Schering-Plough
Global Quality Operations
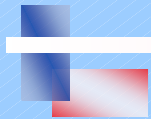
Systems

Sustaining Quality ∧ :

Why is Quality Good for Business?

Diane E. Bergeron
Vice President
Global Quality Operations
Schering-Plough

The Goal: "Good for Business"

◆Some Indicators of "Good Business"

- ■ Customer Satisfaction

- ■ Top Line Growth

- ■ Bottom Line Growth

- ■ Speed to Market for New Products

- ■ Employee Retention

Continuous Improvement

The Quality Strategy for Good Business

◆ Senior Management Involvement

◆ Competency & Governance

◆ Quality "Systems" Thinking

◆ Quality Improvement Model/ Framework

◆ Culture of Commitment to Continuous Improvement

The Quality Strategy...
Senior Management Involvement

◆ Continuous improvement must be driven from the top

◆ Senior Management must be vocal, visible & involved in the change process
- Timelines
- Deliverables
- Accountabilities
- Competencies
- Behaviors

◆ Active participation in Leadership and Governance processes

The Quality Strategy…
Competency & Governance

◆ Competency – **know how to do things right**
- Problem Solving/ Root Cause Analysis
- Validation
- Training
- Continuous Improvement Tools
- Cross-functional Teams
- Project Management

◆ Governance – **do the right things**
- Quality Councils
- Steering Committees

The Quality Strategy…
Quality *Systems* Thinking

A Quality System is...

- Set of interrelated processes that <u>working together</u>, assure product safety, strength, identity, purity and quality

  - Elements that prevent, detect & correct deficiencies in the normal process

  - Systems depend, interrelate, input/output

  - Together provide for predictable and consistent performance and responses to adverse situations or changes

Some Quality Systems

Prevention	Detection	Correction
← Documentation →		
Training	Regulatory Audits	Training
Calibration & Maintenance	Complaints	Calibration & Maintenance
Technology Transfer	Stability	Investigations/CAPA
Process Validation	Materials & Sampling	
Change Management	APR's	
Warehousing & Distribution		
Line Controls		
Contractors & Suppliers		
Facility Control		
Computers		

