



TRACEGAINS WEBINAR

# How to Approach Process Validation

Analyzing the Data, Stages, and Authorities

November 30<sup>th</sup>, 2022



*Meet*  
Your Moderator

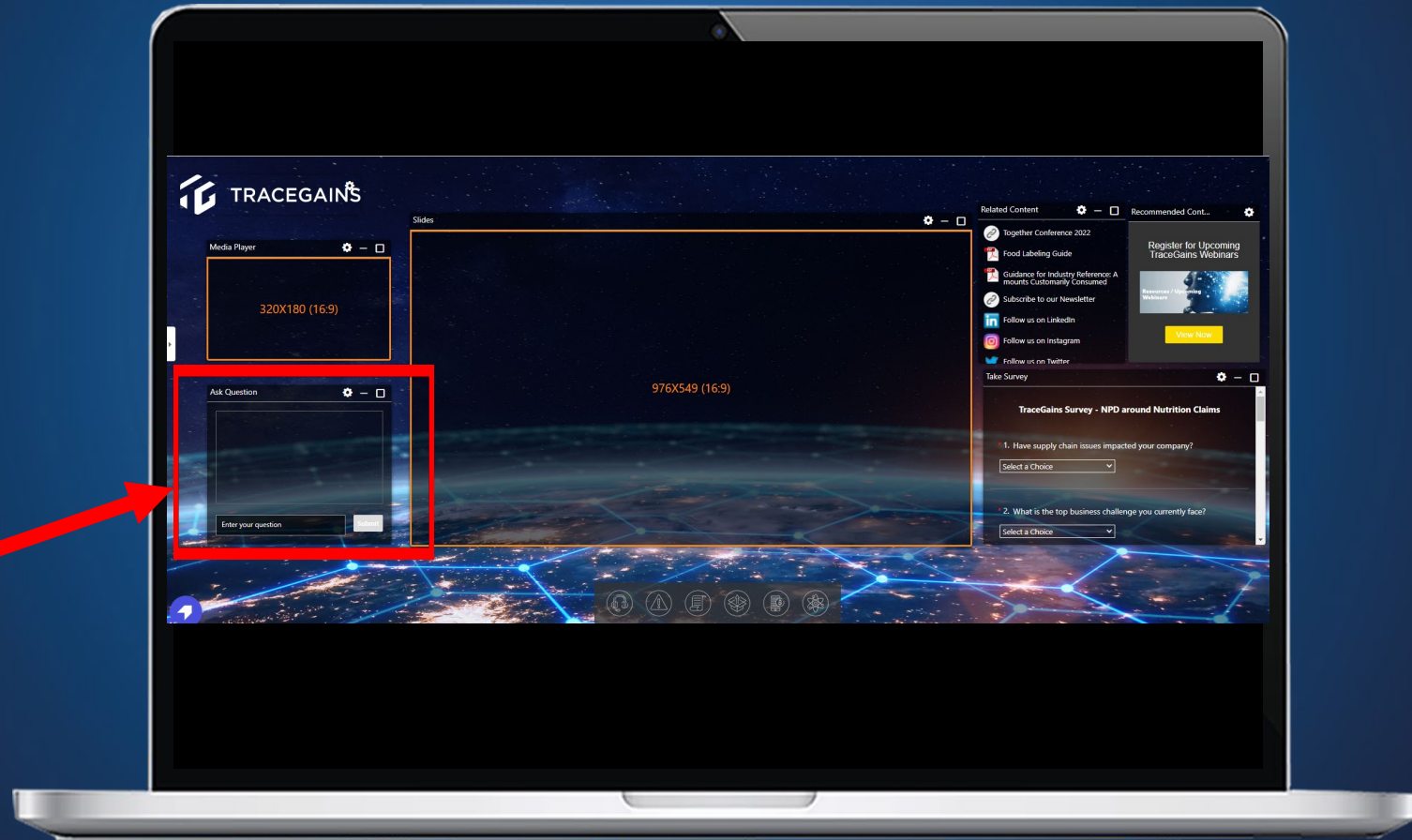


**Kristen Goodale**  
Marketing Coordinator



# 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

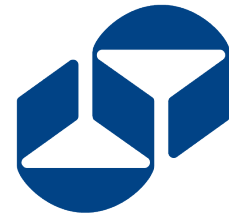


**Dr. Alex Brandt**  
Chief Science Officer  
Food Safety Net Services



**Kevin Dineen**  
Account Executive  
TraceGains





**Certified Group**

Laboratory Testing | Regulatory Consulting

# How to Approach Process Validation

**NOV 30 2022**

# Certified Group

- Leading North American provider of testing and regulatory consulting services. Thirty locations and ~1500 employees.
- USA, Canada, and Mexico
- Family of Companies:
  - Certified Laboratories – Food and Beverage
  - FSNS – Food and Beverage
  - Micro Quality Labs – Supplements, Personal Care, Cosmetics, Cannabis/CBD
  - Microconsult Inc – Supplements, Personal Care, Cosmetics, Cannabis/CBD
