

# BODYBIO

SOP # 04-054.1	Standard Operating Procedure	Written/Revised By/Date: <i>Elly Lopez 7/7/23</i>
Effective Date  JUL 07 2023	HACCP SOP	Approved By/Date: <i>Daniel Nunez 7-7-23</i>
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### 1.0 Purpose

This SOP aims to identify potential hazards (chemical, physical or biological) in the production processes and implement control measures to prevent their occurrence in the products manufactured by BODYBIO or its contract manufacturer (CMOs) for safe consumer consumption.

### 2.0 Scope

This procedure applies to all departments involved in the manufacturing, processing, packaging, and holding of products at BodyBio Facility 1 and Facility 2 and products made at any of BodyBio's contract manufacturers.

### 3.0 Responsibility and Frequency

The HACCP team is responsible for developing, implementing, and maintaining the HACCP system. The team includes the Senior Quality Control Manager, Manufacturing Manager, Demand & Logistics Manager, and any designee by the team. The team leader is responsible for overseeing the implementation of the HACCP plan.

The Quality Control Manager is responsible for overseeing the development, review, completion, and compliance of the plan. Tasks can be assigned and conducted by any trained and qualified personnel in food safety.

Quality Control Manager shall document and implement an annual review of the Food Safety Management System and update senior management during an annual management review meeting, or as needed based on change management that is related to raw materials, processes, products, and/or corrective and preventative actions (CAPA).

Quality Control will subscribe to the FDA-TRACK for email updates from the FDA to remain updated and compliant with all relevant regulatory requirements.

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#### 4.0 References

- 21 CFR 117.126
- Personal Hygiene SOP 04-021
- General Manufacturing Equipment Cleaning SOP 02-008
- General Manufacturing, Packaging, Laboratory and Warehouse area Cleaning SOP 02-007
- Receiving of Inventory Materials SOP 03-002
- Approved Chemicals SOP 02-004
- Manufacturing Product and Packaging Procedures SOP 02-001
- Failure Investigation and Disposition/ CAPA SOP 04-009
- Pest Control SOP 04-031
- Warehouse Management SOP 03-004
- Quality Standard Specification SOP 04-007
- Employee Training SOP 01-001
- Document Control SOP 04-030

#### 5.0 Definitions

**HACCP:** Hazard Analysis and Critical Control Points: a food safety management system that is used in the food and dietary supplement industry to identify potential hazards in the manufacturing processes.

**SOP:** Standard Operating Procedure: a written procedure outlining how a task is performed to ensure process control in compliance with cGMP requirements.

**CMO:** Contract Manufacturing Organization: A third-party manufacturing organization that is outsourced by BodyBio to manufacture products for BodyBio.

**Facility 1:** BodyBio Manufacturing Facility, located at 45 Reese Road, Millville, New Jersey, 08332.

**Facility 2:** BodyBio Manufacturing Facility located at 25 Driskill Street, Millville, New Jersey, 08332.

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cGMP: Current Good Manufacturing Practice: regulations established by FDA to ensure products meet safety, purity, and potency expectations; also referred to as “GMP”.

CAPA: Corrective Action; Preventative Action: These are actions taken when there is any non-conformances to correct the issues immediately, as well as provide a long-term solution to the issues.

CoA: Certificate of Analysis

CoC: Certificate of Conformance

## 6.0 Documents

- Receiving Log Book
- Receiving Record Sheet
- Inventory Tag

## 7.0 Procedures

BodyBio follows the HACCP major steps for identifying and controlling any potential hazard to any manufacturing processes and these steps are outlined below:

- Assembling the HACCP Team.
- Product(s) Description, Including its ingredients and packaging component.
- Identify the Intended Use
- Develop a Manufacturing Flow Diagram
- Conduct a Hazard Analysis
- Determine the Critical Control Points (CCPs)
- Establishment of Critical Limits
- Establishment of Monitoring Procedures for the Critical Limits established
- Establishment of Corrective Actions and Preventive Actions for any non-conformances

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- Establish a Record Keeping Process
- Establish a Verification Process
- Implementation and Maintenance of the HACCP Plan

## 8.0 Product Description:

The following products have been identified to go through the HACCP processes at BodyBio and its CMOs:

