IPA
INNOVATION. QUALITY. GLOBAL REACH.

10TH GLOBAL PHARMACEUTICAL QUALITY SUMMIT

NAVIGATING THE NEXT DECADE OF GLOBAL EXCELLENCE

Quality Culture in Manufacturing Excellence

NSF

Dr Samantha Atkinson
Executive Vice President, NSF & Former Chief Quality & Access Officer, UK MHRA

Dr Sam Atkinson

BSc (Hons), MSc, PhD, MBA, MRSC

Exec Vice President, NSF Health Sciences

- Former Chief Quality & Access Officer, UK MHRA.
- 20+ years experience of pharmaceutical industry, 16 years experience of which at the MHRA (Inspectorate through to Board level)
- Regulatory Compliance Strategy
- Business Strategy & Transformation
- Emergency Response & Incident Management
- Leadership Development
- Quality & Risk System Optimisation

India - “The Pharmacy of the World”

- India’s Pharma Industry is recognized as one of the largest in the world, contributing significantly to global healthcare.
- India is the largest provider of generic drug, accounting for around 20% of global supply by volume.
- The industry is also a major supplier of vaccines, contributing 60% of global demand.
- India supplies 40% of the US generic drug market and 25% of all medicines in the UK.
- Over 650 USFDA approved manufacturing facilities operating in India.
- Exports from India were US $25.4 bn in 2023 and anticipated to be US $28bn for 2024.
- The Indian Pharma Market was valued at US $42bn in 2021, is anticipated to be valued at US $65bn in 2024 and predicting to grow to US $130bn by 2030.

Getting it right matters!

Medicines & Healthcare products Regulatory Agency

MHRA

Towards Excellence in Quality

IPA Annual Conference

23rd February 2016

Gerald Heddell

Director, Inspection, Enforcement and Standards

Excellence in Quality?

"Individual efforts can bring excellence but only collective efforts can deliver effectively"

Medicines & Healthcare products Regulatory Agency

MHRA

Building a strong Quality Culture

Gerald Heddell

Director

Inspection Enforcement and Standards

Hallmarks of a Quality Culture

1. Values clear from the top –CEO and Board
2. Leadership by example – walking the talk
3. True priorities understood and owned – patient first
4. Openness and transparency – processes in place
5. Responsibilities defined and understood – training
6. Doing what is right is more important than looking good
7. Learning from mistakes is our most valuable investment – continuous improvement

Quality Excellence, Culture and Maturity

EUROPEAN MEDICINES AGENCY

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Home > News > Data integrity: key to public health protection

Data integrity: key to public health protection

11 August 2016

News · Corporate

New guidance now available on EMA's website

The European Medicines Agency (EMA) has released newgood manufacturing practice (GMP) guidan to ensure the integrity of data that are generated in the process of testing, manufacturing, packagi distribution and monitoring of medicines. Regulators rely on these data to evaluate the quality, safe and efficacy of medicines and to monitor their benefit-risk profile throughout their life span.

Regulators stress need to build a culture of quality at IPA meet

By Sanjiv Das — On Feb 24, 2017

LATEST UPDATES

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O, US FDA, MHRA, EMA, EDQM officials share updates in regulatory guidances, identify weak spots and suggest to bridge these gaps

U.S. FOOD & DRUG ADMINISTRATION

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CDER Quality Management Maturity

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What's New

- **2024 QMM Prototype Assessment Protocol Evaluation Program:** During calendar year 2024, CDER evaluated nine establishments as part of the initial year of the voluntary Quality Management Maturity Prototype Assessment Protocol Evaluation Program. Following each assessment, CDER provided the establishment with a QMM report that highlighted strengths and opportunities for improvement.

Content current as of: 12/31/2024

Regulated Product(s) Drugs

GOV.UK

Blog

MHRA Inspectorate

Organisations: Medicines and Healthcare products Regulatory Agency

Quality Culture: Learning from History

David Churchward, 28 February 2019 · Compliance matters, Good manufacturing practice

ISPE

PHARMACEUTICAL ENGINEERING

ISSUES · SECTIONS · TOPICS · WHITE PAPERS

ISpeak Blog | 22 April 2024

Quality Management Maturity: The Strategic Vision for Biopharmaceutical Excellence

