

## Protein Research Quality Agreement

**Parties:**            **Rritual Superfoods Inc.**

Located at **151 West Hastings Street, Vancouver, BC, Canada V6B 1H4**, referred to below as **"Customer"**

And

**Protein Research** Protein Research

Located at **1852 Rutan Drive, Livermore, CA 94551**, referred to below as **"Supplier"**

**Date:** 12102020

**Recitals:**

- A.        The Customer from time to time requires third parties to provide contract manufacturing services, which may require the Supplier and Customer, jointly referred to as **"Parties"** to comply with Good Manufacturing Practices; and
- B.        The parties wish to define the Good Manufacturing Practice (GMP) roles and responsibilities for the supply of Customer products and enter into this Quality Agreement (**"Agreement"**).

**Accordingly, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree to the following as a condition of all transactions between them:**

### **QUALITY STATEMENT**

The Customer is a distributor of Dietary Supplements (collectively referred to as **"Products"**). Dietary Supplements are defined in the United States as a product that is intended to supplement the diet that contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by humans to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.

As a product manufacturer producing products for distribution by customer, Supplier is required to meet appropriate government manufacturing guidelines, where applicable. Supplier and Customer understand and complies with the applicable sections of Good Manufacturing Practices (GMP) as detailed in Title 21, United States Code of Federal Regulations (CFR), Part 117 (in accordance to Food

Safety Regulations), and Part 111 (for dietary supplements), and they agree expressly to supplement any such requirements as needed, pursuant to the terms of this Agreement.

### **Quality Agreement**

The purpose of this Agreement is to ensure a mutual understanding of key responsibilities of the Quality Program between the Parties and to assure Customer's products are manufactured, filled, packaged, labeled, tested, stored, and released according to the specifications and comply with governing regulations and corporate policies. This Agreement is not a purchase agreement, nor does it limit or supersede any other contractual agreement, unless stated herein. This Agreement covers all Customers' products as set forth herein. It is acknowledged that this will be a continuously evolving process.

CONFIDENTIAL

## **1.0 Purpose**

- 1.1 This Agreement defines quality requirements and establishes the roles and responsibilities of the participating parties.

## **2.0 Scope**

- 2.1 This Agreement describes the Technical, Quality, and Good Manufacturing Practice (GMP) responsibilities between Customer and Supplier as it relates to how the Supplier, manufactures, packages, labels and/or tests Customer products.
- 2.2 This does not include:
  - 2.2.1 Other Technical, Quality, and Good Manufacturing Practice (GMP) agreements in place or agreed upon at some future date between Customer and their suppliers, vendors, or clients.
  - 2.2.2 Other Technical, Quality, and Good Manufacturing Practice (GMP) agreements in place or agreed upon at some future state between Supplier and their suppliers, vendors, or clients.

## **3.0 General Responsibilities**

- 3.1 Both Customer and Supplier bear unique and shared responsibilities with how raw material, components and finished goods are procured, transported, received, examined, stored, used, compiled, dispositioned, and distributed. Customer maintains the final responsibility as it applies to their product in commercial distribution.
- 3.2 Customer and Protein Research are responsible for adhering to the terms as specified in this Agreement. Both Parties shall promptly inform the other of any conflicts with the commitments as stated and work amicably towards resolution.

## **4.0 Quality Systems**

- 4.1 Supplier shall manufacture, fill/package, label, and store nutritional products and dietary supplements in compliance with current GMPs. For auditing purposes, the Supplier maintains SQF, Organic and Gluten Free Certifications while NSF Certification is pending to support adherence to current Good Manufacturing Practices for Dietary Supplements under the Certified for Sport program. Upon reasonable notice, Customer can assume access and to the Supplier's facility(ies) (except restricted areas) used for the manufacture, filling,

labeling, packaging, and storage of the Customer's products. Customer will provide Supplier at least eight weeks written notification prior to scheduling a site visit to observe practices. The Supplier's response to findings must be received by Customer within 30 business days of receipt of the report unless otherwise agreed upon in writing by the Parties.

