Best Practices in Communicating Business, Product and Compliance Risks to Top Management

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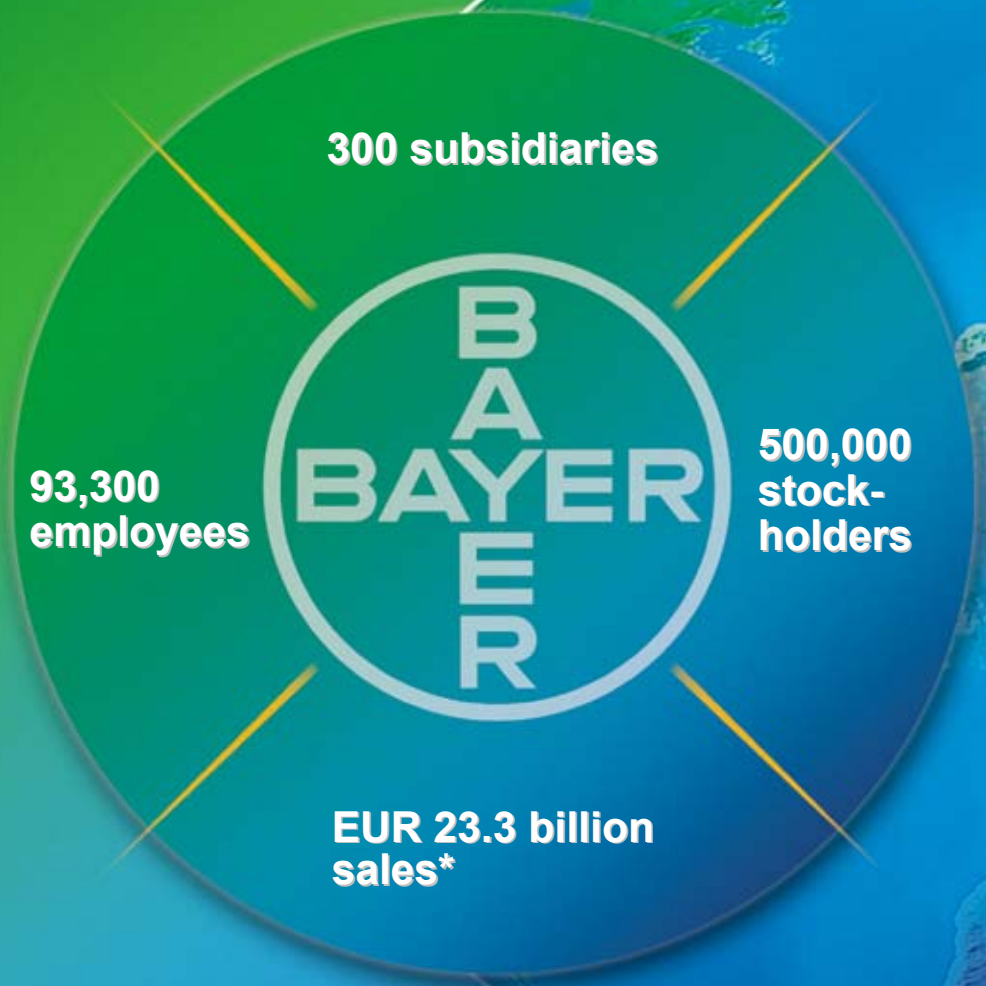
Sr. VP QA/RA/HES

The Medical Device Regulatory and Compliance Congress

Bayer Group



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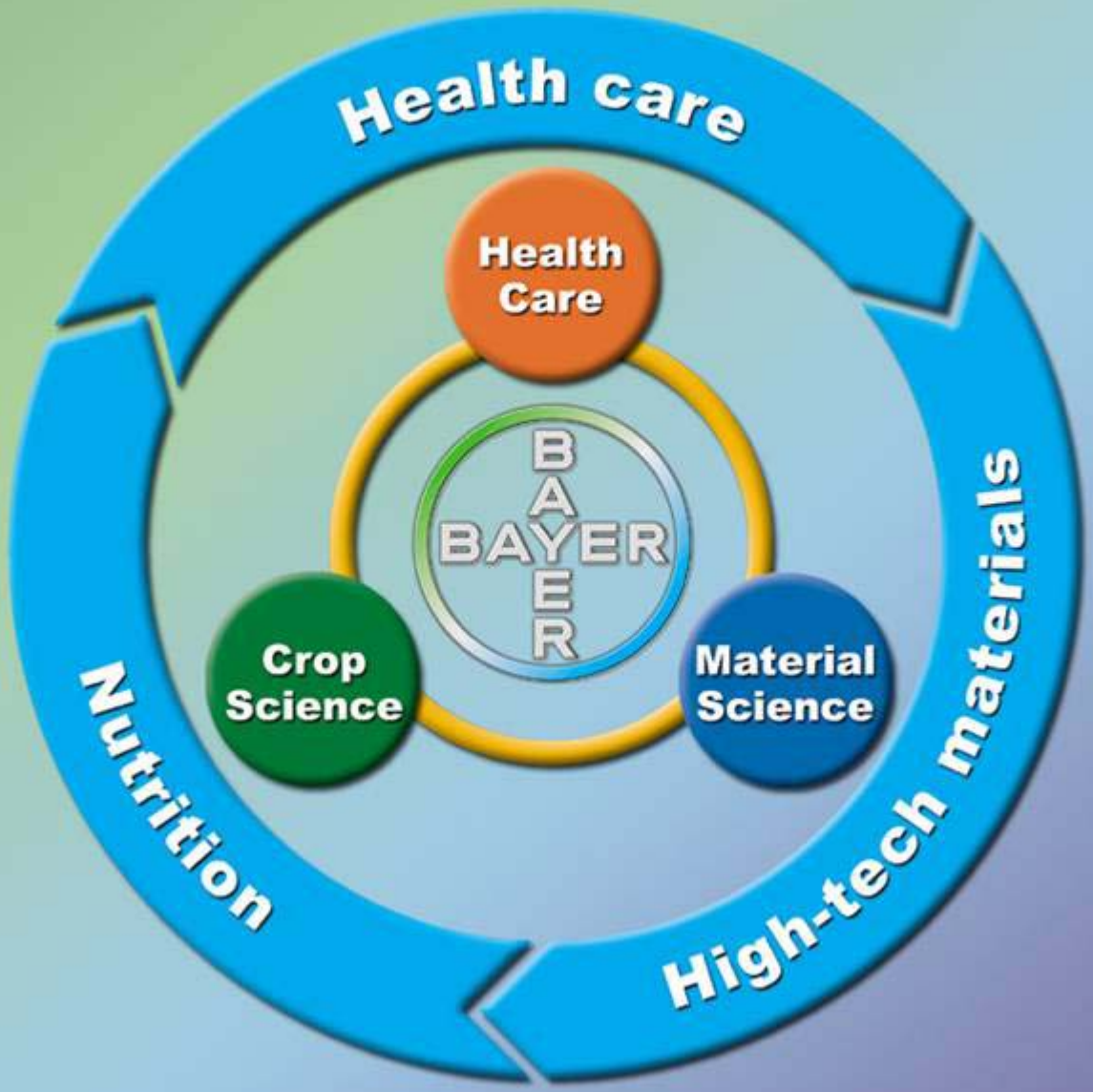
Bayer: Science For A Better Life



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Bayer HealthCare

Employees 35,300

Sales (2004) EUR 8,485 million

Animal Health

Livestock

Companion Animals

Biological Products

Hemophilia

Consumer Care

Non-prescription drugs

Vitamins

Pharmaceuticals

Cardiovascular risk management (including diabetes

Diagnostics

Near Patient Testing

Laboratory Testing

Molecular Testing

Diabetes Care

Blood glucose monitoring systems

as at December 31, 2004

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Agenda

- Business Environment
- Fundamental Gaps
- Best Practices in Communication: Closing the Gaps
- Best Practices: Results
- Messages to Take Away

Business Environment

Industry Trend

- QMS Evolution focus from product to enterprise
- PHARMA regulation changing to be more process and system vs. product
- Similarity between Sarbanes – Oxley and ISO 9001
- Combination products (drug and device)
- Japan and Canada regulations have changed to be risk-based oriented
- Post-market Challenges

Interesting Information

DRUGS

- Only **1** in 20,000 products gets FDA approval
- It takes **15 years** for the company to launch a product
- Typical cost is **$850,000,000**