- Phosphatidylcholine Liquid
- Phosphatidylcholine Softgels
- Balance Oil
- Balance Oil Softgels
- Mineral Supplements
- Evening Primrose Oil
- Evening Primrose Oil Softgels
- Fish Oil Softgels
- B-Vitamin (High Dose)
- Tauroursodeoxycholic Acid
- Calcium Magnesium Butyrate
- Sodium Butyrate
- Gut+
- Liposomal Glutathione
- Liposomal Vitamin C
- Calm

A detailed description, ingredients, packaging components, and intended use of each product can be found in their respective HACCP Product Plan.

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## 9.0 Hazard Analysis

The Hazard Analysis for each product will identify the potential biological, chemical, and physical hazards that may occur during production processes. This analysis includes the raw materials, processing, packaging, and storage of the product.

Steps to performing Hazard Analysis:

- Identify potential hazards:
  - Make a list of all the potential hazards associated with the product. These hazards can include physical, chemical, and biological hazards. The list of all potential hazard such as physical, chemical, and biological hazards associated with each product can be found in the Product HACCP Plan for each product manufactured by BodyBio and/or its CMO partners.
- Evaluate the severity of each hazard:
  - Determine the potential severity of each hazard, considering the potential harm it could cause. This is specific for each product and detailed for each product can be found in the Product HACCP Plan for each Product manufactured by BodyBio and/or its CMO partners.
- Assess the likelihood of occurrence:
  - Determine the likelihood of each hazard occurring. This can be based on the probability of the hazard occurring and the frequency of exposure. This is specific for each product and detailed for each product can be found in the Product HACCP Plan for each Product manufactured by BodyBio and/or its CMO partners.
- Determine the risk level:
  - Based on the severity and likelihood of occurrence, determine the risk level associated with each hazard. This is specific for each product and detailed for each product can be found in the Product HACCP Plan for each Product manufactured by BodyBio and/or its CMO partners.
- Develop control measures:
  - Develop appropriate control measures to prevent, mitigate or eliminate each hazard. This could involve redesigning the product, modifying production processes, and implementing safety procedures. This is specific for each product and detailed for each product can be found

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in the Product HACCP Plan for each Product manufactured by BodyBio and/or its CMO partners.

- Implement and monitor control measures:
  - Implement the control measures identified and monitor their effectiveness. And continuously review and update the hazard analysis as necessary to ensure that the product remains safe.

The hazard Analysis of each product listed in this SOP can be found as an attachment to their respective SOP.



## 10.0 Critical Control Points (CCPs)

Determine the CCPs in the process where control measures can be applied to prevent, eliminate, or reduce hazards to acceptable levels.

The CCPs for BodyBio include:

- Raw Material Receipt
- Raw Material Inspection
- Packaging Component Receipt
- Packaging Component Inspection
- Raw Material Storage
- Packaging Component Storage
- Reverse Osmosis (RO) water system
- Raw Material Weighing
- Raw Material Blending
- Processing of Raw Materials
- Filling or Bottling
- Labeling
- Finished Product Storage
- Finished Product Distribution

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Each of the CCP identified is outlined in product specific HACCP plan.

## 11.0 Critical Limits:

Establish critical limits for each CCP. These critical limits for each product should follow the below process:

- Raw Material & Packaging Component Receipt:
  - Packing Slip, CoA, and CoC match the raw materials and/or packaging component container labels, with the Manufacturing Date or Expiration Date (if applicable), Supplier/Vendor information, and Lot or Batch Number.
- Raw Material & Packaging Component Inspection:
  - Visual Inspection of drums, containers, and bags.
- Raw Material & Packaging Component Storage:
  - Proper temperature and humidity set for the storage area.
- Reverse Osmosis (RO) water system:
  - Visual Inspection and Filter Change.
- Weighing:
  - Visual checks on weights.
- Blending:
  - Visual, Cleaning, and Swab-test.
- Manufacturing (Processing):
  - Cross-contamination and no introduction of environmental contaminants and Batch Records.
- Filling or Bottling:
  - The correct weight and fill level, Visual checks on packaging components such as glass to ensure it's not broken. Nitrogen blanket for moisture.
- Labeling:
  - Visual checks for label for the actual product, per batch record.
- Finished Product Storage:
  - Proper temperature and humidity set for the storage area and distributed with approved logistics partners.

