



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Quality Culture in Global Manufacturing

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An agency of the European Union 



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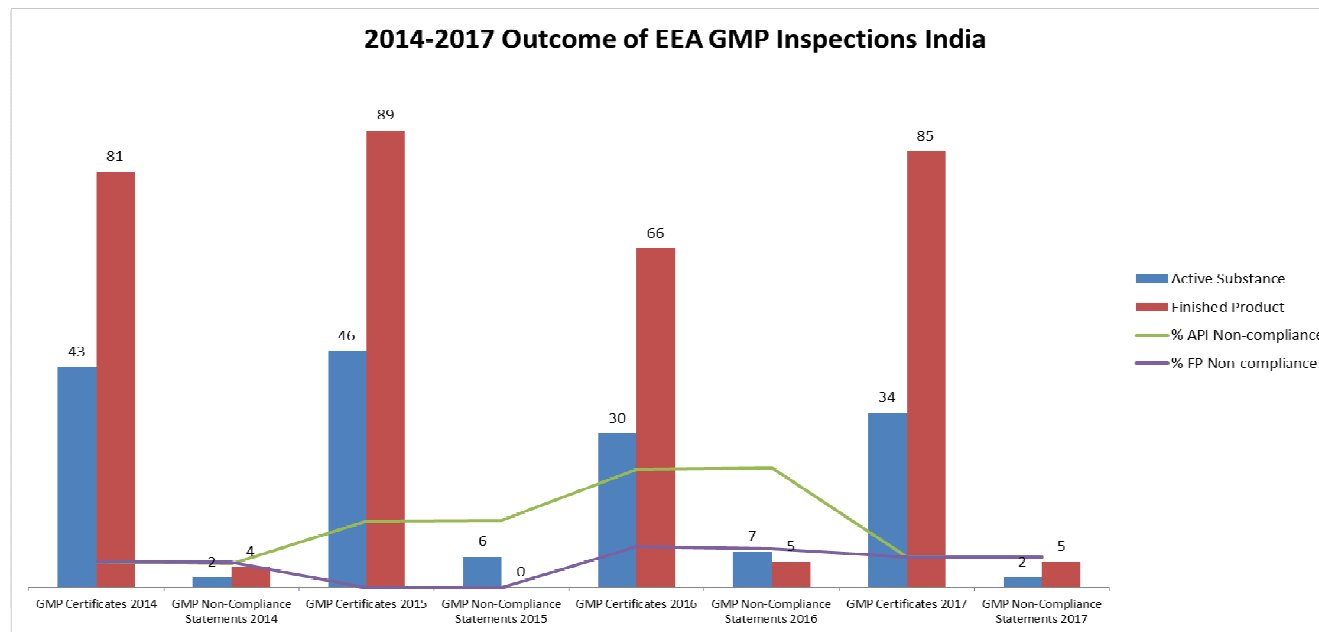


# 1. Global GMP Issues

- **Non-compliant sites due to basic GMP failings**
- **Product recalls, potential or actual shortages due to manufacturing and quality problems**
  - Lack of supply chain resilience;
  - Lack of proactivity in risk-assessment and risk mitigation measures;
  - Reduction in manufacturing capacity with no alternatives registered in Marketing authorisation.
- **Known problems in development getting through to commercial manufacturing: failures in technology transfer**
  - Lack of continuous improvement;
  - Lack of investment;
  - Poor quality interactions / communication between the industry and the regulator.



## 2. Summary of Inspections and Outcomes





## GMP Non-Compliance Results - India

- 40% decrease in SNC previous year (7 vs 12 SNCs)
- For all 7 sites it was the first EEA GMP SNC (for 3 it was the first EEA inspection)
- Only 1 site was re-inspected in the same year conducting to SNC being withdrawn
- Issues that led to GMP SNC, examples:

*Cleaning of rooms and also of direct-product-contact equipment were not verifiable or not successfully performed, but documented as duly done.*

*QC personnel used a single sample from one batch in a campaign to provide data for all batches under the direction of QC management. Stability testing was significantly behind schedule and time points were skipped due to inadequate QC laboratory resource.*



## What is the impact of GMP non-compliance?

- Following the issue of GMP Non-Compliance Statement the average re-inspection interval is **~ 1 year**
- Following the issue of GMP Non-Compliance Statement there will be an impact on Product Marketing Authorisation (MA) which may take **several months and maybe years to resolve**
- Where a shortage occurs, the median time to resupply is **7 MONTHS**

**Impact on product availability and Public Health!**



### 3. How can Quality Culture be achieved

Eudralex Volume 4, Part I,

Chapter II:

**“The correct manufacture of medicinal products relies upon people.”**





## Driving Cultural Transformation - People

- Leadership is essential to establish and maintain a company-wide commitment to quality
- Changing the mindset at employee level
  - All employees need to understand their role and...
    - how this fits in the business objective
    - how this can impact the product and the patient
  - Promoting a transparent communication across the organization
  - Lead through positive examples
- Investment in people – knowledge and experience
- Proactive review of the organisation





# Driving Cultural Transformation – Organisation (1)

## Be Prepared

- Are you **proactive** in picking up on evidence of a developing problem or only reacting after the problem has become significant?
- Can you **detect** signs of increasing risk especially if production pressure is increasing?
- How do you get top management to **engage**?
- How do you **encourage** staff to take ownership for quality and good behaviour



## Driving Cultural Transformation – Organisation (2)

### Be Transparent

- Do you **identify** and **monitor vulnerabilities**?
- To what extent is **information** about quality / compliance problems **shared** within your organisation?
- Shared within your **supply network**?
- Shared with **regulators**?
- How do you **encourage** staff dealing with suppliers to focus on the aspects that really matter, as opposed to price?



## Driving Cultural Transformation – Organisation (3)

### Be Flexible

- How do you **adapt** to change, disruptions and opportunities?
- Is your supply chain **resilient** and robust?
- Can you **invest in quality** at those times when it appears to be unaffordable?



## Key Messages

- Majority of inspections in India in 2017 were positive with fewer non-compliant sites compared to 2016
- Many of the findings noted can be linked to issues with quality culture
- Leadership is essential to establish and maintain a company-wide commitment to quality
- Shift focus from reactive to proactive risk management
- Improve pre- and post-incident communication on disruptions
- Develop supply chain resilience



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# Thank you for your attention

## Further information

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## Summary of GMP inspections performed by EU inspectorates