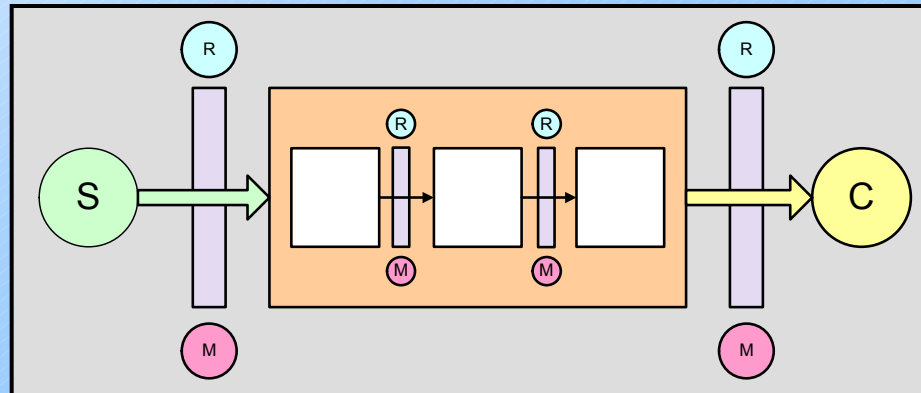# Quality System Interdependencies

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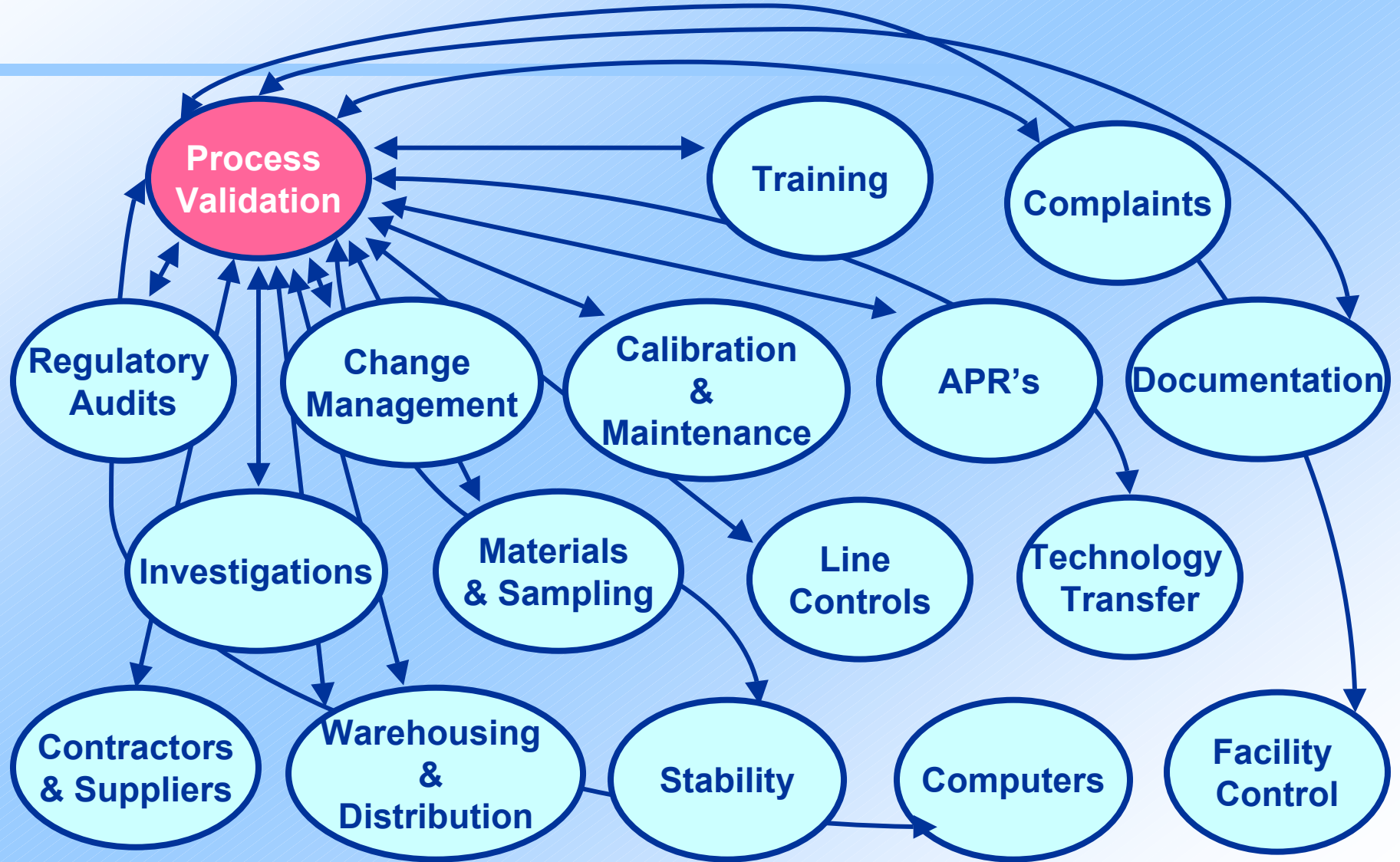
The Quality Strategy…
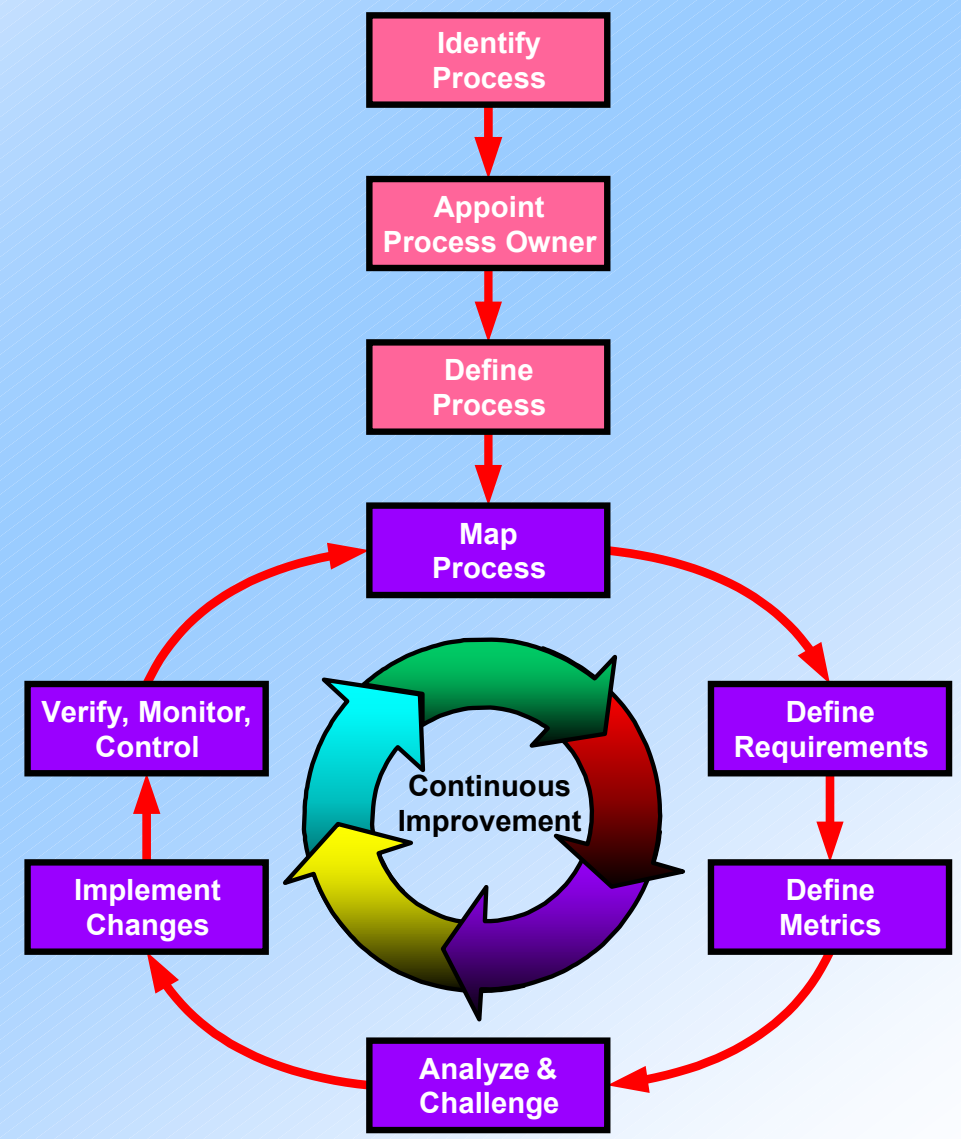# Quality Improvement Model/ Framework

