BODYBIO

SOP # 04-054.2	Standard Operating Procedure	Written/Revised By/Date: 10/22/24
Effective Date: NOV 0 6 2024	HACCP SOP	Approved By/Date: 10/22/2024
Supersedes: 07/07/2023		Page 1 of 15

1.0 Purpose

1.1 This SOP aims to identify potential hazards (chemical, physical or biological) in the production processes and implement control measures to prevent their contaminations in the products manufactured, packaged, processed, and distributed by BodyBio for safe consumer consumption.

2.0 Scope

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

3.0 Responsibility and Frequency

3.1 The HACCP team is responsible for developing, implementing, and maintaining the HACCP system. The team includes the Director of Quality Assurance and Quality Control, Manufacturing Manager, Manufacturing Engineer, Senior Vice President of Operations, and any designee by the team. The team leader is responsible for overseeing the implementation of the HACCP plan.

3.2 The Director of Quality Assurance and Quality Control 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.

3.3 The Director of Quality Assurance and Quality Control will review 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).

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

3.5 The Quality Team will be responsible for ensuring that all Contract Manufacturers follow HACCP plans during the Quality audit of their site.

4.0 References

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

5.0 Definitions

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

5.2 Standard Operating Procedure (SOP): a written procedure outlining how a task is performed to ensure process controls are in compliance with cGMP requirements.

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

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

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

5.6 Current Good Manufacturing Practice (cGMP): regulations established by the FDA to ensure products meet safety, purity, and potency expectations; also referred to as "GMP".

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

5.8 Certificate of Analysis (COA): a document that verifies a product's quality, composition, and characteristics by comparing its analysis results to established standards.

5.9 Certificate of Conformance (CoC): a document issued by manufacturers or designated personnel with authority to assure customers or buyers that the product has been manufactured with test results showing compliance to international or regulatory standards.

6.0 Procedures

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

- 6.1.1 Assembling the HACCP Team.
- 6.1.2 Product(s) description, including its ingredients and packaging component.
- 6.1.3 Identify the intended use
- 6.1.4 Develop a manufacturing flow diagram
- 6.1.5 Conduct a hazard analysis

6.1.6 Determine the critical control points (CCPs)
6.1.7 Establishment of critical limits
6.1.8 Establishment of monitoring procedures for the critical limits
6.1.9 Establishment of corrective actions and preventive actions for any non-conformances
6.1.10 Establish a record keeping process
6.1.11 Establish a verification process
6.1.12 Implementation and maintenance of the HACCP Plan

7.0 Product Description:

7.1 Products manufactured or processed at BodyBio will go through the HACCP process.
7.2 A detailed description, ingredients, packaging components, and intended use of each product can be found in their respective HACCP Product Plan.

8.0 Hazard Analysis

8.1 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.
8.2 Steps to performing Hazard Analysis:
8.2.1 Identify potential hazards:
8.2.1.1 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 or processed by BodyBio.
8.2.2 Evaluate the severity of each hazard:
8.2.2.1 Determine the potential severity of each hazard, considering the potential harm it could cause. This is specific for each product and details for each product can be found in the Product HACCP Plan for each product manufactured or processed by BodyBio.

8.2.3 Assess the likelihood of occurrence:

8.2.3.1 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 details for each product can be found in the Product HACCP Plan for each product manufactured or processed by BodyBio.

8.2.4 Determine the risk level:

8.2.4.1 Based on the severity and likelihood of occurrence, determine the risk level associated with each hazard. This is specific for each product and details for each product can be found in the Product HACCP Plan for each product manufactured or processed by BodyBio.

8.2.5 Develop control measures:

8.2.5.1 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 details for each product can be found in the Product HACCP Plan for each product manufactured or processed by BodyBio.

8.2.6 Implement and monitor control measures:

8.2.6.1 Implement the control measures identified and monitor their effectiveness. Continuously review and update the hazard analysis as necessary to ensure that the product remains safe.