Medical Devices

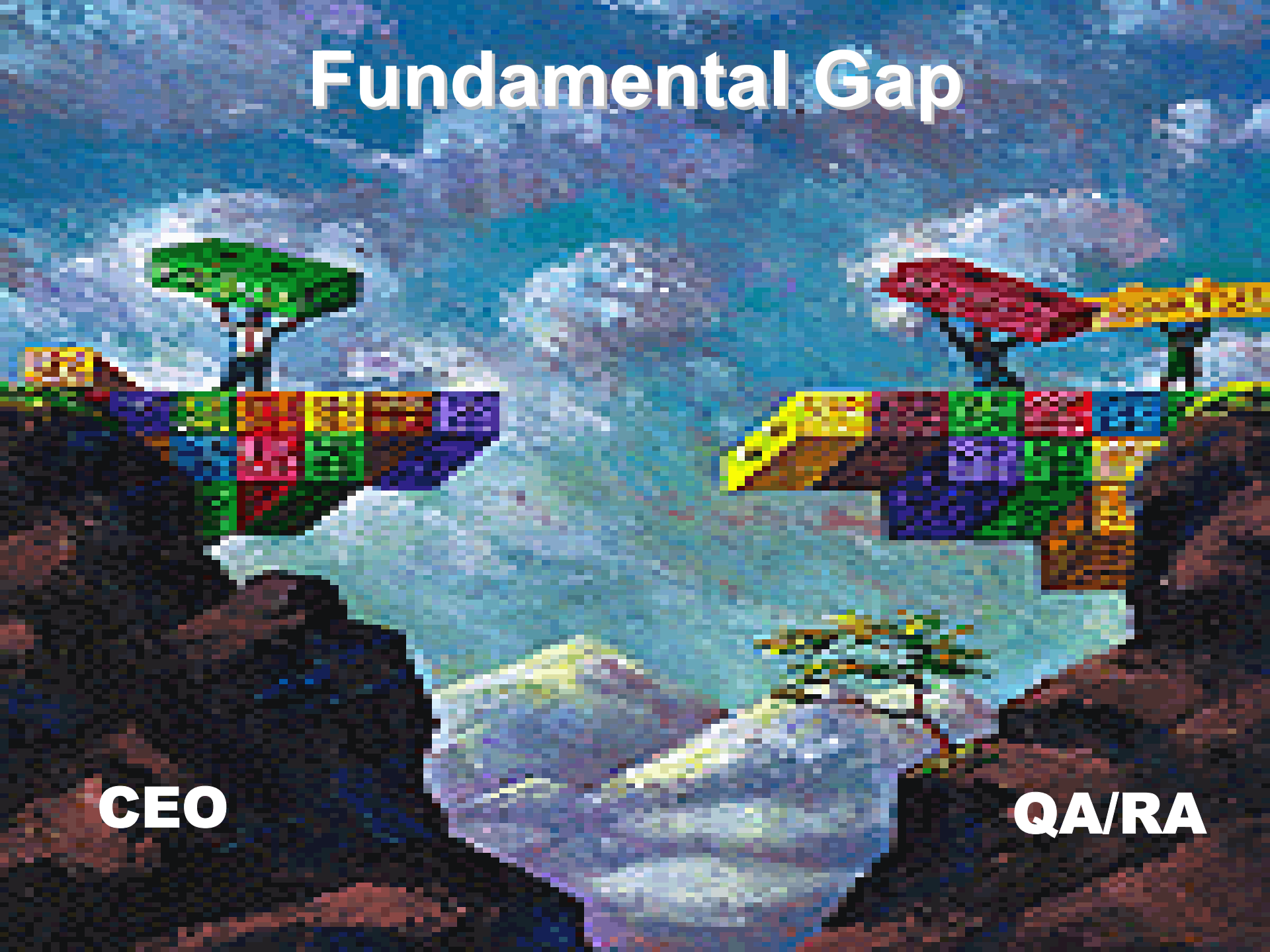
- Average product life cycle is **2 to 5 years**
- Average R&D investment is **7% to 10%** of sales

Interesting Information

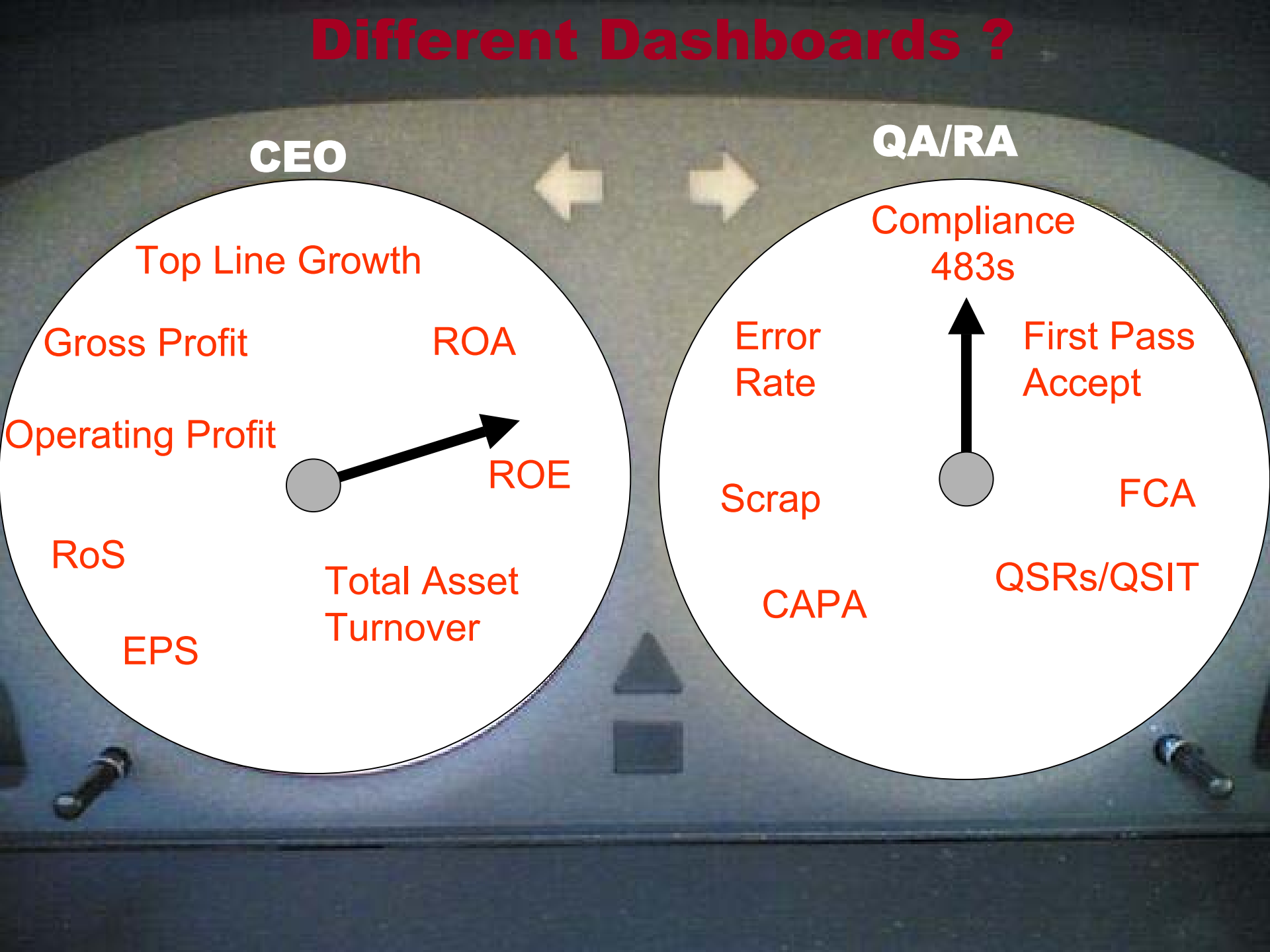
Compliance Alliance Survey February 2005

- 1024 Medical Device Companies Responded
  - **Top Management**
    - 226 thought QA/RA was a necessary *evil*
    - Viewed QA/RA as a *deterrent* to revenue goals
  - **QA/RA**
    - 383 felt there was *inadequate commitment* from senior executives
    - 377 felt they had *inadequate authority*
    - 333 felt they were *ignored by sales*
    - 337 felt they were *ignored by marketing* department
    - 185 felt that they were *ignored by senior management*

Fundamental Gaps


Fundamental Gap
CEO
QA/RA

Different Dashboards ?



