



TRACEGAINS WEBINAR

Root Cause Analysis

Tackle Any Challenge with Confidence

November 8th, 2022



Meet
Your Moderator

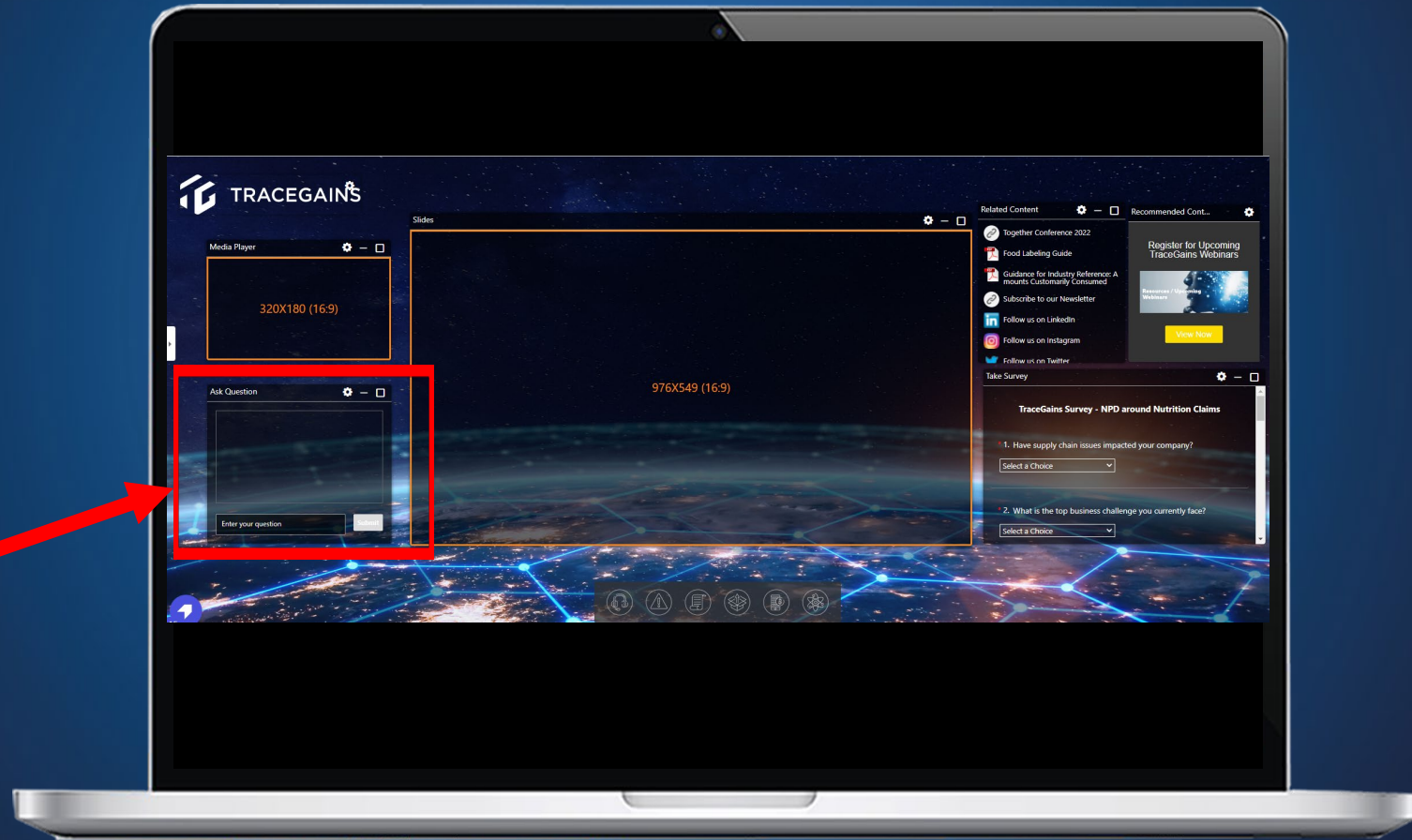


Kristen Goodale
Marketing Coordinator



Slides And Recording Will Be Shared

We want to hear from you! Please type your questions in the chat box.