By David Dolecki, Miss Prudence Edwards, Joseph Oliveiroski

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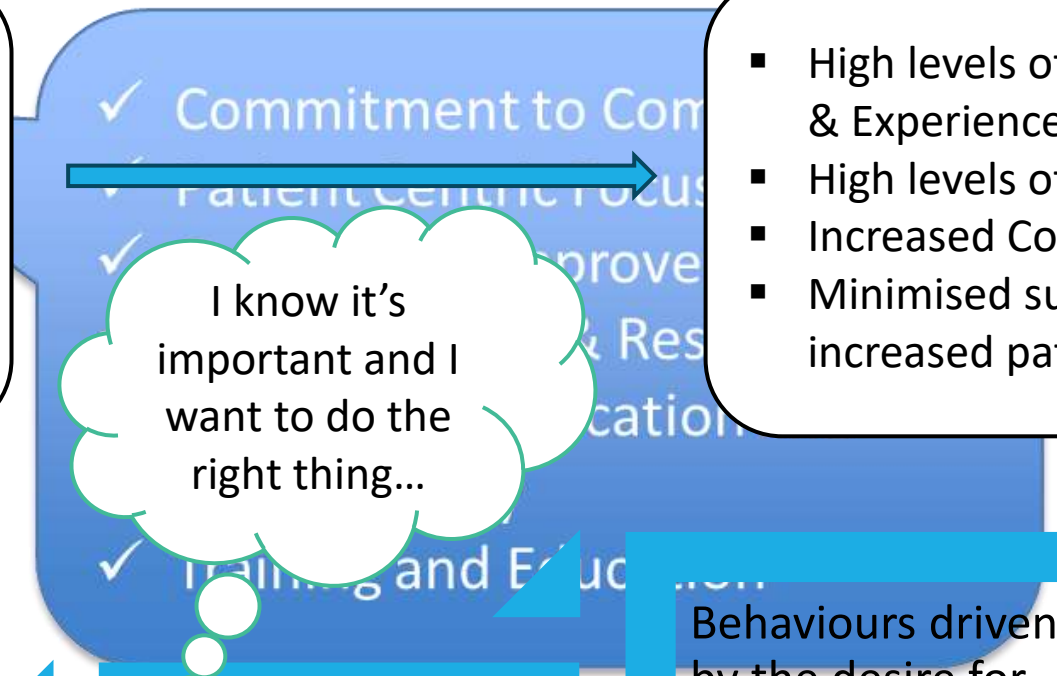
What is Quality Culture?

- Low levels of Employee Engagement
- Low levels of Customer Service
- Compliance & Performance Issues
- Supply disruptions and reduced patient outcomes



- High levels of Employee Engagement & Experience
- High levels of Customer Service
- Increased Compliance & Performance
- Minimised supply disruptions and increased patient outcomes

I have to do this…

Behaviours driven by the need to comply

Behaviours driven by internal focus on Quality Maturity and desire to succeed

Behaviours driven by the desire for Quality Excellence and Patient Outcomes

I know this is important to the patient because…

Low Maturity → High Maturity

The Employee

Employee Experience

- Engagement
- Motivation
- Innovation
- Commitment
- Retention
- Productivity
- Performance

Customer Experience

- Loyalty
- Satisfaction
- Builds reputation
- Increased sales
- Referrals

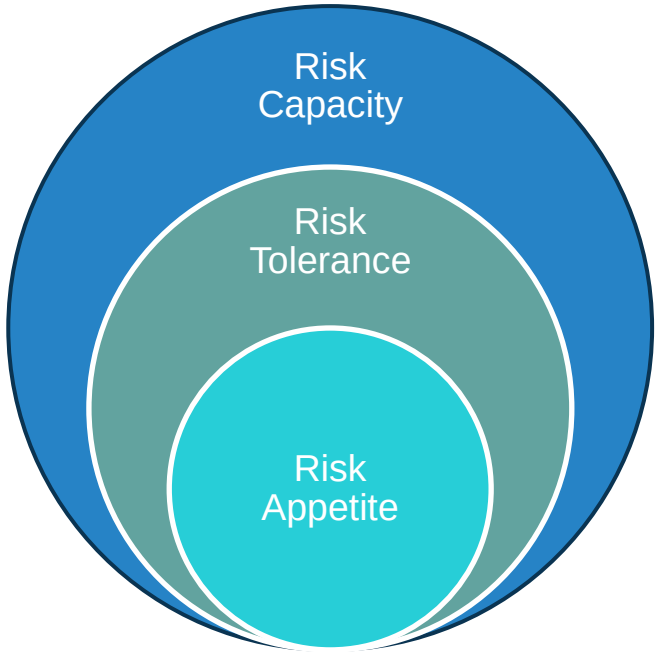
Business Success & Patient Outcomes

- Revenue
- Growth
- Reputation
- Compliance
- Supply chain robustness
- Reduced regulatory burden

The Organisation

Aligned Leadership

- Quality and Business Objectives
- Risk and Strategy
- Desired Values and Behaviours
- Metrics and Measures
- Reward and Recognition
- Structure & Processes



