



# *Agile Innovation: Reformulation Strategies to Outmaneuver Supply Chain Disruption*

Joseph Springer, PhD, Threshold  
Kevin McHugh, MegaFood  
Leah Johnston, TraceGains

together<sup>2022</sup>



# Helpful Tips



## Tech Issues

First try refreshing your browser! If issues persist, send us a private chat.



## Q&A

Type questions into the Q&A tab and we'll address them after the presentations.



## On-Demand

Everything is being recorded and will be accessible for 90 days post event.



## Feedback

Your opinion matters. Don't forget to take our survey at the end of the session!

# Meet Your Moderator



**Leah Johnston**

Director, Dietary Supplements National Sales



TRACEGAINS

# Today's Supply Chain



Winning R&D  
Strategies



Centralized  
Collaboration



NPD Best  
practices



# Meet Your Speakers



**Joey Springer, PhD**  
Director, Product Development  
& Technical Services



**Kevin McHugh**  
Director, Quality

# Agile Innovation: Product Reformulation Strategies to Outmaneuver Supply Chain Disruption

A little about who we are:

With 45 years of experience, Threshold Enterprises is an honored recipient of awards for the quality of our products, outstanding customer service, educational-based marketing, great deals and a successful history of industry advocacy.

We share a vision to support each individual's potential to enjoy optimal health and well being by providing a wide variety of the highest quality dietary supplements and nutritional education.

We do this in part with...



# Agile Innovation: Product Reformulation Strategies to Outmaneuver Supply Chain Disruption

800 Raw Materials  
300 Packaging Components  
1000 Bulk Products  
3000 Finished Goods

**Change has been our only constant.**

# An Ever-Changing Formulation Fabric

Active Ingredients    Common Excipients    Capsule Shells    CoMan Partners  
How to achieve a stable output when all the inputs are changing?



RESEARCH & DEVELOPMENT





# An Ever-Changing Formulation Fabric

Major Goals for Managing Reformulations

Maintain Formulation Quality

Control Costs

Get in/Stay in Stock



## REFORMULATION & DEVELOPMENT



# “Forever Formula” Workgroup to Stabilize Top Products



Purchasing



Quality

R&D



# “Forever Formula” Workgroup to Stabilize Top Products



Comprehensive Formula Review

Country of Origin

Seasonality

Historic Availability

Material Quality

Reliability

Scalability

Cost

Alternative Forms

Alternative Sources

Learn

# “Forever Formula” Workgroup to Stabilize Top Products



## Formula Improvement Strategies

Streamline Formulas

Problematic whole herbs replaced  
with high quality extracts  
improved micro testing outcomes  
reduced seasonality



Process development – getting it right  
Anywhere, Every Time





# “Forever Formula” Workgroup to Stabilize Top Products



## Sourcing Improvement Strategies

“Overbuy” with Intention

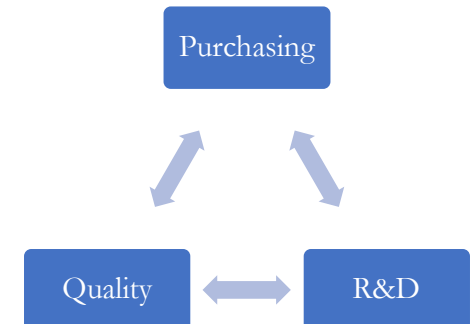
Secondary Suppliers

Geographic Diversification

Solve

**FACILITATED BY:**  
**GATHER and SUPPLIER MANAGEMENT**

Sourcing Review Board



PLANETARY  
HERBALS





**Top Products: Improved, Stable, In Stock**  
**What about the Rest of the Portfolio?**



**PURCHASING AND LOGISTICS**



- Find Suppliers
- Connect
- Qualify Supplier
- Qualify Item

A blue bracket on the left side of the text, grouping the list of sourcing steps with the subsequent text.

**NEEDS TO HAPPEN -  
QUICKLY AND FREQUENTLY!**

An orange sunburst graphic with several lines radiating from a central point, located to the left of the text.

**TRANSFORMATION DRIVEN BY:  
SUPPLIER MANAGEMENT**

An orange sunburst graphic with several lines radiating from a central point, located to the right of the text.