About TraceGains

Together we do more



Food and Beverage ••• **Dietary Supplements** ••• **Retail** ••• **Consumer Packaged Goods**



TRACEGAINS

Discover the Power of Networked

What Makes TraceGains Different?

On average, companies find that 80% of their suppliers are already on TraceGains Network.



Meet

Your Speakers



Sara Jane Bellocchi
Networked Ingredients
Functional Consultant



Kevin Dineen
Account Executive



Root Cause Analysis

Sara Jane Bellocchi
Networked Ingredients Functional Consultant
November 2022



Disclaimer

This session and discussions arising from this content are not meant as legal advice.

What We'll Cover Today

Learning Objectives

- Definitions (RCA, CAPA, etc.)
- When to do a Root Cause Analysis
- Root Cause Analysis in Steps
 - Identify various types of data and tools
- Example Scenarios
- How TraceGains can help

The real issue with recurring problems is courage to confront reality.

Important Definitions

- **RCA = Root Cause Analysis**
 - Tool to identify and eliminate the cause or potential cause of a non-conformity
- **CAPA = Corrective Action, Preventive Action**
 - Correction – action to eliminate a detected non-conformity
 - Corrective Action – action to eliminate the cause of a detected non-conformity or non-conforming product
 - Preventive Action – action to eliminate the fundamental underlying cause (root cause) of a detected non-conformity and prevent recurrence
- **CARs = Corrective Action Request/Report**

When to do a Root Cause Analysis

Reasons to do an RCA

- Audit findings or non-conformances
- Customer complaints
- Product withdrawal or recall
- Process control reports
- Adverse trends from data analysis
- Increased risks from risk analysis

Root Cause Analysis Steps

- 1 Immediate Corrective Action
- 2 Assemble a cross functional team
- 3 Define the problem and collect data
- 4 Investigate the root cause
- 5 Create a proposed action plan and define time scales
- 6 Implement proposed action plan
- 7 Verification and monitoring of effectiveness

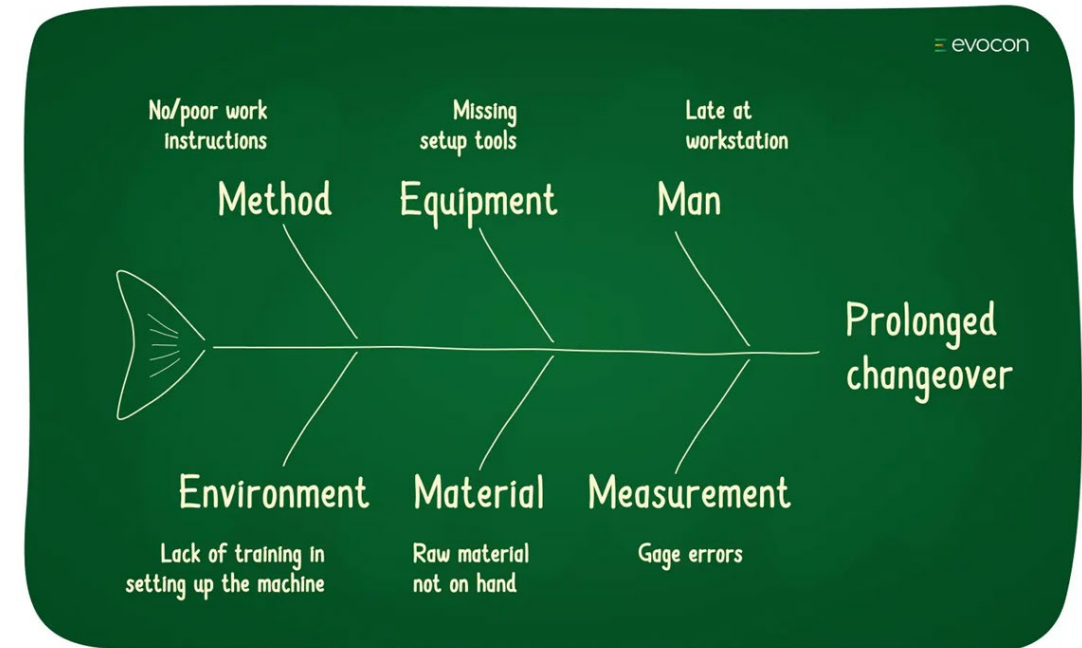
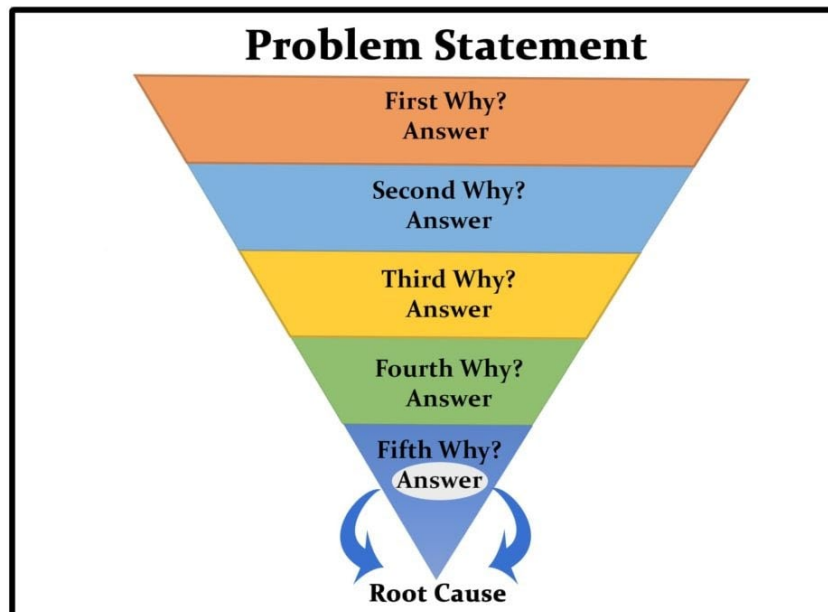
Examples of Data to Collect