Must Speak the Same Language

CEO

RA/QA

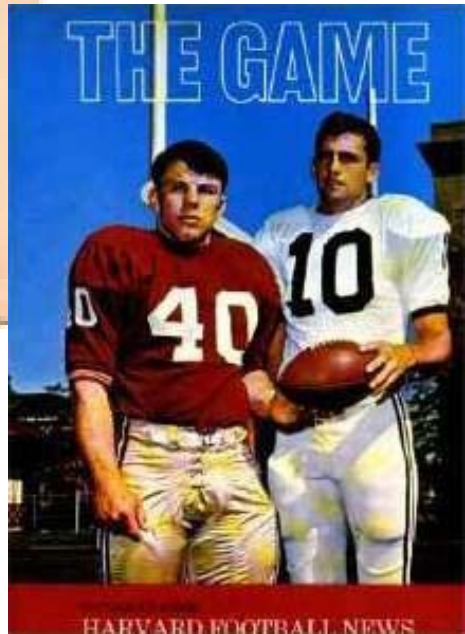

HARVARD BEATS YALE, 29-29

The Harvard Crimson

Harvard Students Set Up School For Teens Ejected From Sudbury

Champi's Passing Quiets Yale Fans


YALE
VS.
HARVARD
at
Harvard Stadium
SAT., NOV. 23, 1968
1:30 P.M.
Enter Stadium Thru Gates 24 — 26
SEC. TS
ROW A
SEAT 47
Est. Price $6.00
THIS TICKET IS NOT REDEEMABLE



Regulatory Global Requirements

Regions of the World Regulations and Standards

INFARMED, TGA,

Multiple Country Ministries of Health

Japanese Regulations and Standards

MHLW

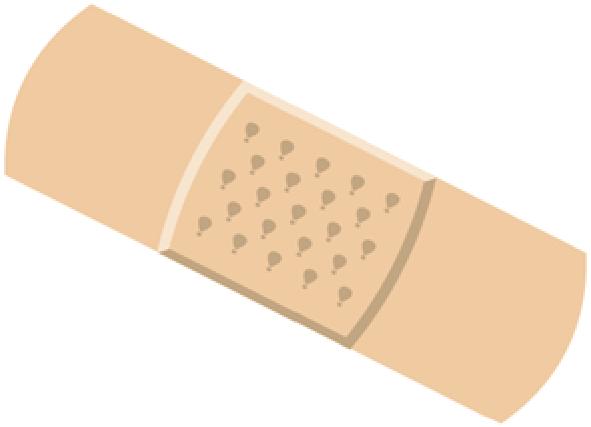
European Regulations and Standards

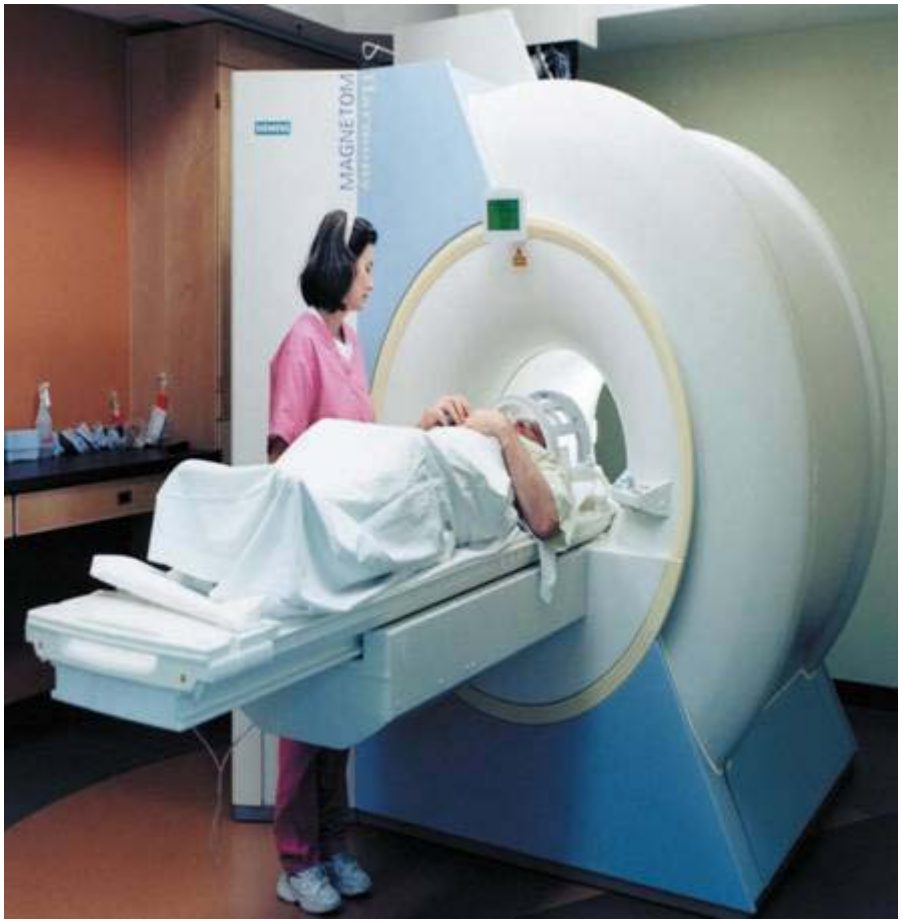
PEI, ADM, EMC, MDD, IVDD

U.S. and other North American Regulations

FDA, TPP

Regulations are Vague
Devices are Broadly Defined

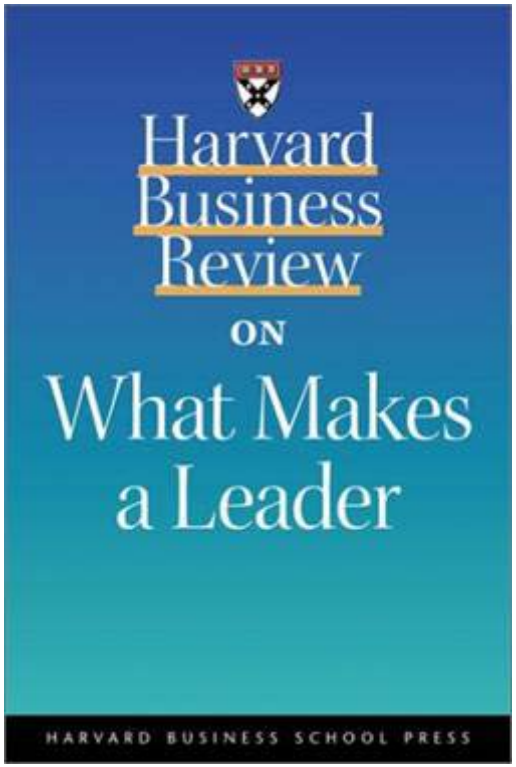




Interpretation of Regulations

What's Your Focus

Business or Compliance First ?



Are the Customer and Patient at the center of your universe?

What is QA/RA role in the Enterprise ?

Where do you add Value ?

New thinking

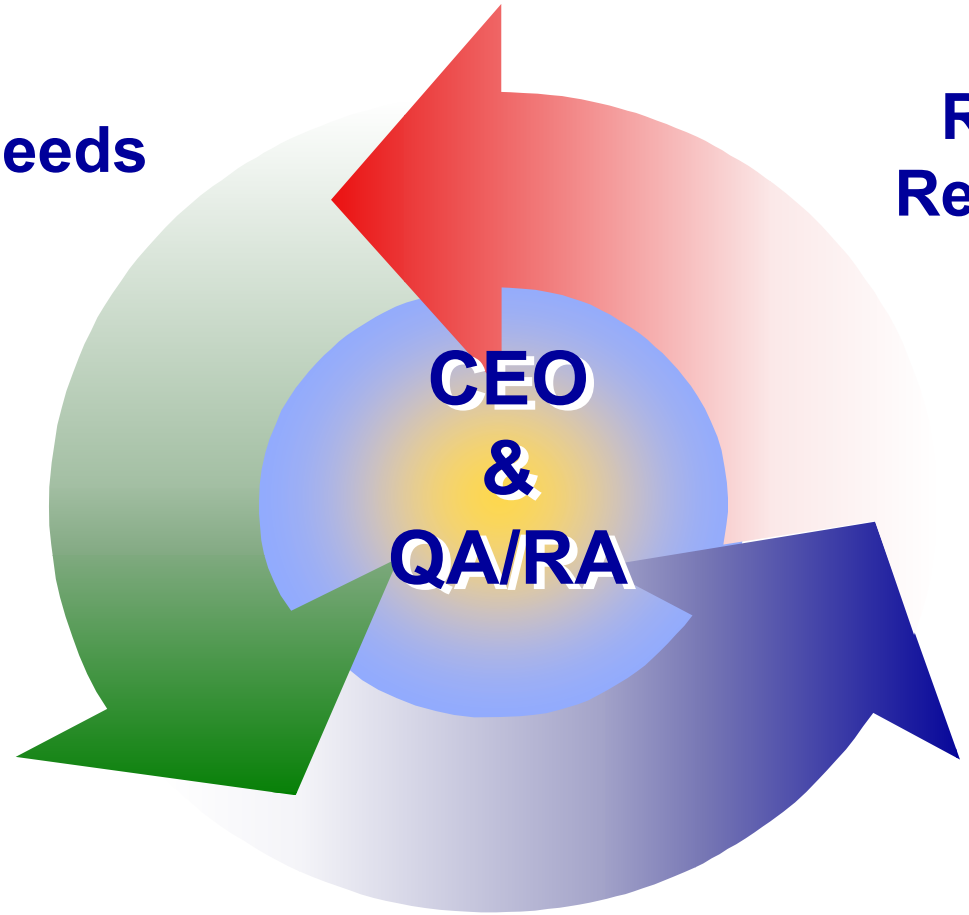
- Advisor, counselor and coach
- Add value to organization
- Provides confidence and consistency
- A tool for business improvement
- Speeds time to market

