



# Leadership and Management of Quality in different industries

Is it all the same?

Ron Shah, Global Quality Director, Ocean Optics

**“Management is doing things right; Leadership is doing the right things”**

*- Peter Drucker*

# About myself

- ▶ **My family** – Wife and two daughters (15 & 7 years old), living in Orlando, FL for last 20 years.
- ▶ **Education** – M.S. (I.E); M.B.A.
- ▶ **Experience** – Worked for Global companies – Danaher, Pall Corporation, US Filter, Ocean Optics (Halma Group)
  - ▶ Progressive roles in Quality, Engineering, Operations and R&D
- ▶ **Industries Worked** – Aerospace, Automotive, Biopharm, Micro-Electronics, Machinery and Equipment, Industrial
- ▶ **Last Position** – Global Quality Manager handling Fortune 500 accounts worth \$1B





# Leadership of Quality in different industries

**“Before you are a leader, success is all about growing yourself. When you become a leader, success is all about growing others.”**

- Jack Welch, Former CEO, GE



# Leadership Principles

- ▶ **Focus (80/20)**

- ▶ Optimized use of resources, producing desired results (Goals / KPIs)

- ▶ **Clarity of Mind**

- ▶ Improves Decision-making process, Helps Employee engagement by providing clear and detailed directions

- ▶ **Sense of Urgency**

- ▶ Customer First approach creating amazing Customer Satisfaction thereby increasing revenues / job security
- ▶ Customer(s) pay our 'Pay-checks'

- ▶ **No Complacency**

- ▶ Always try using a different approach to create a robust process / system
- ▶ Continual Improvement is a journey



# Leadership Traits & Values

- ▶ **C.A.T.T.** – **C**ommunication **A**wareness **T**ools **T**raining
- ▶ **A.R.T.T.** – **A**ccountability **R**esponsibility **T**raceability **T**ransparency
- ▶ **H.A.R.T.** – **H**onesty **A**ttitude **R**espect **T**rust

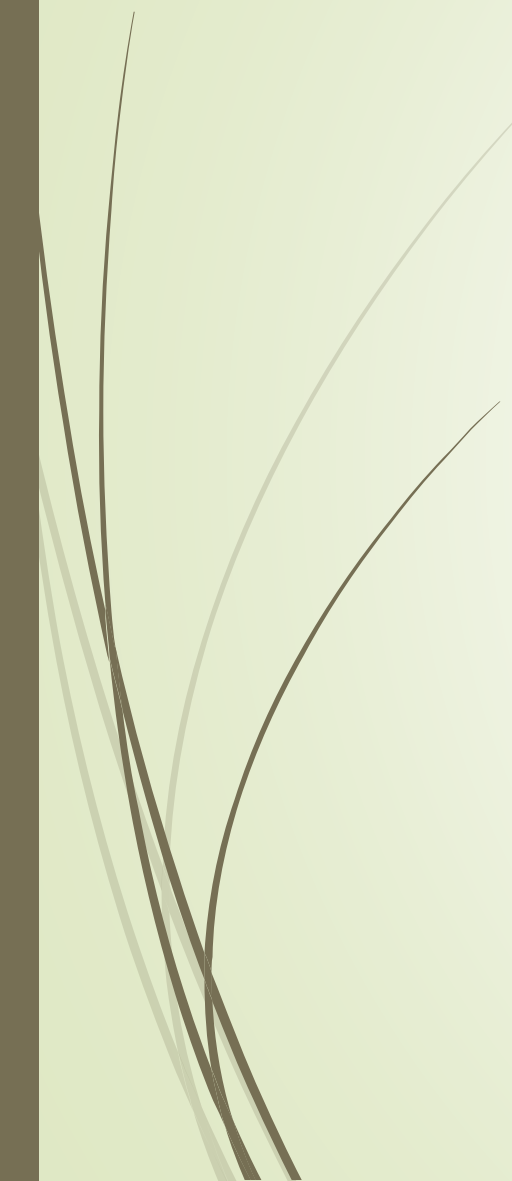


# Leadership Skills

- ▶ Goals / Key Performance Indicators (**KPIs**)
  - ▶ **S.M.A.R.T** Goal(s)
  - ▶ Follow **S**upplier **I**nput **P**rocess **O**utput **C**ustomer (**SIPOC**) Approach
    - ▶ Supplier PPM
    - ▶ Supplier NCR Rate
    - ▶ First Pass Yield (FPY)
    - ▶ Customer PPM
    - ▶ Customer RMA Cycle Time
- ▶ **Follow-up** via Daily Management
  - ▶ Quick 15-20 min standup meeting
  - ▶ Defined Owners for each Goal/KPI
  - ▶ Discuss only KPIs in '**Red**' and resources required to bring back in '**Green**'