September 2021: 42% of Raw Materials (337 items) Required Imminent Sourcing Needs

September 2022: 6% of Raw Materials (50 items) Require Imminent Sourcing Needs

**DONE WITH LESS RESOURCES!**

## Agile Decision-Making Followed by Structured Implementation

Robust Request Queue and Reporting System

Talented Cross-functional Team Driving Change Management

Cascade of Changes

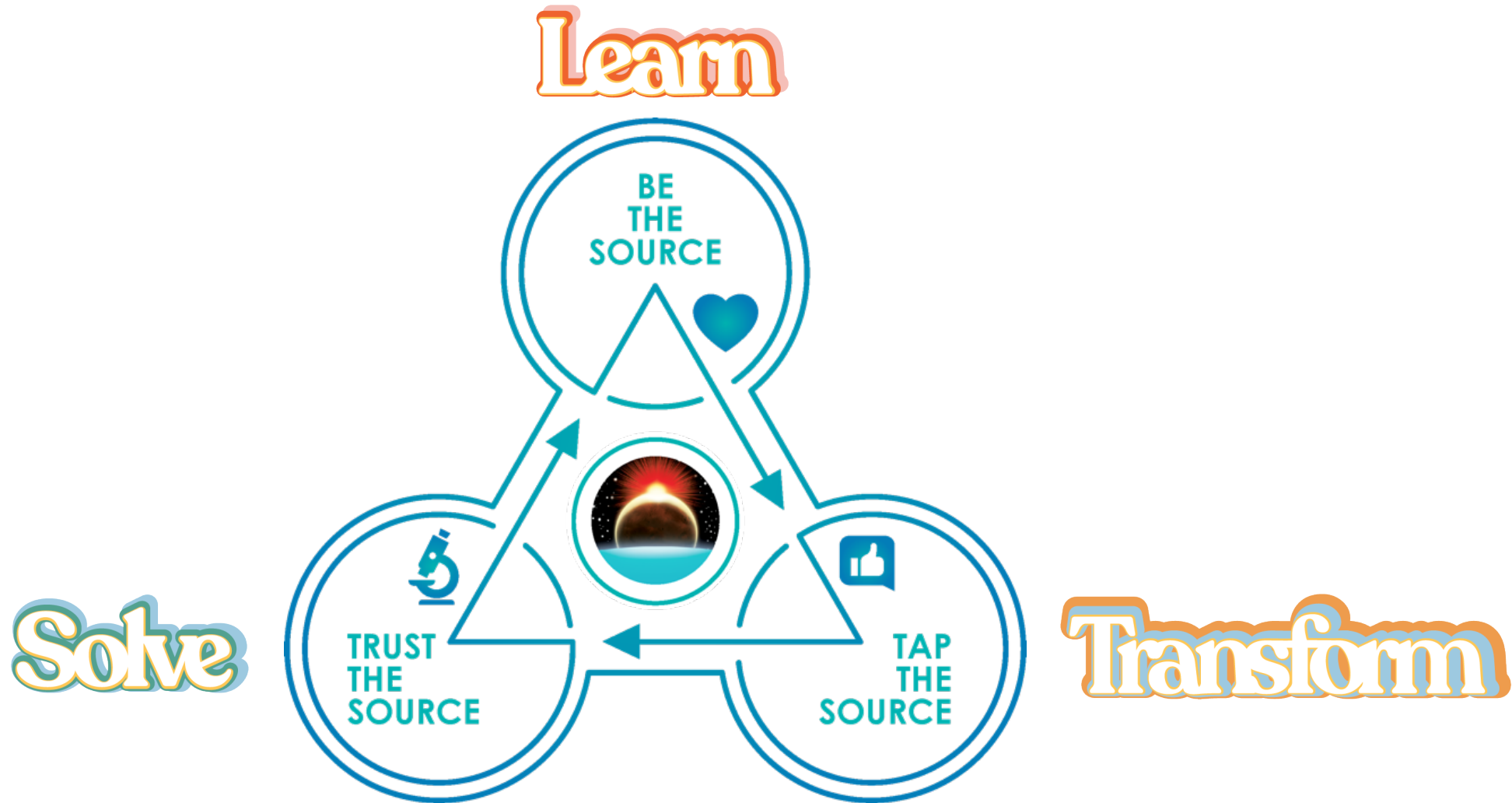
Specifications

Master Manufacturing Records

Labels

Research-based marketing collateral

The word "Transform" is written in a large, stylized, orange-outlined font with a blue-to-white gradient fill.The text "FACILITATED BY:" is centered at the top. Below it, "SUPPLIER MANAGEMENT and SPECIFICATION MANAGEMENT (FORMULATION MANAGEMENT)" is centered. The text is flanked by two sets of orange lines radiating outwards, resembling stylized sun rays or a fan.