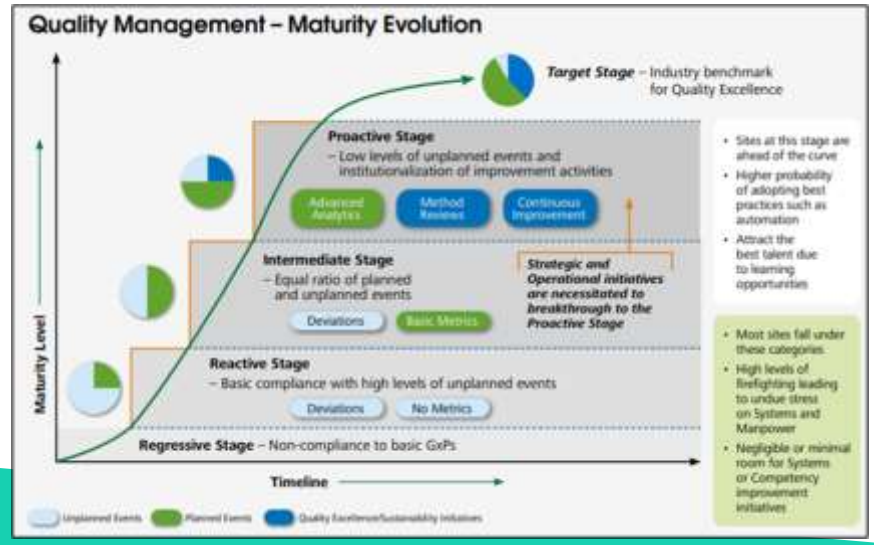
Employee & Organisation

Opportunities for Leading in Pharmaceutical Manufacturing Excellence

Tools:

- Quality Management Maturity Assessment to:

  - ✓ Design a Quality Maturity Roadmap
  - ✓ Culture Roadmap
  - ✓ Drive continued improvement and reflection



Leadership development to facilitate:

- Convergence of Risk appetite, in turn to ensure:

  - ✓ A clear vision
  - ✓ An aligned quality policy
  - ✓ Appropriate goals and measures
  - ✓ Empowerment and accountability
  - ✓ The development of a learning organisation
  - ✓ Employees are engaged on the journey

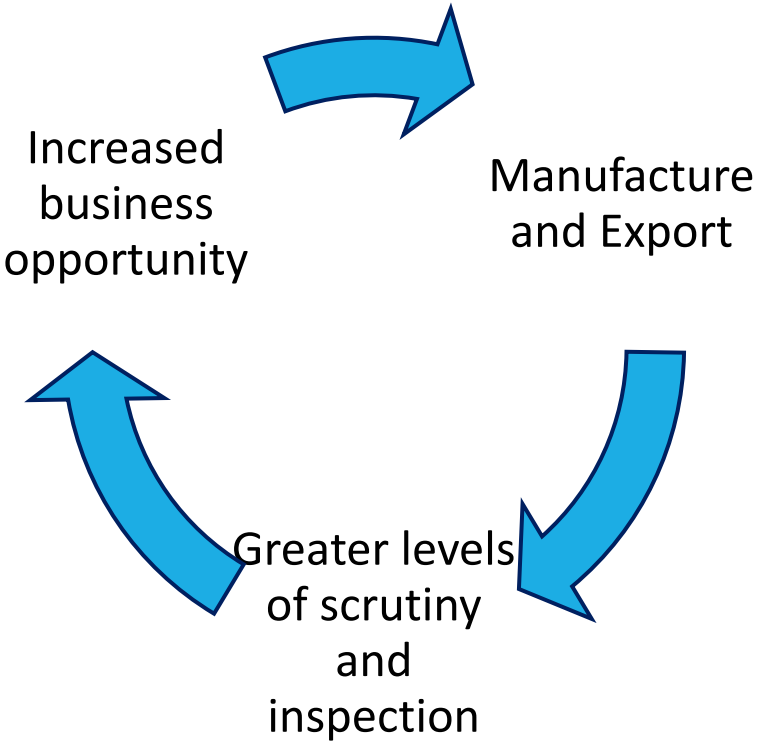
Indian Pharmaceutical Sector

Regulatory Oversight

“Pharmacy of the World”

Indian Pharmaceutical Sector

Context



Other considerations

- Affordability vs Access
- IP vs Innovation

Identifying leadership opportunities

Indian Pharmaceutical Sector

Opportunities for Leading in Pharmaceutical Manufacturing Excellence

- Opportunities for Industry
  Standards that protect business
  and quality activities

- Thought Leadership
- Guidance and Technical Leadership

- National Integration
- International Influence an
  Collaboration

Final Reflections

Pharma · 4 Min Read

The Indian Pharmaceutical Industry: A Remarkable Journey

The Indian pharmaceutical industry's journey began with significant steps towards global recognition. The introduction of the Indian Patents Act in 1970 and the Drug Policy of 1978 set the stage for Indian companies to establish themselves in international markets. By the 1980s, India had transformed from a major medicine importer to a leading exporter. The 1984 Hatch-Waxman Act in the U.S. boosted the production of generic medicines, benefiting Indian drug makers. The economic reforms of 1991 further propelled the Indian pharmaceutical industry onto the global platform by removing licensing restrictions.

Online Bureau · ETHealthWorld
Updated On Sep 2, 2023 at 12:15 PM IST

Read by:
5853 Industry Professionals

Many Congratulations to IPA on the 10th Anniversairy Global Pharmaceutical Summit

Thank You

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