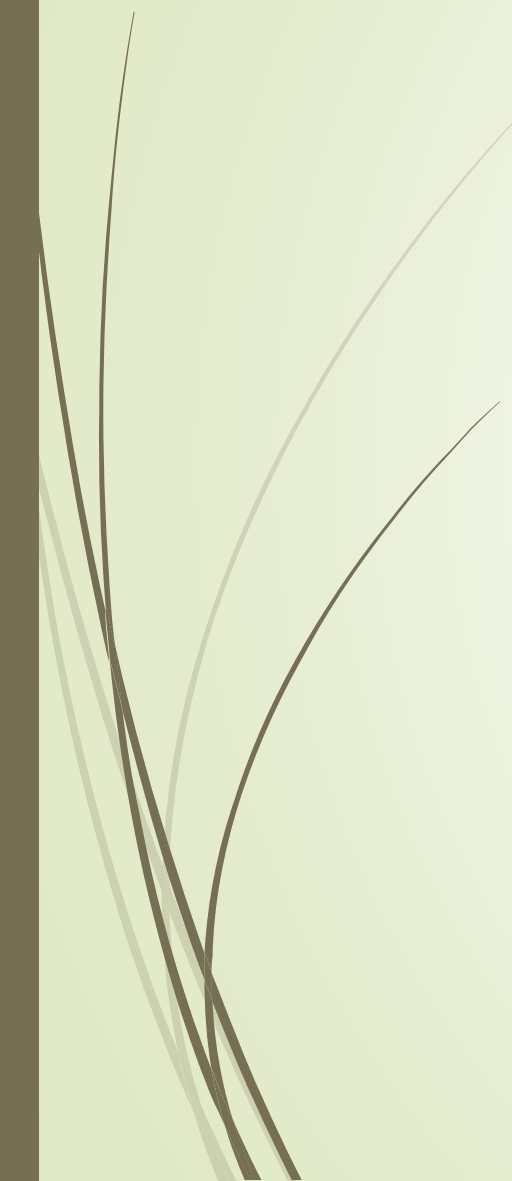


# Leadership Style

- Go to Gemba (Actual work-place)
  - Link Operators/Technicians as the end-user of their own products – Creates ownership
  - Creating Quality Culture – Proactive Quality instead of Reactive Quality
  - Lead by example
  - Total Quality Management (TQM) approach
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# Leadership of Quality – Is it all the same?

- ▶ My fundamental leadership style has been the same over the years but yes, I have tailored some of these Leadership style(s) over time based on my experiences
  - ▶ A leader has to adopt based on their senior leadership style, their colleagues, their employees and their learnings
  - ▶ In my opinion, 70% - 80% of the leadership stays the same across different industries, the remaining 20% - 30% you have to adopt to the environment around you and change to make it efficient and effective
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# Management of Quality in different industries

**“Quality means doing it right when no one is looking”**

*- Henry Ford*

# Aerospace – Management of Quality Systems

- **AS9100** – Laid on the foundation of ISO 9001 but more focused on 'Risk Management' from Supply Chain standpoint in terms Delivery, Quality and Business Continuity
- **International Traffic in Arms Regulations (ITAR)** – To control export and import of defense related articles and services
- **Government Source Inspection (GSI)** – All government orders get approved/ signed by an inspector before it is shipped to the Government
- **Customer Source Inspection (CSI)** – Many of the Aerospace Customers have either trained Supplier personnel as designated CSI or they send their own inspector to perform CSI before it is shipped to them
- **Redundant Inspection** – Inspection is performed at every component and assembly level and then Final inspection before parts are presented to CSI / GSI.
- On-going Customer audits, Government personnel audits, ITAR compliance audits, Customer(s) Portal compliance, etc.



# Automotive – Management of Quality Systems

- ▶ **TS16949** – Laid on the foundation of ISO 9001 but more focused on defect prevention, variation and waste reduction in the entire supply-chain
- ▶ **Automotive Industry Action Group (AIAG)** – It laid the framework for quality improvement in Automotive Industry
  - ▶ **Advanced Product Quality Planning (APQP)** – It is a framework of procedures and techniques used to develop products for automotive industry
  - ▶ **Production Part Approval Process (PPAP)** – Used to establish confidence that Customer specs are understood and will be consistently met (Total 19 elements, where **Part Submission Warrant (PSW)** summarizes the entire PPAP package; other critical elements used were Process flow chart, Control Plan, PFMEA, DMFEA etc.)
- ▶ On-going Customer audits – verification of live FMEAs, Control Plans, Corrective & Preventive Action implementation, etc.



