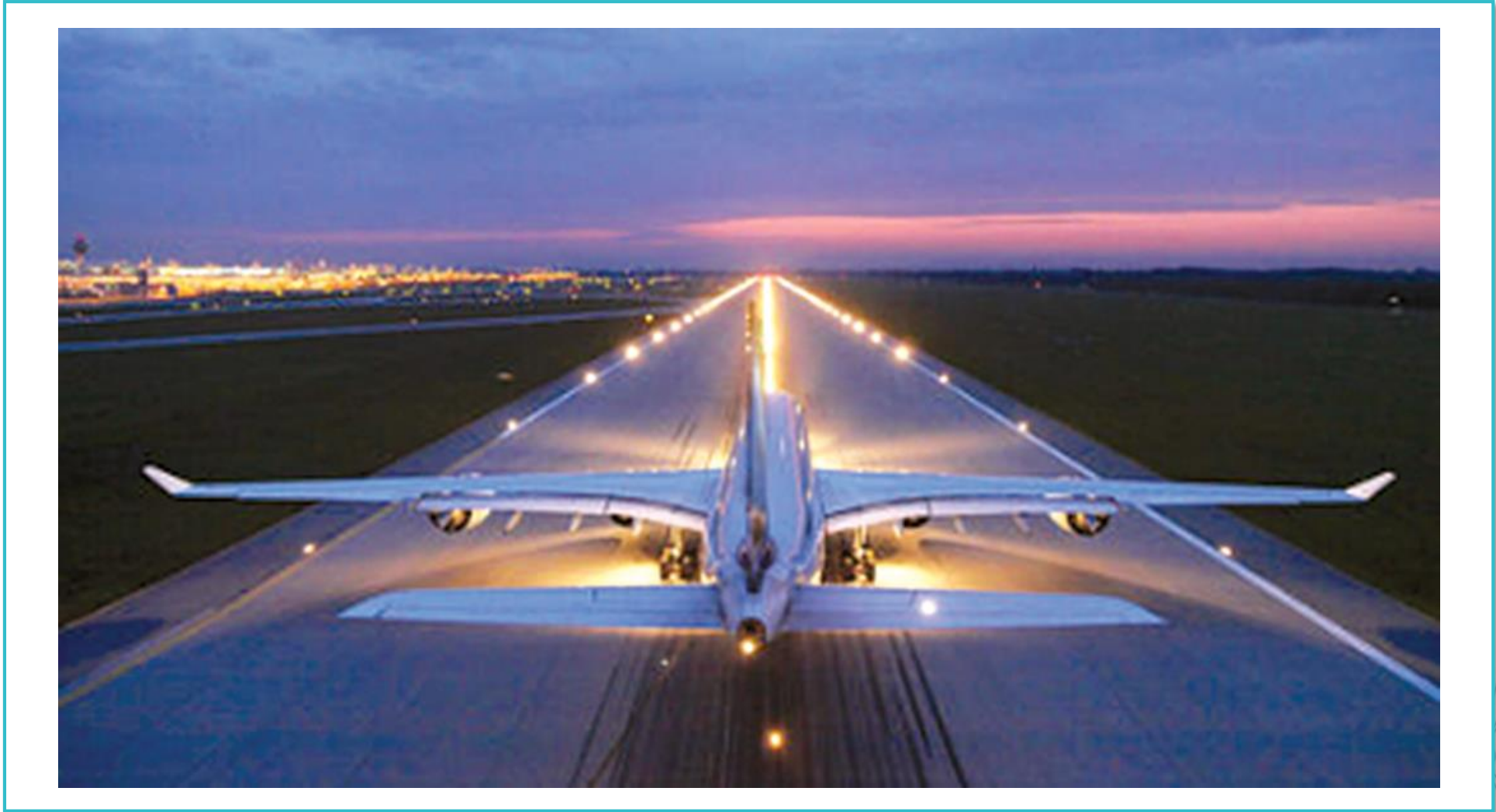


**Best Practices, Metrics and Symbolic Action**  
February 27-28, Mumbai

**Ms. Jila Breeze**  
Senior Vice President & Global Head, Quality and Compliance  
Sun Pharmaceutical Industries Limited



# Metrics : How Healthy is your Organization?



# Metric – Definition

## Dictionary meaning

noun; plural - metrics

*A system or standard of measurement.*

## FDA Definition

*Quality metrics are used throughout the pharmaceutical industry to monitor quality systems, processes and drive continuous improvement efforts in drug manufacturing. Quality Metrics (QM) are the refined and systematic representation of Quality manufacturing operation.*





# IPA Collaboration Programs Journey

## IPA QF Mission



Be the conduit of change through thought leadership, knowledge development, and best practice sharing

Measure, benchmark, and publicise the achievements of the Indian Pharma Industry in Quality

Expand the size and base of Quality talent in India

Deepen, and strengthen the industry's relationship with key stakeholders – both within and outside India

Provide platforms for members and other stakeholders to interact and network

The IPA Quality forum was setup 3 years back, by a group of 6 founding member companies, and supported by McKinsey & Company as their knowledge partner

# Metrics: Purpose for SUN ?

- Measure current performance to enable continuous improvement
- Bring cost efficiencies
- It is an expectation from Regulator Agencies
- Would enhance risk-based surveillance inspection
- Predicts future failures for prevention
- Reduce recalls
- Revert Quality related drug shortages



# A Glance at SUN Metrics and how does it helps us

Parameters used to measure quality, performance and analyze trends

- Assigned a weightage based on criticality
- Quality score for each parameter in percentage
- Overall Site Quality Index is cumulative score of individual parameters
- Targets set for Site Quality Index
  - >95 : Green
  - 85-94 : Yellow
  - ≥85 : Red

## Scoring Parameters

- Change Control (CC)
- Unplanned Deviation (UPD)
- Out of Specification (OOS)
- Corrective and Preventive Action (CAPA)
- Product Quality Complaint (PQC)
- Lot Rejection Rate / Lot Failure Rate
- Stability
- Regulatory Inspections
- Field Alert Report
- Product Recall / Sales Return
- Right First Time

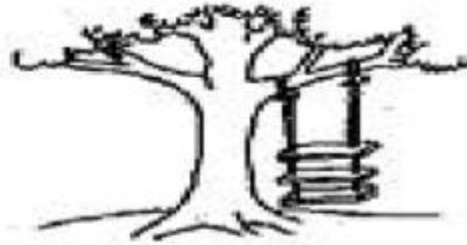
## Monitoring Parameters

- Lot(s) Pending for Disposition > 30 Days
- Lot(s) Reprocessing Rate
- Out of Trend (OOT) and Laboratory Event
- Environment Monitoring and Media Fills
- QC Productivity
- Service Level – Testing turnaround time
- Instrument Utilization
- Adherence of Preventive Maintenance / Calibration / Qualification schedule
- Scale-up / Pre-validation issues
- Internal Audit observation closure
- Quality cost and Manpower Ratio

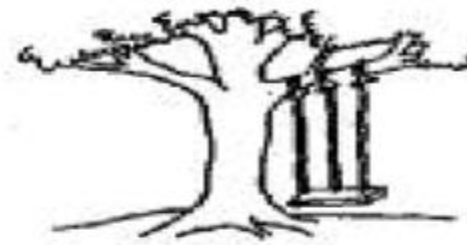


# Harmonized Definition is a Must

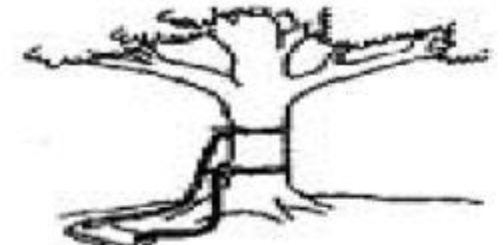
- Each one will measure based on what they wants
- Align on the purpose and requirement and measure uniformly , assure your data is accurate



