Deviation procedure

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Overview

• Introduction
  – What is a deviation
  – Relevant legislation

• Deviation procedure
  – What to consider
  – Documentation

• Worked examples
What is a deviation?

A deviation is a non-conformance with:

- Approved standard operating procedures
- Established GDP standards such as the EU GDP Guidelines, relevant EU Regulations and Directives
Why is a deviation procedure needed....

Murphy’s Law

If it can go wrong,
it will go wrong.
Relevant legislation

• EU GDP Guidelines 2013/C 343/01
  – Chapter 1, Paragraph 1.2 Quality System
    • The quality system should ensure that:
      (v) deviations from established procedures are documented and investigated
Deviation procedure: What to consider...

- The procedure should detail the process of:
  - identifying,
  - documenting,
  - investigating and
  - closing deviations.
- RP involvement
- Incorporate quality risk management
- Deviations log and an associated form
Deviation procedure: Documentation

What happened?

How do you plan to address this?

What was the outcome?
Deviation procedure: Documentation

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1</td>
<td>Description of the deviation – planned/unplanned Initial classification (QRM) RP notification</td>
</tr>
<tr>
<td>Section 2</td>
<td>Investigation of deviation including root cause analysis Risk assessment of the incident (QRM)</td>
</tr>
<tr>
<td>Section 3</td>
<td>Proposed action plan including proposed time frames for completion (QRM) RP review and approval</td>
</tr>
<tr>
<td>Section 4</td>
<td>Documentation of actions taken Close out of deviation</td>
</tr>
</tbody>
</table>
Worked examples:
1. Temperature Excursion

• RP notices a temperature excursion is recorded by a staff member (S1) during their monthly review of temperature records.

• The company’s procedure states that product should be kept below 25°C and that the RP is to be informed if temperatures above this are recorded.

• A deviation is raised to address the two issues identified.
### Deviation form

<table>
<thead>
<tr>
<th>Section 1</th>
<th>On 9th Nov 14 temp on temp probe 1 was recorded by S1 as 25.4°C. RP not notified. RP review of temp conducted on 31st Nov 14. Deviation raised. Unplanned. Potential out of spec product supplied. Major deviation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 2</td>
<td>Review of product in storage area at the time - requirements for storage of the medicinal product in the storage area was up to 30°C Review of external temperature – higher than average Review of staff training records - No additional training in temp SOP Risk assessment - outcome acceptable</td>
</tr>
<tr>
<td>Section 3</td>
<td>No CAPA relating to the product – stored within the requirements S1 to be given additional training on relevant procedures – 2 weeks RP review and approval</td>
</tr>
<tr>
<td>Section 4</td>
<td>Training complete and deemed acceptable RP approval; signature and date</td>
</tr>
</tbody>
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**Worked examples:**

1. **Temperature Excursion**
Worked examples:
2. Non-wholesale return

• Ambient temperature medicinal product is returned from a non wholesale customer outside the ten days.

• The procedure states the medicinal product returns from a non wholesale customer cannot be returned to saleable stock and must be sent for destruction.

• There is an indication that this may be an exceptional circumstance and the company wish to return the goods to saleable stock.

• A deviation is raised in relation to this.
## Worked examples:
### 2. Non-wholesale return

<table>
<thead>
<tr>
<th>Section 1</th>
<th>On 11\textsuperscript{th} Nov 14 Company X (non-wholesale company) returned medicinal product. Company X indicate exceptional circumstance. Deviation raised. RP notified. Planned. No immediate consequences. Timeline – immediate.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 2</td>
<td>Investigation of reason for return – needs of individual patient changed, exceptional circumstance Review of storage requirements – ambient product Risk assessment - outcome acceptable</td>
</tr>
<tr>
<td>Section 3</td>
<td>Decision to be made by the RP – return to saleable stock Deviation to be captured in returns records and product subject to routine goods in checks RP review and approval</td>
</tr>
<tr>
<td>Section 4</td>
<td>Product returned to saleable stock RP approval; signature and date</td>
</tr>
</tbody>
</table>
Summary

A deviation procedure enables a company to document and control non-conformances under their quality management system.
Thank you for your attention

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