Old thinking

- Police mentality
- Bottleneck (barrier)
- Problem-focused inspectors
- Paper-oriented

Best Practices in Communication: Closing the Gaps

Top Management Language Integrates:

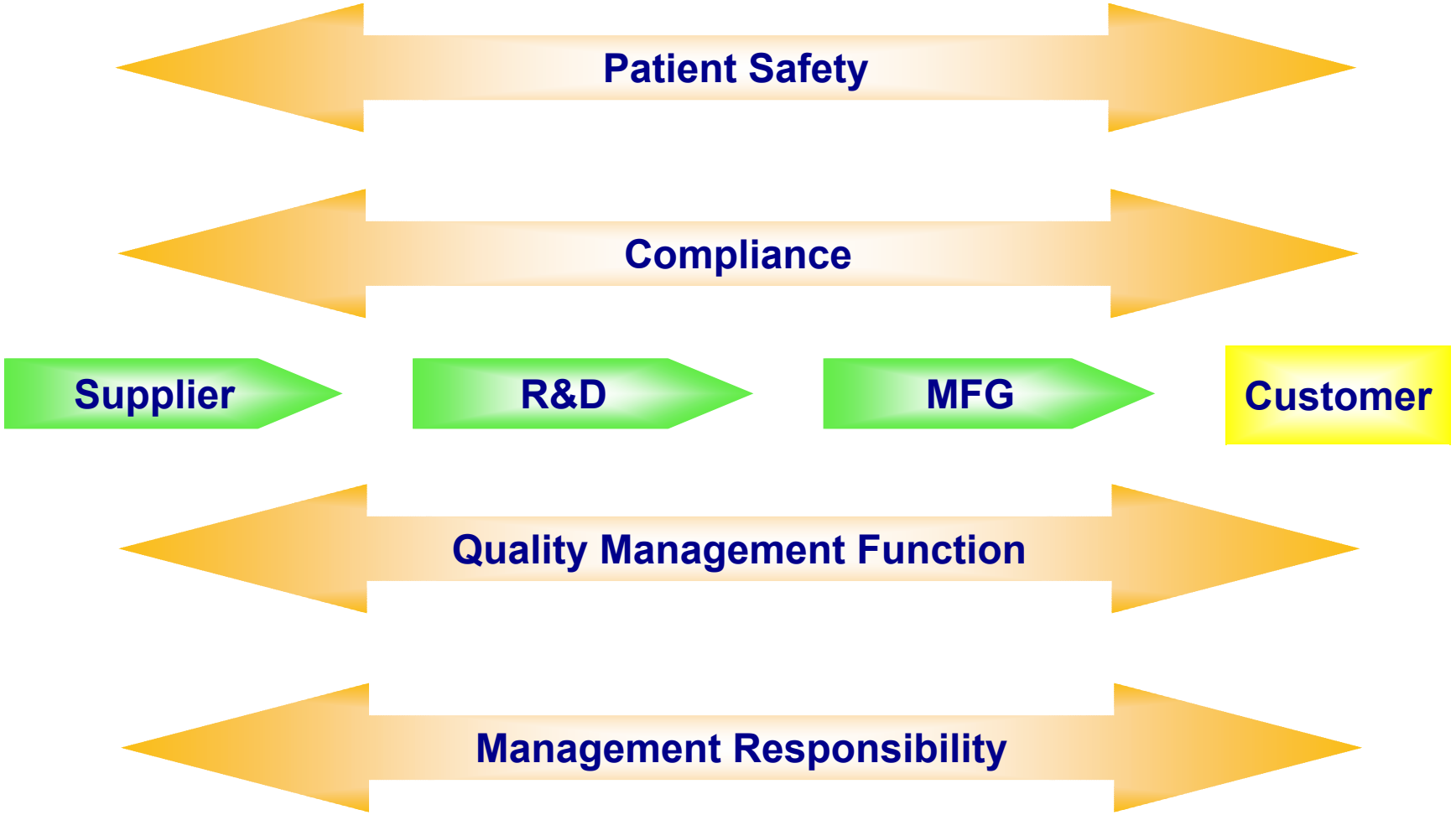


How?

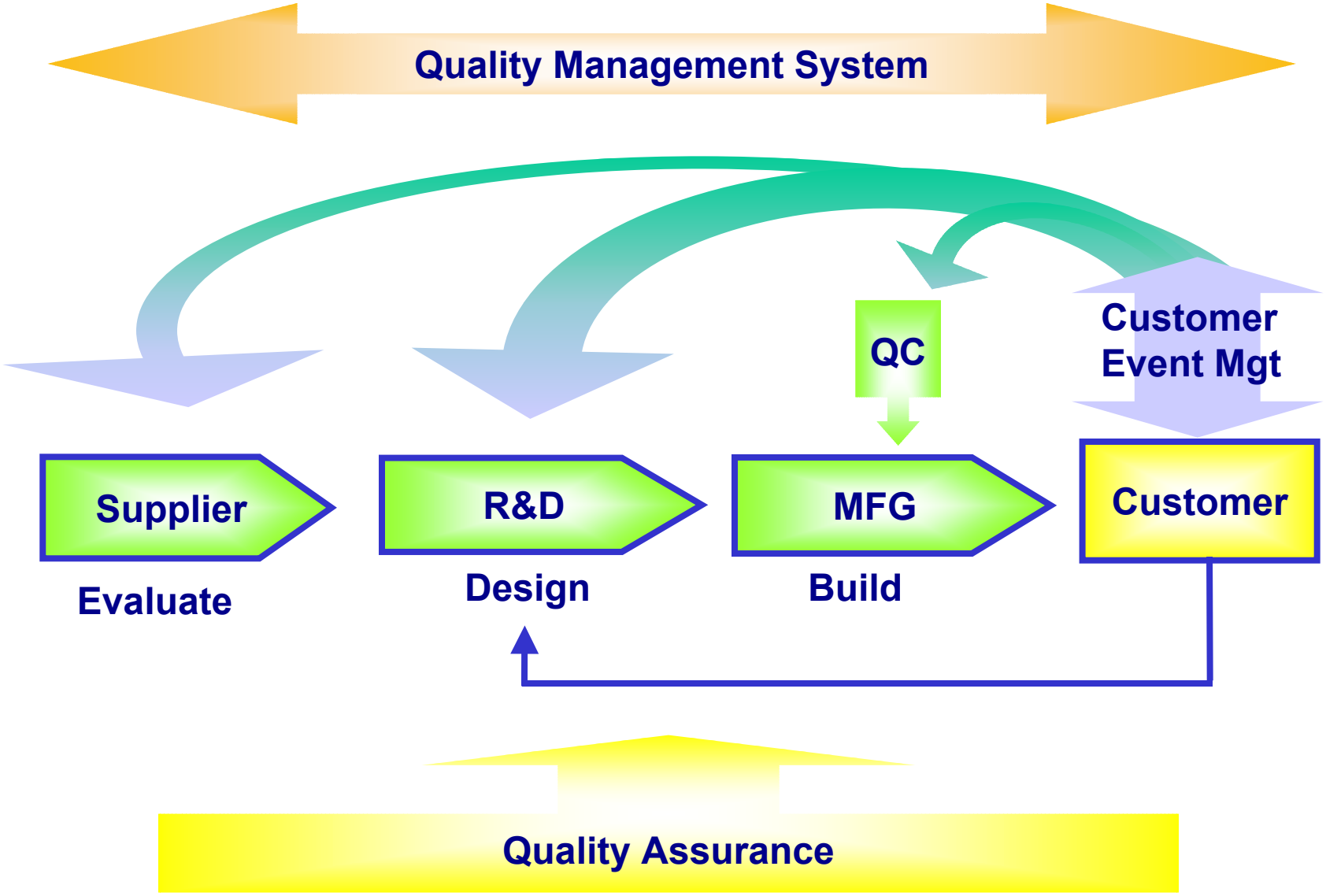
Consider….

Quality is more than just products...

Design Quality Systems Outside In



Four Pillars of the Quality Management System



Define Responsibilities by Value Added in Each

Regulatory Affairs

. Pre-market Role .

- Worldwide Regulatory Plans
- Regulatory Filings
- Preparation and filing of X-US Dossier
- Interaction with Europe, Japan, Canada and ROW RA Colleagues to support X-US Registration

- Assist in FDA audits

. Post-Market Role .