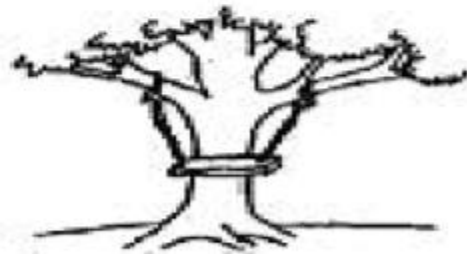
**As proposed  
by the project  
sponsor.**



**As specified  
in the project  
request.**



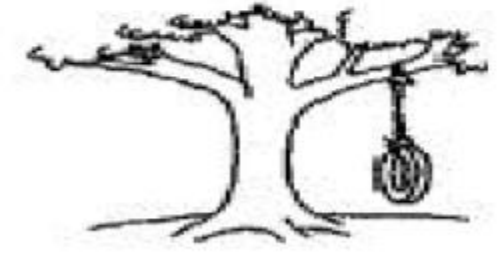
**As designed  
by the senior  
architect.**



**As produced  
by the  
engineers.**



**As installed at  
the user's  
site.**



**What the  
customer  
really wanted.**

# Tools as enablers for Data Analysis and Trending globally in a reliable manners

TW Workflows for:

- Change control
- Investigations
- OOS
- CAPA
- Deviations
- Complaints
- Global Assessments
- Recall Management



- Learning Management
- Curriculum based on Roles
- Training Material
- Employee Database

Quality Management Systems

QC Laboratory

Business Process Procurement-to-Release

Document Control & Management

Training & Learning



- Approved Test Procedures and Specification for raw material, packaging material and finished product on LIMS
- Sample management and results in LIMS
- Chromatography instrument on Empower 3



Policy, Standards and Procedures on EDMS



# Example – Global Quality Index Dashboard

## Quality Index Dashboard

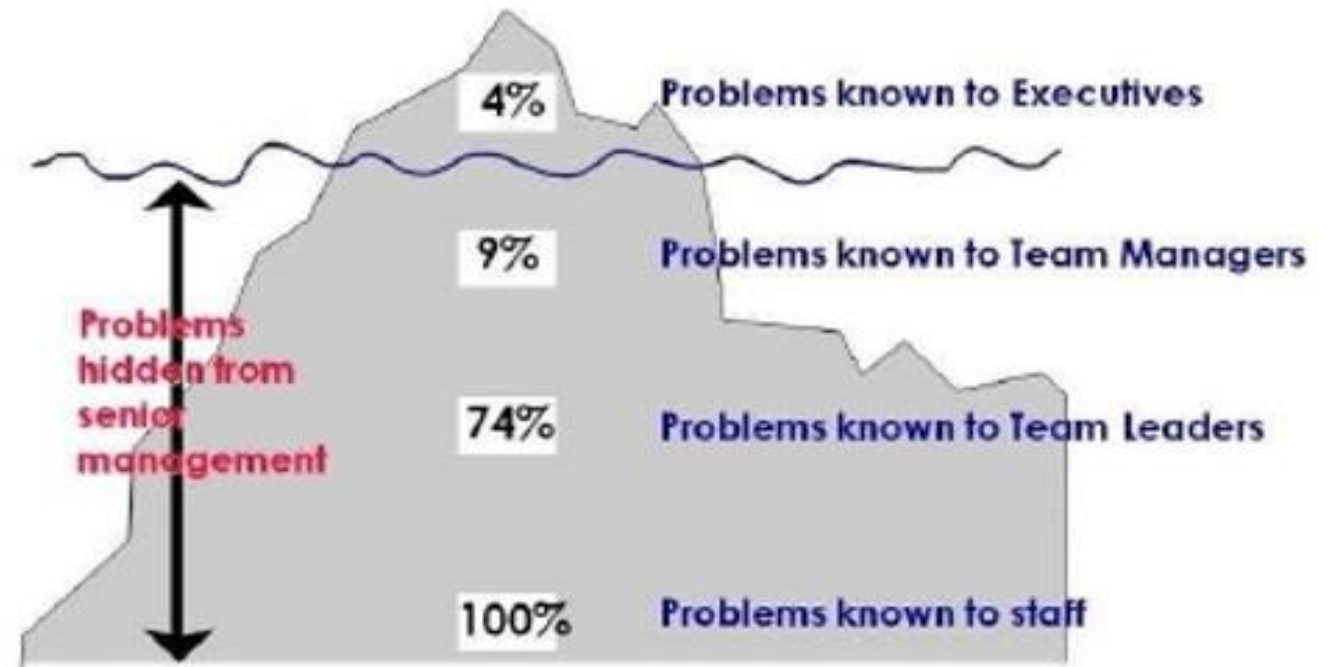
Target ≥ 95 85-94 < 85

Sites Name	Quality Index	Parameter												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Site 1	99	10.0	10.0	10.0	10.0	2.0	8.0	10.0	2.0	8.0	10.0	2.0	8.0	8.9
Site 2	76	4.7	4.0	10.0	5.0	2.0	8.0	7.3	2.0	8.0	4.8	NA	10.0	9.8
Site 3	99	10.0	10.0	10.0	10.0	2.0	8.0	10.0	2.0	8.0	10.0	NA	10.0	9.5
Site 4	88	10.0	10.0	10.0	5.0	2.0	8.0	5.0	2.0	6.5	10.0	NA	10.0	9.3
Site 5	100	10.0	10.0	10.0	10.0	2.0	8.0	10.0	2.0	8.0	10.0	NA	10.0	9.6
Site 6	99	10.0	10.0	10.0	10.0	2.0	8.0	10.0	2.0	8.0	10.0	2.0	8.0	9.4
Site 7	100	10.0	10.0	10.0	10.0	2.0	8.0	10.0	2.0	8.0	10.0	NA	10.0	10.0
Site 8	100	10.0	10.0	10.0	10.0	2.0	8.0	10.0	2.0	8.0	10.0	NA	10.0	9.9
Site 9	100	10.0	10.0	10.0	10.0	2.0	8.0	10.0	2.0	8.0	10.0	NA	10.0	10.0
Site 10	95	10.0	10.0	10.0	10.0	2.0	8.0	5.0	2.0	8.0	10.0	NA	10.0	10.0
Site 11	95	10.0	10.0	10.0	10.0	2.0	8.0	5.0	2.0	8.0	10.0	2.0	8.0	9.8
Site 12	100	10.0	10.0	10.0	10.0	2.0	8.0	10.0	2.0	8.0	10.0	NA	10.0	10.0
Site 13	95	10.0	5.0	10.0	10.0	2.0	8.0	10.0	2.0	8.0	10.0	2.0	8.0	9.8
Site 14	83	10.0	10.0	10.0	5.0	2.0	8.0	10.0	2.0	8.0	5.0	NA	10.0	9.8
Site 15	89	5.0	10.0	10.0	10.0	2.0	8.0	10.0	2.0	8.0	5.0	NA	10.0	9.3
Site 16	93	10.0	10.0	10.0	10.0	2.0	8.0	10.0	2.0	6.8	10.0	NA	5.0	9.7
Site 17	85	5.0	5.0	10.0	5.0	2.0	8.0	10.0	2.0	8.0	10.0	NA	10.0	9.6

