

# Quality at Pfizer: More than a competitive advantage

Uma Iyer – Emerging Markets Quality Leader



# Our motto



**Critical to balance all three;  
We make difficult and tough choices...**  
*...however, compromise to Quality/Compliance is NOT an option*

# Pfizer Values



## Customer Focus

*commitment to meeting the needs of customers and constant focus on customer satisfaction*



## Quality

*Business practices and processes designed to achieve quality results that exceed the expectations of all stakeholders*

[https://www.youtube.com/watch?v=jYj\\_R4oCTPI](https://www.youtube.com/watch?v=jYj_R4oCTPI)

# What we do - R&D



**Science Driven Innovation**



**Operating in a collaborative  
cross company ecosystem**



**Collaboration between  
regulators**



**Therapies for unmet  
medical needs**



**Increased availability of  
medicines in emerging markets**

- Pfizer Global Supply - Internal and external

Manufacture all the products that are marketed by Pfizer  
*with a relentless focus on quality*

world-class performance with no tolerance for defects

leadership accountability for success

effectiveness over efficiency

elimination of identified defects

repeat deviations

rejection/reprocess/rework

# Establishing a Quality Culture GLOBAL SUPPLY

An environment in which each and every person understands and embraces their responsibility for protecting product quality and patients safety

Building a quality culture is not an easy task  
It does not happen just by accident

It requires the commitment of every person

Our final objective is to consolidate a collective accountability culture focused on our customers (both internal and external)

# To ensure we can reliably provide quality medicines to patients



## A robust quality culture is essential

# Definition of Quality Culture

Each individual takes ownership for quality outcomes



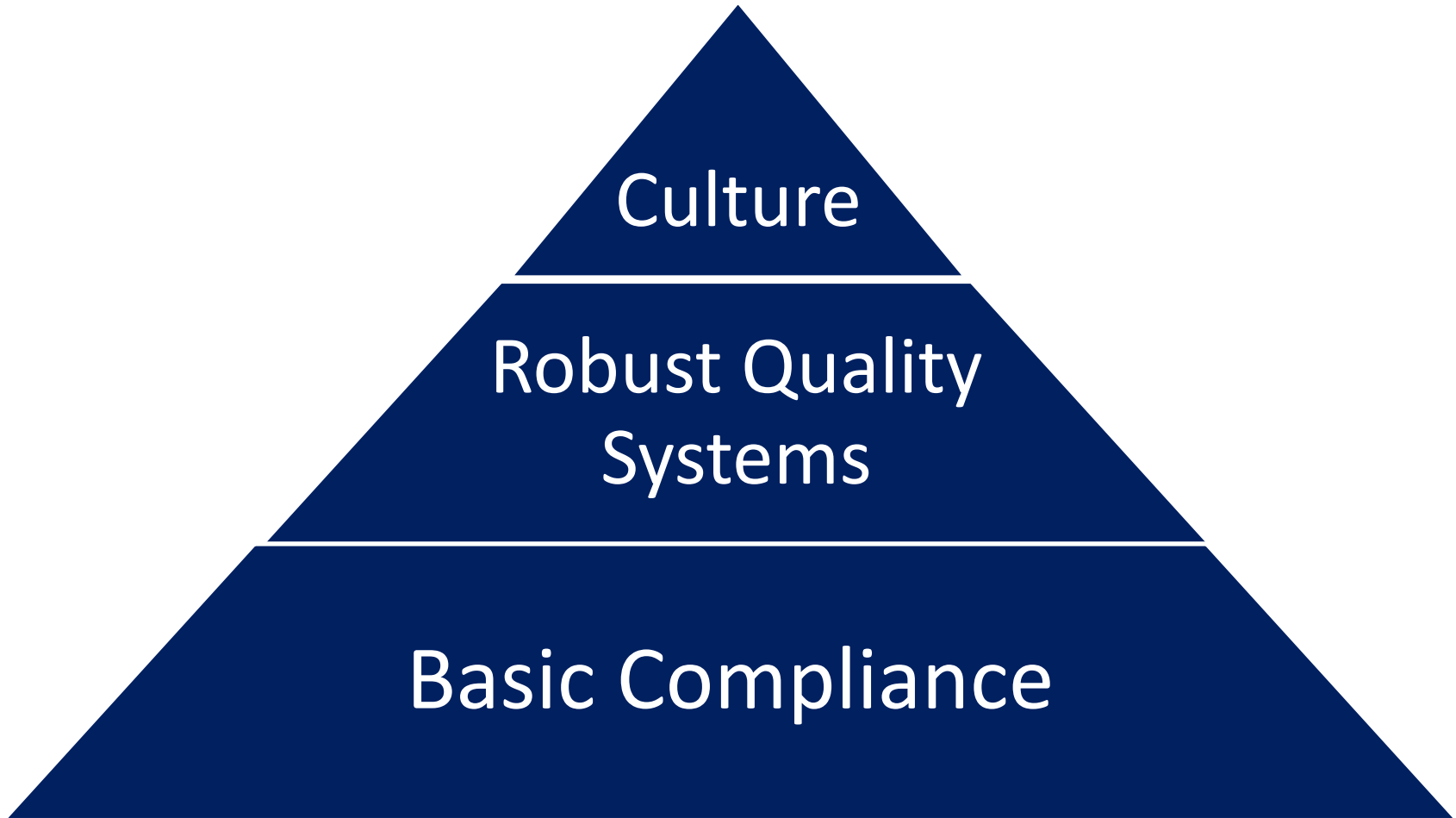
Decisions are made based on what is best for patients