  - ABC Testing Inc – Supplements
  - Labs-Mart – Supplements, Cannabis/CBD
  - Labstat – E-Cigarettes and Nicotine
  - EAS Consulting – Consulting Services

# Speaker Background

- Education and research in food science and microbiology.
- Employed with FSNS for eight years.
- Leads the contract research laboratory known as Lab+.
- Lab+ conducts challenge studies, process validations, method validations, and other project-based services.
- Lab+ also conducts other non-routine testing services such as foreign material identifications, spoilage investigations, pathogen subtyping, meat speciation, GMO testing, etc.



# Process Validation Overview

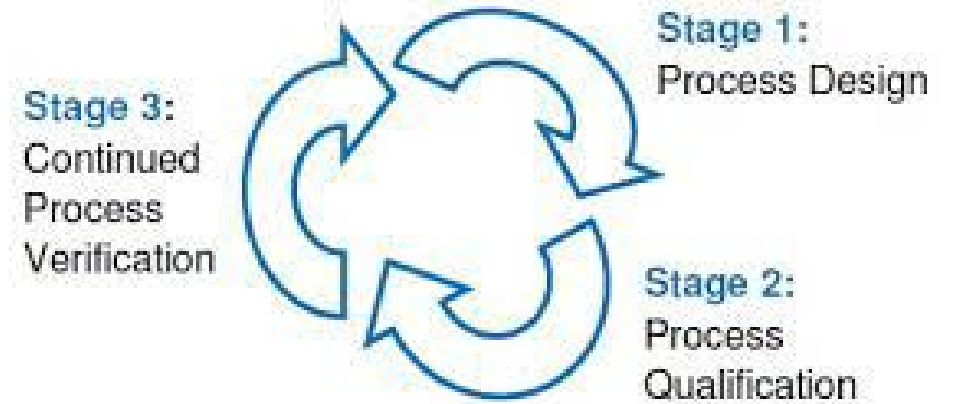
- What is a Process Validation?
- How to know if a process validation is needed
- Where and how do we conduct process validations?
- Processing validation types and considerations
- Process Authority Services
- Best Practices
- Certified Group Services