- Advocacy
- Import/Export Mgt.
- Regulatory reporting (MDR, Vigilance)
- Adverse information management

- Product Registrations

Supplier → **R&D** → **MFG** → **Customer**

- Supplier Audits
- Quality Cost Delivery

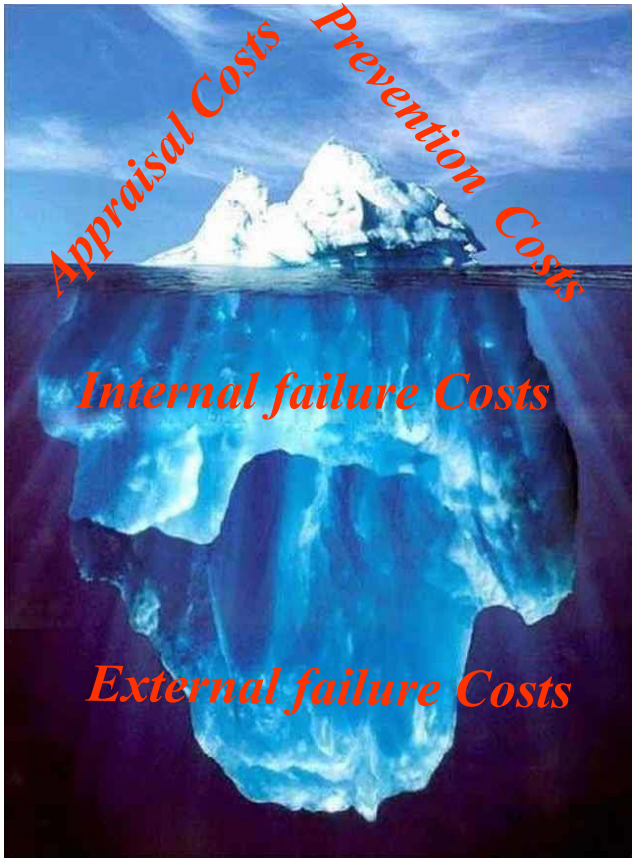
- Design Control: Design Validation
- Quality Plan
- Reliability: Data review for translation to claims
- Documentation: Assurance DMR in order

- Review supplier performance, seek corrective action
- Finished goods release
- Change control management
- Documentation management
- Process Control: Review, approve, monitor validation plan

- Customer Event management
- Quality monitoring tools development and implementation

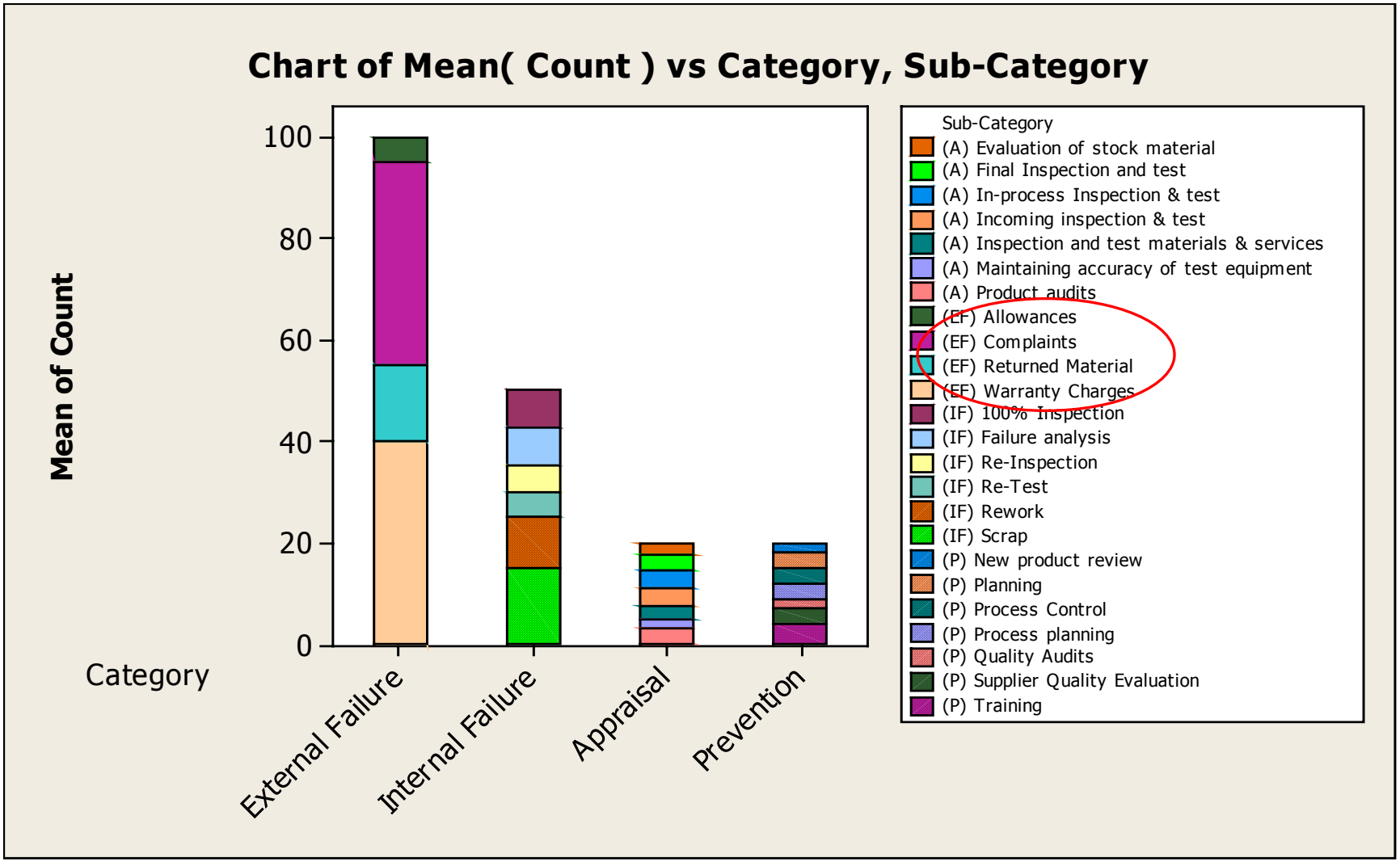
Quality Assurance

Cost of Poor Quality



- The costs associated with poor quality are not readily identifiable.
- There is a significant business & customer benefit to determining the true COPQ and taking actions to prevent these costs.

Sub-Categories of COPQ Cost



Utilize Management Review

- Prepare Agenda
  - Practice, Drill, Rehearse
- Use Executive Language
  - Quantitative
- Make it a Business Plan
  - Encompasses 3Ps
  - Multiple Choices
  - Make a Commitment

Utilize Management Review

Make it Interactive

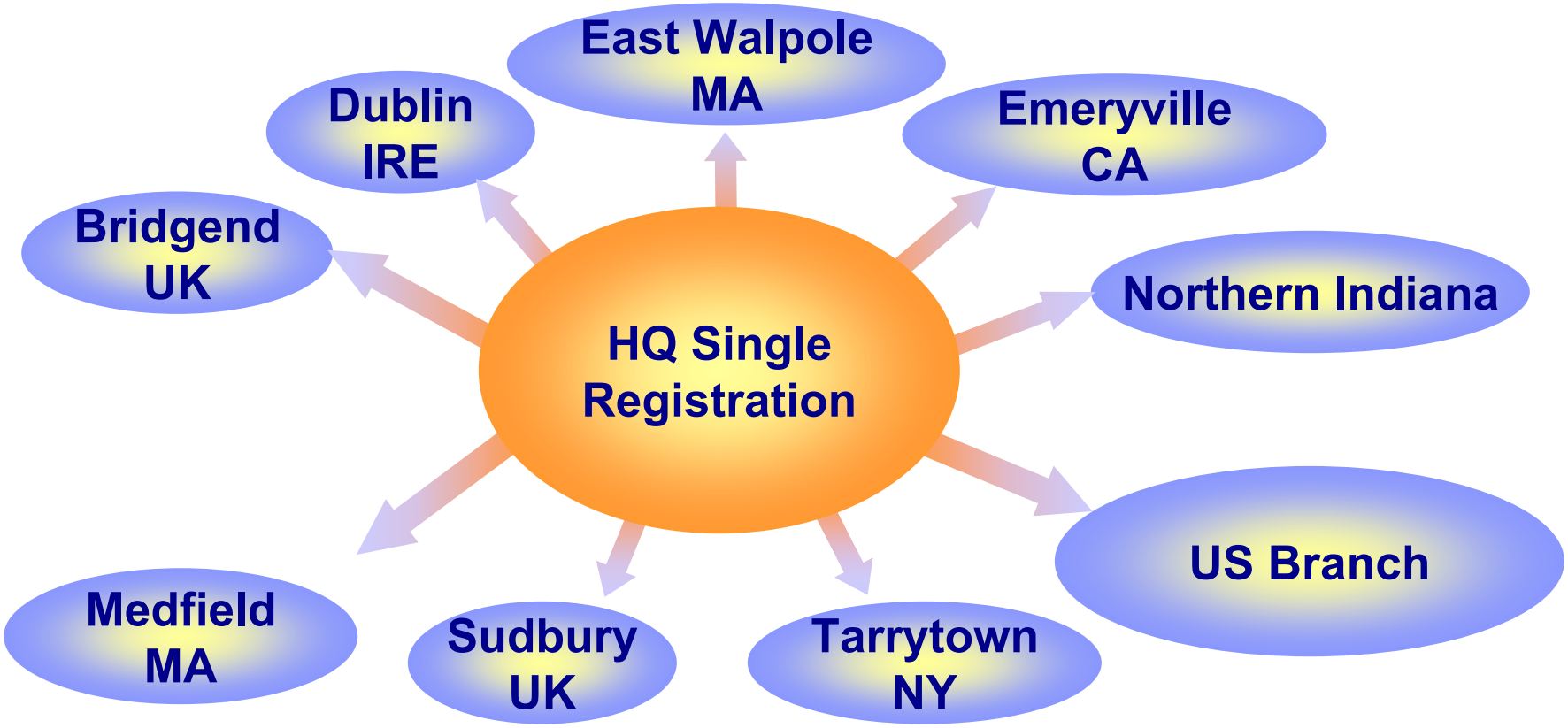
- Are they Reading or Thinking?