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## 12.0 Monitoring Process

The HACCP team will be responsible for monitoring the CCPs as required. This team includes the Senior Quality Control Manager, Manufacturing Manager, Demand & Logistics Manager, and any designee by the team. The team leader is responsible for overseeing the implementation of the HACCP plan.

- Raw Material & Packaging Component Receipt:
  - The Demand & Logistics Manager or Designee will verify the packing slip and CoA/CoC and ensure it is matching with the label on the containers, and will also verify the lot/batch number matches prior to receiving into the BodyBio inventory system (SAGE).
- Raw Material & Packaging Component Inspection:
  - The Demand & Logistics Manager or Designee will inspect that the lot/batch number matches with the CoA/CoA and pull samples according to the sampling SOP 04-017.5.
- Raw Material, Packaging Component & Finished Product Storage:
  - The Manufacturing Manager or Designee will ensure that a monitoring log/device that records temperature and humidity is available in the warehouse for record keeping every week.
- Reverse Osmosis (RO) water system:
  - The Manufacturing Manager will ensure that the line/hose carrying the water is intact and will ensure that the filter is changed as needed. This is monitored at the beginning of every production.
- Weighing:
  - The Manufacturing Manager or Designee will ensure that the weight is calibrated and ready to use. They will ensure weight is properly “tared” and recorded before use.
- Blending:
  - The Senior Quality Control Manager, Manufacturing Manager, or Designee will ensure that the blender is swabbed and released prior to use, except for the blender that is specific for Phosphatidylcholine.

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- Manufacturing Process:
  - The Manufacturing Manager or Designee must ensure that a line clearance inspection is done to monitor the raw materials as described in the batch record.
- Filling or Bottling:
  - The Manufacturing Manager or Designee must ensure there is a line clearance inspection done to monitor the packaging components and ensure the tablets/capsule counters are set, and fillers are set to the level they should.
- Labeling:
  - Monitored by visual inspection by Manufacturing Manager, Senior Quality Control Manager or Designee before packaging. Line clearance inspection is done to monitor the product label.
- Packaging of Finished Product:
  - The Manufacturing Manager or Designee is to run the metal detector through the packaging line to confirm that there is no metal introduced and that all parts are cleaned, counters are set, and fillers are set based on batch records for packaging.

## 13.0 Corrective Action

The following actions must be taken if there is any deviation in the CCPs steps outlined above.

- Raw Material & Packaging Component Receipt:
  - The receiver or designee will note the receiving records and contact the supplier to provide the documentation missing.
- Raw Material & Packaging Component Inspection:
  - Reject and Dispose of any contaminated or adulterated materials or packaging components.
- Raw Material, Packaging Component & Finished Product Storage:
  - Adjust temperature or humidity and re-inspect.
- Reverse Osmosis (RO) water system:
  - Change filter and hose and re-inspect.
- Weighing:
  - Adjust weight and fill level and reinspect.

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- Blending:
  - Reprocess or rework if possible or reject and dispose of materials that cannot be reprocessed or reworked.
- Manufacturing Process
  - Reprocess or rework if possible or reject and dispose of materials that cannot be reprocessed or reworked.
- Labeling:
  - Correct label and reinspect.
- Packaging of Finished Product:
  - Investigation, training on line clearance inspection.

#### 14.0 Verification Process:

Verifying that the HACCP system is working effectively requires an internal audit and product testing. The internal audit should be performed according to Audit Procedure (see SOP-04-016) and performing product testing annually by a third-party laboratory. In addition to the above,

- Review the HACCP system and Plan/records during the annual management review.
- Review deviations and product dispositions.
- Confirm that CCPs are properly monitored and kept under control.
- Get management sign-off that no deviations took place or that all deviations were properly documented and recorded.
- Ensure Plan is scientifically and technically sound.
- All hazards have been identified.
- CCPs/PCs are effective and valid and if the food safety plan is properly implemented that these hazards will be effectively controlled.