# What is Process Validation?

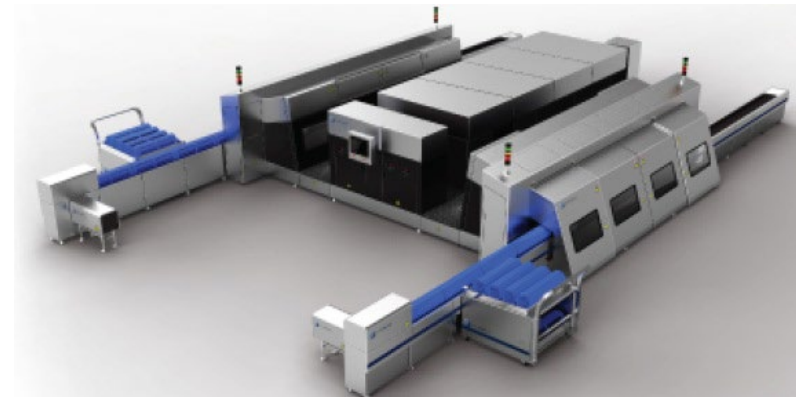
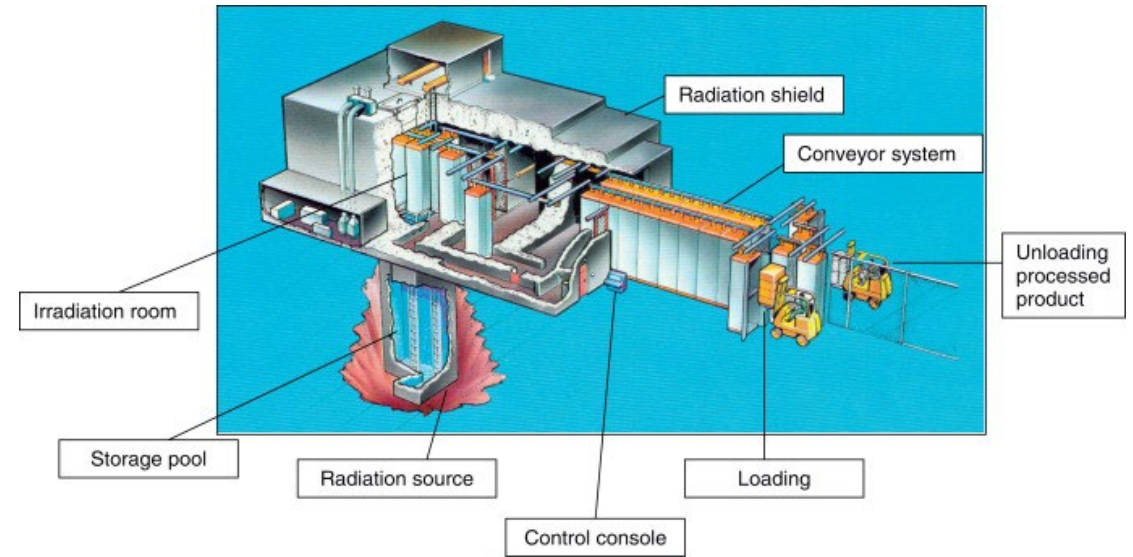
- Verification of the Efficacy of a Process
  - Does this process achieve its intended effect?
    - E.g. 5-log reduction of vegetative pathogens of interest
  - Most often a comparison of initial organism concentration to post-process concentration
- Most multi-disciplinary and complex study type
  - Microbiology
  - Engineering
  - Food Science/Safety
  - Chemistry
  - Regulatory/Legal

## Process Validation



# Process Validation Types

- As many as there are food processes
  - Thermal
    - Extrusion
    - Dry-heat
    - Steam heat
    - Blanching
  - Irradiation
  - Sanitizer
  - Pressure (HPP)
  - Microfiltration
  - Bactericidal Product Properties
  - Fermentation/Curing
  - Consumer Cook Instructions
  - Commercial Sterility/Retort



# Do I Need Process Validation?

- New regulations increase focus on preventative action
- FDA-FSMA requires validation and verification of a kill step for all RTE/RTD products (21 CFR 507.3)
- USDA-FSIS regulated plants are required to validation Critical Control Points [9 CFR 417.4(a)(1)]



# Do I Need Process Validation?

- Some processes are considered “safe harbor”
  - Require verification of processing parameters, but not necessarily direct evaluation with inoculated product
  - Process Authority detailing performance standards and reviewing data supporting compliance may be sufficient
- Inoculated study may not be needed in some cases:
  - Traditional pasteurization processes
  - Certain meat cooking processes
  - Certain baked goods processes





# Do I Need Process Validation?

- Is necessary if:
  - Insufficient publicly available data and/or regulatory guidelines to support many processes via Process Authority alone
    - Therefore, data needs to be generated and a process validation is often the optimal means for doing so
  - Verification of the processing parameters is difficult-to-impossible
    - For example, cannot confirm internal product temperature achieved during production
  - Significant changes to the process/product since previous validation was performed



# Process Validation - Where?

- The Conundrum
  - Most validations are focused on foodborne pathogens
  - And, the most accurate estimation of the efficacy of a process would be achieved by running the actual in-plant process
  - But, bringing pathogen laden product to a food production facility is a risky proposition and can be disruptive to operations...



