GMP FORUM 2023

GMP Compliance signals: Sponsors actions

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Workshop Overview

GMP Compliance Guidance	Presentation	5 minutes
What is a GMP non-compliance Signal? Some examples	Poll	10 minutes
Case Study – at your Tables	Workshop	30 minutes
Lessons learned	Presentation	10 minutes

Workshop Objectives

- A better understanding of the responsibilities for reporting GMP non-compliance signal
- The TGA management of GMP non-compliance signals
- Sponsor responsibilities in response to a GMP non-compliance investigation
- TGA Regulatory Enforcement Actions

Guidance on the Management of GMP compliance signals

This applies to

- licensed manufacturers in Australia
- sponsors responsible for any overseas manufacturing site

Sponsor /manufacturer responsibilities

Report potential or known GMP compliance signals

- concerns raised by the manufacturers where it is identified there is a potential or actual breach of the Good Manufacturing Practices.
- any regulatory actions by any competent authority for the manufacturing sites.

GMP non-compliance signals

- Data and information from various internal and external intelligence sources

- Routine monitoring of overseas compliance systems and databases published by other overseas regulatory authorities

What are GMP non-compliance signals

Slido questions

- ❑ Scan QR code with your device
- ❑ Respond to the Slido Questions
- ❑ Responses are **anonymous**

GMP non-compliance signals

1. FDA Import Alert - Yes

The US FDA may place manufacturing sites with compliance findings on import alert prior to a warning letter being issued.

2. FDA warning letter - Yes

This is a GMP non-compliance signal, as noted in the guidance.

3. US FDA Form 483 - No

A US FDA Form 483 is a list of deficiencies and may not lead to enforcement actions. However, sponsors should be advised of the outcome of regulatory inspections as part of the responsibilities of GMP agreements and determine if there is a risk to products being supplied.

4. Request for consent to release products that fail specification - No

The authorised person for release for supply is responsible for decision to release products in accordance with the marketing authorisation. However it is recommended that a full and thorough assessment of the risks of continued supply.

GMP non-compliance signals

4. EUDRA non-compliance report - Yes

This is a GMP non-compliance signals, as noted in the guidance.

5. A letter of non-compliance from a non-PICs authority - Recommended

Information from regulatory agencies on the compliance of the manufacturer is a signal of potential non-compliance at the site.

6. The release of a batch of non-compliant product for supply in Australia- No

Yes this needs to be reported to the TGA however this should be reported to TGA Recalls – Recalls@health.gov.au

GMP non-compliance signals

7. The manufacture of a batch of non-compliant product in quarantine and not released for supply in Australia- No

As no product has been released to the market, there is no requirement to advise the TGA.

8. A non-compliance report for an API manufacturer that does not hold a GMP Clearance - Yes

Evidence of GMP non-compliance such as FDA warning letters for manufacturers in the supply chain for medicines supplied in Australia should be reported to GMP Compliance irrespective of the requirement for a GMP Clearance.

Workshop on FDA Warning letter

Group activity

- ❑ Review the Warning letter
- ❑ Consider the information you will provide to support the risk assessment for sterile/non-sterile product type with justifications
- ❑ Nominate a spokesperson for your table to summarise the group discussion

Our non-compliance signal Investigations

Guidance on the management of GMP compliance signals

- Once we receive and triage a GMP non-compliance signal, the information undergoes a review and investigation process.
- Sponsors are requested to provide a risk assessment and information on the supply of any impacted products. It is expected that sponsors assess the risks in relation to the supply of products in Australia.
- TGA reviews the information provided and determines if regulatory enforcement actions are required.

Potential Compliance outcomes for overseas manufacturing sites

- No Further Action
- Action on GMP Clearance
- Recall action
- TGA Compliance inspection
- Suspension /cancellation from ARTG

Compliance and enforcement tools for licensed manufacturers

Escalation of Compliance actions

1. Report non-compliance
2. Sponsors – Provide Supply information
3. Sponsor - risk assessment
4. Case specific signal outcomes

GMP non-compliance signals

Reach out to us:

GMPCompliance@health.gov.au

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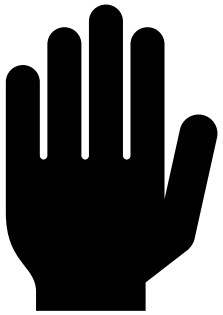
Participate in the Q&A

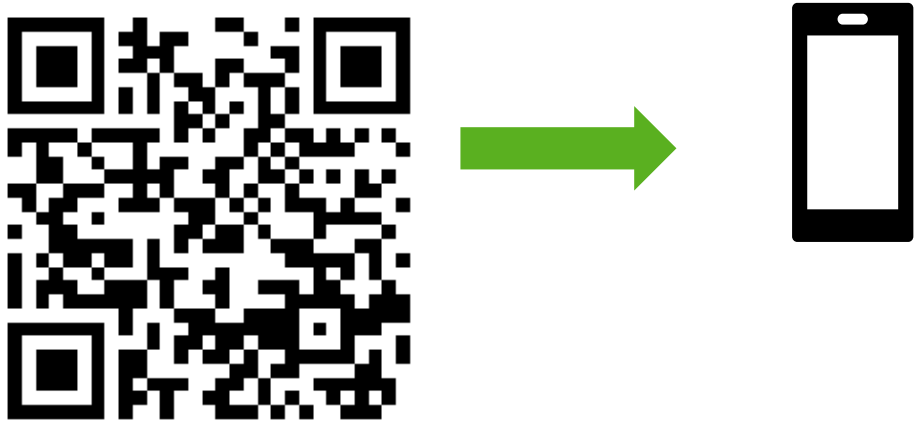
Verbal questions:

Raise your hand to ask a verbal question.



Write your question:

Scan the QR code below or click the link in your calendar to access Slido via your mobile device. You can submit your question, and vote on other questions submitted.



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration