

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

1. Introduction

1.1 Purpose:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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.

Document 5

Similarity Score: 81%

Tag: R

Summary: Different

Comparison Status: Compared

Removed Text: , minimize customer impact, and comply with USFDA regulations

This SOP outlines the procedures for identifying, investigating, and addressing out-of-stock (OOS) situations to ensure timely response.

1.2 Scope:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Date: 2024-08-18

Page 1 of 17

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

Comparison Status: Compared

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

Document 5

Similarity Score: 88%

Tag: M

Summary: Different

Comparison Status: Compared

Added Text: . S t x t d d e d

Removed Text: and cust r v r i f i c a t i o n

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

1.3 Definitions:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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.

Document 5

Similarity Score: 97%

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

Tag: R

Summary: Different

Comparison Status: Compared

Removed Text: inventory

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:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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].

Document 5

Similarity Score: 99%

Tag: R

Summary: Different

Comparison Status: Compared

Removed Text: ...

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

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

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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.

Document 5

Similarity Score: 99%

Tag: R

Summary: Different

Comparison Status: Compared

Removed Text: data

Production: Responsible for monitoring inventory levels, initiating OOS investigations, and implementing corrective actions.

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

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:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

Regulatory authorities will be notified in accordance with applicable regulations.

Document 5

Similarity Score: 4%

Tag: M

Summary: Different

Comparison Status: Compared

Added Text: 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

Removed Text: Regulatory authorities will be notified in accordance with applicable regulations

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

Modified Text: 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.

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:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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

Document 5

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

3.3 External Notification:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

Customers will be notified of product unavailability and estimated delivery dates.

Regulatory authorities will be notified in accordance with applicable regulations.

Document 5

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

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.

Document 5

Similarity Score: 98%

Tag: R

Summary: Different

Comparison Status: Compared

Removed Text: chain

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:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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

Document 5

Similarity Score: 100%

Tag: S

Summary: Same

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

Comparison Status: Compared

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

4.3 Root Cause Analysis:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

A thorough conducted to identify the underlying causes of the SOP.

Potential added corrective actions will be developed. Good text.

Document 5

Similarity Score: 85%

Tag: M

Summary: Different

Comparison Status: Compared

Added Text: analysis will be OO

Removed Text: OP added Good text.

A thorough analysis will be conducted to identify the underlying causes of the OOS.

Potential corrective actions will be developed.

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

5. OOS Communication

5.1 Internal Communication:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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.

Document 5

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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:

Document 4

Similarity Score: 100%

Tag: S

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

Summary: Same

Comparison Status: Compared

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.

Document 5

Similarity Score: 89%

Tag: A

Summary: Different

Comparison Status: Compared

Added Text: There will be handled according to the company's media relations policy.

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:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

Comparison Status: Compared

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.

Document 5

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

All OOS investigations, corrective actions, and customer communications will be documented.

Document 5

Similarity Score: 48%

Tag: M

Summary: Different

Comparison Status: Compared

Added Text: The effectiveness of preventive actions monitored and evaluated

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

Removed Text: All OOS notifications, a customer communication

The effectiveness of corrective and preventive actions will be monitored and evaluated.

7. Backorder Management

7.1 Backorder Process:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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.

Document 5

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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.

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

8. Product Recall (if applicable)

8.1 Recall Initiation:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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

Document 5

Similarity Score: 95%

Tag: R

Summary: Different

Comparison Status: Compared

Removed Text: requirements

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:

Document 4

Similarity Score: 100%

Tag: S

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

Summary: Same

Comparison Status: Compared

All OOS investigations, corrective actions, and customer communications will be documented.

Records will be retained in accordance with company and regulatory.

Document 5

Similarity Score: 95%

Tag: R

Summary: Different

Comparison Status: Compared

Removed Text: and regulatory

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:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

All personnel involved in OOS handling will receive training on this SOP.

Training will be conducted upon hire and annually thereafter.

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

Document 5

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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:

Document 4

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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

Document 5

Similarity Score: 88%

Tag: M

Summary: Different

Comparison Status: Compared

Added Text: . New data t identify the hang

Removed Text: p l i

Compared By: ADMIN

Report Number: DCR1002

Comparison Reason: only testing

This SOP will be reviewed annually or as needed to ensure its effectiveness and compliance with regulations. New data to identify the changes.