- Supplier documents
- Customer information
- Complaint data
- Maintenance records
- Quality data (audits, records, etc.)
- Interview personnel
- Observe
- Inspect
- Perform the process
- Additional testing

Tools for Root Cause Analysis

Best Practices

- Prepare
- Set the Stage
- Brainstorm
- Ask all the questions



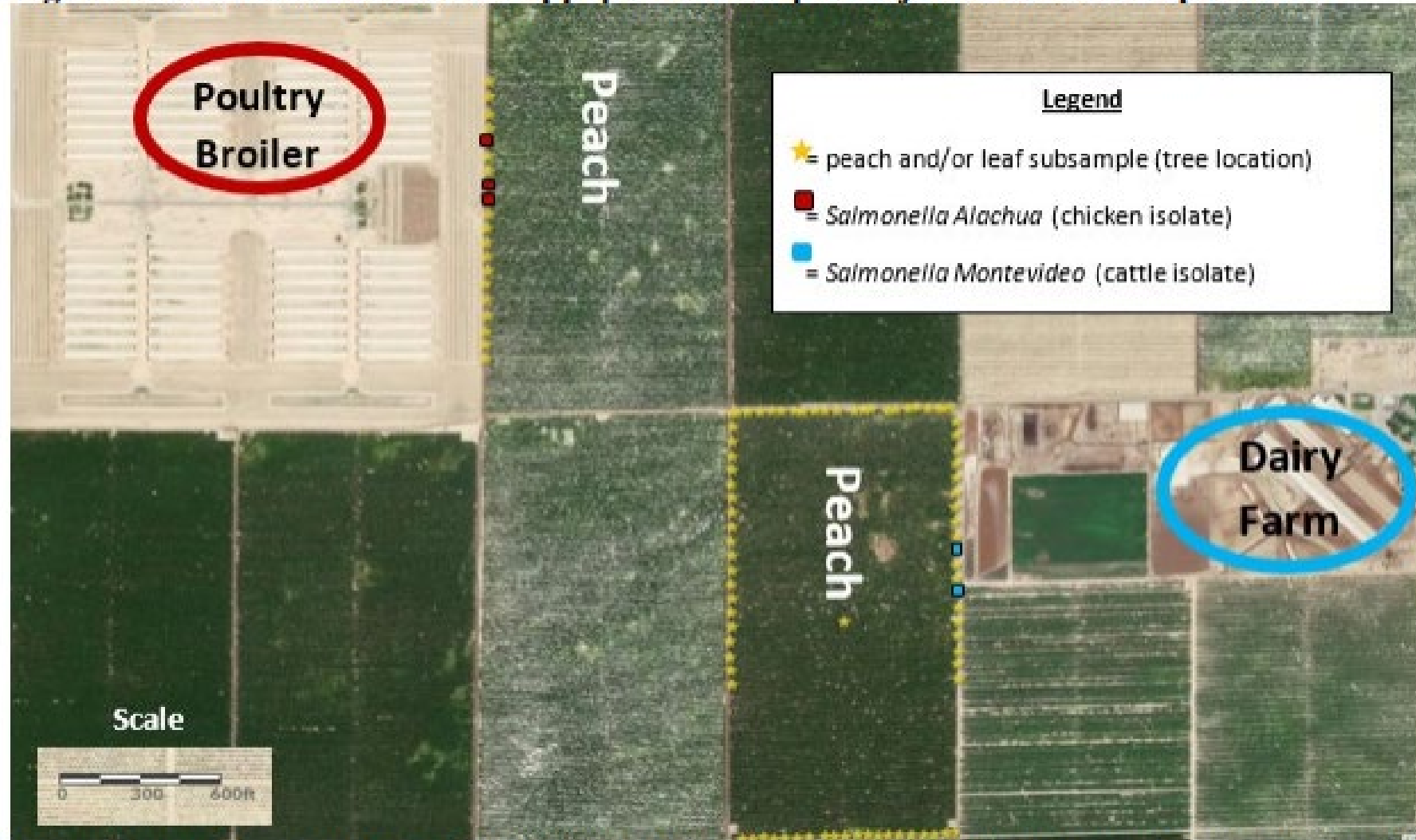
Root Cause Analysis Steps

- 1 Immediate Corrective Action
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Story Time – Real Life Examples

Non-Conformity	Corrective Action	Poor RCA	Good RCA	Proposed Preventive Action
DC Monument Deteriorating	Close the monument so no one gets hurt by falling concrete.	It is the jet fuel and cleaning chemicals causing the deterioration.	Cleaning chemicals for bird poop. Birds eating spiders. Spiders eating midges. Midges like the lights.	Turning off the lights an hour earlier (instead of moving the airport).
Supplier audit for high-risk supplier not completed.	Audit completed.	Not able to travel because of COVID19 restrictions.	Unable to travel because of COVID restrictions and the alternative (temp) supplier approval was not documented.	Ensure procedures for alternates during crisis as well as minimum records and sign-off are documented.
Salmonella Enteritidis on Peaches	Recall.	Peaches were contaminated during handling/packing.	Whole genome sequencing of Salmonella spp. from samples along peach field adjacent to poultry broiler and dairy farm.	Scientific and risk-based approach. Microbiological survey pre-harvest.

Figure 1: Location of *Salmonella* spp. positive samples adjacent to animal operations



Note: This map does not include all positive *Salmonella* spp. locations. *Salmonella enterica* subsp. *Enterica* serovar Montevideo isolates (in blue) are median of 16 SNPs from beef and cattle isolates from 2018, 2019 and 2020. *Salmonella enterica* subsp. *Enterica* serovar Alachua isolates (in red) are identical (0-2 SNP) to a surveillance sample of chicken from 2019.

Key Take-Aways

- **Follow ALL the Steps**
- **Most importantly** – multi-functional team, and not stopping at the first why
- **Document everything**
- **Respond in a timely manner**
- **Follow-up and monitor**

If you are unable to understand the cause of a problem it is impossible to solve it.