◆ ALL WORK IS A PROCESS … and must be made visible

- PROCESS is turning inputs from Suppliers into outputs for Customers
- REQUIREMENTS must be clearly defined
- MEASUREMENTS indicate if Requirements are met
- OWNERSHIP to assure continuous improvement

7 Attributes of Robust Quality Systems

- Process
- Procedures
- Documentation
- QA Role
- Organization
- Infrastructure
- Performance Metrics

Fundamental to sound and robust Quality Systems

Continuous Improvement

How do we know a Good Quality Management System?

◆ Performance Metrics
  ▪ Deviations
    ● Recurrence
    ● CAPA
  ▪ Training
  ▪ Customer Complaints
  ▪ Change Control
  ▪ Stability Study outcomes
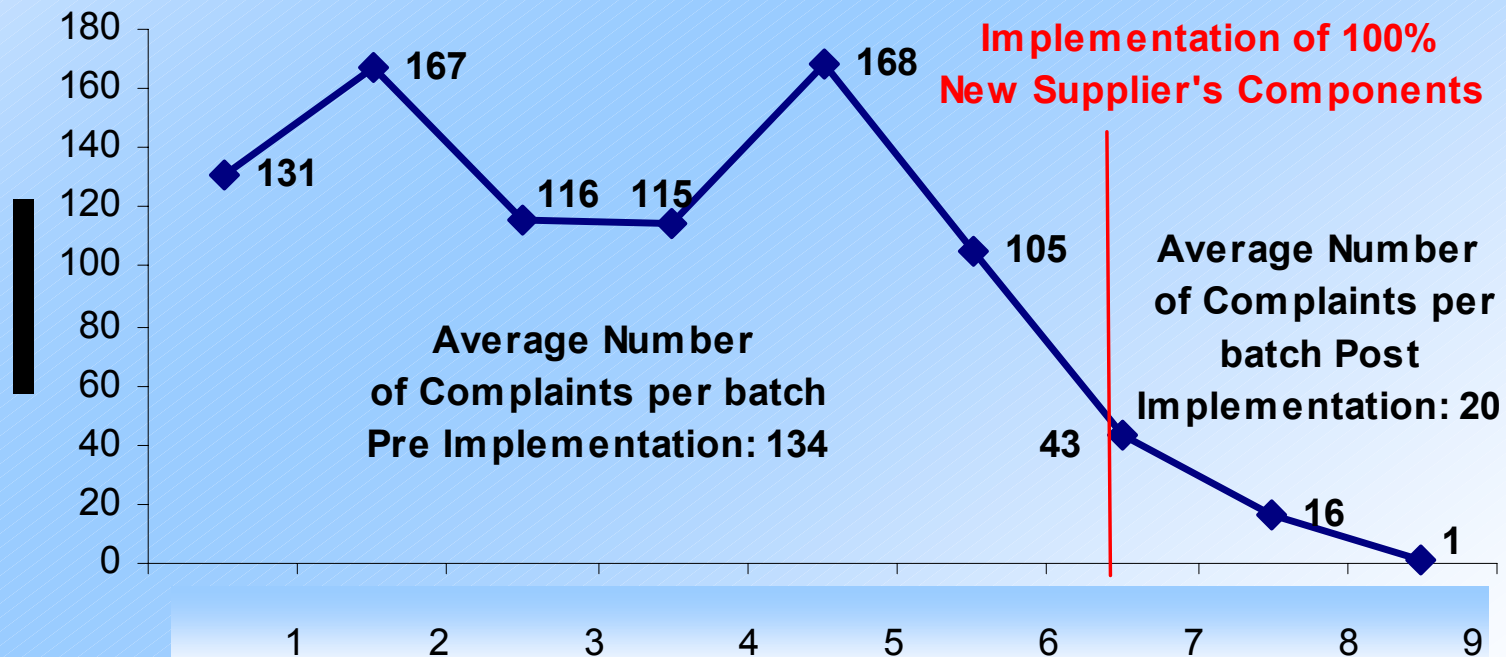 ▪ Equipment Calibration/PM
  ▪ Annual Product Reviews

These Measurements tell us

Continuous Improvement

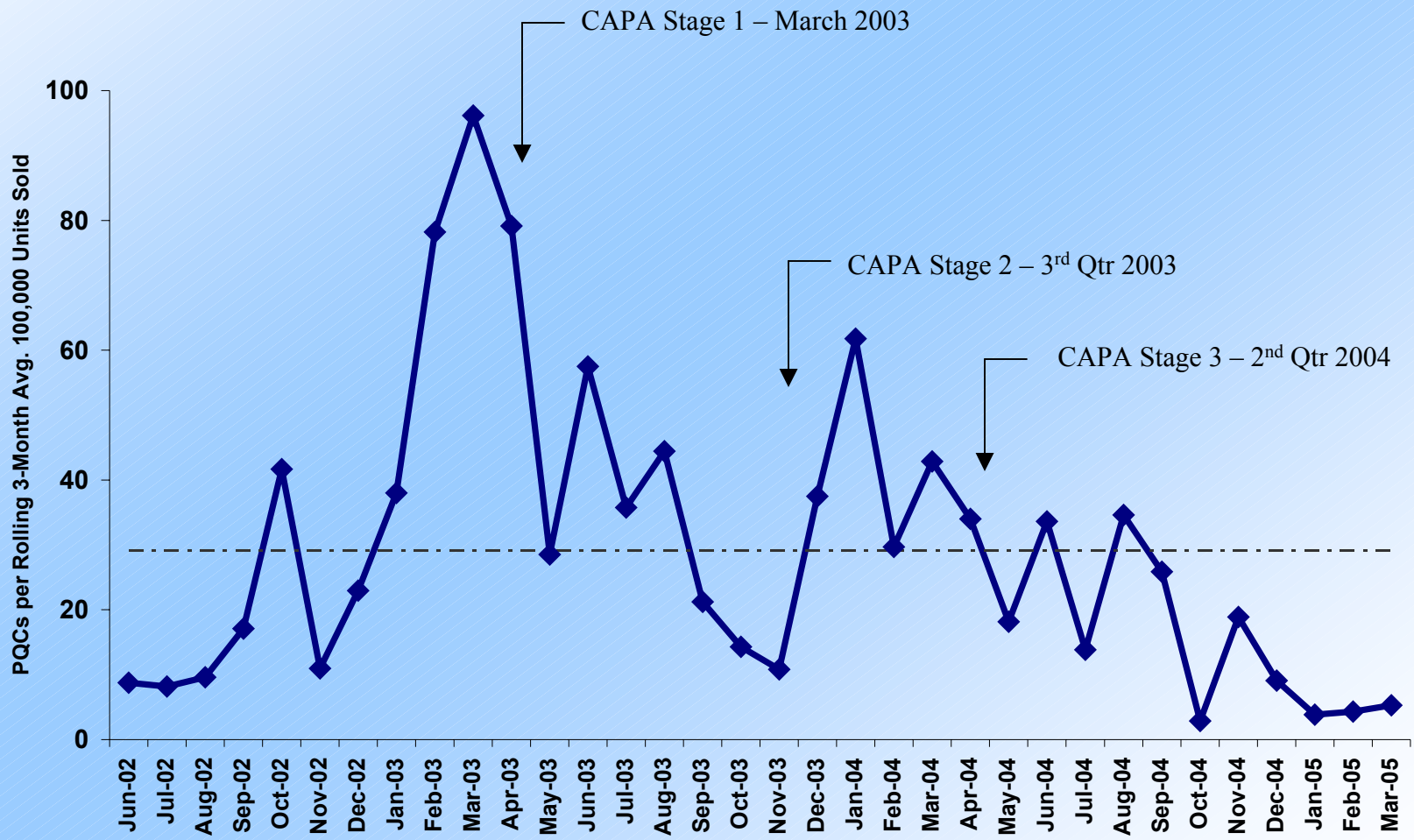# How do we know a Good Quality Management System?

