



QUALITY

Expressway to Patient Satisfaction

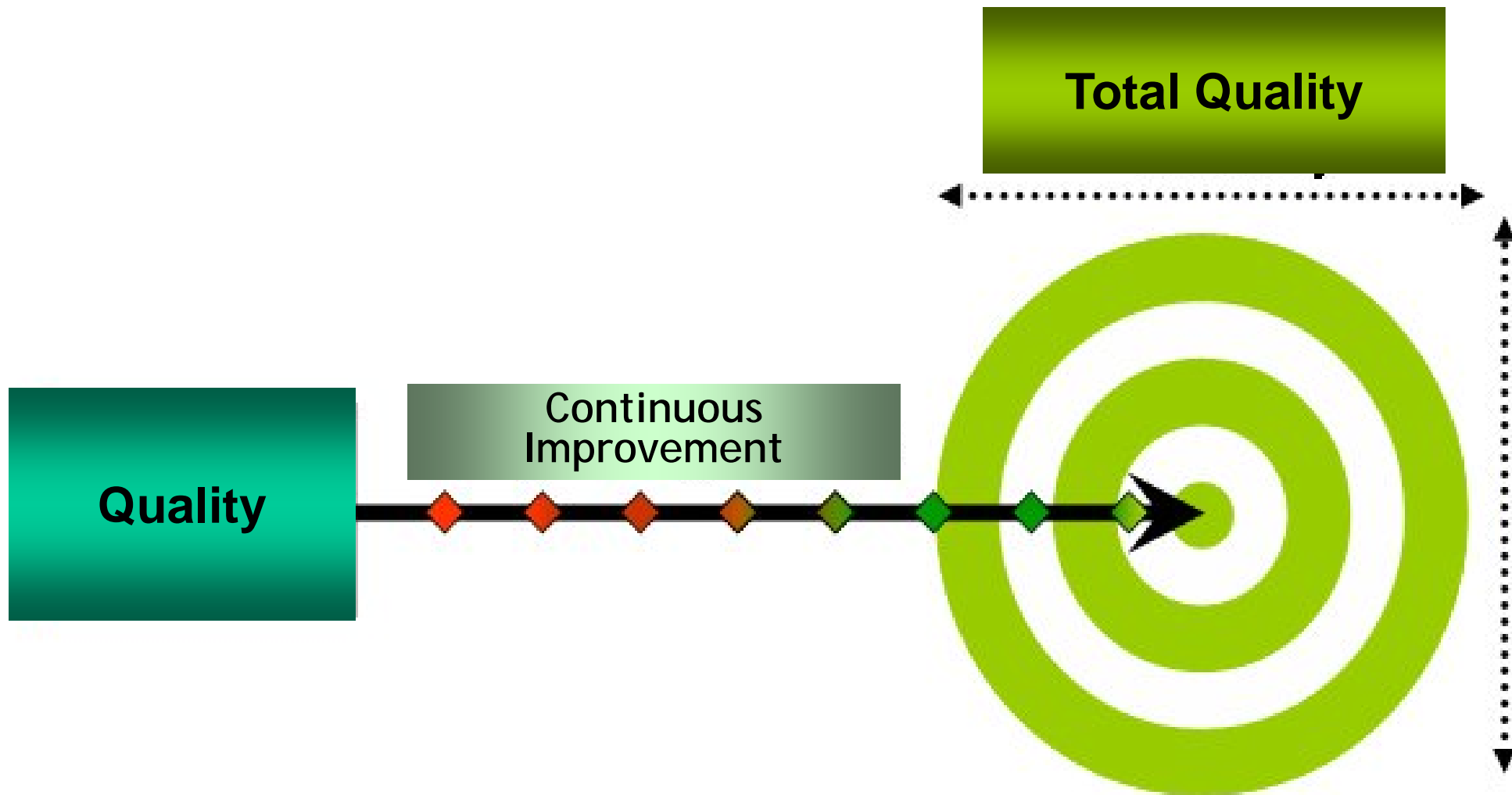


**President,
Organisation of Pharmaceutical Producers of India
Managing Director,
Wyeth Limited**

Ranga Iyer

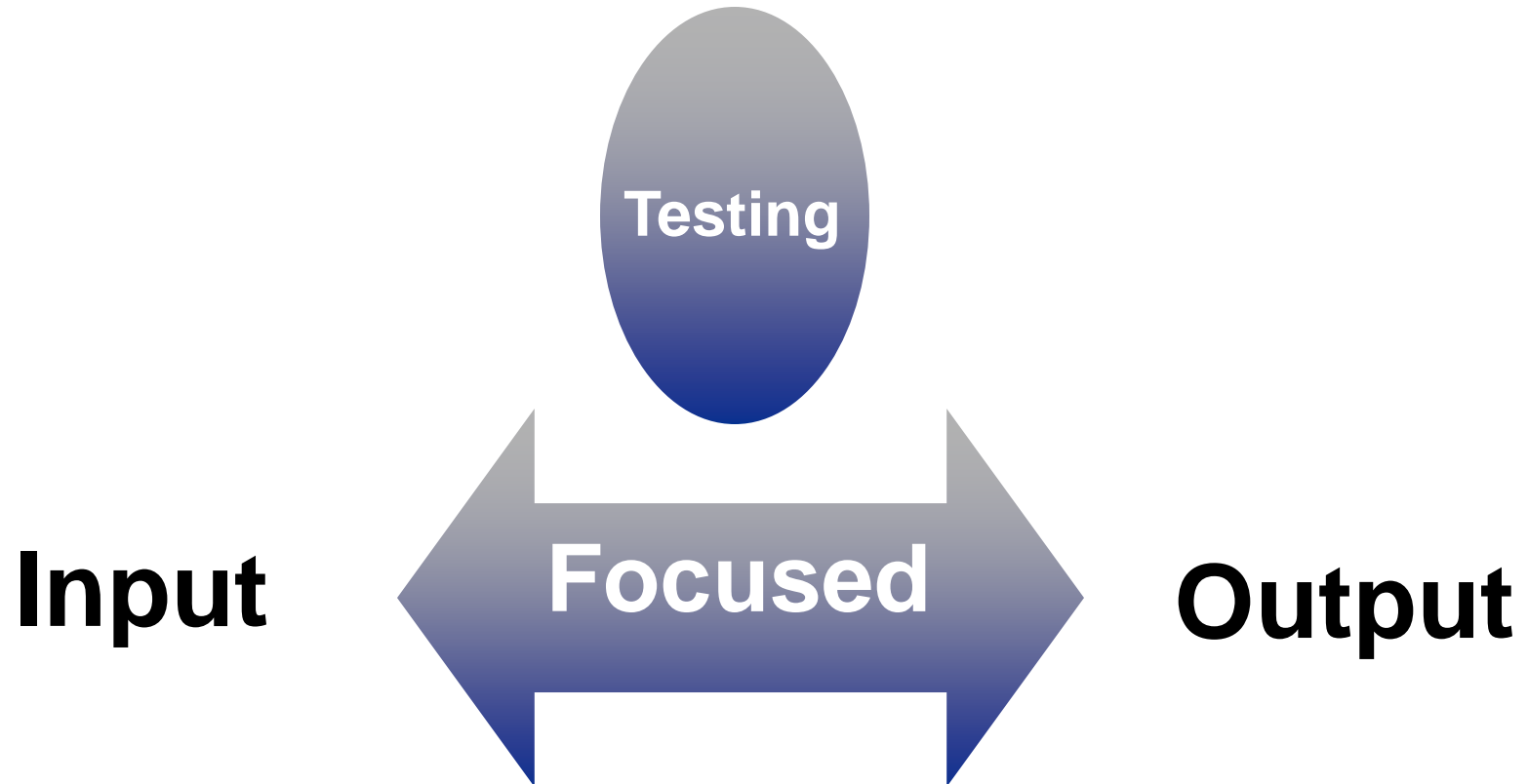


Quality – Changing Dimensions





Quality – Narrow Perspective





Quality Assurance Approach

Quality of care should be defined in light of both **technical standards** and **patients expectations**.

The QA Project approach to improving health services and individual performance incorporates **three core Quality Assurance activities**:





Meaning of Quality

Producer's Perspective

**Quality
of Conformance**

Production

✓ **Conformance to
Specifications**

✓ **Cost**

Doctor / Patient's Perspective

**Quality
of Design**

Marketing

✓ **Quality
Characteristics**

✓ **Price**

**Fitnesss for
Consumer use**



Quality Cycle



Focus
shifted to
Prevention



Life beyond Schedule M



Good Distribution Practices

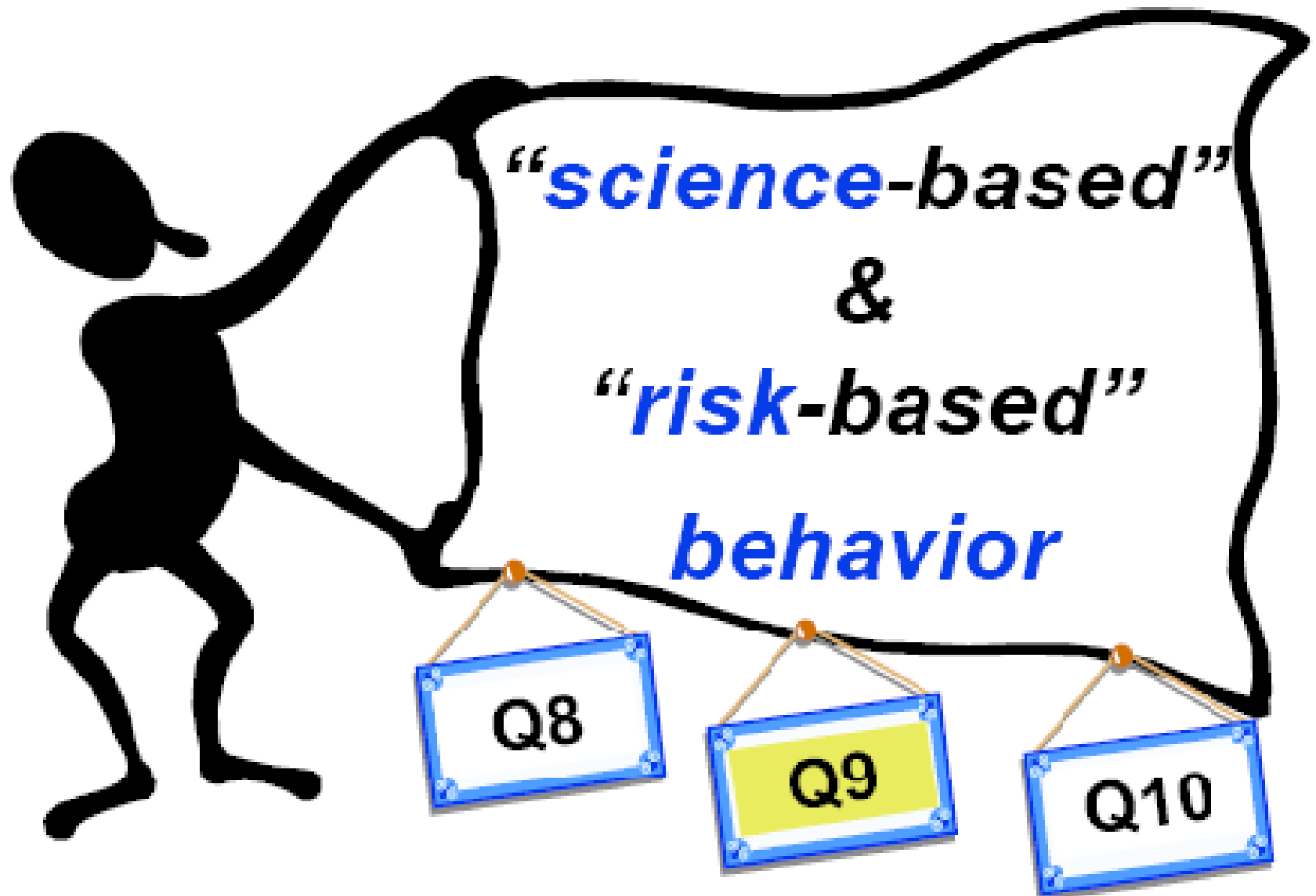
Good Warehousing Practices

Anti Counterfeit measures

Information to Patients

Export requirements

Harmonization of Quality Systems New Paradigm



Harmonization of Quality Systems

Incremental Steps



Pharmaceutical Development (Q8)

Past : Data transfer / variable output

Present : Knowledge Transfer / consistent output

Quality Risk Management (Q9)

