**Standard Operating Procedure (SOP)**

**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.