Step 1

- **Drive Commercial Understanding into your organization**
- **Is your QA/RA group a stereotype?**
- **Hard to develop from within, likely need external infusion.**
- **Attract the brightest and best**

Best Practices: Results

Single Quality System

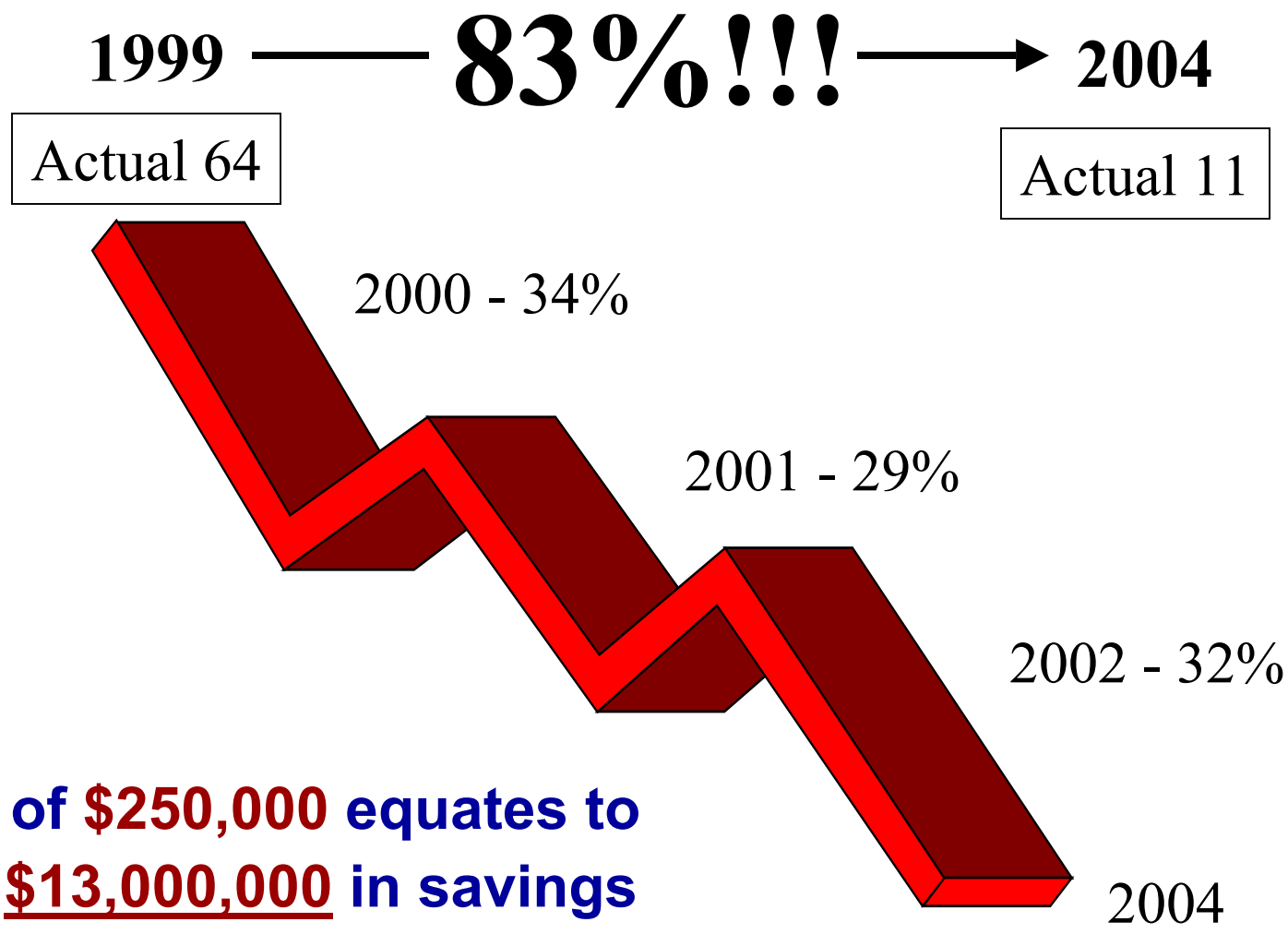


Single Global ISO Registration - Significant Benefits for the Business

Single Quality System

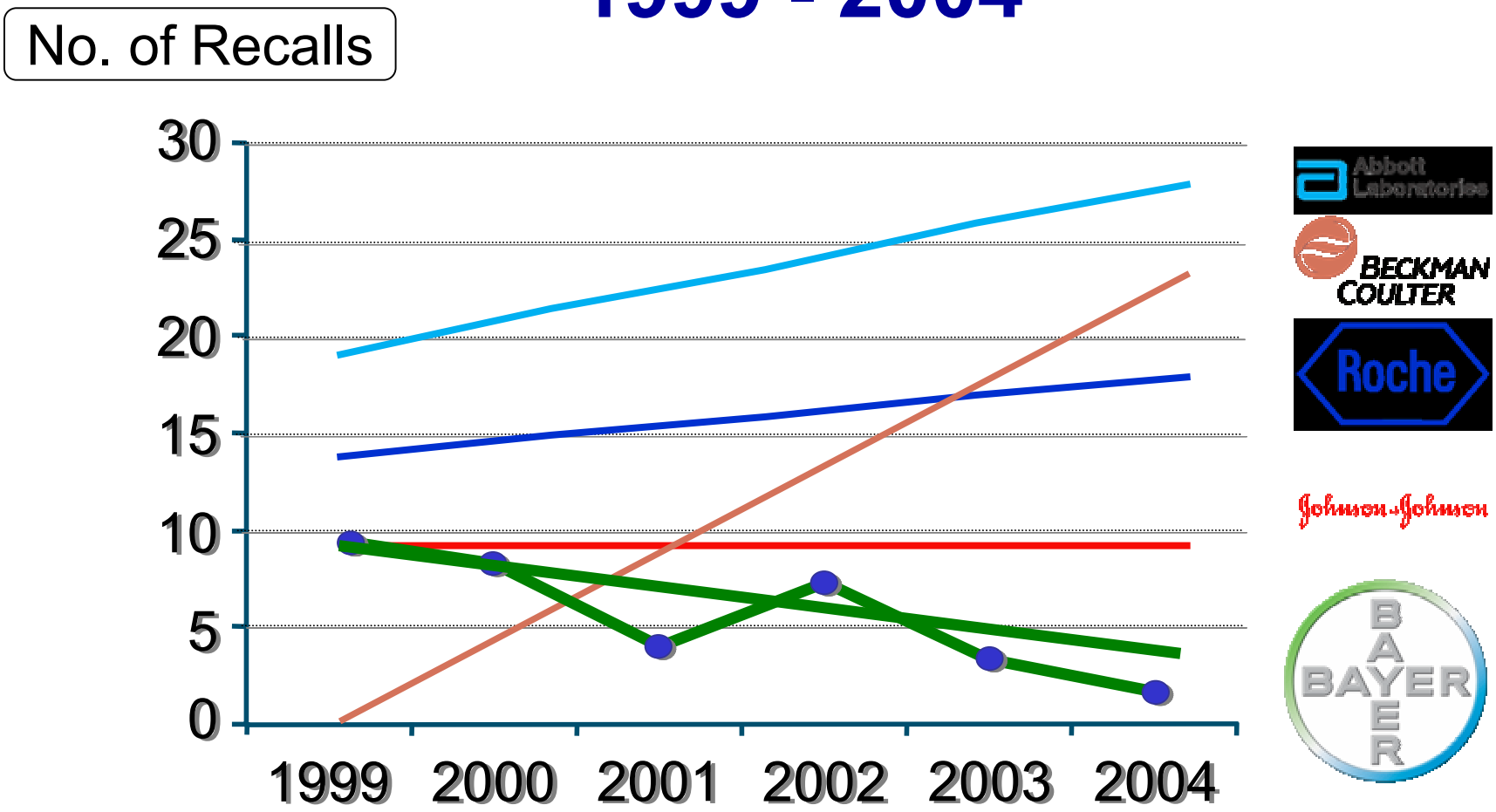
THEN	NOW
• Fragmented Systems	• Centralized, Single System
• Excessive Documentation 10 Quality Manuals 280 GSOP's	• Simplified Documentation 1 Quality Manual 22 GSOP's
• Compliance through Inspection	• Compliance through Prevention
• U.S. Focus	• Global Focus
• Internal Focus	• Customer Focus
• Lacking Key Metrics	• Global Key Metrics
• No Cost of Poor Quality	• Reduced Poor Cost of Quality