Past : Used, However poorly defined

Present : Opportunity to use structured process Thinking

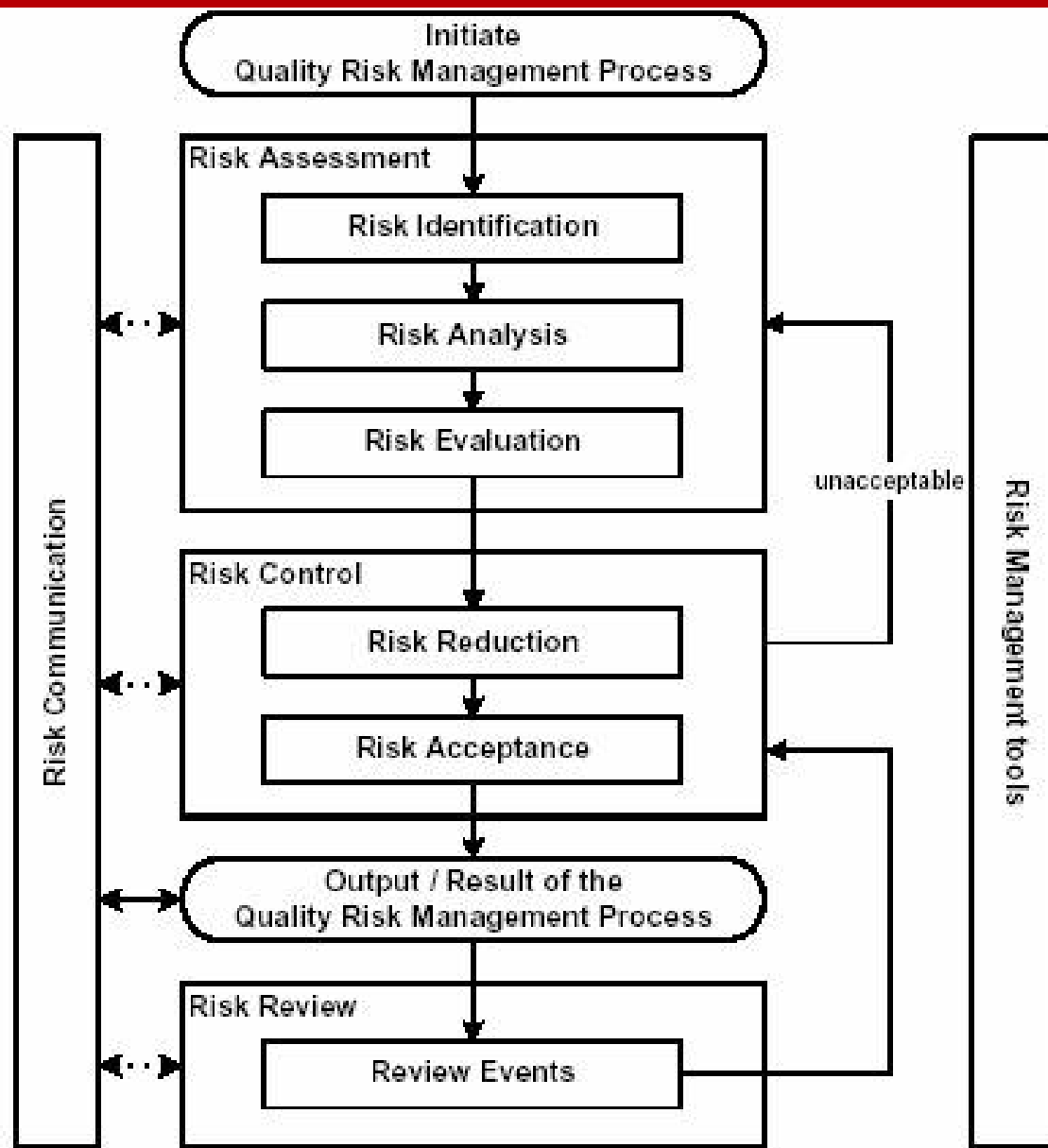
Quality Systems (Q10)

Past : Large variability on Q- Systems

Present : Consistency on Q – systems



Quality – Risk based approach



- Establish Risk Management Policy
- Risk Measurement Matrix
- Risk Escalation Matrix
- Identify Critical Risks / Control Measures / Residual Risk
- Periodical Review of existing Controls
- Anticipating new risks.



Quality Improvement Techniques

Continuous Improvement (CI):

A Business strategy for **ongoing improvement** of Safety, Quality and Efficacy of the product.

Operational Excellence (OE) :

Operational Excellence is a means of conducting business in a manner that **improves quality, obtains higher yields, faster throughput, and less waste.**

Process Analytical Technology (PAT) :

A system for designing, analyzing and controlling manufacturing through **timely measurements** of critical quality and performance attributes with goal of ensuring final product quality.