# Biopharm – Management of Quality Systems

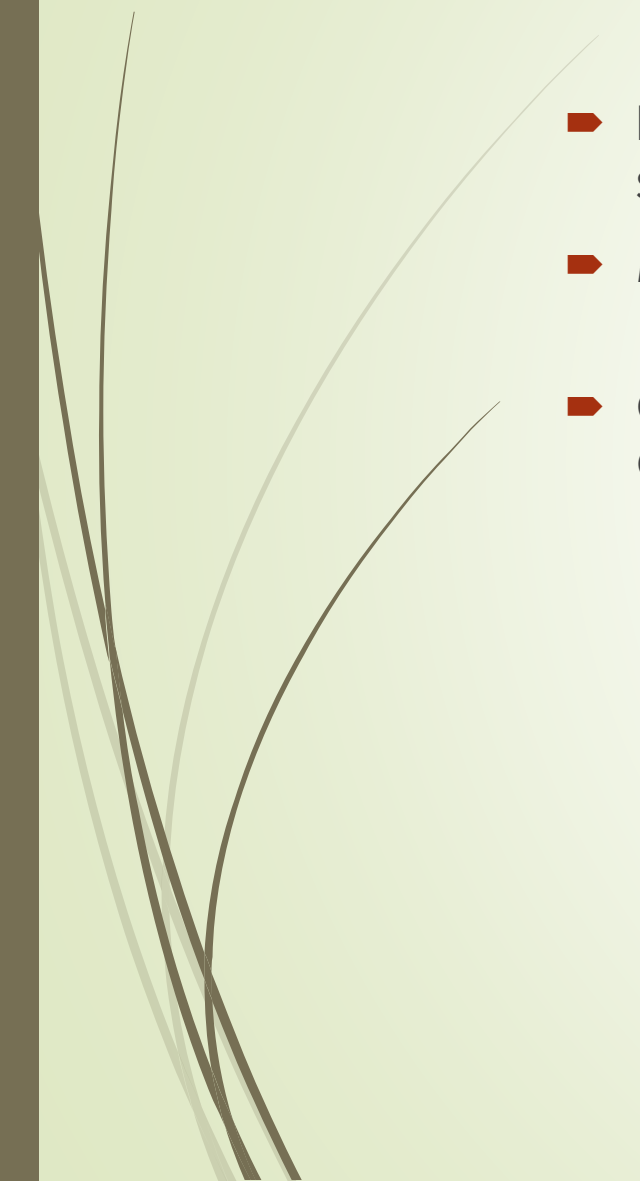
- ▶ **ISO 13485** – Comprehensive QMS for design and manufacture of medical devices. It is more of a regulatory requirement
- ▶ **Key difference** between ISO 9001 and ISO 13485 is that 'Continual Improvement' and 'Customer Satisfaction' are not a part of ISO 13485
- ▶ **Other requirements in ISO 13485** – FDA / CFR compliance, validation of sterile devices, complete traceability for implantable devices
- ▶ Typically, a huge QARA group responsible for record-keeping, maintaining traceability, ensuring compliance, supporting audits, etc.

# Micro-Electronics – Management of Quality Systems

- ▶ **ISO 9001** – Demonstrates the ability to consistently provide products and services that meet Customer and Regulatory requirement(s)
- ▶ **Copy-Exact** – Intel introduced this concept to allow factories that successfully design and manufacture chips to be replicated in locations globally
  - ▶ Matching occurs at all levels from physical inputs all the way through outputs in a statistical manner
- ▶ **Statistical Process Control (SPC)** – Very heavy in using SPC. Customer(s) expect typically having Process Capability Indices (Cp and Cpk) greater than 1.33 (Proactive Quality than reactive Quality)
- ▶ **3 key elements of PPAP** i.e. Process Flow Chart, Process Control Plan and Process FMEA to improve process Quality as well as assure that Customer specification(s) are met by controlling Key Process Characteristics (KPC)