Reduced Field Corrective Actions



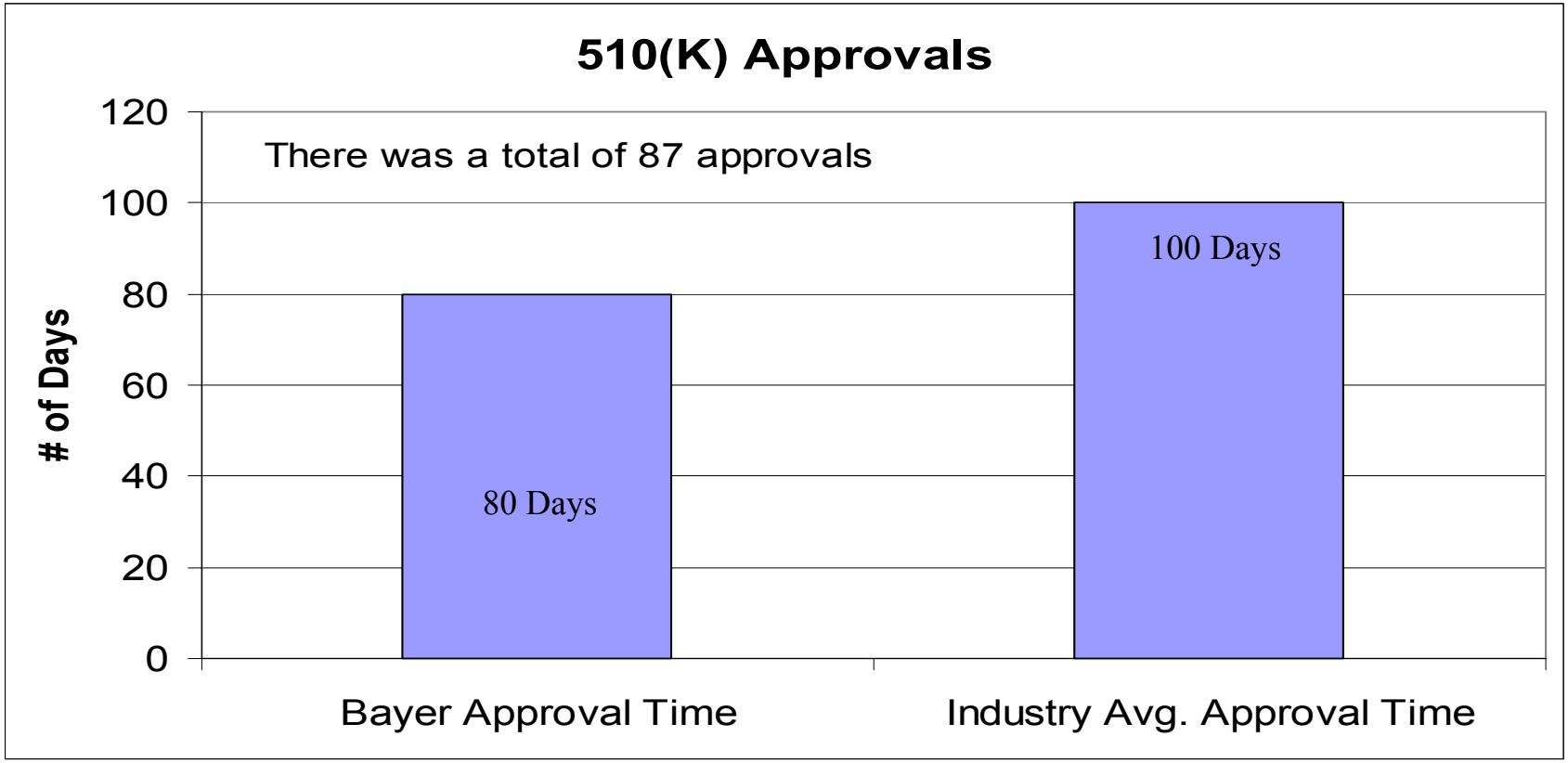
Cost of $250,000 equates to over $13,000,000 in savings through FCA prevention.

Reported Device Recalls Reported 1999 - 2004



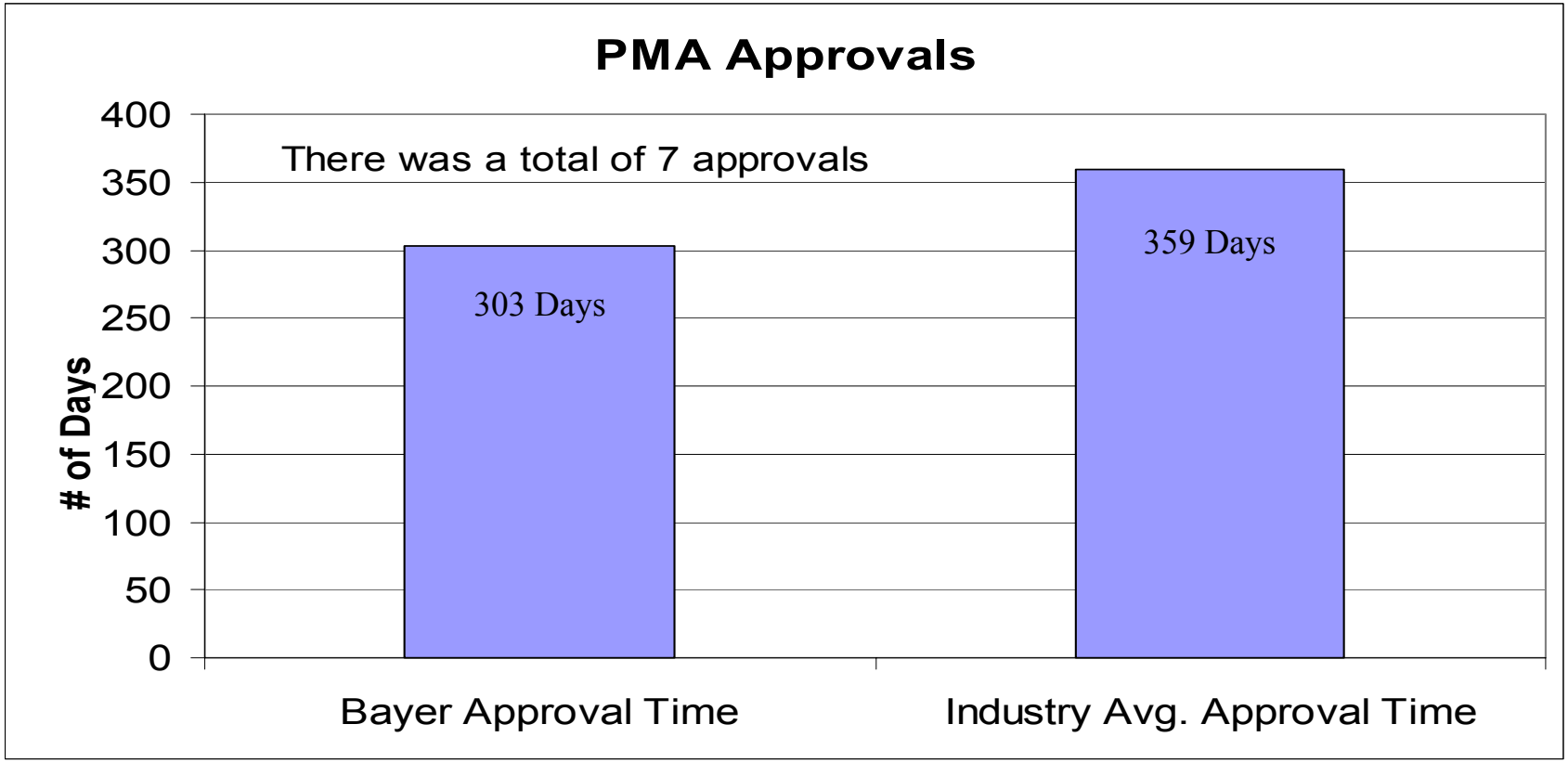
DS and DC 510K Approvals

Bayer Surpasses Industry Avg. 20%!!!



