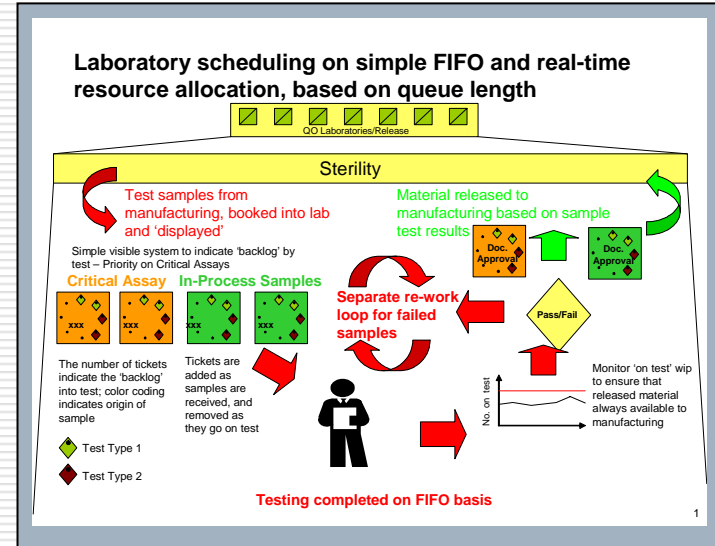
## 5 Stages to Lean Pharmacovigilance

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



# Other Areas of Expertise

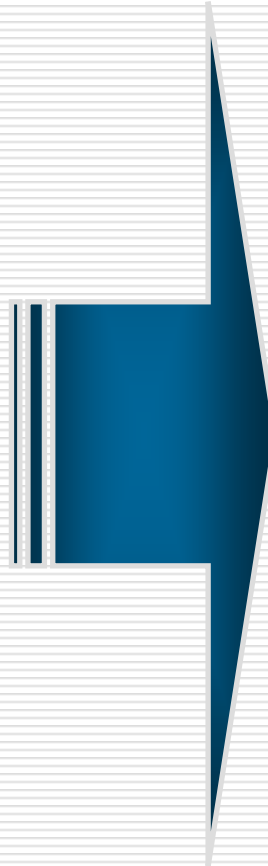
- **Laboratory redesign**
  - Layout and Process Flow
  - LIMS/GLP
  - Virtual
  - Scheduling
  - Testing requirements
- **Documentation design and redesign**
- **SOP/GMP/cGMP**
  - Reviews
  - Audits
  - Redesigns
- **Manufacturing Floor**
  - Lean concepts
    - 5S, SMED, TPM, etal
  - Batch record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



# 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*

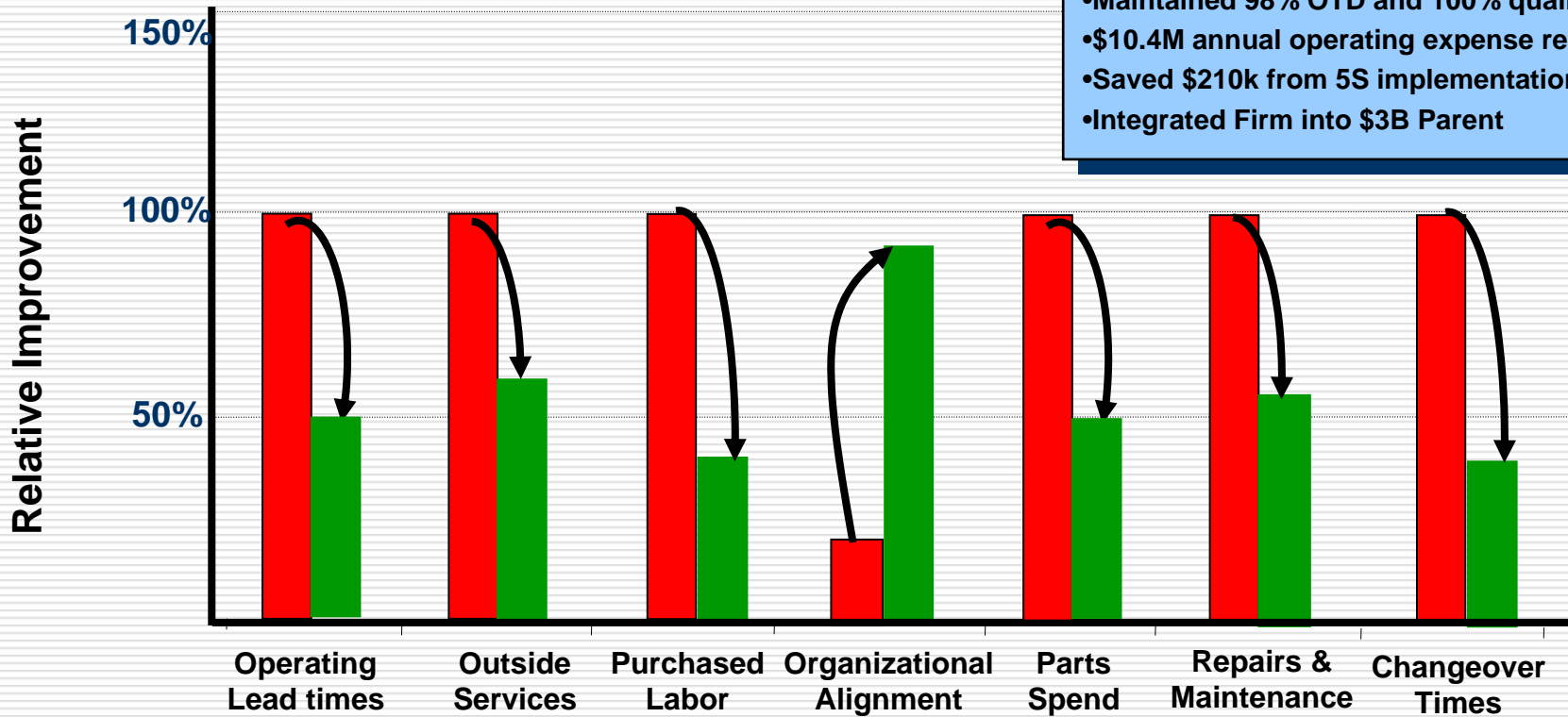
- Average 98% compliance, improve capacity by 105% and removed all NVA steps
- \$10.4M run rate reduction in operating expenses
- Inventory reduction of 50-80%
- Space reduction of 30-60%
- Adherence to schedule of 90-100%
- Improvement in OTD to 96% average
- Reduce time to changeover from hours/days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



# Why Use Value Innovation Partners

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