Compared By: ADMIN

Report Number: DCR1005

Comparison Reason: k.oaspdjnv

1. Introduction

1.1 Purpose:

Document 10

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 11

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.

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1.2 Scope:

Document 10

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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

Document 11

Similarity Score: 89%

Tag: R

Summary: Different

Comparison Status: Compared

Removed Text: and customer verification

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

1.3 Definitions:

Document 10

Similarity Score: 100%

Tag: S

Summary: Same

Compared By: ADMIN Report Number: DCR1005

Comparison Reason: k.oaspdjnv

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. I have changed.

Document 11

Similarity Score: 96%

Tag: R

Summary: Different

Comparison Status: Compared

Removed Text: I have changed.

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.

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1.4 References:

Document 10

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].

Good Manufacturing Practice for Finished Pharmaceuticals.

[Relevant FDA guidance documents].

Document 11

Similarity Score: 80%

Tag: R

Summary: Different

Comparison Status: Compared

Removed Text:

Good Manufacturing Practice for Finished Pharmaceuticals.

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[Relevant FDA guidance documents].

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 10

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.

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

Document 11

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.

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.

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Comparison Reason: k.oaspdjnv

3. OOS Identification and Notification

3.1 OOS Identification:

Document 10

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

□

The text has modified you can check.

□

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

product unavailability and estimated deliver.

Document 11

Similarity Score: 5%

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 sc dules and demand orecasts Customer ser ice will report OOS ased on customer inquiries

Removed Text: T text has modi ied you can check Example, product una aila ility and estimated delivery dates will be notified of
product unavailability and estimated deliver

Compared By: ADMIN Report Number: DCR1005

Comparison Reason: k.oaspdjnv

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 10

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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.

Compared By: ADMIN Report Number: DCR1005

Comparison Reason: k.oaspdjnv

Document 11

Similarity Score: 28%

Tag: M

Summary: Different

Comparison Status: Compared

Added Text: e respons ble depart n imm diately y the r sup rvis r levan
partm n an OOS s u o

Removed Text: s is odifi d tex b d f p oduct unavailability s imated liv ry
da e will be notified product unavailabil y nd es mated delivery dates will be
otified of product unavailability and estimated delivery dates

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

The responsible department will immediately notify their supervisor and relevant

departments of an OOS situation.

3.3 External Notification:

Document 10

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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

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Comparison Reason: k.oaspdjnv

Added updated text to identify the comparison.

Document 11

Similarity Score: 66%

Tag: M

Summary: Different

Comparison Status: Compared

Added Text: Regulatory authorities will be notifi in accor nce wi h applicabl r gula s

Removed Text: Add up d t xt to iden fy the comparis

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 10

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

A designated team will initiate an OOS investigation within [timeframe] of identification.

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Comparison Reason: k.oaspdjnv

The investigation will determine the root cause of the OOS, including factors such as production delays, supply chain disruptions, or increased demand chain.

Document 11

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 10

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

Relevant data will be collected, including production records, inventory levels,

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customer orders, and quality control records.

Document 11

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.

4.3 Root Cause Analysis:

Document 10

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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

Potential corrective actions will be developed.

Document 11

Similarity Score: 100%

Tag: S

Summary: Same

Compared By: ADMIN Report Number: DCR1005

Comparison Reason: k.oaspdjnv

Comparison Status: Compared

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:

Document 10

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 11

Similarity Score: 100%

Tag: S

Summary: Same

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Comparison Reason: k.oaspdjnv

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 10

Similarity Score: 100%

Tag: S

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 11

Similarity Score: 100%

Compared By: ADMIN Report Number: DCR1005

Comparison Reason: k.oaspdjnv

Tag: S

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.

6. Corrective and Preventive Actions (CAPA)

6.1 CAPA Implementation:

Document 10

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

Corrective actions to address the immediate OOS situation will be implemented promptly.

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Comparison Reason: k.oaspdjnv

Preventive actions to prevent recurrence of the OOS will be developed and implemented.

Document 11

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 10

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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

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Comparison Reason: k.oaspdjnv

Some other text.

Document 11

Similarity Score: 90%

Tag: R

Summary: Different

Comparison Status: Compared

Removed Text:

Some other text.

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

7. Backorder Management

7.1 Backorder Process:

Document 10

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

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Comparison Reason: k.oaspdjnv

availability.

Customers will be regularly updated on the status of their backorders.

Document 11

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.

8. Product Recall (if applicable)

8.1 Recall Initiation:

Document 10

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

Compared By: ADMIN Report Number: DCR1005

Comparison Reason: k.oaspdjnv

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

Document 11

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.

9. Recordkeeping

9.1 Documentation:

Document 10

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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

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Comparison Reason: k.oaspdjnv

Records will be retained in accordance with company and regulatory.

Document 11

Similarity Score: 96%

Tag: A

Summary: Different

Comparison Status: Compared

Added Text: requirements

□

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:

Document 10

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

□

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

□

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Comparison Reason: k.oaspdjnv

Training will be conducted upon hire and annually thereafter.

Document 11

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 10

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 11

Similarity Score: 96%

Tag: R

Compared By: ADMIN

Report Number: DCR1005

Comparison Reason: k.oaspdjnv

Summary: Different

Comparison Status: Compared

Removed Text: policies

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