8.3 The Hazard Analysis of each product listed in this SOP can be found as an attachment to their respective HACCP Plan.

9.0 Critical Control Points (CCPs)

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

9.2 The CCPs for BodyBio include:

9.2.1 Raw Material Receipt

9.2.2 Raw Material Inspection

9.2.3 Packaging Component Receipt

9.2.4 Packaging Component Inspection

9.2.5 Raw Material Storage

9.2.6 Packaging Component Storage

9.2.7 Reverse Osmosis (RO) water system
9.2.8 Raw Material Weighing
9.2.9 Raw Material Blending
9.2.10 Processing of Raw Materials
9.2.11 Filling or Bottling
9.2.12 Labeling
9.2.13 Finished Product Storage
9.2.14 Finished Product Distribution

9.3 Each of the CCPs identified is outlined in each product specific HACCP plan.

10.0 Critical Limits:

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

10.1.1 Raw Material & Packaging Component Receipt:
10.1.1.1 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.

10.1.2 Raw Material & Packaging Component Inspection:
10.1.2.1 Visual Inspection of drums, containers, and bags.

10.1.3 Raw Material & Packaging Component Storage:
10.1.3.1 Proper temperature and humidity set for the storage area.

10.1.4 Reverse Osmosis (RO) water system:
10.1.4.1 Visual Inspection and Filter Change.

10.1.5 Weighing:
10.1.5.1 Visual checks on weights.

10.1.6 Blending:
10.1.6.1 Visual, Cleaning, and Swab-test.

10.1.7 Manufacturing (Processing):

10.1.7.1 Cross-contamination and no introduction of environmental contaminants and Batch Records.

10.1.8 Filling or Bottling:

10.1.8.1 The correct weight and fill level, visual checks on packaging components such as glass to ensure it's not broken. Nitrogen blanket for moisture.

10.1.9 Labeling:

10.1.9.1 Visual checks for label for the actual product, per batch record.

10.1.10 Finished Product Storage:

10.1.10.1 Proper temperature and humidity set for the storage area and distributed with approved logistics partners.

11.0 Monitoring Process

11.1 The HACCP team will be responsible for monitoring the CCPs as required. This team includes the Director of Quality Assurance and Quality Control, Manufacturing Manager, Manufacturing Engineer, Senior Vice President of Operations, and any designee by the team. The team leader is responsible for overseeing the implementation of the HACCP plan.

11.1.1 Raw Material & Packaging Component Receipt:

11.1.1.1 The Manufacturing Manager or designee will verify the packing slip and CoA/CoC and ensure it is matching with the label on the containers and verify the lot/batch number matches prior to receiving into the BodyBio inventory system (SAGE).

11.1.2 Raw Material & Packaging Component Inspection:

11.1.2.1 The Manufacturing Manager or designee will inspect that the lot/batch number matches with the CoA/CoC and will pull samples according to SOP 04-017 *Sampling Procedure*.

11.1.3 Raw Material, Packaging Component & Finished Product Storage:

11.1.3.1 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.

11.1.4 Reverse Osmosis (RO) water system:

11.1.4.1 The Manufacturing Manager or designee 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.

11.1.5 Weighing:

11.1.5.1 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.

11.1.6 Blending:

11.1.6.1 The Direct of Quality Assurance and Quality Control, Manufacturing Manager, or designee will ensure that the blender is swabbed and released prior to use.

11.1.7 Manufacturing Process:

11.1.7.1 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.

11.1.8 Filling or Bottling:

11.1.8.1 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.

11.1.9 Labeling:

11.1.9.1 Monitored by visual inspection by Manufacturing Manager, Direct of Quality Assurance and Quality Control or designee before packaging. Line clearance inspection is done to monitor the product label.

11.1.10 Packaging of Finished Product:

11.1.10.1 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.

12.0 Corrective Action

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

12.1.1 Raw Material & Packaging Component Receipt:

12.1.1.1 The receiver or designee will note the receiving records and contact the supplier to provide the documentation missing.

