Quality Culture in Global Manufacturing

IPA Pharmaceutical Forum 2018
22-23 February 2018

Presented by Andrei Spinei
Manufacturing and Quality Compliance, European Medicines Agency
Contents

1. Global GMP Issues

2. Summary of Inspections and Outcomes

3. How can Quality Culture be achieved

4. Key Messages
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

Source: EudraGMDP data 9th January 2018
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- Only 1 site was re-inspected in the same year conducting to SNC being withdrawn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 \(~ 1 \text{ year}\).
- Following the issue of GMP Non-Compliance Statement there will be an impact on Product Marketing Authorisation (MA) which may take \textit{several months and maybe years to resolve}.
- Where a shortage occurs, the median time to resupply is \textbf{7 MONTHS}.

\textbf{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

Quality Culture in Global Manufacturing
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?

Quality Culture in Global Manufacturing
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?

Quality Culture in Global Manufacturing
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
Thank you for your attention

Further information

[andrei.spinei@ema.europa.eu]

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Follow us on @EMA_News
Summary of GMP inspections performed by EU inspectorates

2017 Outcome of EEA GMP Inspections India per State

Source: EudraGMDP data 9th January 2018

Quality Culture in Global Manufacturing