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## 15.0 Record Keeping

Establish procedures to document all aspects of the HACCP system which include monitoring corrective actions and verifications. The book-keeping process includes:

- Monitoring records:
  - Maintained by the Manufacturing Manager or Designee
- Corrective action records:
  - Maintained by Senior Quality Control Manager or Designee
- Verification records
  - Maintained by Senior Quality Control Manager or Designee

## 16.0 Annual Management Review

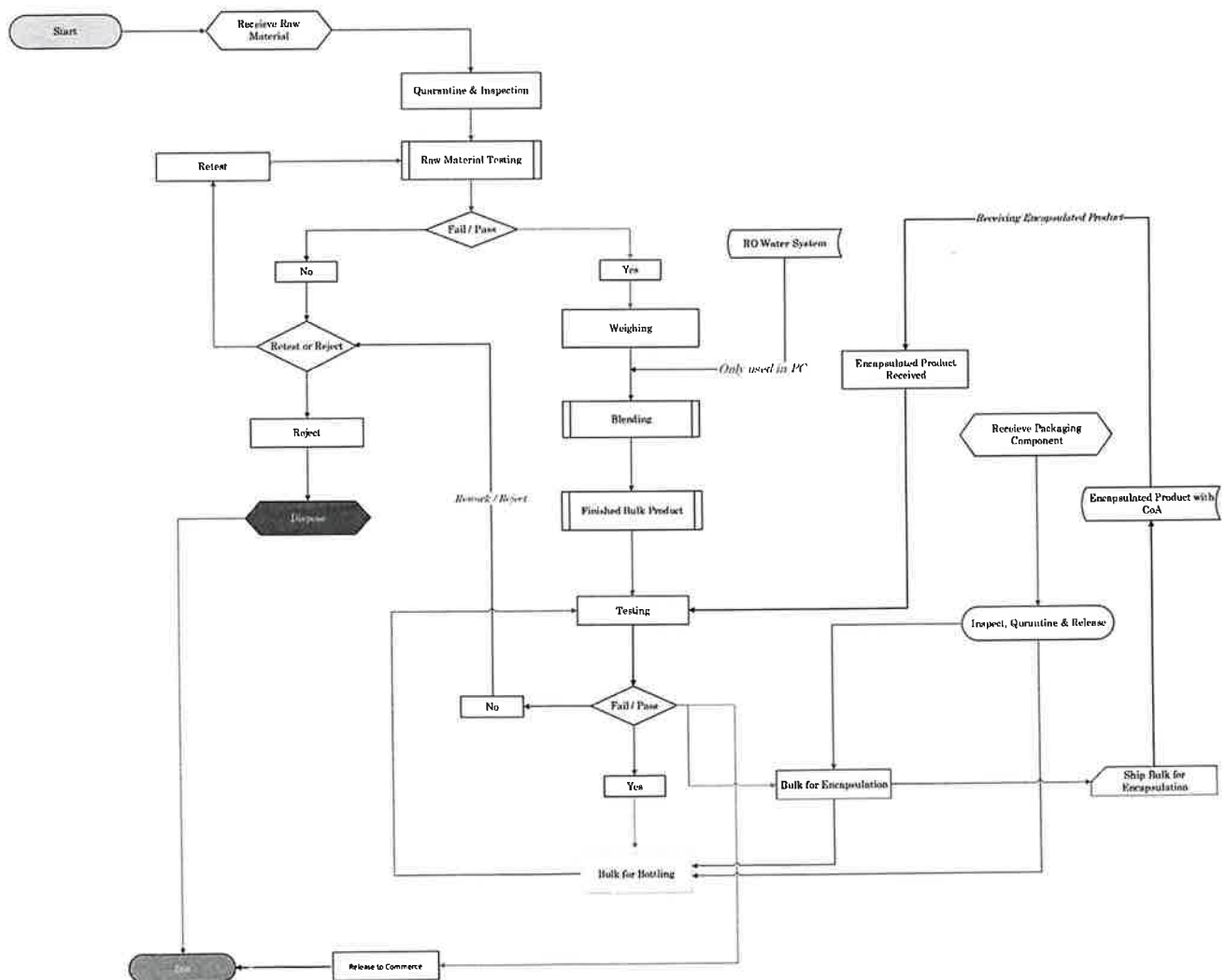
The Annual Management Review shall include the review of all HACCP Plans, and provide detailed updates to the management. The following should happen during the annual management review