**5.0 Production Facilities and Equipment**

5.1 As required, Supplier will maintain appropriate Standard Operating Procedures (SOPs) for all major processes in manufacturing including preventive maintenance, cleaning, sanitizing, pest control, allergen control, chemical control, cleaning, and sanitizing verifications. The execution of these procedures will be documented and Supplier will maintain a supporting Environmental Monitoring Program to ensure the effectiveness of the cleaning and sanitation processes.

**6.0 Bulk Product/Finished Product Specifications**

6.1 Customer will provide Supplier with complete finished product and/or bulk product specifications. If complete specifications have not yet been developed, Supplier will assist Customer in completing specifications required for manufacturing. Prior to any commercial manufacturing, Customer will provide Supplier a final signed formula bill of material sign-off which lists formula ingredients including potency and quantities along with a signed final packaging specification. Once approved and signed-off by Customer, no changes to the final formula will be made by Supplier without written authorization from Customer's QA or authorized designee. The formula and product specification development process are described and documented separately from this agreement for each product contracted with Supplier and must be mutually agreed upon.

**7.0 Master Batch Records**

7.1 Prior to commercial manufacturing, Supplier will create a Master Manufacturing/Master Batch Record for each product to be manufactured.

7.2 Customer will be welcomed to review batch records on site upon required notice. If customer is under a regulatory audit, batch records will be provided within a reasonable time frame.

**8.0 Materials**

- 8.1 Supplier will procure components for the purpose of manufacturing product unless otherwise specified in writing by Customer. Supplier will maintain a supplier quality program that encompasses supplier qualification of components from approved suppliers which will be used in the manufacturing of Customer products. Customer will be responsible for the qualification of the supplier and material that they supply and/or designate, as well as ensure that the material is suitable for use in a Food/Dietary product and complies with 21 CFR 111/117. Supplier will require that Customer provide all documentation and test results (if needed) for any customer supplied material prior to use and Supplier will be required to keep on file.
- 8.2 Customer Supplied materials must have the following documents accompanying them at shipping: packing slip, Certificate of Conformance/CoA and itemized BOL referencing Supplier's P.O. number.

## **9.0 Product Labeling**

- 9.1 Supplier will provide a precursory label review that solely includes analyzing the Ingredient Statement, Allergen Statement, macro and micronutrients within the Nutrition/Supplement Facts Panel for alignment with the formula at the time of manufacture. A precursory label review is not an approval of the label(s). Supplier assumes no liability for regulatory compliance of label attributes including but not limited to formatting, net quantity of content statement, nutrient content claims, structure/function claims, health claims, standard of identity statement, flavor verbiage, etc.
- 9.2 Supplier is not and will not be responsible for proofing/approving Customer's foreign labels. Nor will Supplier be responsible for any regulatory, or compliance issues on the component Customer provides us for product(s) regarding the regulations of the destination country where the Customer is selling product . Any distribution of this product with foreign labels that do not match the signed formulation sheet is considered mislabeling and Supplier will not be liable for any product recall or mislabeling claims. This includes international allergen standards and disclosures, which must be brought to Supplier's attention during development and prior to production if applicable.
- 9.3 All Customer supplied labelled components must have a version number printed on the component. Supplier's system of tracking versions is as follows: V. 1.00. The first numerical value (whole number change) represents hard changes (i.e. something that has to do with the formula or ingredients). The second numerical value (.01) represents soft changes (i.e.

graphics). If Customer utilizes a different system of tracking already, please forward to Supplier.

#### **10.0 GMP Agreement Checklist**

10.1 The GMP Agreement Checklist ("Checklist") is attached as Exhibit A and incorporated herein by reference. This Checklist sets out the responsibility for each activity and indicates the responsibility being assigned to the Customer or to Supplier. Additional space is provided below each defined responsibility to provide additional comments or clarification as needed. To the extent of any conflict or inconsistency between the Agreement and the Checklist, the terms of the Agreement shall prevail.