# Metrics: How to look at Data? Who should look at the Data?

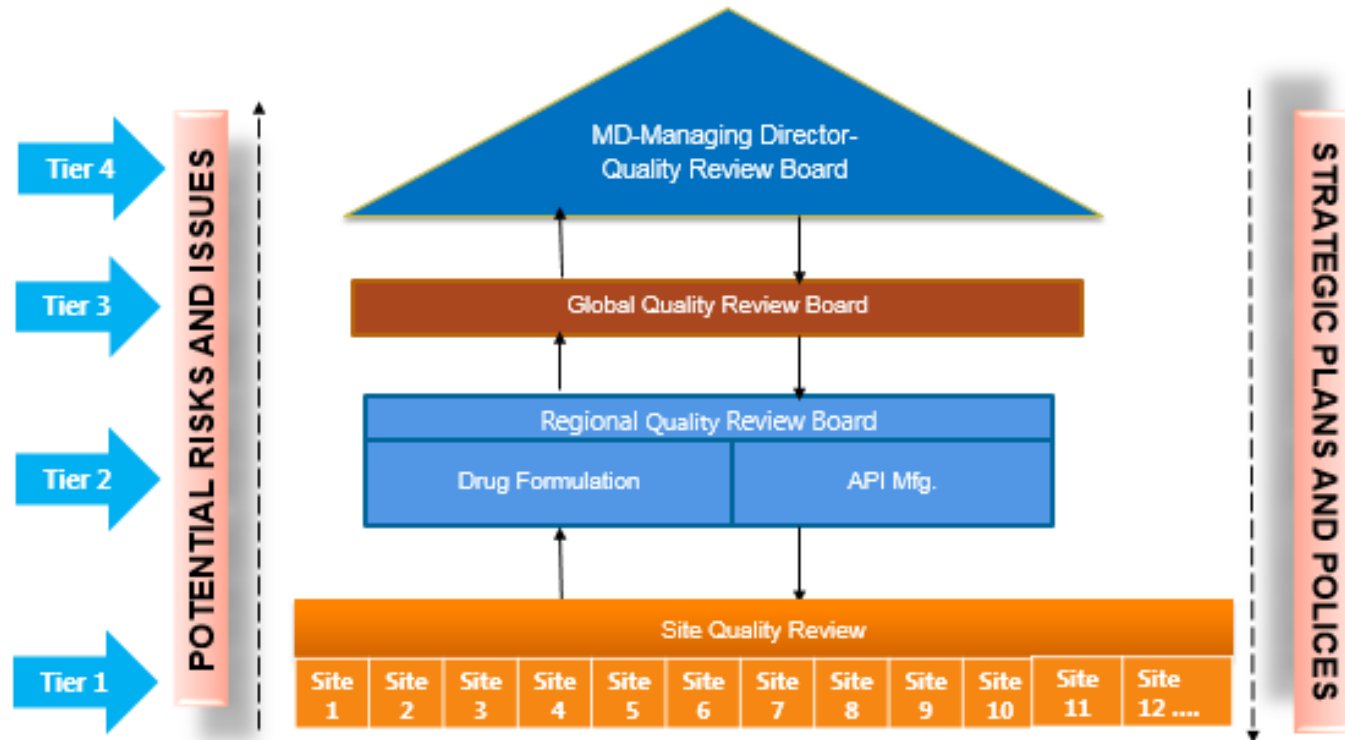
- Why we want to measure?
- What should be measured?
- How do we measure?
- What do we want to achieve?
- Analytics for actions and solutions

## The Iceberg Of Ignorance

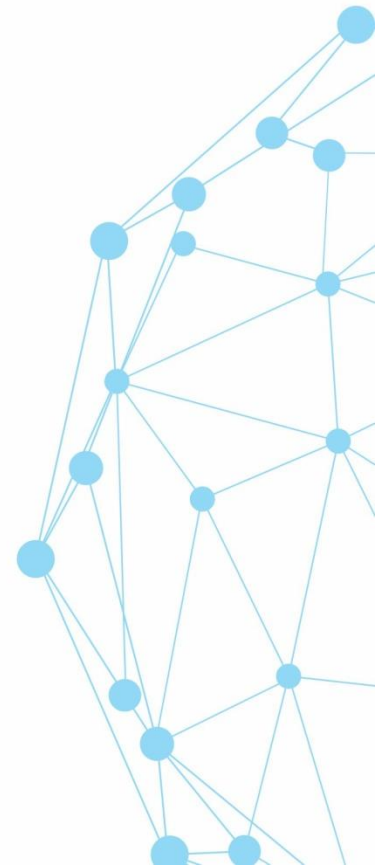


# Metrics Governance and Review Structure

Cross functional involving Quality, Operation, R&D



The management of QRBs shall be executed as a four tier process.





# Shop Floor : Knowing how the Products are doing?

MARKET COMPLAINT ACTION POINT

OEE

PROJECTS

PROCESS-45

TYPE OF QUALITY DEFECTS

information:

knowledge:

@yungreal

**WHAT IS DATA INTEGRITY ?**

**ALCOA CONCEPT**

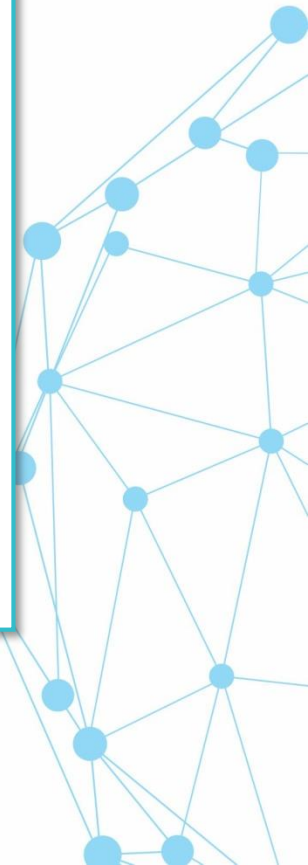
- ATTRIBUTABLE**
  - ✓ Attributable to the person generating the data.
  - ✓ Who performed an action & when?
  - ✓ If a record is changed, who did it & why ?
- LEGIBLE**
  - ✓ Legible (readable) & permanent.
  - ✓ Accessible throughout the data lifecycle.
- CONTEMPORANEOUS**
  - ✓ Data recorded at the time the work is performed.
  - ✓ Date / time stamps should follow in order.
- ORIGINAL**
  - ✓ Original record or a "true copy".
  - ✓ Content & meaning is preserved.
- ACCURATE**
  - ✓ No errors or editing performed without documented amendments.
  - ✓ Conforming to truth or standard.
  - ✓ Free from Error.

REFERS TO THE COMPLETENESS, CONSISTENCY AND ACCURACY OF DATA.