THANK YOU!



*MegaFood*<sup>®</sup>

# TraceGains Journey

October 2022





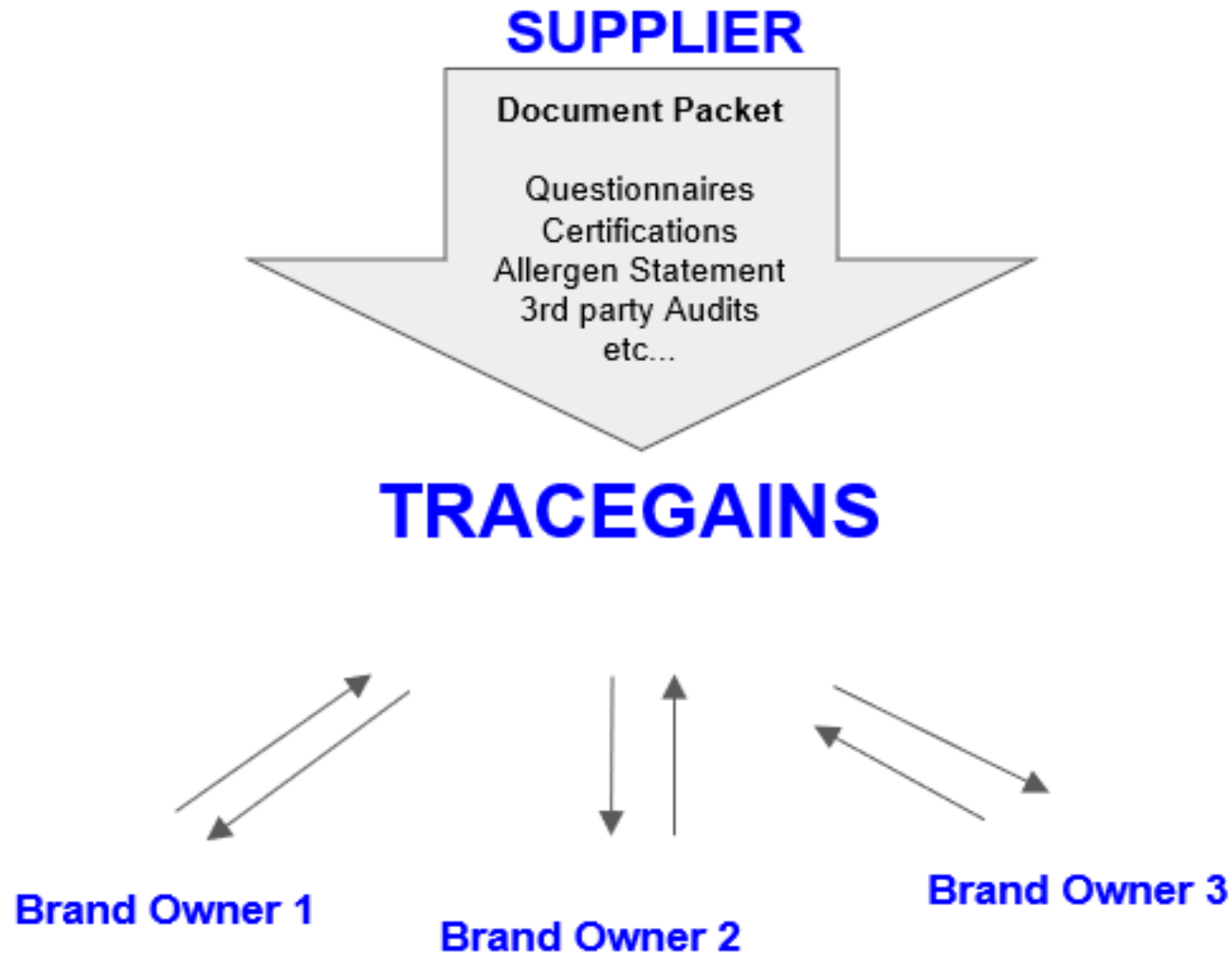
# MegaFood®



# Supplier Documentation!



# Supplier Module Simplicity of Concept



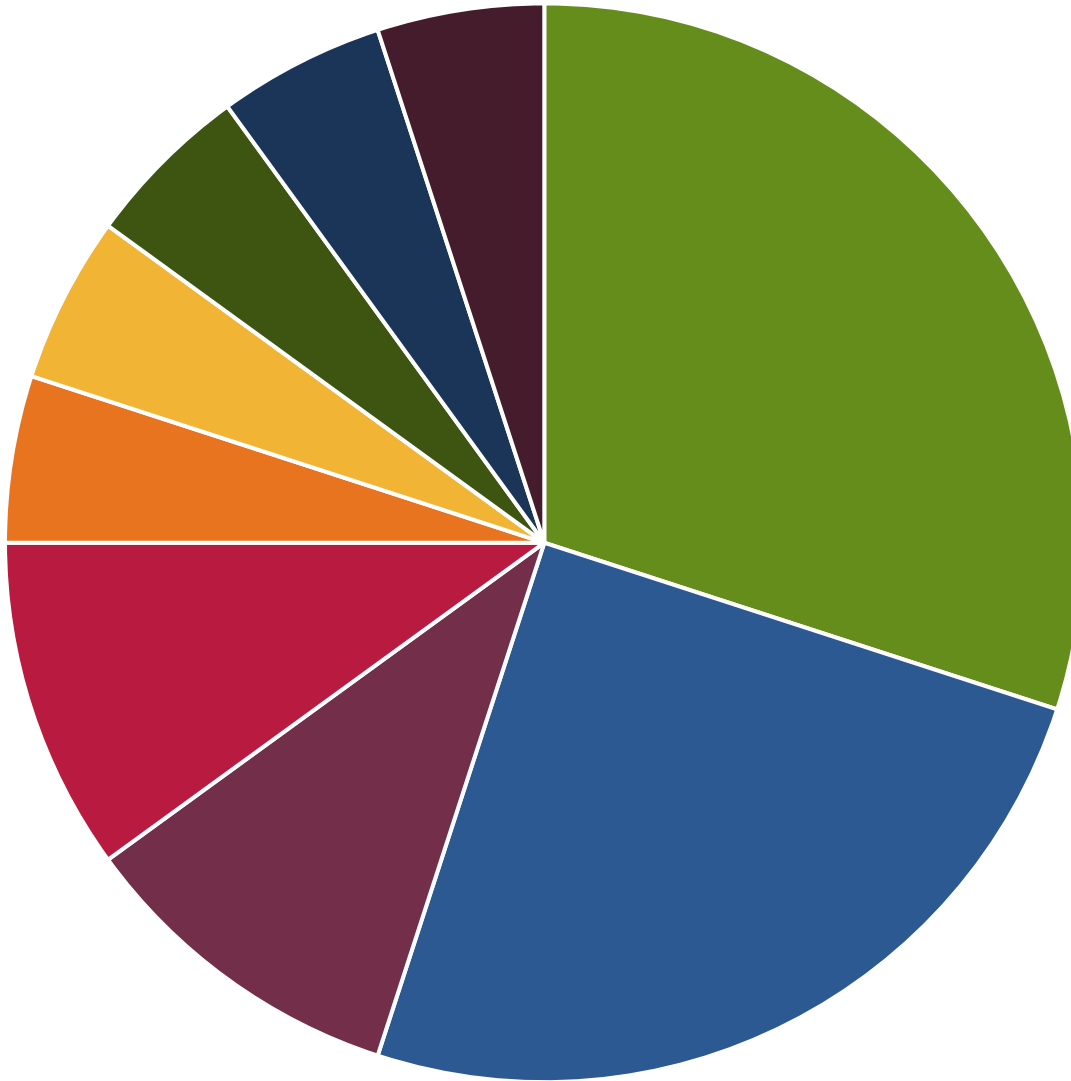


# **Supplier Module Implemented Q1 2022**

**Critical Tool enabling supply changes  
as needed to navigate Covid**

# Quality Module 2021

Quality Systems



■ Hold Log/NCMR ■ Specifications ■ Complaints ■ SOPs ■ Correction Action  
■ Change Control ■ Audit Findings ■ Planned Deviations ■ Forms/COAs