#### **11.0 Miscellaneous**

- 11.1 No modification or amendment to this Agreement shall be binding upon the Parties unless made in writing and signed by the parties.
- 11.2 This Agreement shall be binding on and shall inure to the benefit of the Parties and their respective heirs, executors, administrators, agents, representatives, successors, and assignees.
- 11.3 This Agreement replaces all prior written and oral communication and is the complete agreement regarding current Good Manufacturing Practices for the manufacture of the Customer's product. This Quality Agreement does not include or cover pricing and delivery of the product.
- 11.4 This Quality Agreement shall be reviewed minimally every two years or sooner if required.
- 11.5 Modifications/addenda can be made as required; any such modifications must be in writing and executed by the Parties. This Agreement shall be construed as if all Parties jointly prepared it, and any uncertainty or ambiguity in this Agreement shall not be interpreted against any one Party.
- 11.6 The provisions of this Agreement are severable. If any portion, provision, or part of this Agreement is held, determined, or adjudicated to be invalid, unenforceable, or void for any reason whatsoever, each such portion, provision, or part shall be severed from the remaining portions, provisions, or parts of this Agreement and shall not affect the validity or enforceability of any remaining portions, provisions, or parts.
- 11.7 The Parties acknowledge that this Agreement is executed voluntarily by each of them, without duress or undue influence on the part of, or on behalf of, any of them. The Parties further

acknowledge that they have or had the opportunity for representation in the negotiation for, and in the performance of, this Agreement by counsel of their choice and that they have read this Agreement and have had it fully explained to them by their counsel and that they are fully aware of the contents of this Agreement and its legal effect.

11.8 The Parties have executed this Quality Agreement on the day and year first written above. This agreement will take effect upon receipt of the first purchase order (PO) and will continue as long as Customer remains an active client.

**In witness whereof, the Parties have caused this Agreement to be executed by their respective duly authorized representatives.**

**Customer**

By: “Warren Spence”  
Name Warren Spence  
Title: Director  
Date: January 8, 2021

**Supplier**

By: “Melissa Dethardt”  
Name Melissa Dethardt  
Title: Senior Vice President  
Date: January 14, 2021

# Exhibit A

## Summary of Technical Responsibilities

ACTIVITY		
<b>Compliance:</b>	<b>Supplier</b>	<b>Customer</b>
Obtain and Maintain appropriate Regulatory registrations and licenses.	X	X
Conform to the FDA guidelines of 21 CFR 111, 117 and cGMPs.	X	X
Establish and maintain a quality system ensuring facility, personnel, processes, methods, materials, quality control, storage and distribution of the Product(s) are in compliance to relevant cGMPs to ensure no adverse impact to the Product(s) Safety and Quality.	X	
Responsible for maintaining appropriate regulatory documentation for the product.	X	X
Responsible for assuring appropriate regulatory documentation for distribution of Product, including FDA and other countries regulatory where appropriate.		X
Sole owner of the labeled product and holds sole responsibility for submitting any Pre-Marketing/NDI notice required to the FDA.		X
Mutually agree upon Specifications for the Product(s) which are the subject of this agreement.	X	X
Changes to the agreed upon Specifications must be mutually agreed upon and communicated in writing between the parties to this agreement.	X	X
Manufacture Product(s) that conform to the mutually agreed upon Specifications.	X	
Upon request, provide summaries of recent regulatory agency inspections and findings pertaining to the Product(s). Summaries from Supplier - Information not related to customer may be redacted for confidentiality purposes.	X	X
Notify within 48 hours, during a regulatory inspection, any negative findings made related to the safety or quality of the Product(s) supplied.	X	X
<b>Manufacturing, Packaging, and Labeling</b>	<b>Supplier</b>	<b>Customer</b>
Provide accurate nutrition and supplement facts panel data and ingredient	X	



