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.

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.

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.

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 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 requirements.

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.