 VidyaGxP <small>Data informs. wisdom discerns.</small>	Documents Comparison Report
Compared By: ADMIN	Report Number: CR100433
Comparison Reason: Testing	

1. Introduction

1.1 Purpose:

Document 18

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 19

Similarity Score: 64%

Tag: R

Summary: Different

Comparison Status: Compared


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

1.2 Scope:

Document 18

Similarity Score: 100%

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Tag: S

Summary: Same

Comparison Status: Compared

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

Document 19

Similarity Score: 92%

Tag: A

Summary: Different

Comparison Status: Compared

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

1.3 Definitions:

Document 18

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.

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Document 19

Similarity Score: 97%

Tag: R

Summary: Different

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.

1.4 References:

Document 18

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 19

Similarity Score: 100%

Tag: S

Summary: Same

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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].

2. Responsibilities

Document 18

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.

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


Document 19

Similarity Score: 100%

Tag: S

Summary: Same

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 VidyaGxP <small>Data informs, wisdom discerns.</small>	Documents Comparison Report
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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.

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

3. OOS Identification and Notification

3.1 OOS Identification:

Document 18

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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.

Document 19

Similarity Score: 100%

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Tag: S

Summary: Same

Comparison Status: Compared

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 18

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 19

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.

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3.3 External Notification:

Document 18

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 19

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 18

Similarity Score: 100%

Tag: S

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 VidyaGxP <small>Data informs, wisdom discerns.</small>	Documents Comparison Report
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Summary: Same

Comparison Status: Compared

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.

Document 19

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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 18

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.

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Document 19

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 18

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 19

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.

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 VidyaGxP <small>Data informs, wisdom discerns.</small>	Documents Comparison Report
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5. OOS Communication

5.1 Internal Communication:

Document 18

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 19

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.

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 VidyaGxP <small>Data informs, wisdom discerns.</small>	Documents Comparison Report
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5.2 External Communication:

Document 18

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 19

Similarity Score: 89%

Tag: A

Summary: Different


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

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 VidyaGxP <small>Data informs, wisdom discerns.</small>	Documents Comparison Report
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6. Corrective and Preventive Actions (CAPA)

6.1 CAPA Implementation:

Document 18

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.

Document 19

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 18

Similarity Score: 100%

Tag: S

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 VidyaGxP <small>Data informs, wisdom discerns.</small>	Documents Comparison Report
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Comparison Reason: Testing	

Summary: Same

Comparison Status: Compared

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

Document 19

Similarity Score: 100%

Tag: S

Summary: Same

Comparison Status: Compared

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

7. Backorder Management

7.1 Backorder Process:

Document 18

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.

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Comparison Reason: Testing	

Document 19

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 18

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 19

Similarity Score: 95%

Tag: R

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 VidyaGxP <small>Data informs, wisdom discerns.</small>	Documents Comparison Report
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Comparison Reason: Testing	

Summary: Different

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.

9. Recordkeeping

9.1 Documentation:

Document 18

Similarity Score: 100%

Tag: S

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 requirements.

Document 19

Similarity Score: 91%


Tag: R

Summary: Different

Comparison Status: Compared

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

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 VidyaGxP <small>Data informs, wisdom discerns.</small>	Documents Comparison Report
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Records will be retained in accordance with company.

10. Training

10.1 Training Requirements:

Document 18

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.

Document 19

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.

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 VidyaGxP <small>Data informs, wisdom discerns.</small>	Documents Comparison Report
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11. Review and Update

11.1 SOP Review:

Document 18

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.

Document 19

Similarity Score: 86%

Tag: A

Summary: Different

Comparison Status: Compared

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

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