statement for inclusion on label.		
Provide Master Label documents along with PDF of label for review to Supplier prior to the printed product receipt.		X
Ensures labeled components are reviewed and approved by an FDA regulatory employee, attorney or compliance specialist representing your company confirming that they are in compliance with U.S. regulations.		X
Ensures labeled components are reviewed and approved by a regulatory employee, attorney or compliance specialist representing your company specific to the regulations of the destination country where product will be shipped.		X
Notifies of any changes to existing Master Label documents prior to receipt of printed material.		X
Notify disposition of previous version of labeled components prior to use of new version.		X
All labeled components shall be stored in a limited access area and controlled throughout the labelling process as required by cGMPs.	X	
Equipment used to manufacture Product shall comply with cGMP as well as additional requirements detailed in respective validation documents, and Specifications.	X	
Maintain records for usage, cleaning, maintenance, and calibration of critical equipment used in the manufacturing and packaging.	X	
<b>Validation</b>	<b>Supplier</b>	<b>Customer</b>
Maintain a cGMP compliant preventative maintenance program for equipment used to manufacture of the Product.	X	
Have a cleaning validation program that is compliant with the current cGMP requirements.	X	
<b>Raw Materials</b>	<b>Supplier</b>	<b>Customer</b>
Responsible for the receipt, sampling, testing, and approval of raw materials.	X	X
Responsible for testing Dietary Ingredients for identity, purity, strength and composition and ensuring that the quality of each unique lot and delivery of Raw Materials meet the Specification.	X	
Perform incoming inspection and disposition of raw materials, labels, and primary packaging components.	X	

Sampling plans for the quality control testing shall be statistical.	X	
<b>Specifications</b>	<b>Supplier</b>	<b>Customer</b>
Raw Materials including Customer supplied	X	
Packaging Components including Customer supplied	X	X
Finished Good	X	X
<b>Component Suppliers</b>	<b>Supplier</b>	<b>Customer</b>
A supplier program shall be maintained that encompasses supplier qualification and supplier performance.	X	
Have a documented supplier approval and periodic evaluation program that provides adequate evidence that the raw material manufacturer can consistently provide raw material meeting specifications.	X	
<b>Rework/Reprocess</b>	<b>Supplier</b>	<b>Customer</b>
Critical process deviations, product rejections, and rework that may affect the product from meeting its finished spec shall be communicated to Customer.	X	
Quality Control unit reserves the right to reject any produced or packaged lot that may be considered adverse to the safety, quality, efficacy, or purity of the product.	X	
Before a decision is communicated by Manufacturer to Rework batches that do not conform to established standards or Specifications, an investigation into the reason for the non- conformance shall be performed.	X	
Reworking must be performed in accordance with cGMPs.	X	
Customer or consumer returned Product will be identified, quarantined, and investigated.	X	X
<b>Product Release Testing &amp; Sampling:</b>	<b>Supplier</b>	<b>Customer</b>
Test Product for release in accordance with approved methods and specifications using in-house calibrated equipment and/or qualified third parties.	X	
Have systems in place for management of sample identification and tracking.	X	
Store retained samples in accordance with recommended storage conditions.	X	X
<b>Batch Release:</b>	<b>Supplier</b>	<b>Customer</b>
Product shall only be released for shipment after the batch records and QC test results have been reviewed and reported, and deviations (If applicable) have	X	