-Naoto Kan

Kevin Dineen
Account Executive



TraceGains Product Suite

R&D / NPD TEAMS

QUALITY and REGULATORY COMPLIANCE TEAMS

Marketplace

Formula Management

Networked Intelligence

Spec Management – Raw Materials / Spec Management – Finished Goods

Supplier Management

Audit Management

Supplier Compliance

Quality Management

Customer Management

Explore Concept

Validate Product

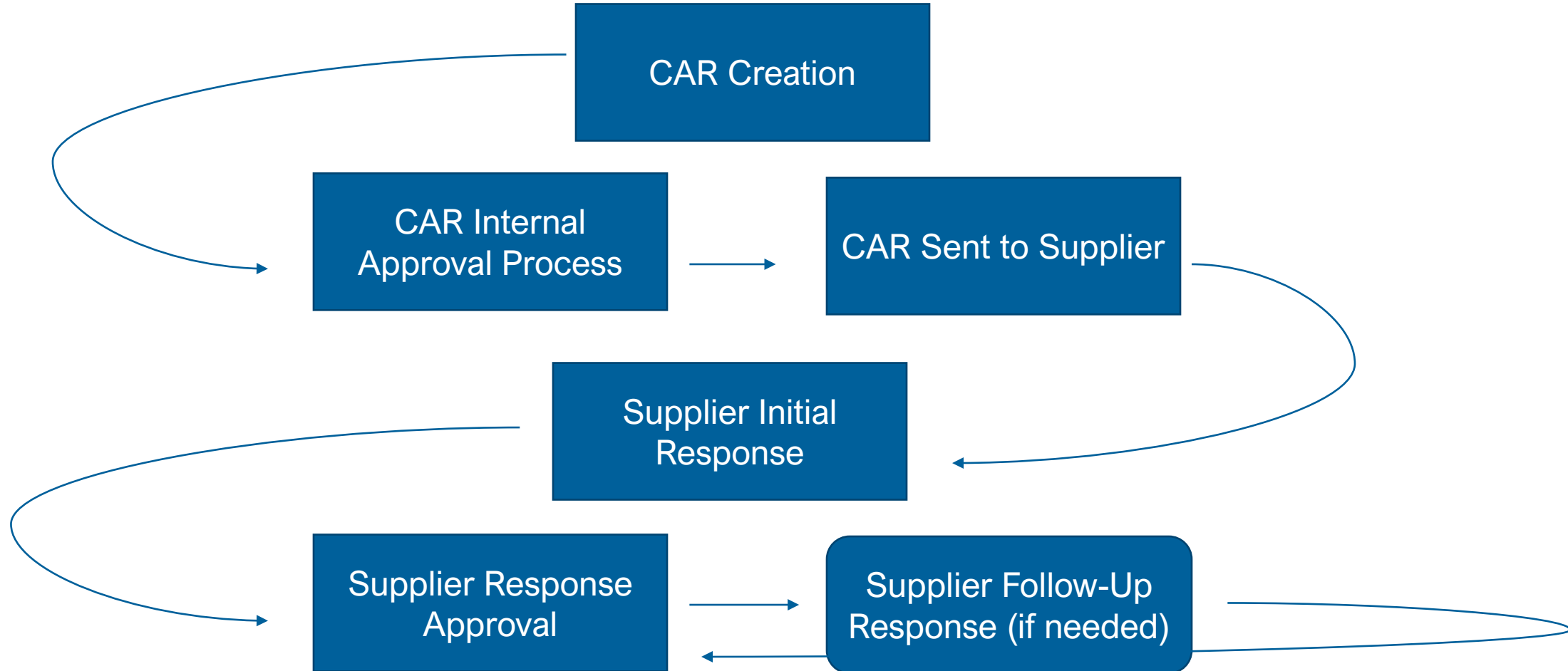
Build/Manage Product

CONCEPT

TRACEGAINS C TO C SUITE

CONSUMPTION

Standard CAR Workflow



CAR Creation

- CARs can be created manually in TraceGains simply by selecting the appropriate Item and Supplier IDs the corrective action is for

- CARs can be created automatically in TraceGains
 - COA Zoning
 - Identifies whether data points are in/out of spec and send CARs accordingly
 - TraceGains Workflow can create CARs based on attribute business rules and/or audit non-conformance values.

The screenshot displays the TraceGains software interface. The main window shows a table of CARs with columns for CAR Creation Date, CAR Status, CAR Type, Supplier/Item Name, Supplier Lot ID, Requester Name, Release for Internal Approval, Request Date, Days to Return, Due Date Reached, and Implementation Date. A 'Create' dialog box is open in the foreground, prompting for 'Item ID' and 'Supplier ID' with 'Continue' and 'Cancel' buttons.