Quality by Design

A systematic approach

to development that

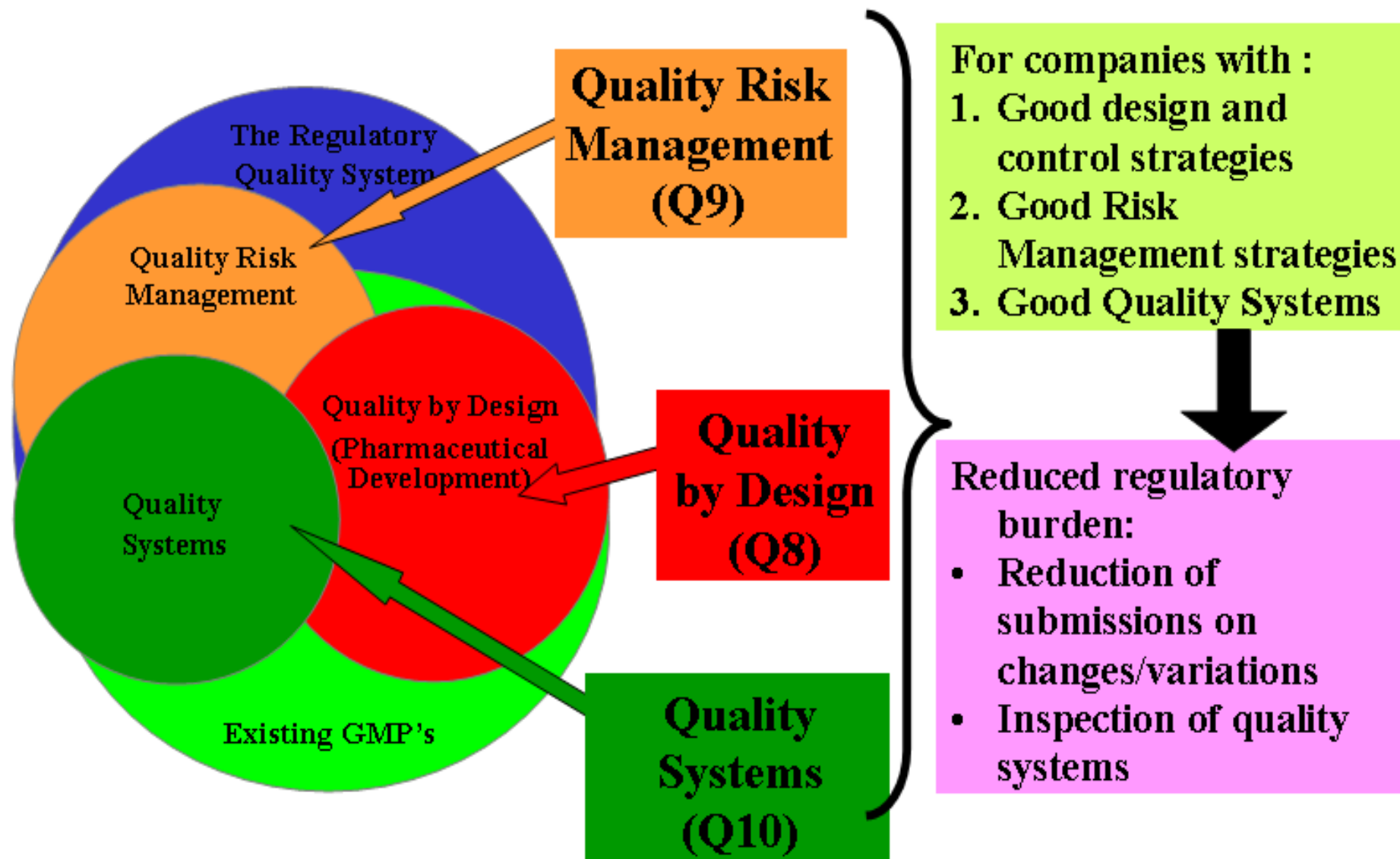
begins with predefined objectives and

emphasizes product and process understanding and process control,

based on sound science and quality risk management.



Future Quality Systems





Management Commitment

Management has greater commitment to and responsibility for

- **Establishing effective quality system**
- **Providing adequate resources**
- **Periodically evaluating quality system**
- **Making changes & adjustments**
- **Inculcate the Quality Culture in the Organization**





Total Quality

Key Strategies

The diagram illustrates the components of 'Total Quality'. At the top, 'Key Strategies' is written in blue. Below it, a central vertical black bar contains eight categories: 'Organisational Effectiveness', 'Laboratory Operations & Analytical Technology', 'Patient focussed Supply Chain', and 'Regulatory Excellence' on the left; and 'Customer Compliance Excellence', 'Product and Process Quality', 'Integrated Standardised System', and 'Product and Site Strategy' on the right. Each category is connected to a corresponding horizontal black bar that extends to the left or right of the central bar. A thin orange arc frames the entire diagram.