WALL OF APPRECIATION

IDEA GENERATION

PERFORMANCE DASHBOARD



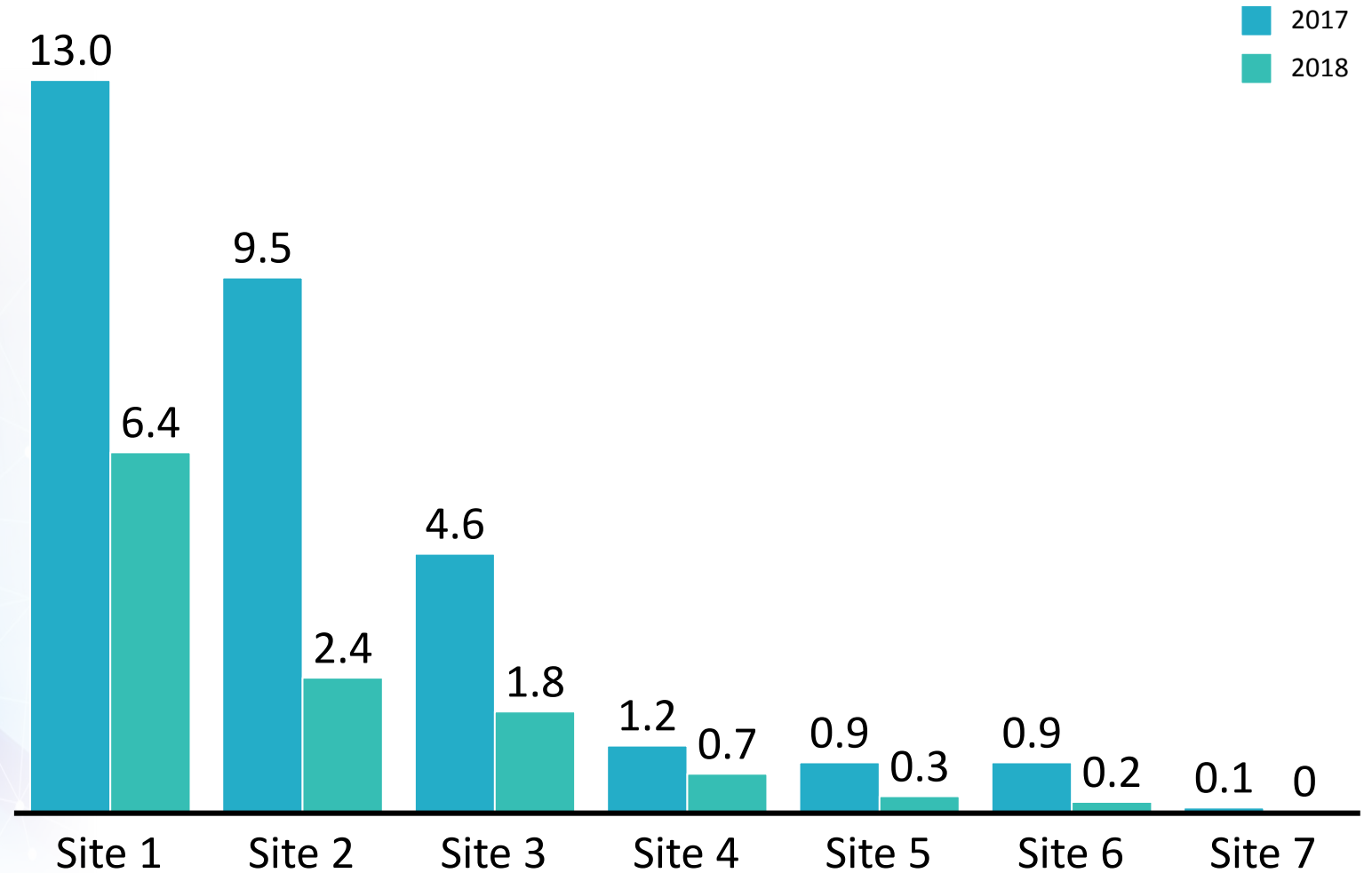
# Training



- Trainer/Coach Qualification Program
- Integrated Site Training Calendar
- Corporate GMP/GxP Training Programs
  - GxP Training Library available 24x7
  - On-going GMP Training
  - On-Boarding GMP Training
- Technical Functional Training Programs
  - Operations Program
  - Sun Pharma Quality Control Program (SPQC)
  - Six Sigma Training for Product Performance and Statistical Analysis
  - Corporate Quality Certification programs: Auditor, Investigator/Approver and Microbiologist
- Behavioral Training and Development Programs
  - Leadership Capability
  - Managerial Capability
  - Supervisor Skills
  - Operator Level

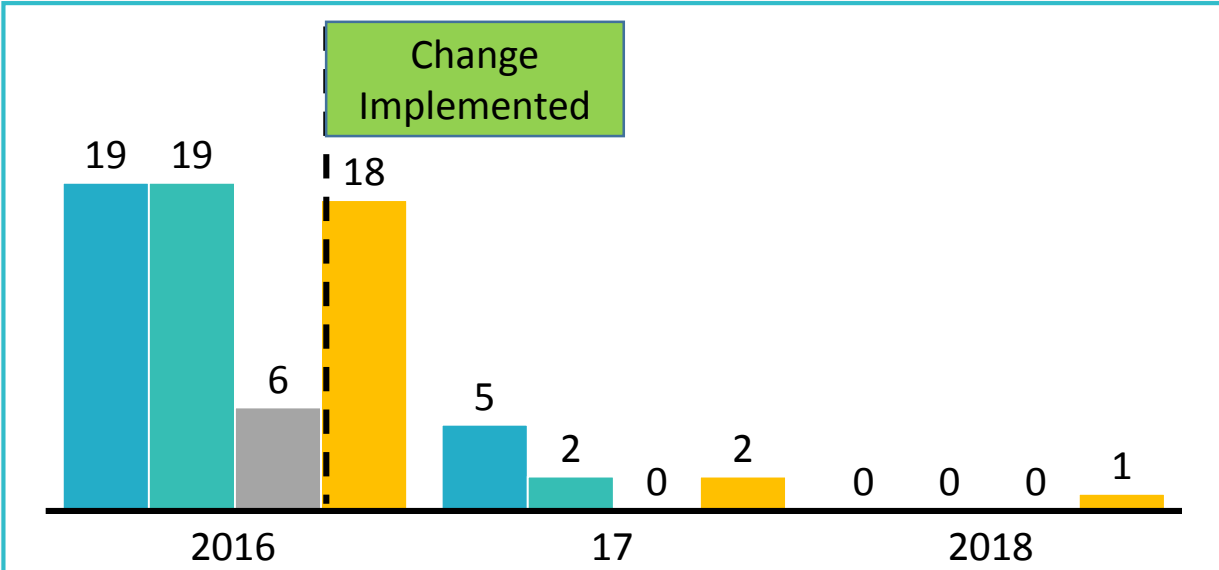
# Example 1 –Lot Rejection

- Assessment of individual rejection to understand whether it is product issue or operational failure
- Statistical trend analysis to understand process capability index and understand the repetitive nature
- Analyze the root cause and fix the problem by correcting the process / analytical method / material / equipment
- Example – dissolution failure due to method change