CAR Creation Date	CAR Status	CAR Type	Supplier/Item Name	Supplier Lot ID	Requester Name	Release for Internal Approval	Request Date	Days to Return	Due Date Reached	Implementation Date
2/4/2019 9:07:54 PM	Requester Review	Audit Supplier	Basic Ingredients, Inc. - Corporate		Ruben Galbraith	Yes	2/4/2019 09:00:00 AM	14	Request Returned	2/5/2019 09:00:00 PM
2/5/2019 9:03:44 PM	Requester Review	Audit Internal	Butterhouse - Production (Capitol Facility)		Ruben Galbraith	Yes	2/5/2019 09:00:00 AM	14	Request Returned	3/1/2019 09:00:00 AM
4/8/2019 11:12:16 AM	Requester Review	Audit Internal	Butterhouse - Raweving Dept		Ruben Galbraith	Yes	4/8/2019 10:00:00 PM	21	Request Returned	4/11/2019 09:00:00 AM
4/16/2019 02:39:02 PM	Open	Audit Supplier	Basic Ingredients, Inc. - Corporate		Ruben Galbraith	No				
6/15/2019 02:46:47 PM	Requester Review	COA Out of Spec	Eyes Food Products	8100-109	Ruben Galbraith	Yes	4/17/2019 03:00:00 PM	14	CAR Due	
6/20/2019 03:05:16 PM	Closed	COA Out of Spec	Wu Da Dai Inc.	W80-222	Ruben Galbraith	Yes	2/11/2019 11:00:00 AM	21	Request Returned	7/31/2019 05:00:00 PM
6/20/2019 03:05:32 PM	Open	Quality Testing	Carmelch Foods							
6/20/2019 03:05:56 PM	Requester Review	Quality Testing	Carmelch Ingredients, Inc.				4/1/2019 10:00:00 AM	7	CAR Due	
6/20/2019 03:21:12 PM	Requester Review	Raweving	Wu Da Dai Inc.				2/14/2019 03:00:00 PM	14	Request Returned	6/31/2019 12:00:00 AM
6/21/2019 12:40:12 PM	Open	Raweving	Midwest Foods							
6/21/2019 02:01:17 PM	Open	Audit Internal	Butterhouse - Warehouse (Downstream)							
6/24/2019 08:51:18 PM	Closed	Audit Supplier	Basic Ingredients, Inc. - Minneapolis				3/13/2019 11:00:00 AM	21	Request Returned	4/30/2019 11:00:00 AM
6/25/2019 10:38:19 AM	Requester Review	Audit Supplier	Basic Ingredients, Inc. - Minneapolis				3/14/2019 11:00:00 AM	80	Request Returned	6/30/2019 10:00:00 AM
11/20/2019 11:02:46 AM	Open	Quality Testing	Onix Sugar							
11/20/2019 01:31:21 PM	Open	Audit Supplier	Basic Ingredients, Inc. - Corporate							
12/20/2019 02:20:52 PM	Open	Audit Supplier	Basic Ingredients, Inc. - Corporate							
12/24/2019 09:30:20 AM	Open	Audit Supplier	Butterhouse - Production (Capitol Facility)							
12/24/2019 09:35:59 AM	Open	Foreign Material	Butterhouse - Warehouse (Downstream)		Ruben Galbraith	Yes	12/4/2019 09:37:00 AM	14	Due Date not Reached	12/4/2019 09:38:00 AM
1/11/2020 02:00:47 PM	Open	Midwest Foods		81-438		No				
1/20/2020 09:40:19 AM	Open	Carmelch Foods		Carth-208		No				
1/24/2020 08:14:59 AM	Open	Carmelch Foods		Carth-208		No				
3/11/2020 02:31:11 PM	Open	Raweving	Eyes Food Products	8100-412	Dave Satt	No	2/11/2020 03:32:00 PM	14		
2/05/2020 10:22:21 AM	Open	Midwest Foods		81-430		No				
2/26/2020 10:31:53 AM	Open	Supplier/ITC				No				
2/26/2020 10:20:20 PM	Requester Review	Audit Supplier	Butterhouse - Warehouse (Downstream)		Ruben Galbraith	Yes	4/20/2020 10:00:00 AM	14	Due Date not Reached	
4/9/2020 14:00:00 PM	Open	Carmelch Foods		Carth-208		No				