# Quality Module

- Within 30 days, using for refreshed corrective action program
- Flood gates opened for many applications



**TraceGains**

FoodState Inc dba MegaFood - QM

Analytics

Task Schedule

Documents

Authoring

Misc Logs

Prerequisite

Controls

Verify & Validate

Preship & Signoff

Training

CARs

TraceGains

FoodState Inc dba MegaFood - QM

Analytics

Ta

All Documents ▾

☐ Show Archived

Analytical QMS Dashboard

Co-Manufacturing Tracking

Dashboard - Material Handler

List of Equipment Qualifications

List of Forms

List of References

List of SOPs & Work Instructions

QC Docs

Quality - CoA (Certificates of Analysis)

Quality - Internal Certificates

Quality - MBR Issuing Dashboard (No Pilots!)

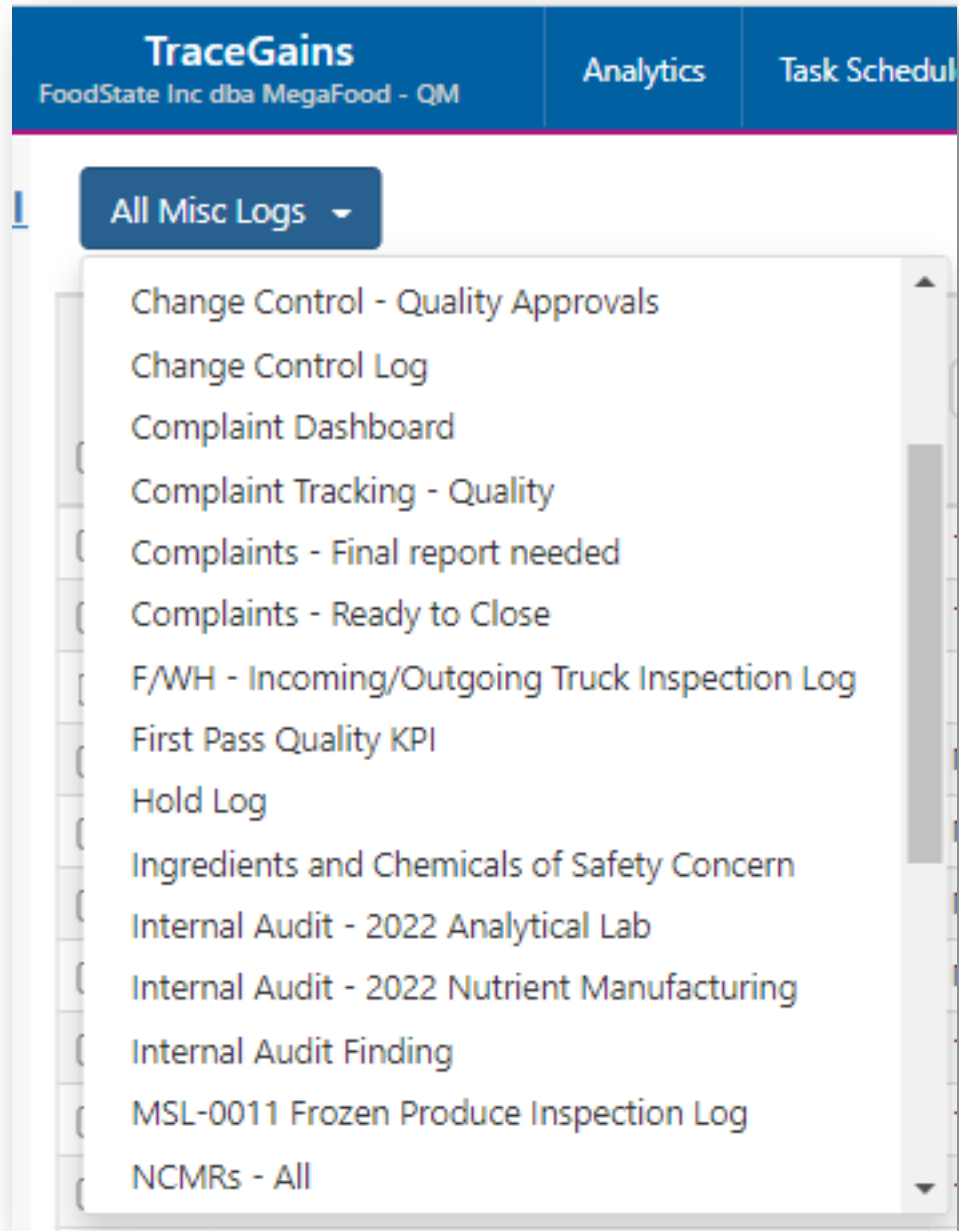
Quality - MBRs (Master Batch Records)