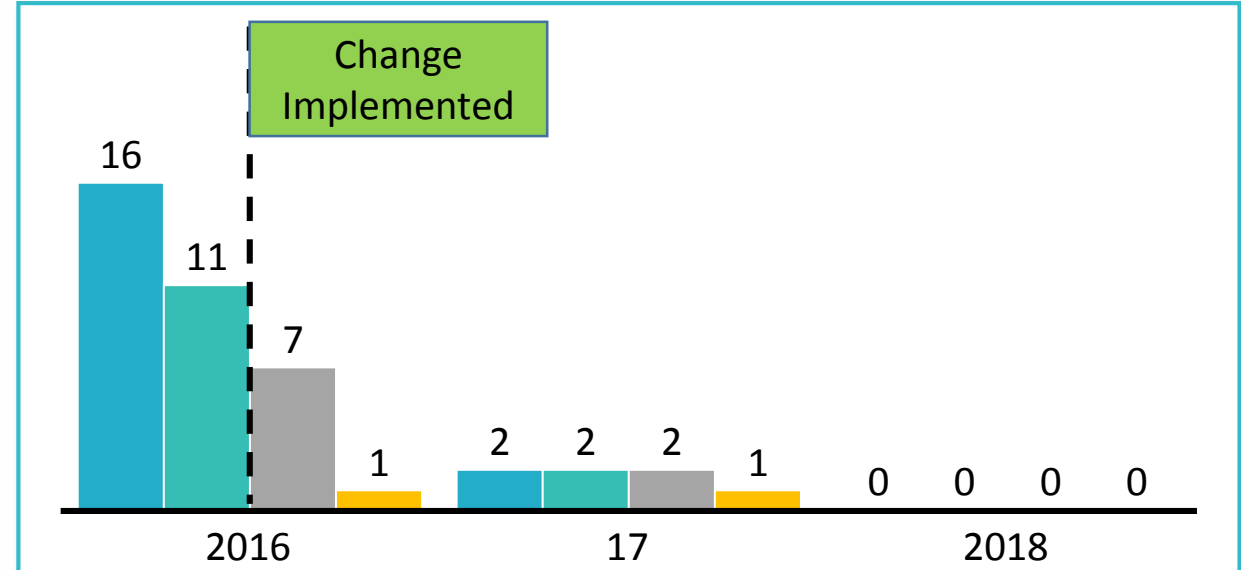


# Example 2 – Product Complaints



## Product 1 - Nasal Spray

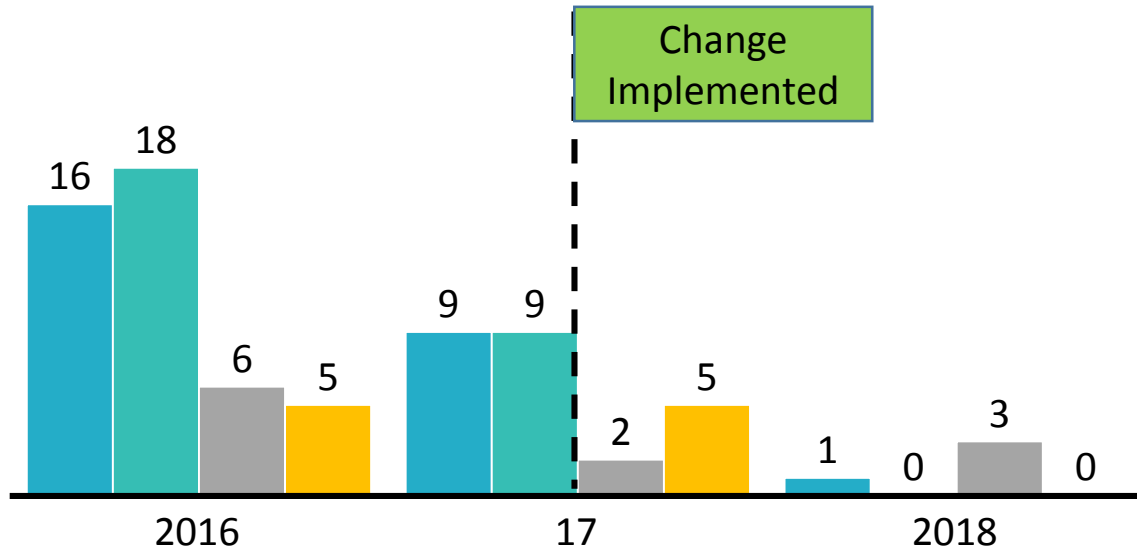
Complaint	Non-operation of device
Root Cause	Complex device operating instructions
Corrective actions:	Design of the device changed for easy operation by end user



## Product 2 - Tablets (Bottle Pack)

Complaint	Broken Desiccant
Root Cause	Silica/Carbon particles coming out of desiccant canister
Corrective actions:	Canister replaced with Sachet

# Example 3 – Product Complaints

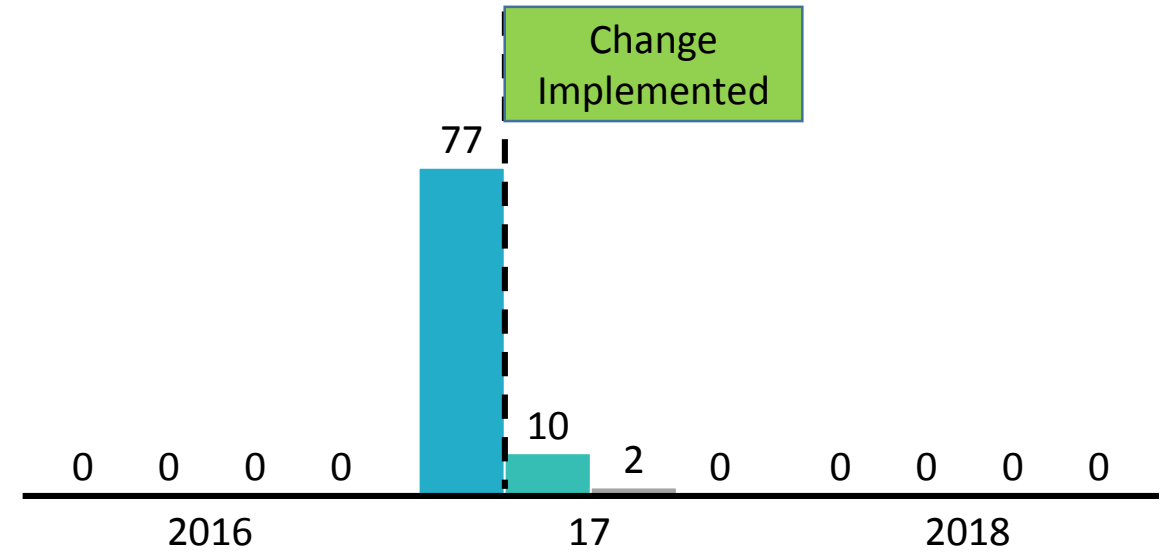


## Product 3 – Tablets (Bottle Pack)

Complaint Broken Tablets

Root Cause Shape and size of the desiccant container

Corrective actions:  
Shape of desiccant container changed



## Product 4 - Tablets (Strip Pack)

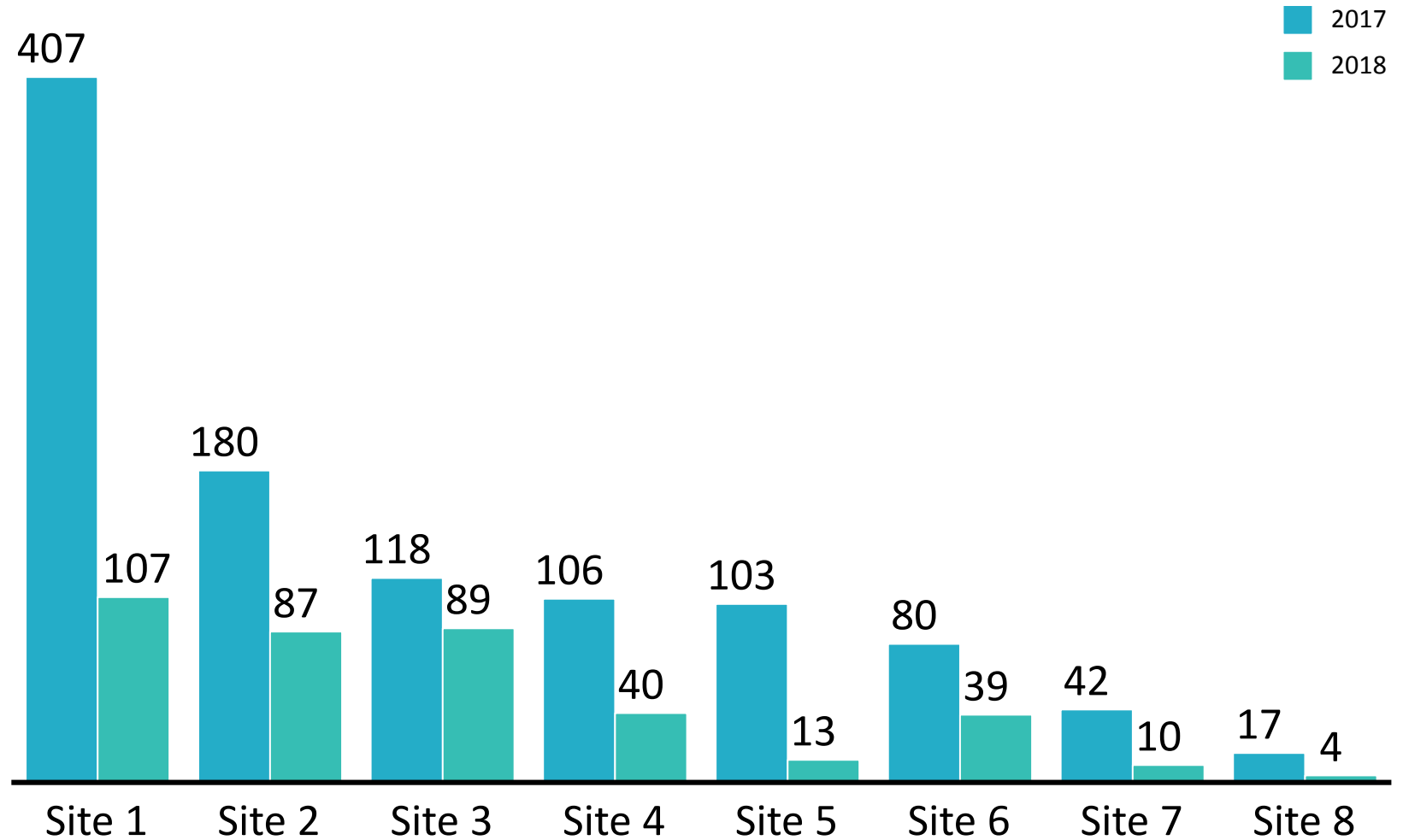
Complaint Bad Smell and Taste

Root Cause Primary packing material (Al foil) containing ethyl acetate in ink used for printing

