

**FAILURES TO COMPLY WITH THE GUIDELINES ON GOOD DISTRIBUTION PRACTICE OF
MEDICINAL PRODUCTS FOR HUMAN USE**

1 CRITICAL

None

2 MAJOR

None

3 OTHER

3.1

3.1.1

The Quality Management System was deficient in that:

Change controls failed to be a fully reflective record of the changes being undertaken as evidenced by change control [REDACTED] and [REDACTED].

Response

Deficiency accepted.

What went wrong

Change Control [REDACTED]

The change control should have had all actionable steps e.g., a variation to be submitted, validity period of [REDACTED] etc.

Change Control [REDACTED] (New Admin Office):

The change did not adequately specify actual dates of completed action points and the appropriate target dates for MHRA and Home Office approval.

Action Taken

Change Control [REDACTED] and **Change Control [REDACTED]** are currently open and awaiting approval of the variation from the MHRA and Home Office, we will ensure all actionable steps are properly documented.

Completion Date [REDACTED]

Change Controls updated and renamed to:

- Change Control Form [REDACTED]
- Change Control Form [REDACTED] Move to New Site Bethnal Green

3.1.2

For deviation [REDACTED] there was non-attributable delays following the deviation until a change control was raised to perform preventative actions.
Reference – GDP Chapter 1.2

Response

Deficiency accepted.

What went wrong

The root cause of the delay was a gap in the communication and oversight process between departments responsible for logging deviations and those initiating the change control including preventative actions.

Whilst the deviation was logged, the process of escalating it for a timely change control and preventive action review should have been monitored to prevent delays.

Action Taken

Change Control [REDACTED] Change Control Tracker has been raised to add new tracker [REDACTED] to monitor the time taken between the identification of deviations and the initiation of change control (where appropriate).

The [REDACTED] is currently discussed [REDACTED]
[REDACTED] This enhancement aims to prevent delays and improve our response times to implement preventative actions and overall quality management.

Completion Date

To be completed by [REDACTED]

3.2

Training was deficient in that it was not documented the competency of staff members to perform delegated duties.
Reference – GDP Chapter 2.4

Response

Deficiency accepted.

What went wrong

The records for duties delegated to staff members by the Responsible Person were present; however, they lacked sufficient detail and robustness.

Action Taken

A Change Control will be raised to review [REDACTED] Delegation of RP Duties. All staff members who have been delegated RP duties will be retrained and appropriate records maintained by the RP.

Completion Date

To be completed by [REDACTED]

3.3
3.3.1

[REDACTED] was deficient in that:

SOP [REDACTED] failed to capture the validity period of the [REDACTED]

Response

Deficiency accepted.

What went wrong

The oversight in SOP [REDACTED] (uncontrolled and awaiting approval of the variation) stemmed from a lack of detailed review during the drafting process of this document.

Action Taken

Change Control [REDACTED] [REDACTED] which remains open will be reviewed to include all actionable steps (refer to deficiency 3.1.1) including the validity period of [REDACTED] and SOP [REDACTED] will be updated.

Completion Date

To be completed by [REDACTED]

3.3.2

There was no provision to ensure supplies are only made to persons who are authorised or entitled to receive medicinal products.

Reference – GDP Chapter 5.9

Response

Deficiency accepted.

What went wrong

Not all actionable steps within **Change Control** [REDACTED] [REDACTED] had been documented (refer to deficiency 3.1.1).

Action Taken

Change Control [REDACTED] [REDACTED] which remains open will be reviewed to include all actionable steps (refer to deficiency 3.1.1) including the update of [REDACTED] [REDACTED] (linked to SOP [REDACTED]) to include the qualification of customers authorised or entitled to receive medicinal products in [REDACTED] [REDACTED]

Completion Date

To be completed by [REDACTED].

3.4
3.4.1

[REDACTED] activities were deficient in that:

The audit of [REDACTED] failed to include all elements of [REDACTED], including but not limited to transportation validation.

Response

Deficiency accepted.

What went wrong

During the audit at [REDACTED] we discussed all elements of the activities performed by [REDACTED]. However, due to an oversight, it became clear during the MHRA inspection that the transportation validation was not documented.

Action Taken

To address this, a Change Control [REDACTED] Revision of Audit Plan has been raised to review the audit plan. This will ensure a more comprehensive assessment of [REDACTED], helping to prevent any recurrence of the identified issues.

Completion Date

To be completed by [REDACTED].

3.4.2

The audit report of [REDACTED] produced 27/06/2024 could not be evidenced of being approved.

Reference – GDP Chapter 7.2

Response

Deficiency accepted.

What went wrong

The audit report for [REDACTED] per **Audit Reference** [REDACTED] had not been signed to indicate approval by the Responsible Person. The audit report was emailed to [REDACTED] for a signature prior to RP approval. This oversight occurred following a delay in response from [REDACTED].

Action Taken

The audit report per **Audit Reference** [REDACTED] was retrospectively signed and approved by the Responsible Person, dated [REDACTED].

Completion Date

All actions have been completed.

3.5

The supply to fulfil special patient needs was deficient in that it was not adequately documented that the medicinal product is for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient.

Reference - The Human Medicines Regulations 2012, Regulation 167

Response

Deficiency accepted.

What went wrong

Whilst initial onboarding of prescribers is performed there was a failure to conduct annual reviews of prescriber onboarding with a declaration that medicinal products were ordered for use for the prescribers' patients who had special needs.

Action Taken

To address this, a Change Control [REDACTED] has been raised to ensure annual onboarding of prescribers with a declaration that medicinal products were ordered for use for the prescriber's patients who had special needs.

Completion Date

To be completed by [REDACTED].

4 COMMENT

None