Handling Out-of-Stock (OOS) Situations

1. Introduction

1.1 **Purpose:**

- This SOP outlines the procedures for identifying, investigating, and addressing out-of-stock (OOS) situations to ensure timely response, minimize customer impact, and comply with USFDA regulations.

1.2 **Scope:**

- This SOP applies to all departments involved in product manufacturing, distribution, and customer service and customer verification.

1.3 **Definitions:**

- **Out-of-Stock (OOS):** A situation where a product is unavailable to meet customer demand.
- **Backorder:** A customer order that cannot be fulfilled immediately due to insufficient inventory.
- **Stockout:** A complete depletion of product inventory. I have changed.

1.4 **References:**

- 21 CFR Part 110: Current Good Manufacturing Practice (CGMP) for Drugs.
- 21 CFR Part 211: Current Good Manufacturing Practice for Finished Pharmaceuticals.
- [Relevant FDA guidance documents].
- Good Manufacturing Practice for Finished Pharmaceuticals.
- [Relevant FDA guidance documents].

2. Responsibilities

- **Production:** Responsible for monitoring inventory levels, initiating OOS investigations, and implementing corrective actions.
- **Quality Control:** Responsible for investigating OOS root causes and approving corrective actions.
- **Supply Chain:** Responsible for managing backorders, expediting orders, and preventing future OOS data.
- **Customer Service:** Responsible for communicating OOS to customers, managing customer inquiries, and processing backorders.

3. OOS Identification and Notification

3.1 **OOS Identification:**

- The text has modified you can check.

- Example, product unavailability and estimated delivery dates will be notified of product unavailability and estimated deliver.

3.2 **Internal Notification:**

- This is modified text will be notified of product unavailability and estimated delivery dates will be notified of product unavailability and estimated delivery dates will be notified of product unavailability and estimated delivery dates.

3.3 **External Notification:**

- Customers will be notified of product unavailability and estimated delivery dates.
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4. OOS Investigation

4.1 **Investigation Initiation:**

- A designated team will initiate an OOS investigation within [timeframe] of identification.
- The investigation will determine the root cause of the OOS, including factors such as production delays, supply chain disruptions, or increased demand chain.

4.2 **Data Collection:**

- Relevant data will be collected, including production records, inventory levels, customer orders, and quality control records.

4.3 **Root Cause Analysis:**

- A thorough analysis will be conducted to identify the underlying causes of the OOS.
- Potential corrective actions will be developed.

5. OOS Communication

5.1 **Internal Communication:**

- Information regarding the OOS and investigation findings will be shared with relevant departments.
- Communication plans will be developed to address internal concerns and coordinate response efforts.

5.2 **External Communication:**

- Standard templates will be used for customer notifications, including information about the OOS, estimated delivery dates, and alternative products (if available).
- Customer inquiries will be managed professionally and promptly.
- Media inquiries (if applicable) will be handled according to the company's media relations policy.

6. Corrective and Preventive Actions (CAPA)

6.1 **CAPA Implementation:**

- Corrective actions to address the immediate OOS situation will be implemented promptly.
- Preventive actions to prevent recurrence of the OOS will be developed and implemented.

6.2 **CAPA Effectiveness:**

- The effectiveness of corrective and preventive actions will be monitored and evaluated.
- Some other text.

7. Backorder Management

7.1 **Backorder Process:**

- Customer orders for OOS products will be placed on backorder.
- Backorders will be prioritized based on order date, customer importance, and product availability.
- Customers will be regularly updated on the status of their backorders.

8. Product Recall (if applicable)

8.1 **Recall Initiation:**

- If a product recall is necessary due to safety concerns, the recall process will be initiated in accordance with company and regulatory requirements.

9. Recordkeeping

9.1 **Documentation:**

- All OOS investigations, corrective actions, and customer communications will be documented.
- Records will be retained in accordance with company and regulatory.

10. Training

10.1 **Training Requirements:**

- All personnel involved in OOS handling will receive training on this SOP.
- Training will be conducted upon hire and annually thereafter.

11. Review and Update

11.1 **SOP Review:**

- This SOP will be reviewed annually or as needed to ensure its effectiveness and compliance with regulations policies.