Quality - Specifications

R&D Dashboard

Sanitation Table of Contents

# Quality Module



# Quality Module

New Dashboard <

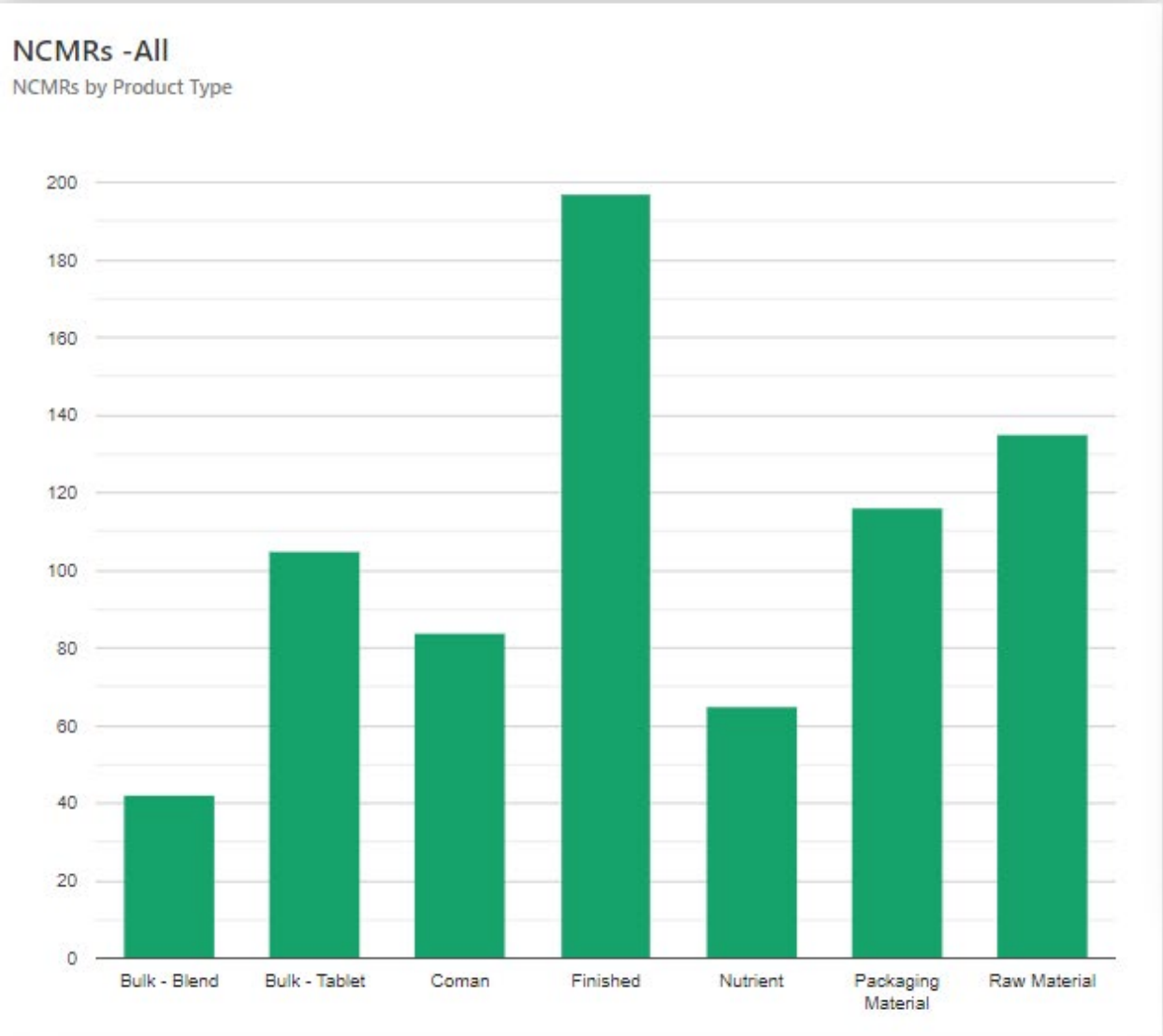
2020 CAR Tracking

2021 CAR Tracking

2022 CAR Tracking

NCMR's 2021

## NCMR's 2021



# Quality Module



# Quality Module

☐ Absorbency/Discoloration

☒ Out of Spec

☐ Pesticide Residue

☐ Potency

☐ Qualification

☐ Suspect Out of Spec/Potency Issue

**\* Comments** ▾

Why is the material non-conforming. Be descriptive. (This comment will be visible in the email notification!)

Partial seals found on the bottles.  
1 pallet impacted. Pallet to be inspected and defective bottles to be resealed.

**\* Attaching Photos?** ▾

Yes ▾

Photo 1





Photo 2



- NCMR (Hold Incident)
- Use of Pictures to detail the defect and the product impacted

All Controls

		QM Program ID	QM Program	Requirement Name
<input type="checkbox"/>				
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	1447B-10-WOMEN OVER 55 ONE DAILY NGP REF...
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	1249B-10-VITAMIN D3 2000 FS
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	1447B-10-WOMEN OVER 55 ONE DAILY NGP REF...
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	1352B-10-BLOOD BUILDER 2.0 FS
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	1249B-10-VITAMIN D3 2000 FS
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	1431B-10-IMMUNE DEFENSE
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	1453B-10-ADRENAL RESPONSE REFORM
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	1431B-10-IMMUNE DEFENSE
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	1443B-10-MENS ONE DAILY NGP REFORM
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	300006-METHYLCOBALAMIN 1.0%
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	1475B-10-BABY & ME 2 MINIS
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	1240B-10-CALCIUM MAGNESIUM
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	1389B-10-BABY AND ME 2 NEW
<input type="checkbox"/>		CTRL-0001	Process Planned Deviation Form	1389B-10-BABY AND ME 2 NEW