12.1.2 Raw Material & Packaging Component Inspection:

12.1.2.1 Reject and dispose of any contaminated or adulterated materials or packaging components.

12.1.3 Raw Material, Packaging Component & Finished Product Storage:

12.1.3.1 Adjust temperature or humidity and re-inspect.

12.1.4 Reverse Osmosis (RO) water system:

12.1.4.1 Change filter and hose and re-inspect.

12.1.5 Weighing:

12.1.5.1 Adjust weight and fill level and reinspect.

12.1.6 Blending:

12.1.6.1 Reprocess or rework if possible or reject and dispose of materials that cannot be reprocessed or reworked.

12.1.7 Manufacturing Process

12.1.7.1 Reprocess or rework if possible or reject and dispose of materials that cannot be reprocessed or reworked.

12.1.8 Labeling:

12.1.8.1 Correct label and reinspect.

12.1.9 Packaging of Finished Product:

12.1.9.1 Investigation, training on line clearance inspection.

13.0 Verification Process:

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

13.1.1 Review the HACCP system and Plan/records annually.

13.1.2 Review deviations and product dispositions.

13.1.3 Confirm that CCPs are properly monitored and kept under control.

13.1.4 Ensure Plan is scientifically and technically sound.

13.1.5 All hazards have been identified.

13.1.6 CCPs/Preventative Controls (PCs) are effective and valid and if the food safety plan is properly implemented that these hazards will be effectively controlled.

14.0 Record Keeping

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

14.1.1 Monitoring records:

14.1.1.1 Maintained by the Manufacturing Manager or designee

14.1.2 Corrective action records:

14.1.2.1 Maintained by Director of Quality Assurance and Quality Control or designee

14.1.3 Verification records

14.1.3.1 Maintained by Director of Quality Assurance and Quality Control or designee

15.0 Annual Management Review

15.1 The Annual Management Review shall include the review of all HACCP Plans and provide detailed updates to the Management Team. The following should occur during the annual management review:

15.1.1 Update on previous management review action plans and timeline to complete.

15.1.2 Review failures of the Food Safety Management System/HACCP Plans; Results on all audits.

15.1.3 Review any customer complaint, non-conformance, and any site crisis or recalls, and observe any trend, discuss plan for improvement.