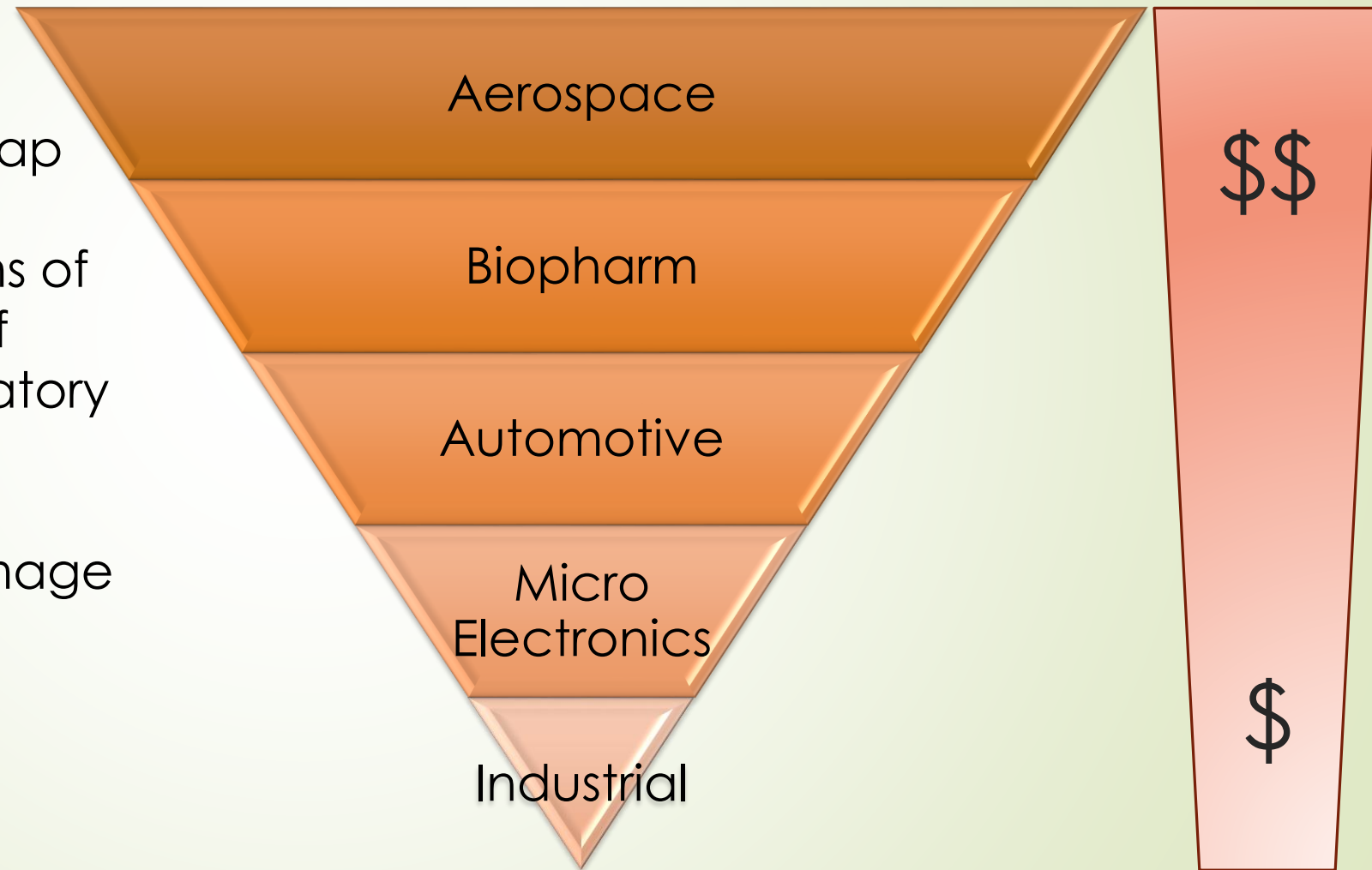


# Industrial – Management of Quality Systems

- ▶ **ISO 9001** – Demonstrates the ability to consistently provide products and services that meet Customer and Regulatory requirement(s)
  - ▶ Mostly maintaining the basic requirements of Quality Management Systems (QMS)
  - ▶ Companies focused more on ‘Reactive Quality’ rather than ‘Proactive Quality’
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# Summary – Management of Quality Systems

- There is an overlap between these industries in terms of Management of Quality & Regulatory Systems
- As seen in the image here, it keeps growing from Industrial to Aerospace





**QUALITY**

*...is everyone's  
responsibility.*

(Deming, W. Edwards)