- Update on previous management review action plans and timeline to complete.
- Review failures of the Food Safety Management System/HACCP Plans; Results on all audits.
- Review any customer complaint, non-conformance, and any site crisis or recalls, and observe any trend, discuss plan for improvement.
- Continuous improvement to the Food Safety Management System.
- Changes to customer and/or regulatory requirements that could affect the Food Safety Management System.
- This SOP should be reviewed and updated as necessary to ensure that the HACCP system remains effective in maintaining food safety and preventing foodborne illness.

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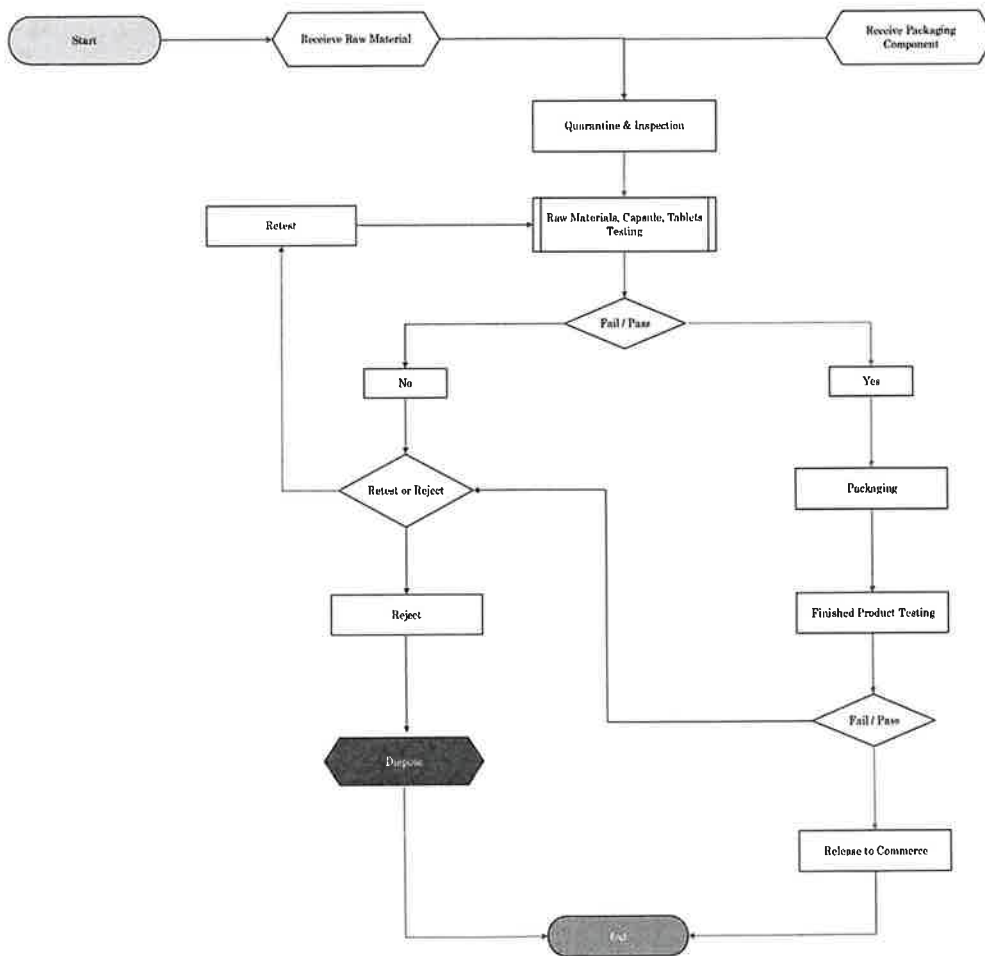
## MANUFACTURING AND PACKAGING PROCESS FLOW FOR BODYBIO PC AND BALANCE OIL PRODUCTS



