USP-APEC RHSC

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Welcome

Aide-Memoire on Product Return: A Risk-based Rationale for Inspecting Returns and its Impacts on GDP Compliance Assessment

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Purpose

- The following Aide-Memoire presents questions and key points to consider in the evaluation of Good Distribution Practices for the handling of **Product Returns**.
- This should not be considered as an exhaustive list of points to be explored during an inspection
- Why Product Returns?

Routine vs. Crisis

- GDP/QMS Assessment Under 2 Situations
  - Routine Assessment
  - Crisis Assessment

ROUTINE ASSESSMENT: How is the QMS operating (Procedure/Records/Improvement)

CRISIS ASSESSMENT: How QMS responds to a critical situation (Robustness of the QMS/Maturity)

Recalls vs. Returns

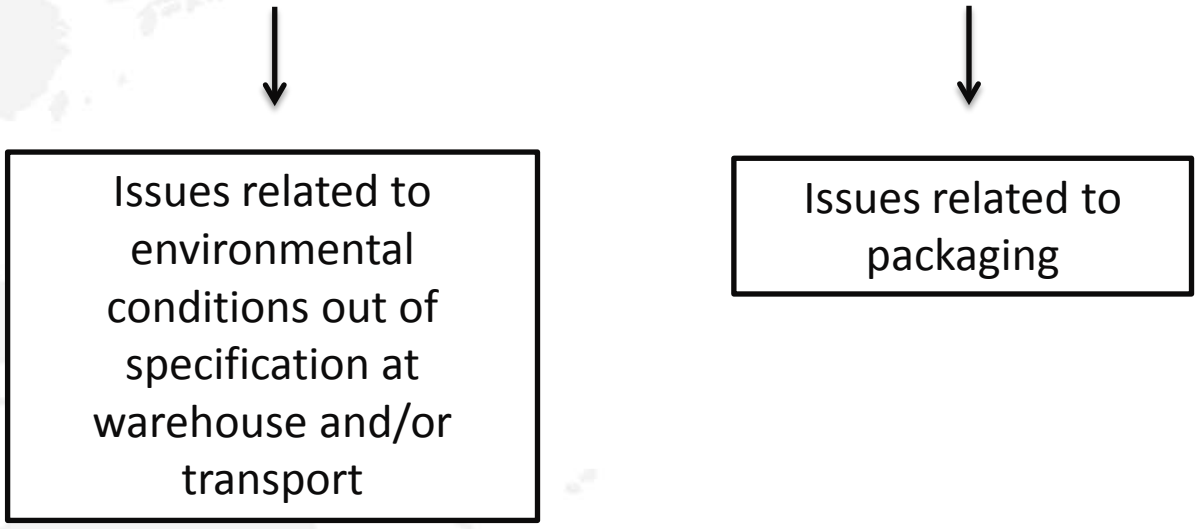
- Both are critical
  - **RECALLS**: Quality/safety/efficacy issue (GMP) recall is necessary to avoid the product from being used.
    - Challenge: Send back what was shipped. However, product will be destroyed
  - **RETURNS**: There is NO quality/safety/efficacy issue. It´s a logistic issue (GDP)
    - Challenge: the core question is deciding if the returned product is acceptable for restocking and resale or whether it should be destroyed.
    - The product could be restocked for new selling (Risk)

Returns and Risk

- What kind of risks are related to a backward flow in returns?
- What kind of strategies the organization should have to mitigate there risks?
- Evidence-based decision is the core for inspecting Returns

Returns and Risk

- Risks related to Product Returns:
  - Accepting for restocking with a loss of quality, or non-integrity



Returns and Risk

- Risks related to Product Returns:
  - Accepting a non-authentic product into the legitimacy supply chain
  - Diversion of an authentic product, within the expiration date, while the product was addressed to destruction

Returns and Risk

- The idea is to evaluate if the organization has a mature quality system that will work on return handling to ensure:
  - In case of restocking, that an authentic, quality and integral product was restocked
  - In case of destruction, a legitimate product within the expiration date was destroyed and not diverted.

What Is Important to Check?

- Return Handling SOP
- Training on Returns
- Return Records (evidence-based decision)

What Is Important to Check?

- Return Handling SOP
  - Details on how the organization handles product returns and if a sound rationale for the investigation and handling of returns are in place, This should include mitigation strategies for controlling risks related to product returns, in order to maintaining product quality and ensuring counterfeited or substandard products don't enter the legitimate supply chain. Important to check if the SOP covers at least:
    - Rational for lab analysis: appearance, identity, assay, microbiological, etc.
    - How the organization requests evidence of transport and storage conditions
    - How the organization ensure a representative sampling for lab analysis
    - How the organization performs a risk-based evaluation of a return, in order to decide if the product could be restocked and resold. Where the returned product is stored (segregate area, quarantined?)
    - Responsibilities within the organization to assess returns and decide for restocking and resale or for destruction
    - How the investigation is recorded and archived.

What Is Important to Check?

- Training on Returns
  - If all personnel involved in return handling was trained on SOPs and if the evaluation of training efficacy was performed.

What Is Important to Check?

- Return Records
  - Important to take a look at all returns records occurred in a period of 1 year. During this assessment insight can be gained into:
    - How many returns occurred and what was the reason?
    - Is the reason the same?
    - If yes, did the organization open a CAPA to investigate the root cause and provide a corrective action?
    - If the cause is variable, is there an impact on the quality system that triggers a CAPA?

  A good practice would be to choose 1 to 3 return records and fully inspect.

  The case study presented provides an example of a Return and serves to illustrate what kind of questions or considerations an inspector could make when auditing this topic.

Case Study: Returns – Questions and Considerations

- Check if the organization:
  - Evaluated the appearance and integrity of the product, to ensure the product was not damaged.
    - Important to ensure the authenticity of the product.
  - What kind of lab analysis was performed: Assay (dissolution, friability, sterility, etc)?
    - Was it a representative sample?
  - Was there a temperature data logger with the cargo?
    - If yes, after downloading the data, were the temperature results in or out of specification?
    - Was there any excursion? If so, how did the organization handle it.
      - If there was an excursion this brings uncertainty to the evaluation.
  - How was the product stored to the customer and back to manufacturer?

Case Study: Returns – Questions and Considerations

- Check if the organization:
  - How was the product stored at the transporters warehouse (during the 3 days).
  - Did the manufacturer check the temperature results from the monitoring at the transporter warehouse? Any excursion?
  - Was transporter authorized to warehouse, or only transport?
  - Was the transporter qualified (for transport and warehousing)?
  - What were the laboratory results?
  - What was the final disposition of this product: restock and resale? Or destruction?
    - If restocked, is there any identification this product was returned?
    - If destroyed, check the destruction records.

Returns and Good Distribution Practices

Quality Management System

Returns

Documentation (SOP and records); Training; CAPA (Corrective and Preventive Action); Risk Management; Key Performance Indicators; Deviation handling

Environmental Condition Management

Evidence of conditions in which the cargo was transported and stored throughout the entire time, excursion handling and duration of time between the original shipment and its return

Supply Chain Integrity and Security

Appearance and integrity of the original packaging, that provides insights of how the product was handled and also about the authenticity of the product, in order to avoid counterfeited medicines to enter legal supply chain

Good Importation Management

The custody of product changed along the forward and backward flows and the organization does not know how this product was storage and transported. For importation/exportation this relation if more critical, since it involves Customs and Licenses

Questions

Thank You