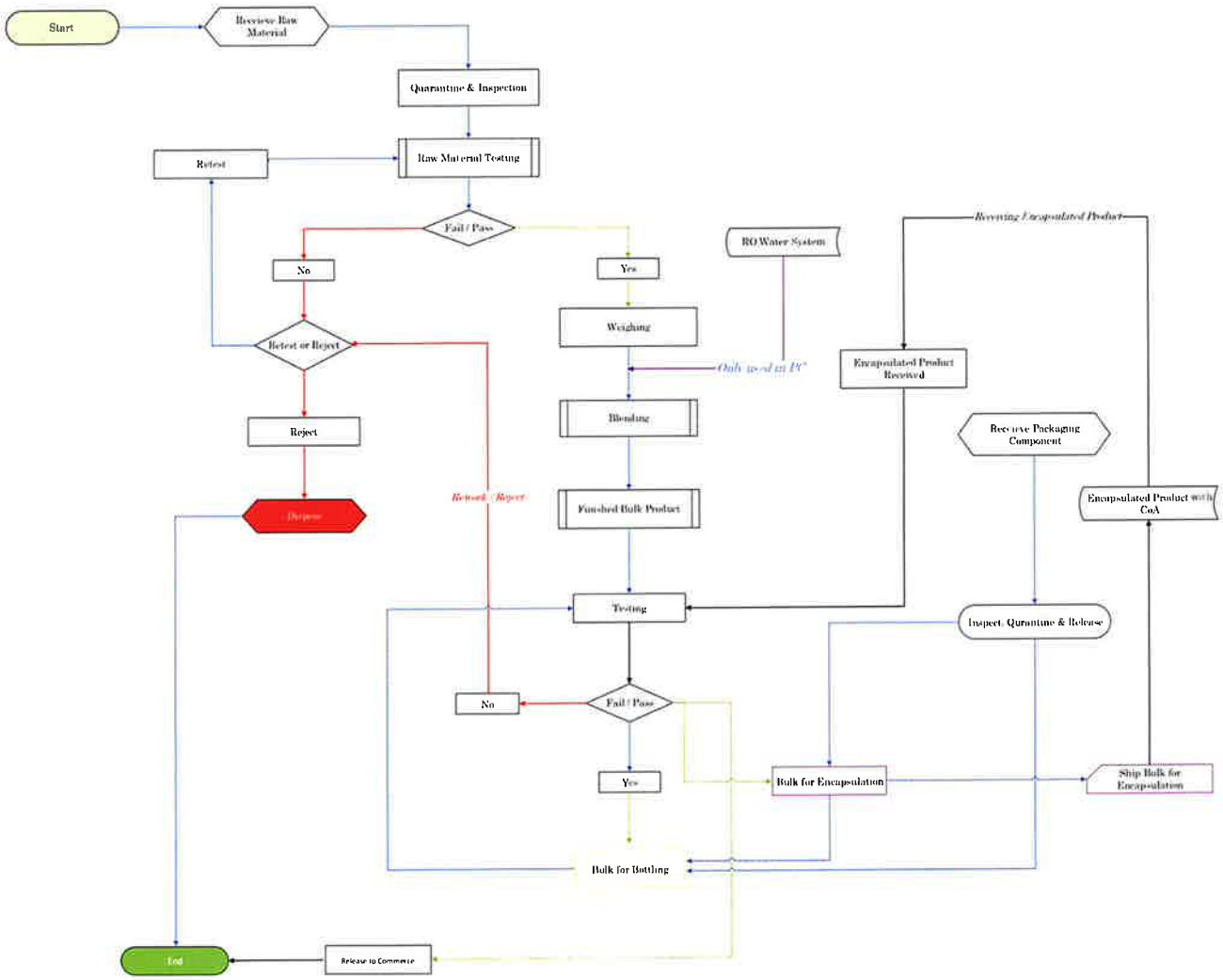
15.1.4 Continuous improvement to the Food Safety Management System.

15.1.5 Changes to customer and/or regulatory requirements that could affect the Food Safety Management System.

15.1.6 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.

SOP # 04-054.2	Standard Operating Procedure	Written/Revised By/Date: 10/22/24
Effective Date: NOV 0 6 2024	**HACCP SOP**	Approved By/Date: 10/22/2024
Supersedes: 07/07/2023		Page 11 of 15