Corrective actions:  
Change to solvent free ink for printing on Al foil

# Example 4 – Invalidated OOS *due to Human Error*

- Establish investigation teams to help identify correct root cause
- Revise test procedures to include clear instructions for chemist
- Providing test kits to the chemist which includes all glassware required for testing
- Feedback from chemist converted into solution themes for improvement

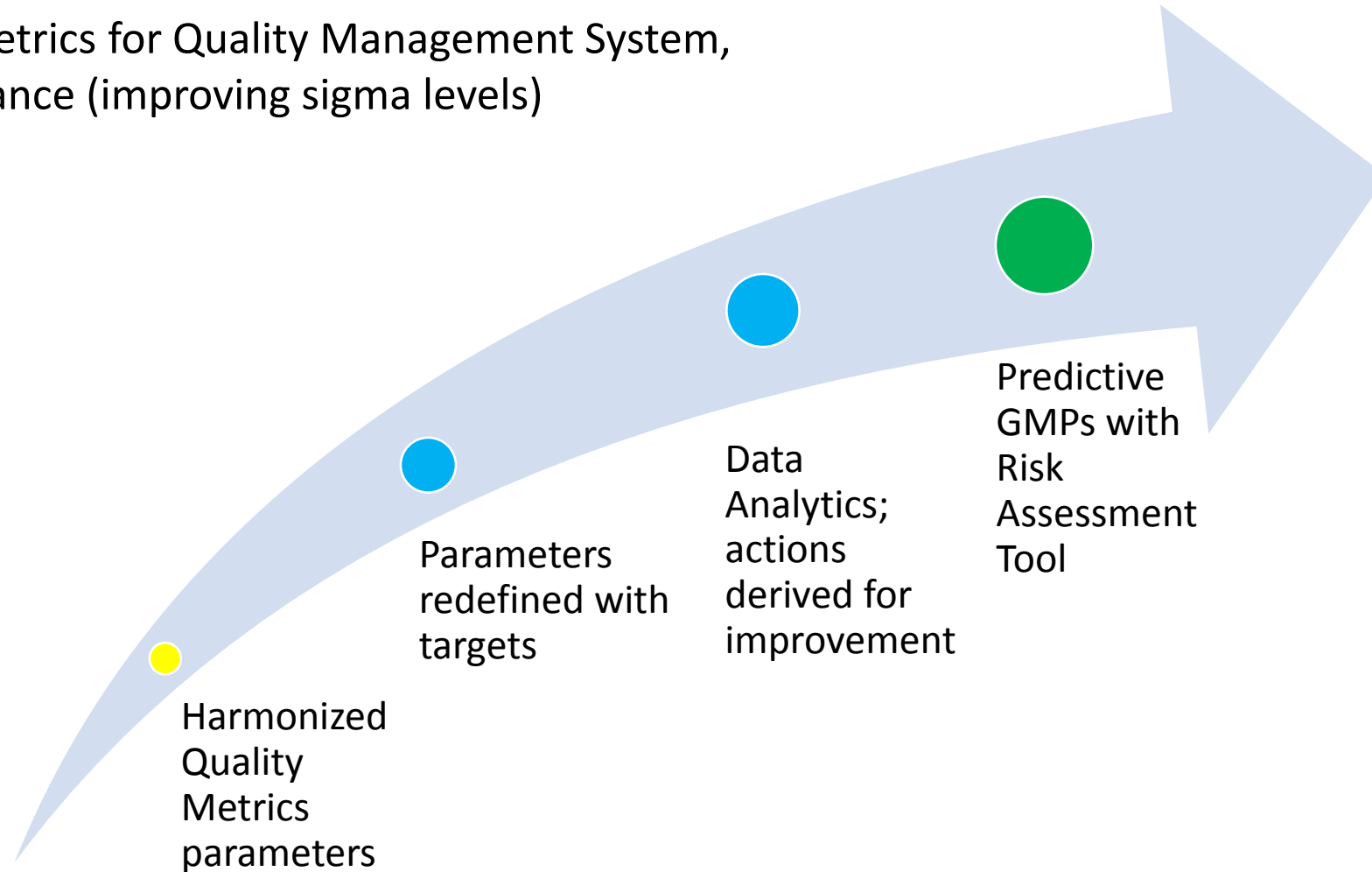




# Sun - Quality Metrics Journey

Expanding, beyond metrics for Quality Management System,  
into Product performance (improving sigma levels)