# Quality Module

TraceGains odState Inc dba MegaFood - QM		Analytics	Task Schedule	Documents	Authoring	Misc Logs	Prerequisite	Controls	Verify & Validate	Preship & Signoff	Training	CARs
Analytic - 2022												
	?	CAR Open Year	CAR ID	Title of CAR	CAR Open Date ▼	CAR Status	Person Responsible for CAR					
		2022										
<input type="checkbox"/>												
<input type="checkbox"/>	⚙	2022	20220929 - 21047288	Improperly centered line caused bad seals.	9/29/2022 12:00:00 AM	B - In Process	Rich Eovine	Devo				
<input type="checkbox"/>	⚙	2022	20220922 - 969979523	MBR not used during oscillation of Silicon Dioxid...	9/22/2022 02:03:51 PM	B - In Process	Drew Mills	Cat La				
<input type="checkbox"/>	⚙	2022	20220919 - 625289740	Chemical awareness - CD572 foamer diluted	9/19/2022 04:22:34 AM	B - In Process	Rich Eovine	Devo				
<input type="checkbox"/>	⚙	2022	20220913 - 2086437838	Consumer found a knob in Womens Over 55 One...	9/13/2022 03:25:03 PM	B - In Process	Rich Eovine	Olga				
<input type="checkbox"/>	⚙	2022	20220909 - 1663110330	Foreign material consumer complaint with metal ...	9/9/2022 01:07:27 PM	C - Complete	Dave Gaudet	Olga				
<input type="checkbox"/>	⚙	2022	20220908 - 210848426	MBR R13528-10393 called out 74.5kg of stearic i...	9/8/2022 04:27:14 PM	C - Complete	Cat Lansman	Olga				
<input type="checkbox"/>	⚙	2022	20220907 - 340882646	Dirty parts stored in clean parts area.	9/7/2022 12:00:00 AM	C - Complete	Glen Guilmet	Adam				
<input type="checkbox"/>	⚙	2022	20220822 - 1341979841	1387B-10 Turmeric for Whole Body blends had cli...	8/22/2022 12:00:00 AM	C - Complete	Olga Rivera	Cat La				
<input type="checkbox"/>	⚙	2022	20220812 - 1196768906	Vitamin D3 Potency	8/12/2022 12:00:00 AM	C - Complete	Kevin McHugh					
<input type="checkbox"/>	⚙	2022	20220810 - 2139338454	Moisture Specification Updates for Related to Ite...	8/10/2022 08:29:21 AM	C - Complete	Brian Martyniak	Kalei				
<input type="checkbox"/>	⚙	2022	20220805 - 930960275	Glyphosate Reporting Limit Issues with Environm...	8/5/2022 08:53:11 AM	B - In Process	Brian Martyniak	Kevin				
<input type="checkbox"/>	⚙	2022	20220801 - 1559257249	Butterfly valve inspections not complete for the ...	8/1/2022 12:20:09 PM	C - Complete	Rich Eovine	Adam				
<input type="checkbox"/>	⚙	2022	20220727 - 107235275	Two blends are showing 10Kg & 11Kg over MBR ...	7/27/2022 12:00:00 AM	C - Complete	Drew Mills	Olga				