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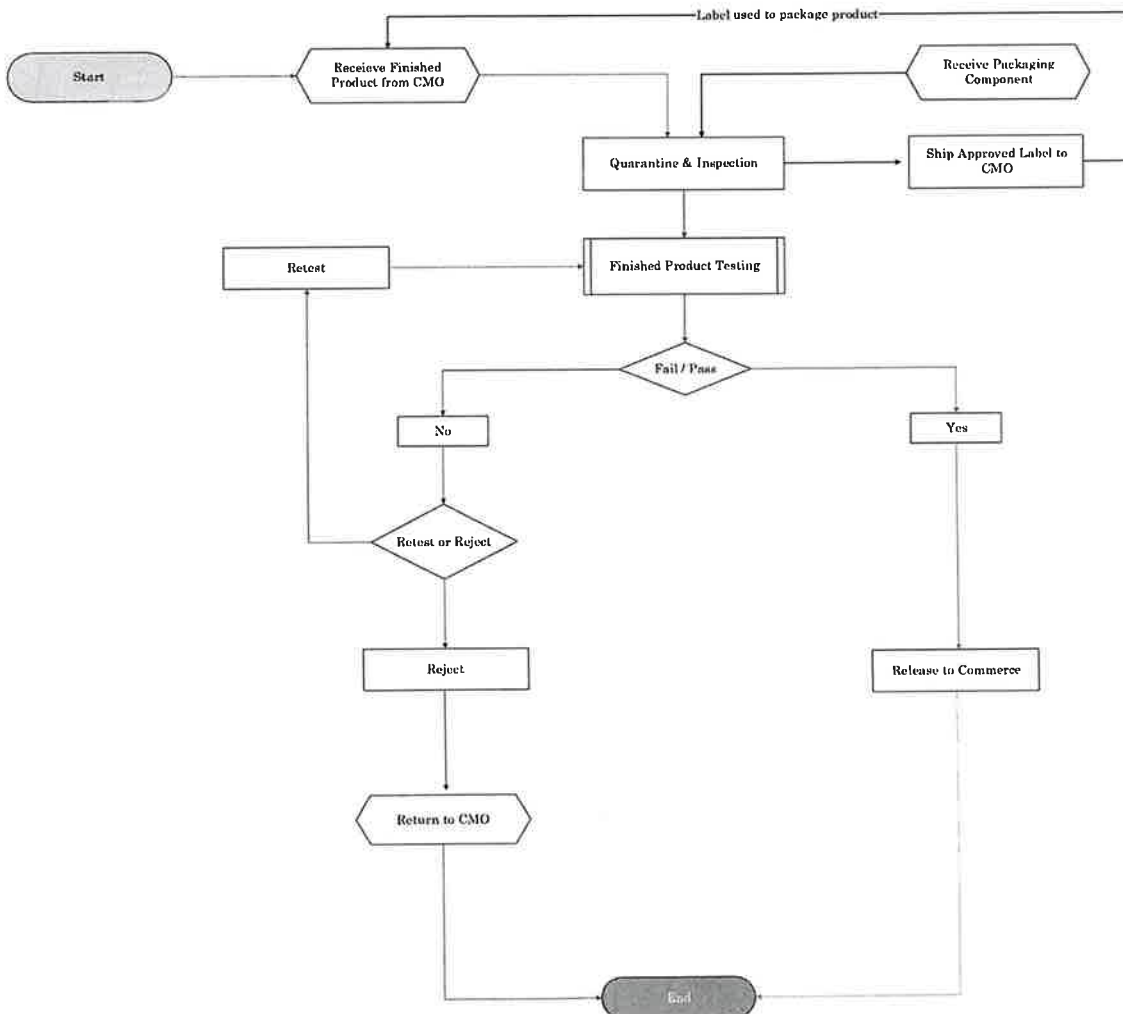
## MANUFACTURING AND PACKAGING PROCESS FLOW FOR BODYBIO PRODUCTS



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## PACKAGING PROCESS FLOW FOR BODYBIO PRODUCTS FROM CMOs



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## REVISION HISTORY

Date	Revision	Comments
August 23, 2022	0	New
	1	Revamp SOP to be comprehensive and more concise. Added Manufacturing Flow Chart for all products