CARs in TraceGains

CAR Kickoff & Type (1/3)

Sections

1. Audit Summary and Key Results
2. CAR Kickoff
3. Internal Review
4. Supplier Initial Response
5. Supplier Response Approval
6. Supplier Follow-Up Response (if needed)

 Documents

Audit Summary and Key Results

* Supplier/Site ID  

000041

Supplier/Site Name

Basic Ingredients, Inc. - Minneapolis

Audit Specifics

Date of Audits  

3/6/2019 01:00:00 PM

Audit Type

BA Supplier Audit

Audit Awareness

Announced Audit

Audit Firm

N/A

Attendee Details

Just Ruben attended this round.

Audit Results

Audit Pass/Fail

Fail

Critical Non-Conformance Totals

2

Major Issues

3

Minor Non-Conformance Totals

1

CAR Kickoff

CAR Status

Response Review 

Designated CAR Approver

Approver Name

Ruben Galbraith

[Use my full name](#)

* Approver Email 

ruben@smcbutterhouse.com

[Use my email address](#)

Designated CAR Requestor

Requestor Name

David Scott

[Use my full name](#)

* Requestor Email 

das@smcbutterhouse.com

[Use my email address](#)


CAR Details

Request Date

3/14/2019 11:00:00 AM

CAR Type

Audit (Supplier) 

* CAR Audit Category 

Food Safety 

* Complaint Text 


In regards to "HACCP & Quality Management" audit portion, particularly Parts 1-3 on missing documentation and procedures. We need you to provide us with updated versions of these, and reasoning as to why it was missing, what you will do to remedy, etc. Thanks.

CARs in TraceGains

Supplier Response (2/3)

Sections

1. Audit Summary and Key Results
2. CAR Kickoff
3. Internal Review
4. Supplier Initial Response
5. Supplier Response Approval
6. Supplier Follow-Up Response (if needed)

 Documents

Internal Review

Approval 1 Status

Approved 

Approval 1 Comment

Move forward to supplier response stage.

Supplier Initial Response

CAR Response Logistics

Days to Return

60

Request Due Date

Supplier Response Date

4/10/2019 03:00:00 PM

Due Date Reached

Request Returned

Supplier Response

Supplier Response Name

Bob Garcia

Root Cause

Staff turnover caused documentation tracking to fall by the wayside.

Corrective Actions

We have rehired the position, a very qualified individual. Their first task was to ensure all our HACCP/HARPC planning on point for the year.

Preventative Measures

We licensed a wonder software system called TraceGains to track our documentation, and send auto alerts when anything goes missing or expired.

CARs in TraceGains

Sections

1. Audit Summary and Key Results
2. CAR Kickoff
3. Internal Review
4. Supplier Initial Response
5. Supplier Response Approval
6. Supplier Follow-Up Response (if needed)

 Documents

Review / Approval (3/3)

Supplier Response Approval

Approval 1 CAR Response Approval

Approval 1 CAR Response Comments

Comment to Supplier

Supplier Follow-Up Response (if needed)

Supplier Revised Response

Supplier Revised Response Date

Documents Show Archived

Drop Files Here

Comments	Online Form	File Name	Type ▲	Status	Workflow	Expiration Date	Doc Creation Date
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

CAR Dashboard

- Provides a place to monitor all CARs in the system. Multiple dashboards can be created, columns can be added/removed, sorted, and filtered as needed.