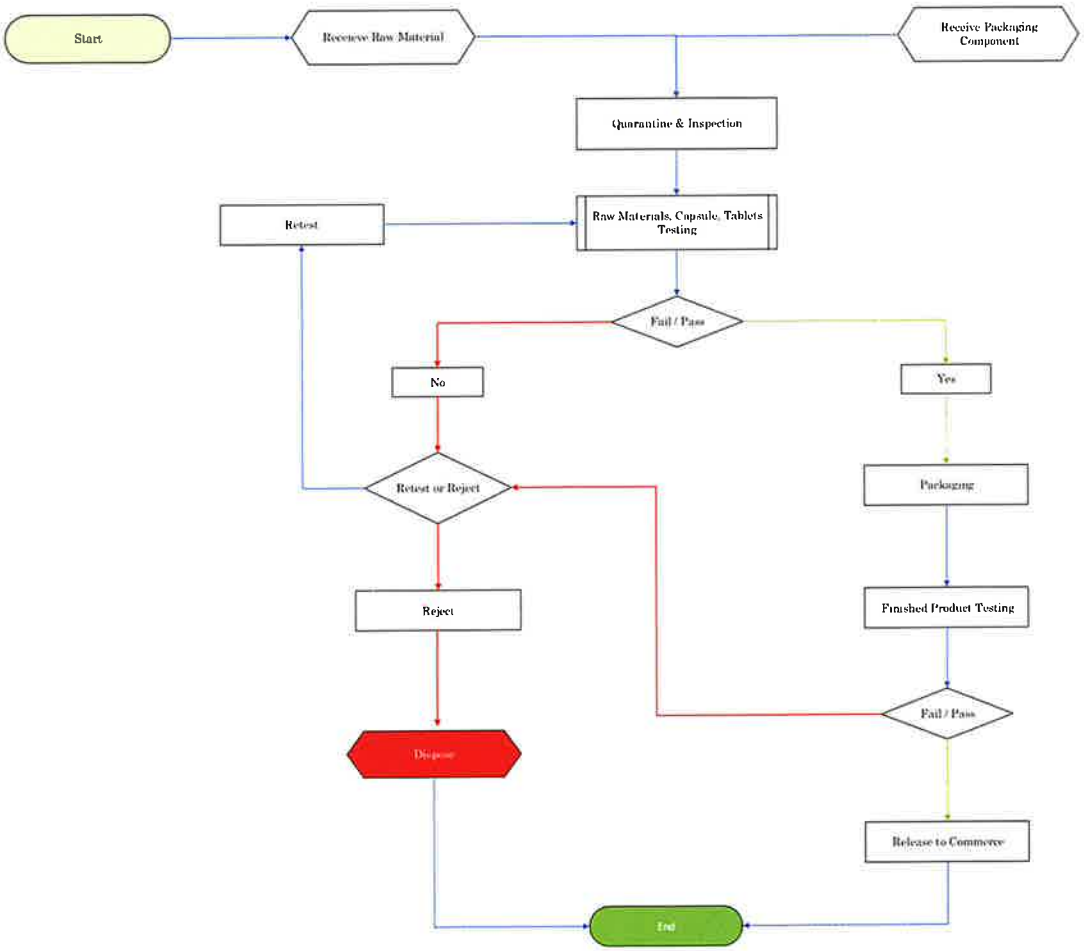
MANUFACTURING AND PACKAGING PROCESS FLOW FOR BODYBIO PC AND BALANCE OIL PRODUCTS (Reese Rd.)