Quality and safety are first - there is a conviction that this is a competitive advantage



# Building blocks of a sustainable quality performance



# Basic Compliance

Meeting the minimum requirements

May or may not include a fundamental understanding of “the why”

May be seen by some firms as a competitive advantage

Not enough to assure reliable quality supply

Does not enable transformation

# Robust Quality Systems

(As defined in ICH Q10) - the elements include

- Process performance and product quality monitoring
- Corrective and preventive actions
- Change management
- Management review

A significant step beyond basic compliance but still not enough

# Fully functioning quality system GLOBAL SUPPLY

The outcomes of the quality system are only as good as its inputs

Quality systems don't drive behaviors

Must understand decision-making



# Implementation of Quality Culture GLOBAL SUPPLY



Leadership

Focus on the Fundamentals

Continuous Improvement

Must create an organization that is capable of making decisions that protect product quality

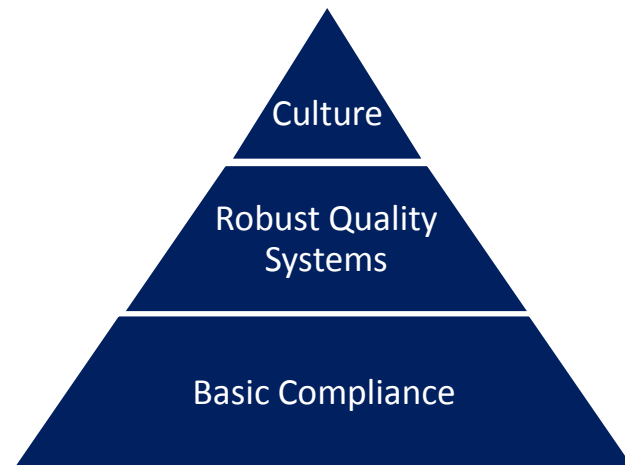
- Doing the right thing and doing things right is valued and rewarded
- Skilled resources are available for both preventive and corrective actions
- A balance is maintained between focusing on effectiveness and efficiency (lean vs RFT)

Must consistently demonstrate that strong quality performance with patients uppermost in mind is the expectation

## Must have the building blocks

Capable, adequately staffed workforce that understands “the why”

- Robust equipment, processes, and controls
- Well-maintained infrastructure
- Quality culture cannot exist in the absence of fundamentals



# Continuous Improvement



Relentless focus on driving improvements in all areas

Investment in systems, people, expertise, equipment, technology

Metrics and measures that are meaningful

Feedback loops for prevention, detection, correction



## Leadership Assessment

Extent of engagement in quality initiatives, metrics, issues

Level of engagement with employees on the importance of quality

Determine if leadership “walks the talk” by providing resources (people, time, money) and making decisions aligned with a quality and patient-centered focus

## Assess fundamentals

Investment in equipment and facilities

Span of control of supervisors

Extent of quarantine shipping

Quality on the floor

Amount of overtime/percent and tenure of temporary workers

## Assessment of continuous improvement

Robustness of self-inspection process

Use of APRs to identify and drive enhancements

Ppk calculated

Use of tools and completion of projects focused on enhancing quality

Use of visual management in the facility

Quality culture should be assessed on a regular basis and continually enhanced

All three building blocks of quality performance must be in place to achieve the desired state