Illustrates the effectiveness of performing root cause analysis and taking appropriate action. Root cause was isolated to a specific component supplier…Corrective Action was to single source with the higher quality supplier. Result was a reduction in complaint activity from 134 per batch to 20 per batch (non-related issues).

Product XYZ CAPA Effectiveness Chart

Chart data points: 131, 167, 116, 115, 168, 105, 43, 16, 1

Implementation of 100% New Supplier's Components

Average Number of Complaints per batch Pre Implementation: 134

Average Number of Complaints per batch Post Implementation: 20

X-axis: 1 2 3 4 5 6 7 8 9

How do we know a Good Quality Management System?

Product Quality Complaints Normalized

First-time Approval Rate
Change Authorizations Approved 2002 thru Q1-2005
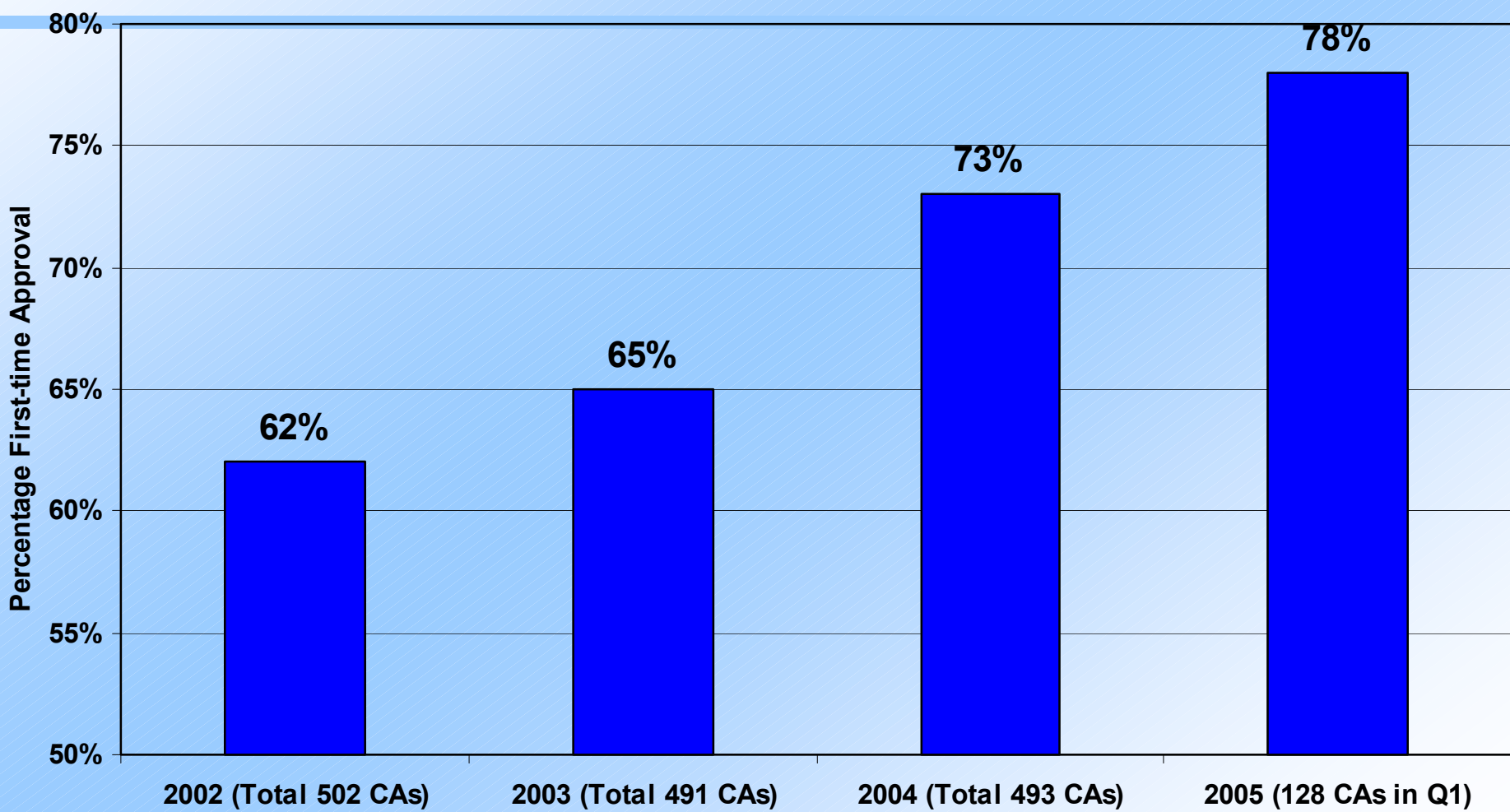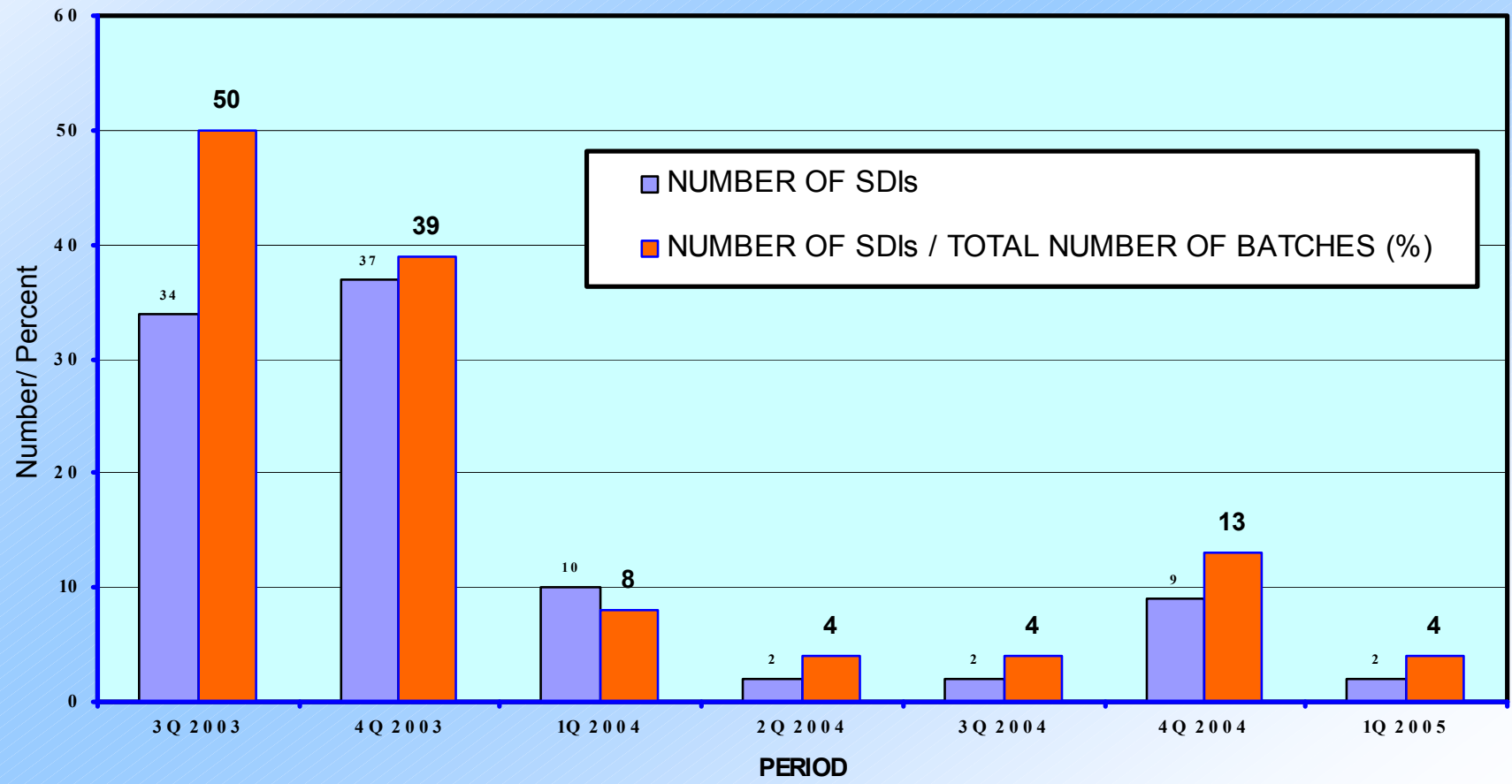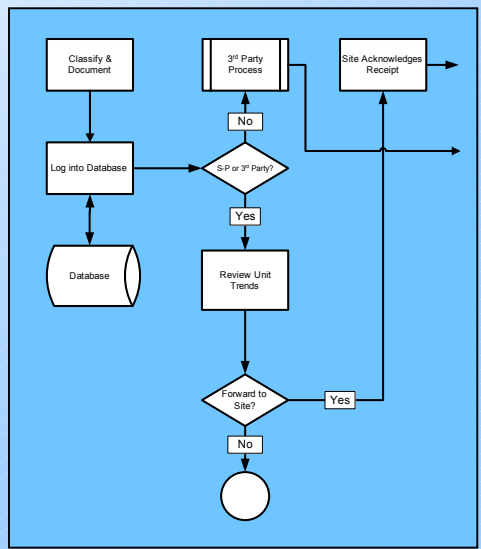
Quality Systems …
Designed for Commitment