been investigated and closed by a qualified person or designee.		
Each lot of product manufactured by supplier, along with batch documentation shall be reviewed and approved by the quality control unit prior to release.	X	
With each delivery of Product(s), provide a Certificate of Analysis certifying that the Product(s) is suitable for release.	X	
<b>Documentation and Records</b>	<b>Supplier</b>	<b>Customer</b>
Quality Agreement	X	X
Quality Systems	X	
Certificate of Analysis shall be supplied with each unique lot and product SKU(s).	X	
Records required by the Quality System will be maintained for a period of 1 year from the date of product expiration or three years after manufacturer date, whichever is longer.	X	
<b>Storage and Distribution</b>	<b>Supplier</b>	<b>Customer</b>
Authorized to release finished product and ship to Customer designated distribution center per Customer designated shipping carrier and method.	X	
Coordinate shipping methods, shipping conditions, transit and qualification of carriers transporting Finished Product.		X
<b>Retention of Samples</b>	<b>Supplier</b>	<b>Customer</b>
Retained samples of Raw Materials shall be maintained for a minimum of one year past the shelf life of the finished product that contains a unique lot of Dietary Ingredient.	X	
Finished Product(s) retention samples will be retained for a period of 1 year from the expiration date. Product without shelf life/expiration date on product will be kept for 3 years after manufacture date. *It is suggested that Customer retain the determined amount of Finished Product samples for any additional product testing/internal investigation that may be needed.	X	X
Serious Adverse Events under the definition outlined in the Dietary Supplement and Nonprescription Drug Consumer Protection Act; Public Law 109-462 109 <sup>th</sup> Congress dated December 22, 2006 shall be reported by Customer.		X
In the event Customer notifies Supplier that there is a Serious Adverse Event (SAE) associated with any given batch, Supplier will retain the records and	X	

retention samples for six years in compliance with current regulations.		
<b>Non-Conformance</b>	<b>Supplier</b>	<b>Customer</b>
Non-conformances to process or specifications should be investigated. Where applicable, this includes the identification of the root cause, a risk analysis (including the risk to other lots and the impact to other test results) of the actions taken for correction of the problem, prevention of future occurrence and the formal conclusion by Supplier's Quality Assurance. If an investigation reveals that there is an impact to Product(s) received by Supplier, Co-Manufacturer shall inform Customer without delay. The quality control unit of Supplier reserves the right to reject any produced or packaged lot that may be considered adverse to the safety, quality, efficacy, or purity of the Product. This decision shall be communicated to Customer QA for concurrence prior to official rejection and/or destruction of the Product.	X	
<b>Deviations</b>	<b>Supplier</b>	<b>Customer</b>
If significant deviations from an established process are recorded, there should be evidence of suitable investigations and a review of the quality of the Product(s).	X	
<b>Complaints</b>	<b>Supplier</b>	<b>Customer</b>
All complaints, regardless of source, will be handled by Customer.		X
Responsible for submission of Serious Adverse Event (SAE) reports to the FDA.		X
Responsible to notify Supplier of the SAE submission.		X
Customer's QA will forward critical complaint information (detailing complaint verbatim, product description/code, and Lot number) to Supplier when an investigation is required.		X
If Supplier receives a complaint directly that complaint must be forwarded to Customer within 48 hours of receipt.	X	
Maintain a complete complaint database and complaint files.		X
Have a written procedure to investigate and document quality related complaints. A root cause analysis, actions taken for correction of the problem, prevention of future occurrence and the formal conclusion will be provided to Customer.	X	

The parties shall cooperate in the exchange of information required to effectively conduct an investigation.	X	X
<b>Recalls</b>	<b>Supplier</b>	<b>Customer</b>
In the case of a quality issue that necessitates a recall of the Product(s), Supplier shall inform Customer without delay.	X	
Have a written recall procedure.	X	X
Customer shall notify Supplier of any finished product recall which has been investigated or is under investigation and has potential to be related to the quality of the Product(s), as soon as possible.		X
The parties shall cooperate in the exchange of information required to effectively conduct a recall or recall investigation.	X	X
<b>Stability</b>	<b>Supplier</b>	<b>Customer</b>
Determine the Expiration/Best By/Use By date (if any) to be applied to the product.		X
Assure stability studies are performed as expected FDA guidelines and that results support the expiration dating assigned to the product.		X
Provide Stability documentation and results to Supplier.		X