BODYBIO

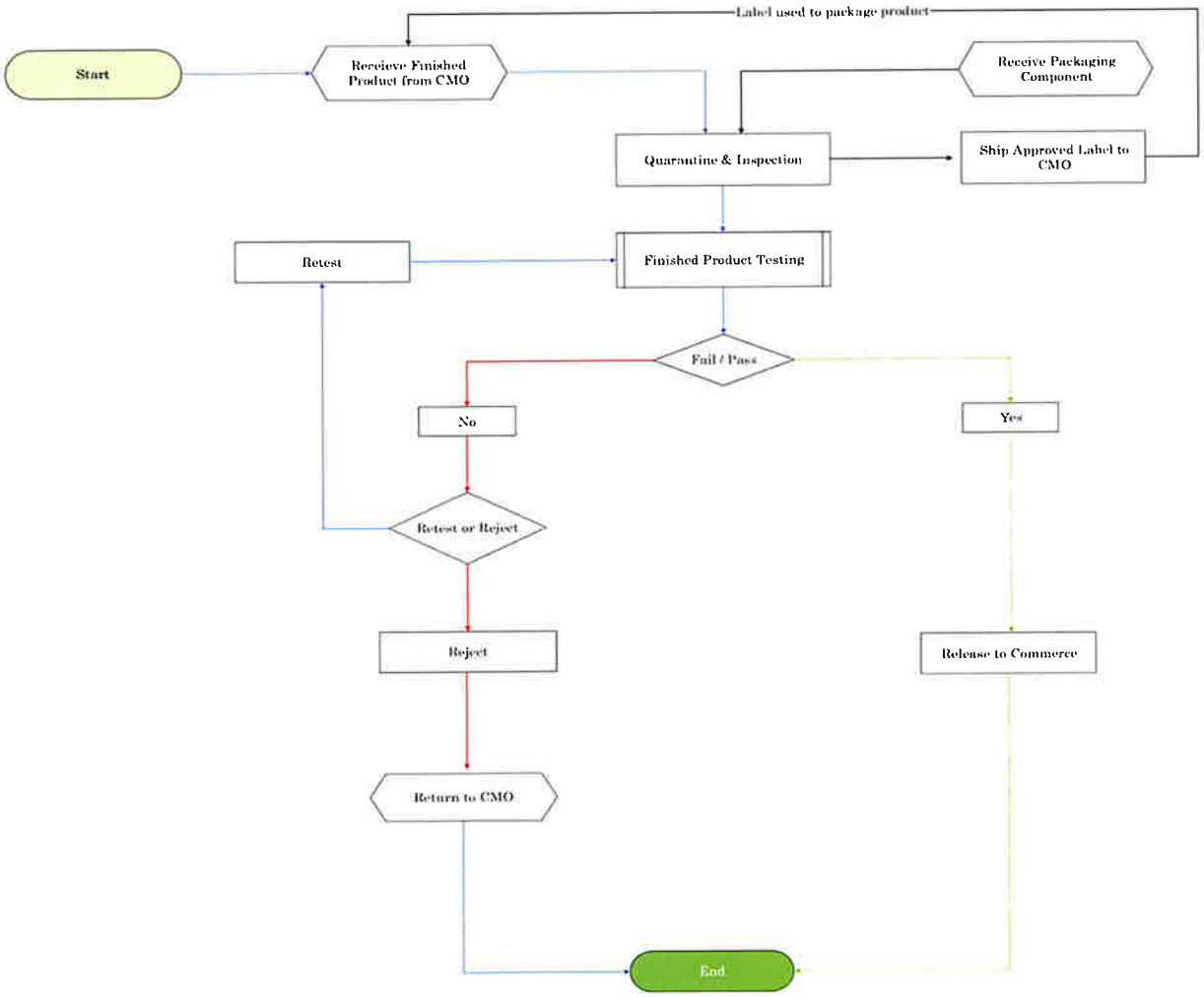
SOP # 04-054.2	Standard Operating Procedure	Written/Revised By/Date: AMD 10/22/24
Effective Date: NOV 0 6 2024	HACCP SOP	Approved By/Date: 10/22/2024
Supersedes: 07/07/2023		Page 12 of 15

MANUFACTURING AND PACKAGING PROCESS FLOW FOR BODYBIO PRODUCTS (Reese Rd)