DS PMA Approvals

Bayer Surpasses Industry Avg. 16%!!!



Bayer Diagnostics Audit Success

18 FDA inspections in the last 4 years

60% of Inspections with NO 483's

Messages to Take Away

Where are challenges today?

Customer

- Demanding shorter time to market for innovative new products

Markets

- Investors are rewarding companies not only with strong research and development pipelines but the ability to **commercialize**
- Best-in-class companies leverage **quality** as a **business advantage** in highly competitive markets

Medical Devices

Regulatory

- Tightening regulations on manufacturing and process control
- Consumers are demanding greater protection and safeguards.
- Liability resulting from regulatory penalties (fines, market perception, jail, etc.)

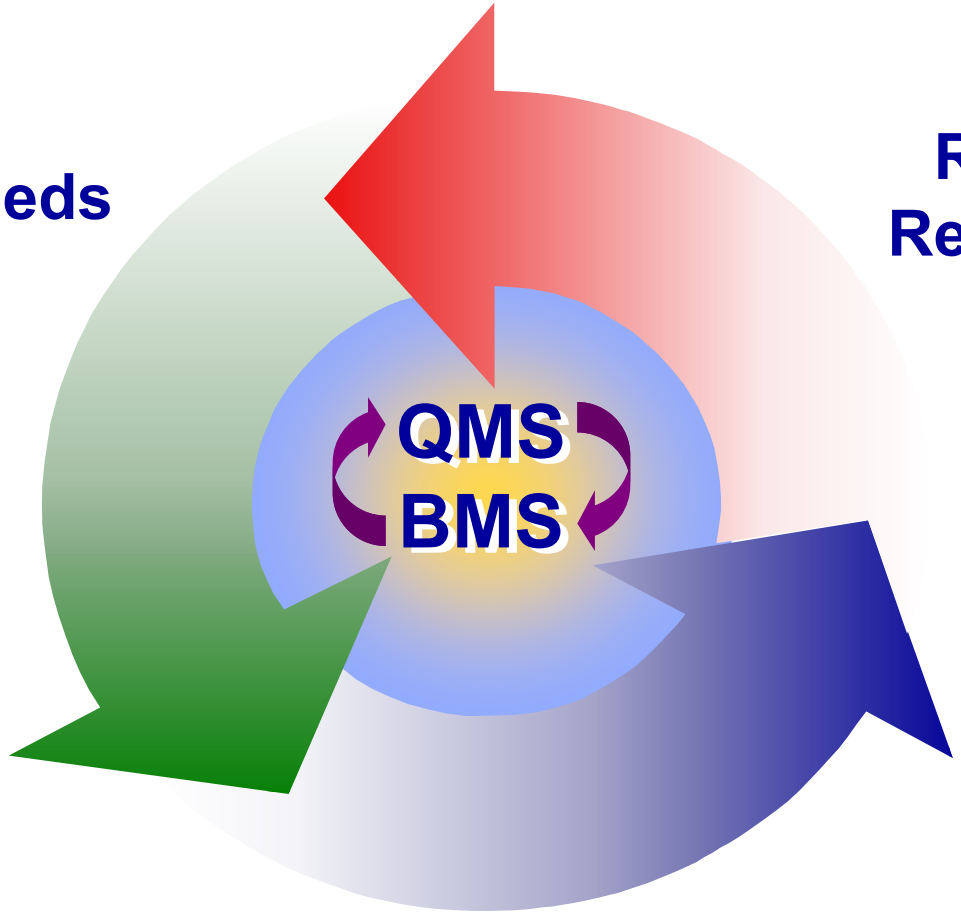
Companies

- Increased Merger & Acquisition activity
- Funding of R&D through profitable **commercial operations**

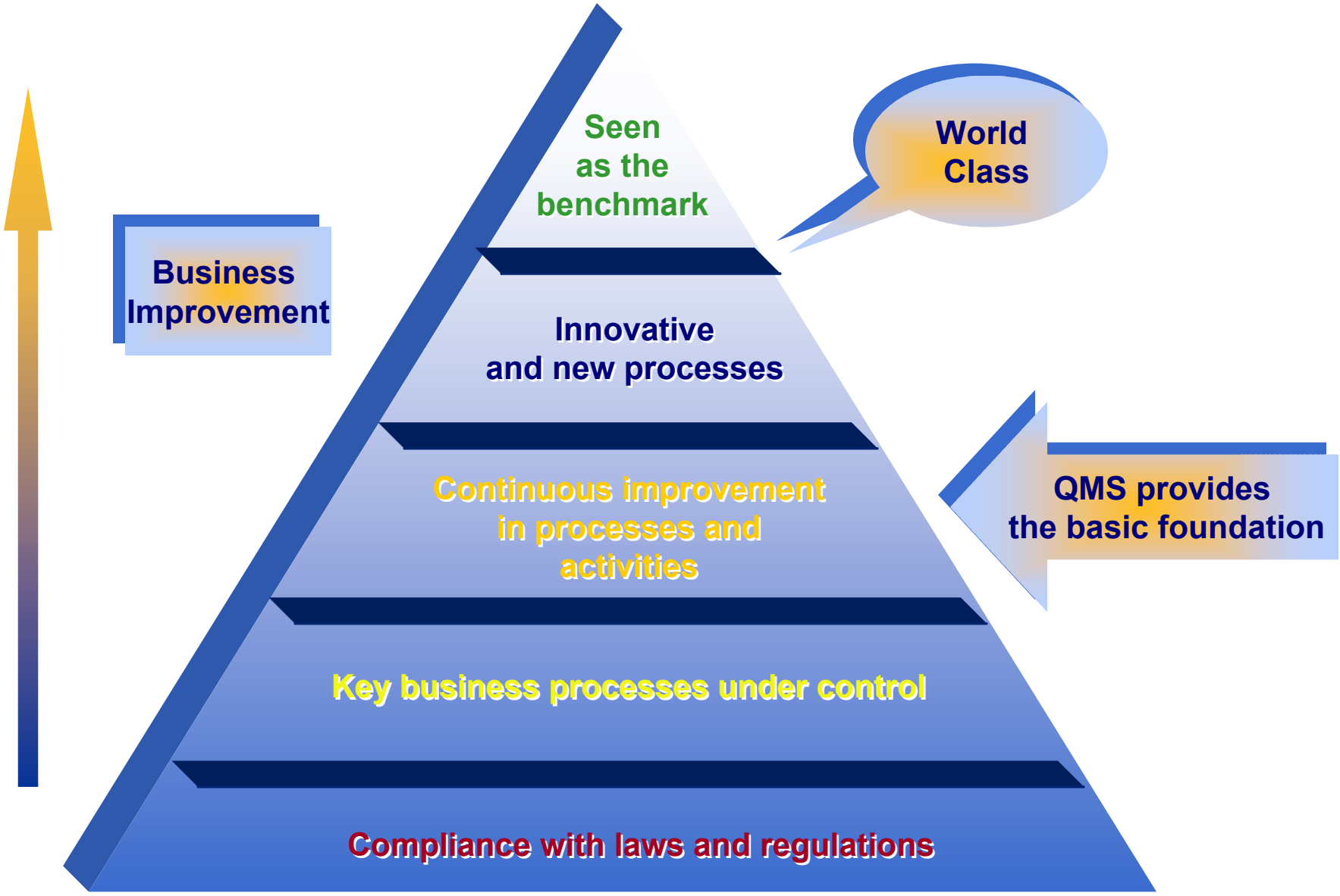
Executive Needs of QA/RA Professionals

- ✓ Strategist
- ✓ Partner
- ✓ Systematic Communication
- ✓ Logical Metrics
- ✓ Set an Example
- ✓ Trusted Advisor
- ✓ Recognize Progress
- ✓ Incent Success
- ✓ Independent Review
- ✓ Teach Others

Top Management Language Integrates:



Compliance is only a Baseline for Success



Best Practices For Effective Communication

- Management Review: Effectiveness of Quality System in Adding Value to the Business
- Cost of Poor Quality
- 6 Sigma
- Effectiveness of Internal Audit and Risk Management
- Improvement of Customer Satisfaction