<input type="checkbox"/>	⚙	2022	20220726 - 1197652277	Formic Acid Bottle Overflow in Acid Cabinet in A...	7/26/2022 11:42:25 AM	C - Complete	Drew Mills	Brian				
<input type="checkbox"/>	⚙	2022	20220725 - 1884687109	Inconsistent rice grain size causing issues in press...	7/25/2022 12:00:00 AM	D - Closed	Rich Eovine	Cat Pa				
<input type="checkbox"/>	⚙	2022	20220725 - 701950981	Lot R100021060 tested calcium concentration at ...	7/25/2022 12:00:00 AM	C - Complete	Cat Lansman	Brian				
<input type="checkbox"/>	⚙	2022	20220725 - 1301766859	Roof hatch left open during production.	7/25/2022 12:00:00 AM	D - Closed	Glen Guilmet	Adam				
<input type="checkbox"/>	⚙	2022	20220713 - 773396637	Moisture Analysis Study - Comparison of Nutrien...	7/13/2022 02:28:06 PM	D - Closed	Brian Martyniak					
<input type="checkbox"/>	⚙	2022	20220630 - 980248023	210211 Stearic was put through an 8 Mesh scree...	6/30/2022 12:00:00 AM	C - Complete	Phil Aiken	Olga				
<input type="checkbox"/>	⚙	2022	20220606 - 115263044	High Total Plate Count D3 Nutrient 100023 lot 022	6/6/2022 12:00:00 AM	C - Complete	Glen Guilmet	Cat Pa				
<input type="checkbox"/>	⚙	2022	20220606 - 305516783	B12 Tablet Blending Uniformity	6/6/2022 12:00:00 AM	C - Complete	Ben Schneider	Nicol				
<input type="checkbox"/>	⚙	2022	20220526 - 564939510	Flora lots are mixed in the freezer. Some boxes la...	5/26/2022 12:00:00 AM	C - Complete	Matt DeVits	Olga				
<input type="checkbox"/>	⚙	2022	20220525 - 381628351	Black Goo on BIO Blow Off Pipe	5/25/2022 09:29:00 AM	C - Complete	Ben Schneider	Kevin				
<input type="checkbox"/>	⚙	2022	20220518 - 909649526	Absorbance Test Plate Calibration Date	5/18/2022 12:00:00 AM	C - Complete	Dave McKeen	Nicol				

# Quality Module

## Corrective Action Log

# Keys to Success

- Cross Functional Ownership/Buy-in
- Super User Identification (SME)
- Self Initiative
- Commitment to Resources during Launch Phase
- Build Relationship with TraceGains Staff



# Why TraceGains

- “The” Industry Leader in Supplier Documentation
- Configurable – software enables user to uniquely configure
- TraceGains Support Staff
- TraceGains Seeking to Understand Industry Needs

# What's Next?

- Formulation Module
- Co-manufacturing Module

Please type your  
questions into  
the Q&A box.



together<sup>2022</sup>

Thank you!