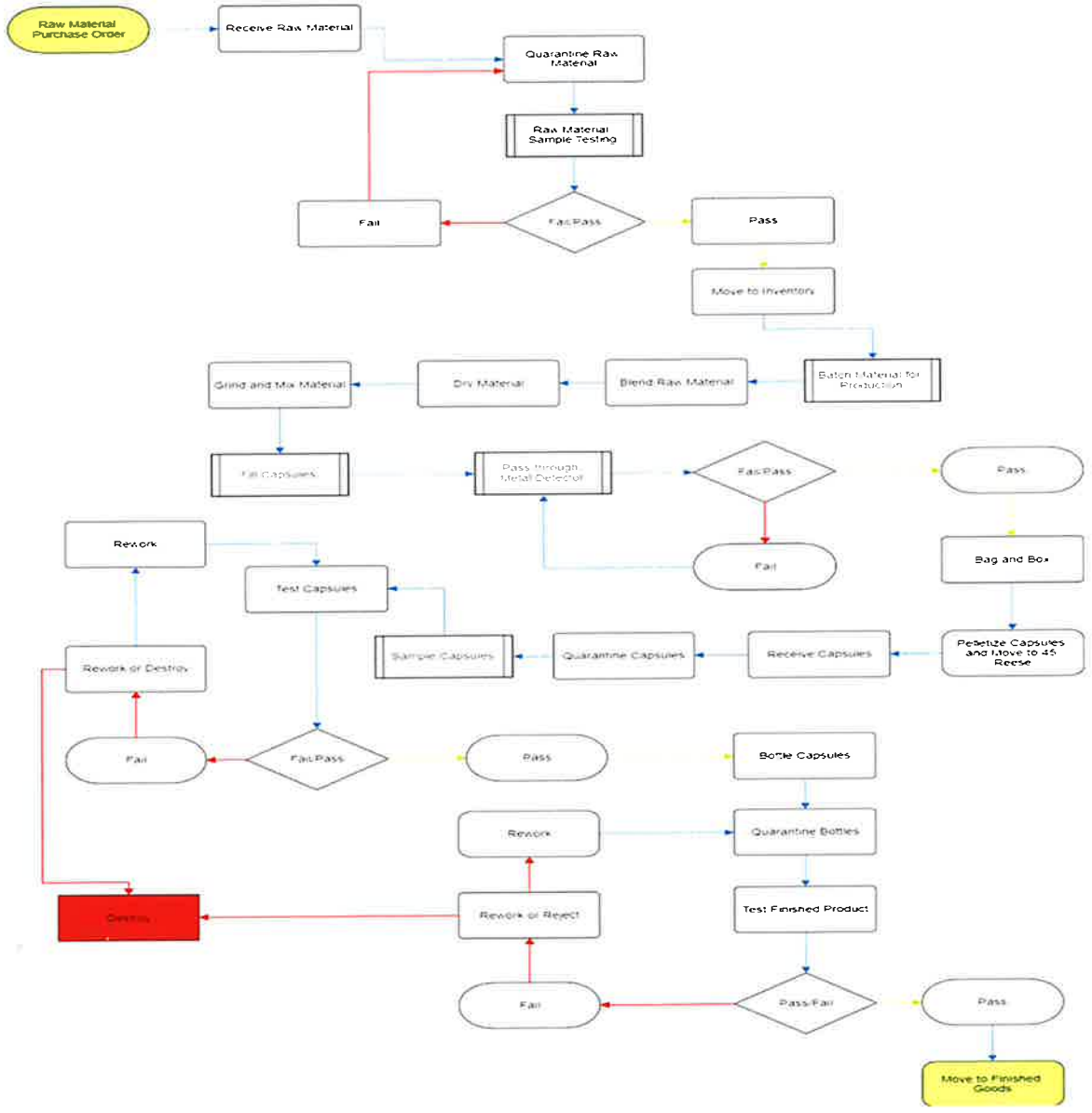
SOP # 04-054.2	Standard Operating Procedure	Written/Revised By/Date: 10/22/24
Effective Date: NOV 0 6 2024	**HACCP SOP**	Approved By/Date: 10/22/2024
Supersedes: 07/07/2023		Page 13 of 15

PACKAGING PROCESS FLOW FOR BODYBIO PRODUCTS FROM CMOs (Reese Rd.)



SOP # 04-054.2	Standard Operating Procedure	Written/Revised By/Date: 10/22/24
Effective Date: NOV 0 6 2024	**HACCP SOP**	Approved By/Date: 10/22/2024
Supersedes: 07/07/2023		Page 14 of 15

MANUFACTURING PROCESS FLOW FOR BODYBIO BUTYRATE (Driskill St.)



BODYBIO

SOP # 04-054.2	Standard Operating Procedure	Written/Revised By/Date: 10/22/24
Effective Date: NOV 0 6 2024	**HACCP SOP**	Approved By/Date: 10/22/2024
Supersedes: 07/07/2023		Page 15 of 15

REVISION HISTORY

Date	Revision	Change Control	Comments
08/23/2022	0		New
07/07/2023	1		Revamp SOP to be comprehensive and more concise. Added Manufacturing Flow Chart for all products
NOV 0 6 2024	2	2731	• Updated formatting through out this SOP. • Updated Responsibility and Frequency Section. • Removed Document Section and added/updated References. • Added Flow Chart for Driskill process. • Minor grammatical changes made throughout this SOP. • Removed product list to enhance the scope for all BodyBio products manufactured in the future.