Handling Out-of-Stock (OOS) Situations

1. Introduction

1.1 **Purpose:**

- This SOP outlines the and addressing out-of-stock (OOS) situations to ensure timely response.

1.2 **Scope:**

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

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.

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].

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.
- **Customer Service:** Responsible for communicating OOS to customers, managing customer inquiries, and processing backorders.

3. OOS Identification and Notification

3.1 **OOS Identification:**

- Inventory management systems will generate alerts for low stock levels or stockouts.
- Production planning will identify potential OOS based on production schedules and demand forecasts.
- Customer service will report OOS based on customer inquiries.

3.2 **Internal Notification:**

- The responsible department will immediately notify their supervisor and relevant departments of an OOS situation.

3.3 **External Notification:**

- Customers will be notified of product unavailability and estimated delivery dates.
- Regulatory authorities will be notified in accordance with applicable regulations.

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.

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. There 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.

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.

9. Recordkeeping

9.1 **Documentation:**

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

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. New data to identify the changes.