Started this journey  
in 2015

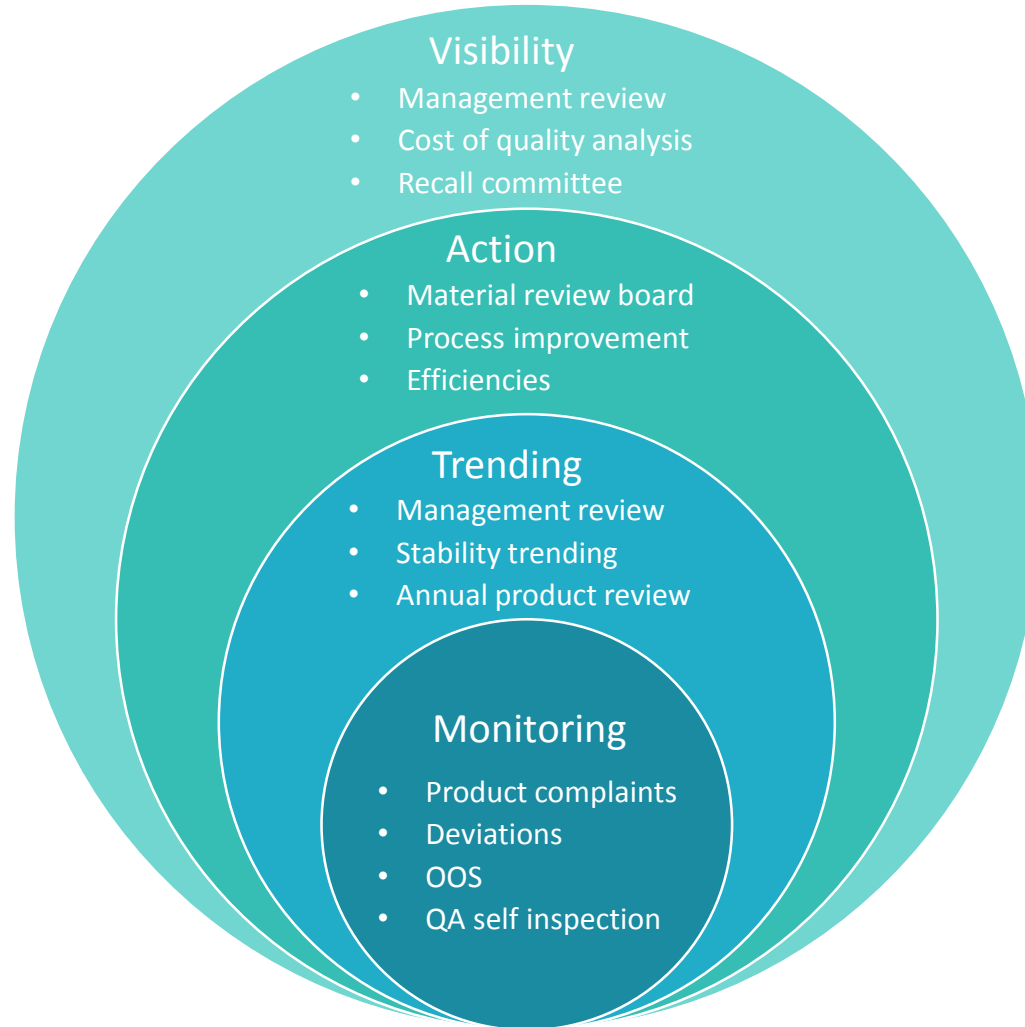


Currently aiming  
in 2019

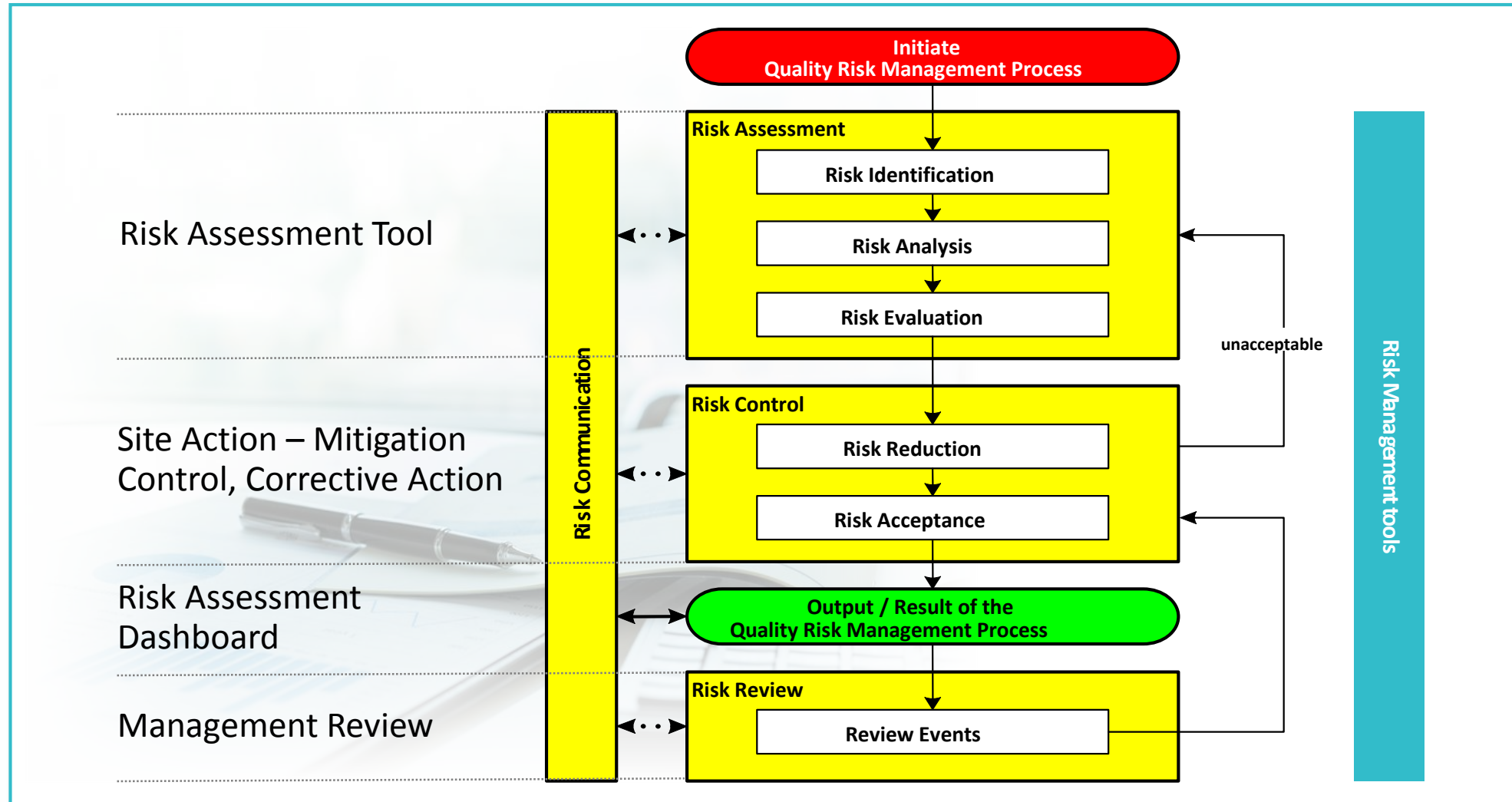
# Risk and escalation

Risk visibility

Quantity



# Overview of Site Risk Assessment Model

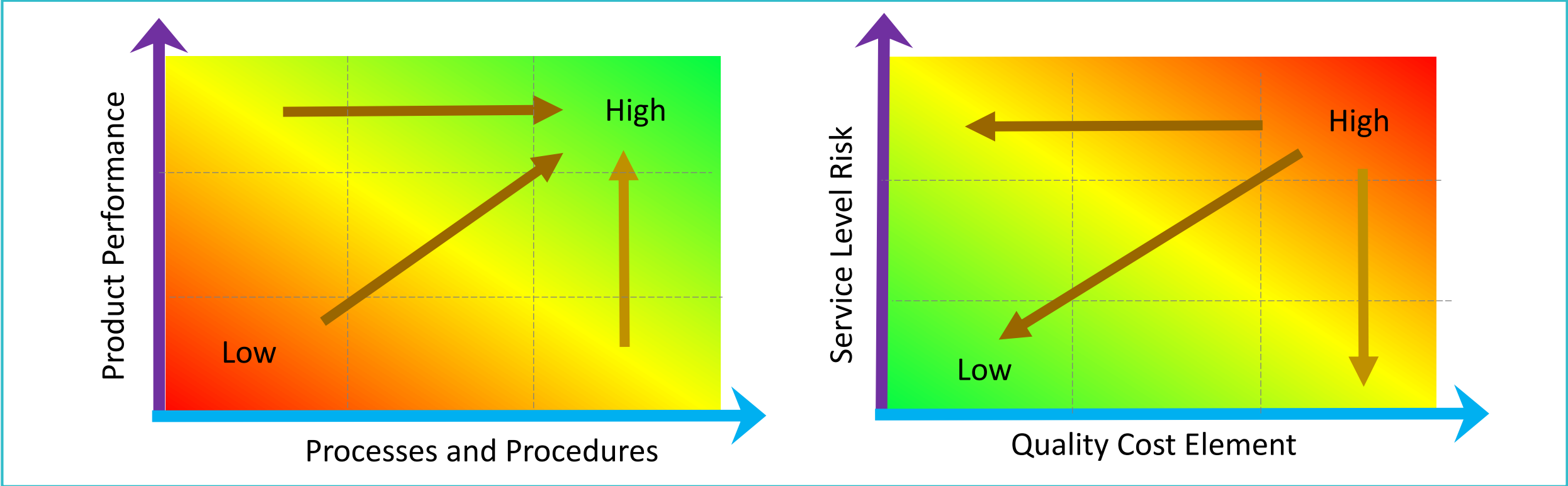




# Risk Assessment Tool

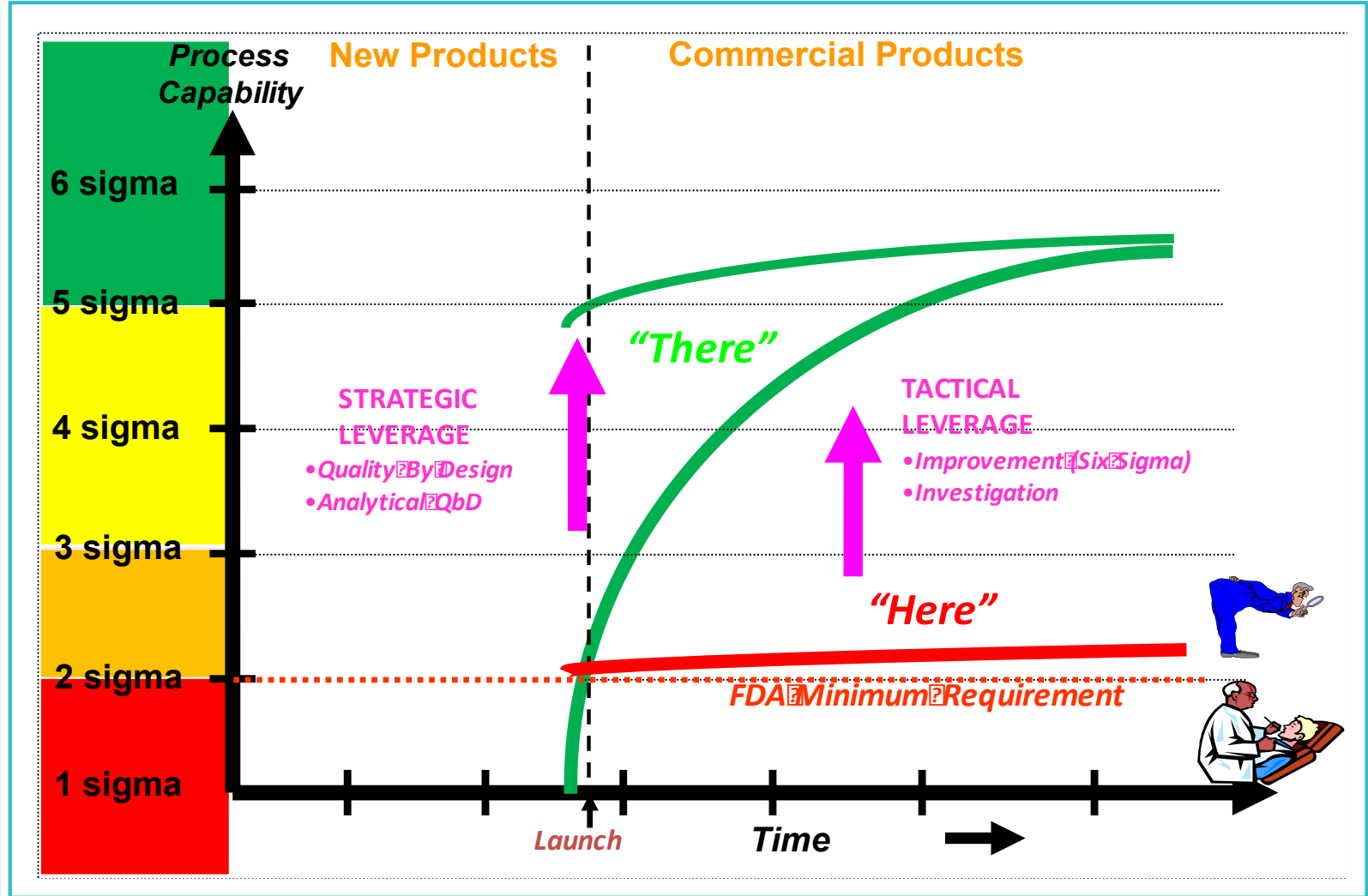
Risk Assessment Tool covers

- GMP Compliance: Processes & Procedures and Product Performance
- Business: Service Levels and Quality Cost Element



# Product Quality – True Root Cause Analysis

- 21st Century Quality Initiative for supplying robust products to patients
- An initiative on the lines of ICH Q10 for Product Lifecycle Management including post approval changes
  - Process Understanding
  - Product, Process & Analytical Assessment
  - DMAIC approach for improvement
  - Filing changes with Regulatory agency



# Product Quality – PUR and PAR

## ❑ Product Understanding Report (PUR)

- Process Map
- Product & Process details
- Specifications
- Fish Bone – mapping the CQAs to the process steps
- Control Strategy for materials and process steps
- Heat map & FMEA for process parameters and its variable versus impact on CQAs
