

Engineering and User needs in large Pharma

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Personal introduction

- 34 years with ICI / AstraZeneca in Engineering and Packaging roles mainly at UK Operations Macclesfield Works with some Global interaction.
- Engineering roles in UK and France leading a number of projects with the objective of improving processes – ie: validation, operations, in process testing and changeovers
- Chair of the IMechE Pharmaceuticals committee, visiting lecturer at the University of Manchester and an active member of the CFPE industry forum.



Topics for today

- The Pharma industry today
- What do we need to achieve ?
- What does Operations need ?
- Examples of successes
- What about the future
- Summary



The Pharma Industry today

- Global medicines prices are declining
- Governments are taking measures to reduce healthcare costs
- R&D and Operating costs are increasing
- Customer demands more of our products, delivery methods, packaging and our ability to supply
- Product lifecycles are shortening
- Innovative medicines are increasingly more difficult to develop
- Market segregation is increasing
- Legislation continues to change



What do we need to achieve?

- Maintain our license to operate
- Compliance – patient, regulatory, statutory
- Innovative products which improve the quality of life
- Adapt to customer needs more quickly
- Reduced “cost of goods”
- Supply consistency
- Competitive edge



In all we do

- The safety, well being and protection of the patient must remain paramount.
- The industry is no place for people who are “**just passing through**” or technicians who “**adjust the equipment to make it run better**” !

Build the quality in, control it and record it.



What does Operations need ?

- Lets look at certain areas within Operations, firstly close to the User and then Engineering -
 - The User & Suppliers
 - Engineering & Technology
- and where change has influenced how we operate in these areas



The User - Simplicity

- Processes must be repeatable, consistent and reproducible when subject to human variability
- Changeovers must be quick and simple
- Utilisation & yield must be high
- Equipment must be easy to clean and decontaminate
- HSE & GMP compliance must be readily attainable
- “Silver standard” may often suffice, gold is not always necessary. What have others done ?



Suppliers - Partnerships

- Develop “cradle to grave” relationships for equipment, components & service providers
- Consider all customer / suppliers relationships throughout the supply chain
- Establish true partnerships that deliver win-win benefits
- Build upon your suppliers quality systems, work together
- Agree value adding Service Level Agreements
- Outsource as appropriate, concentrate on core business

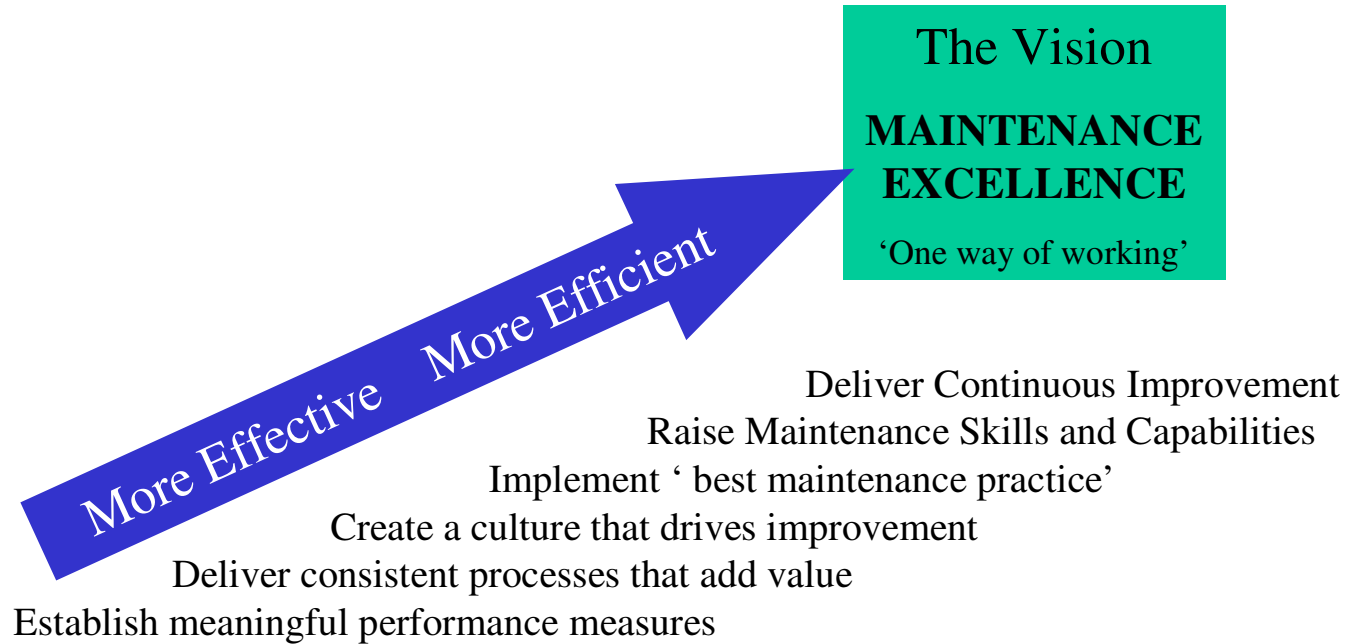


Engineering - Efficiency

- Maintain the validated state of processes
- Control the change
- Use Predictive, non-intrusive methods
- Develop a solid culture using CI tools
- Capable skill base that can adapt quickly
- Data acquisition which delivers tangible benefit
- Risk based approach to compliance
- Maintenance Excellence



The Maintenance Challenge



THE PROBLEM:
Inconsistent vision, Maintenance and Resource Strategy and Business Processes



Maintenance Excellence Vision

Maintenance enables the business to use assets, time and effort more effectively

Maintenance delivers sustainable increase in value for money across UK

Achieved by...

**DELIVERING
MAINTENANCE
EXCELLENCE**



Technology - Appropriate

- RFID
- Computer based systems
- Robotics
- Servo drives / HMI's
- Composite materials
- PAT
- Modular design
- Print on line



Examples of CI tools used

- Value Stream mapping
- OEE
- SMED
- RCA / CAPA
- 5 Why's
- Gemba Kanri
- Short Interval Control
- 5S
- Poke Yoke
- ITS / Control Charts
- Kaizen Blitz
- DMAIC
- FMEA / FMECA
- 7 Wastes
- Ishikawa
- PDCA



Examples of some successes

- CO's reduced by >70%
- Documentation data entries reduced by 75%
- RFT docs from 12% to 89%
- Operator travel down by 60%
- Operator waiting down by 96%
- OEE increased from 30% to 45%
- 50% ↑ shift time = 100% ↑ in output
- Stock turns from 1.4 to 1.8



What about the future ?

- Reducing the cost base is a given
- Reduce the product lead time
- Improve customer service
- Push hard to reduce all aspects of waste
- Challenge the historical ways of working
- Adapt processes from other industries
- Culture of Continued improvement on all aspects
- Sustain the benefits & embed the culture



Summarising

- Cost of goods must continue to reduce
- Change must be cultural and sustainable
- Cultural changes to “ways of working” can deliver large benefits
- Technology is not always the best way
- Historically the industry is too slow in changing and too risk averse, we must increase the pace
- What we do is not Rocket Science !
- The industry is not that different !



Thank you for listening

Any questions ?

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