Organisational Effectiveness

Laboratory Operations & Analytical Technology

Patient focussed Supply Chain

Regulatory Excellence

Customer Compliance Excellence

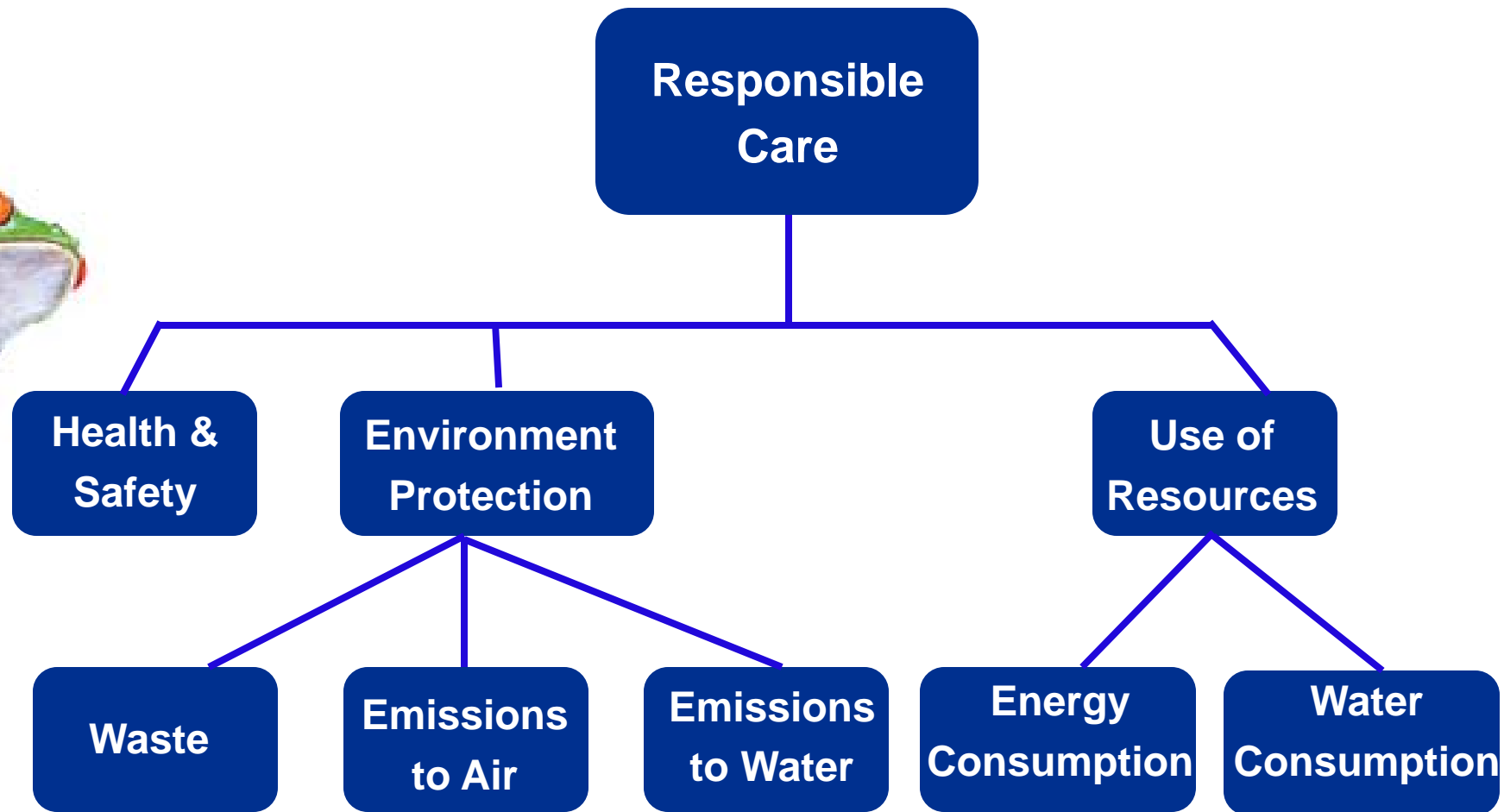
Product and Process Quality

Integrated Standardised System

Product and Site Strategy



Pharma Industry and Responsible Care





Quality – Changing Dimensions



**The Race for
Patient
Satisfaction
has
no Finishing Line**