TraceGains SMC Butterhouse Inc.																			
Market Hub	Smart Alerts	Analytics	Formulas	Items	Suppliers 5	Sites	Auditors	Audits	Items Supplied	Documents	Specifications	POs	COA Monitor	COAs	QA	CARs	Need Help?	Configuration	
<div style="display: flex; justify-content: space-between; align-items: center;"> CARs (All) ▾ New Filter Reset Export </div>																			
<input type="checkbox"/>		CAR Creation Date ▲	CAR Status	CAR Type	Supplier/Site Name	Supplier Lot ID	Requestor Name	Release for Internal Approval	Request Date	Days to Return	Due Date Reached	Implementation Date							
<input type="checkbox"/>		2/4/2019 01:07:54 PM	Response Review	Audit (Supplier)	Basic Ingredients, Inc. - Corporate		Ruben Galbraith	Yes	2/4/2019 06:00:00 AM	14	Request Returned	2/28/2019 06:00:00 PM							
<input type="checkbox"/>		2/5/2019 03:35:44 PM	Response Review	Audit (Internal)	Butterhouse - Production (Capsule Facility)		Jason Mueller	Yes	2/8/2019 10:00:00 AM	14	Request Returned	5/1/2019 12:00:00 AM							
<input type="checkbox"/>		4/4/2019 11:32:19 AM	Response Review	Audit (Internal)	Butterhouse - Receiving Dock		Ruben Galbraith	Yes	4/4/2019 12:00:00 PM	21	Request Returned	4/11/2019 09:00:00 AM							
<input type="checkbox"/>		4/18/2019 03:06:00 PM	Open	Audit (Supplier)	Basic Ingredients, Inc. - Corporate		Jason Mueller	No											
<input type="checkbox"/>		5/30/2019 02:48:45 PM	Awaiting Response	COA Out of Spec	Byco Food Products	BYCO-109	Ruben Galbraith	Yes	4/17/2019 03:00:00 PM	14	CAR Due								
<input type="checkbox"/>		5/30/2019 03:05:16 PM	Closed	COA Out of Spec	We Be Gel Inc.	WBG-226	Ruben Galbraith	Yes	2/11/2019 11:00:00 AM	21	Request Returned	7/31/2019 05:00:00 PM							
<input type="checkbox"/>		5/30/2019 03:05:38 PM	Open	Quality Testing	Castletech Foods	Castle-286	Ruben Galbraith	No											
<input type="checkbox"/>		5/30/2019 03:06:04 PM	Awaiting Response	Quality Testing	Connected Ingredients, Inc.	CII-657	Ruben Galbraith	Yes	4/1/2019 12:00:00 AM	7	CAR Due								
<input type="checkbox"/>		5/30/2019 03:21:13 PM	Response Review	Receiving	We Be Gel Inc.	WBG-226	Ruben Galbraith	Yes	2/13/2019 03:00:00 PM	14	Request Returned	5/31/2019 12:00:00 AM							
<input type="checkbox"/>		5/31/2019 12:40:12 PM	Open	Receiving	Michael Foods	BI-438		No											
<input type="checkbox"/>		6/3/2019 02:01:17 PM	Open	Audit (Internal)	Butterhouse - Warehouse (Downtown)			No											
<input type="checkbox"/>		9/4/2019 05:51:18 PM	Closed	Audit (Supplier)	Basic Ingredients, Inc. - Minneapolis		Jason Mueller	Yes	3/13/2019 11:00:00 AM	21	Request Returned	4/30/2019 11:00:00 AM							
<input type="checkbox"/>		9/5/2019 10:38:15 AM	Response Review	Audit (Supplier)	Basic Ingredients, Inc. - Minneapolis		David Scott	Yes	3/14/2019 11:00:00 AM	60	Request Returned	6/30/2019 10:00:00 AM							
<input type="checkbox"/>		10/24/2019 10:21:40 AM	Open		United Sugar			No		14									
<input type="checkbox"/>		11/22/2019 01:33:21 PM	Open		Basic Ingredients, Inc. - Corporate			No		14									
<input type="checkbox"/>		12/3/2019 02:20:35 PM	Open		Basic Ingredients, Inc. - Corporate			No		14									
<input type="checkbox"/>		12/4/2019 09:33:20 AM	Open		Butterhouse - Production (Capsule Facility)			No		14									
<input type="checkbox"/>		12/4/2019 09:35:56 AM	Open	Foreign Material	Butterhouse - Warehouse (Downtown)		Ruben Galbraith	Yes	12/4/2019 09:37:00 AM	14	Due Date not Reached	12/4/2019 09:38:00 AM							
<input type="checkbox"/>		1/21/2020 02:02:51 PM	Open		Michael Foods	BI-438		No		14									
<input type="checkbox"/>		1/23/2020 09:40:39 AM	Open		Castletech Foods	Castle-286		No		14									

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Live Q&A

Type your questions
into the chat box!

Win a Cup of Coffee...

Take our survey and be
entered to win a \$10 gift
card to your favorite coffee
shop!





Thank You

Together we do more