- Heat map & FMEA for analytical method and its variable versus impact on CQAs
- Risk Assessment for input material attributes versus CQAs
- Risk Assessment for CPPs versus CQAs

## ❑ Product Assessment Report (PAR)

- Statistical evaluation of historical data
  - Critical Process Parameters
  - Critical Process Attributes
  - Stability Data and Trends
- External Quality Assessment
  - Confirmed Market Complaint
  - FAR
  - Recall
- Internal Quality Assessment
  - Confirmed OOS (In-process, Finished product, Stability)
  - Major Changes
- Define Sigma Level for the Product



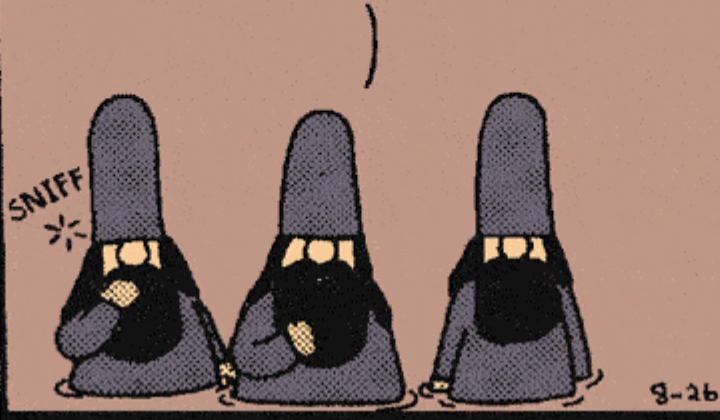
DILBERT TEACHES ELBONIA  
"TOTAL QUALITY" METHODS.

YOU START BY  
IDENTIFYING  
PROBLEM AREAS.



S. ADAMS E-Mail: SCOTTADAMS@AOL.COM

HMM... SOMETIMES OUR  
MITTENS GET STUCK TO  
OUR NOSES AND WE  
CAN'T BREATHE.



9-26

YORGI! TRY  
TO BREATHE  
WITH YOUR  
MOUTH!

PEOPLE!  
LET'S TALK  
METRICS,  
PLEASE!

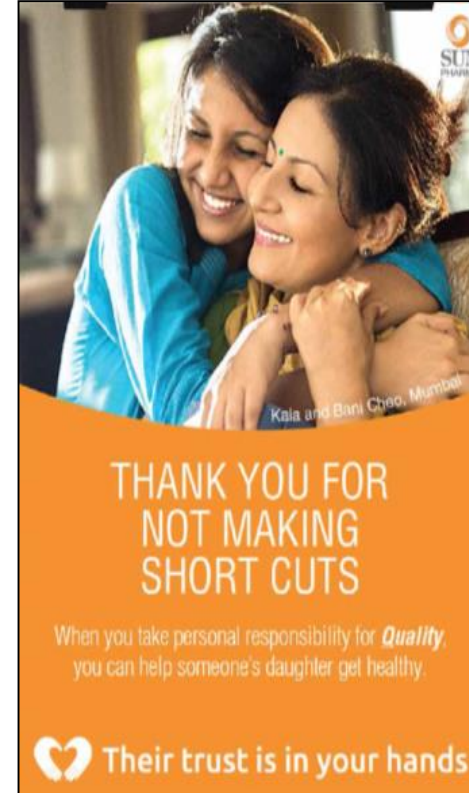


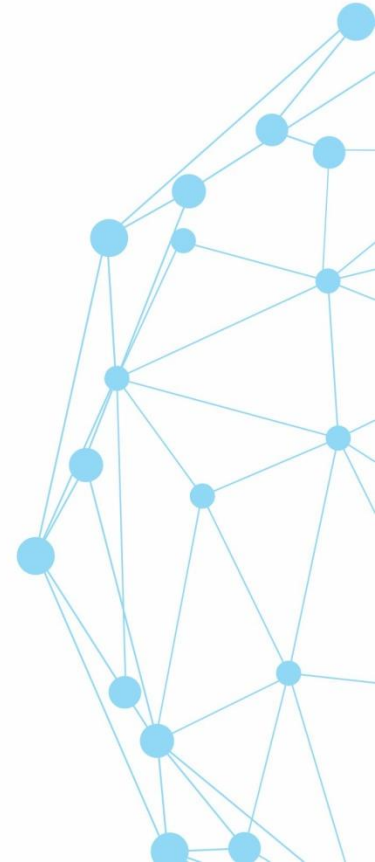
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# Utilizing Data to Drive a Culture Change towards Patient Care

## Caring for Patients







*Thank  
you*