- ◆ Simple, easily understood

- ◆ Clear roles & responsibilities & governance/ownership

- ◆ Controls & checks that help responsible people do their jobs

- ◆ Reflect Company's Vision & Values

- ◆ Promote commitment

The Quality Strategy

Management Involvement
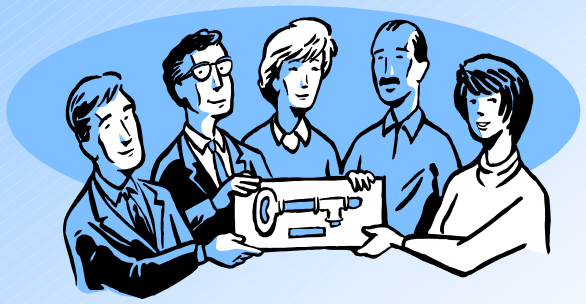
+

Competency and Governance

Well-designed Systems

+

Continuous Improvement

Methodology for Improvement

+

Committed People

Sustaining Quality is Good for Business

Sustaining Quality Systems… Good for Business

◆ Effective and Efficient Quality Systems lead to:
- ■ Customer Satisfaction and Top Line Growth
  - Patients, Doctors
  - Regulators
- ■ Contribute bottom line growth
  - Effective and efficient systems
  - Fewer process/ system failures
  - Less Regulatory risk
- ■ Speed to Market for New Products
  - Regulatory approvals
  - Successful transfers
- ■ Employee retention
  - Commitment to Continuous Improvement
  - Personal and professional growth

Identify Process

Appoint Process Owner

Define Process

Map Process

Define Requirements

Define Metrics

Analyze & Challenge

Implement Changes

Verify Monitor Control

Continuous Improvement