# Process Validation - Where?

- The Solutions
  - Laboratory Simulation
  - Surrogate Validation Study
  - In-Plant Validation via Surrogate
  - Client-Side Pilot Plant Facility



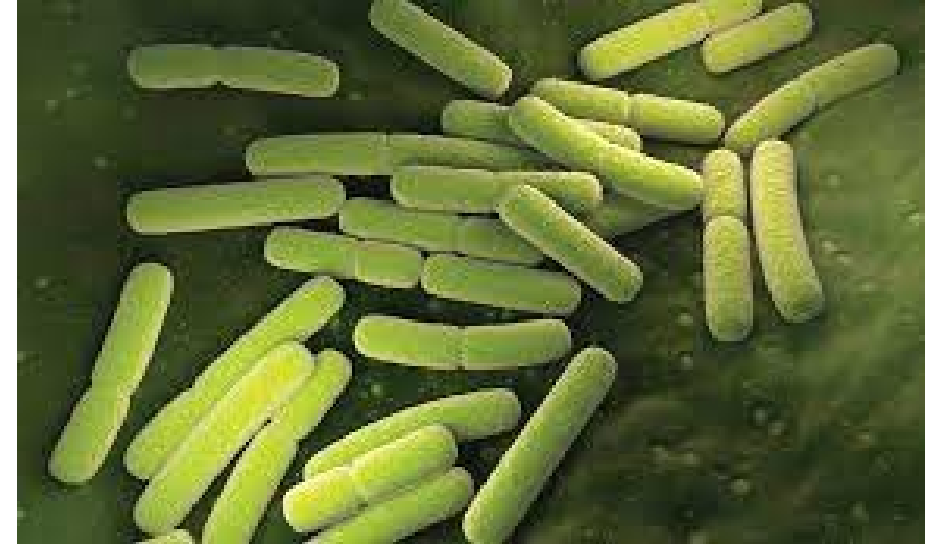
# Laboratory Simulation

- Replication of process in a laboratory environment where live pathogens can be used
- Can be sufficient in and of itself as verification of a process
  - Depends on expected fitness/precision of simulation
- Protip: Adding a surrogate candidate alongside the pathogens can qualify a surrogate for future in-plant studies



# Surrogate Validation

- What is a surrogate organism?
  - Benign organism that serves as a suitable proxy for estimating the effect of processing conditions on the organism of interest (e.g. pathogens)
- Verification of the suitability of the candidate organism should be done prior to using a surrogate for in-plant validation
  - Surrogates for some products and processes are already established and do not require surrogate validation
  - If not, laboratory simulation with a surrogate candidate included is often the best place to start



# In-Plant Validation

- Surrogate organism introduced to product or ingredient at high levels ( $10^7 - 10^8$ )
- Material then run through the manufacturing process
- Comparison of the initial organism concentrations to the finished product concentrations determines log reduction achieved

Subtraction

$$7 - 5 = 2$$

minuend                      subtrahend                      difference

©www.basic.math.explained.com



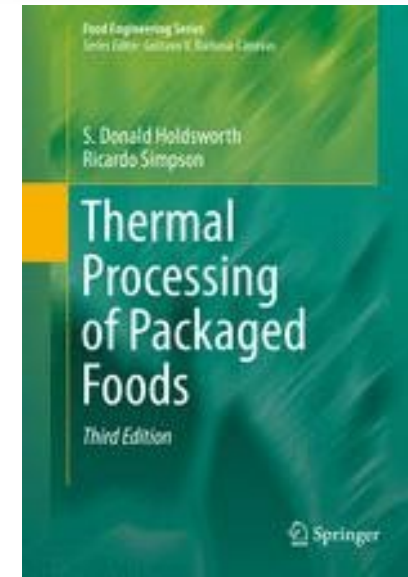
# Client-Side Pilot Plant

- Access to manufacturing equipment that serves as a direct analog to the production facility
- Can introduce live pathogens?
  - If completely removed from commercial operations and never used to produce food intended for consumption, yes
- Unfortunately, this is rarely an option
  - Most clients do not have pilot plants
  - Those that do often want to make test batches that can be consumed.



# Thermal Validation

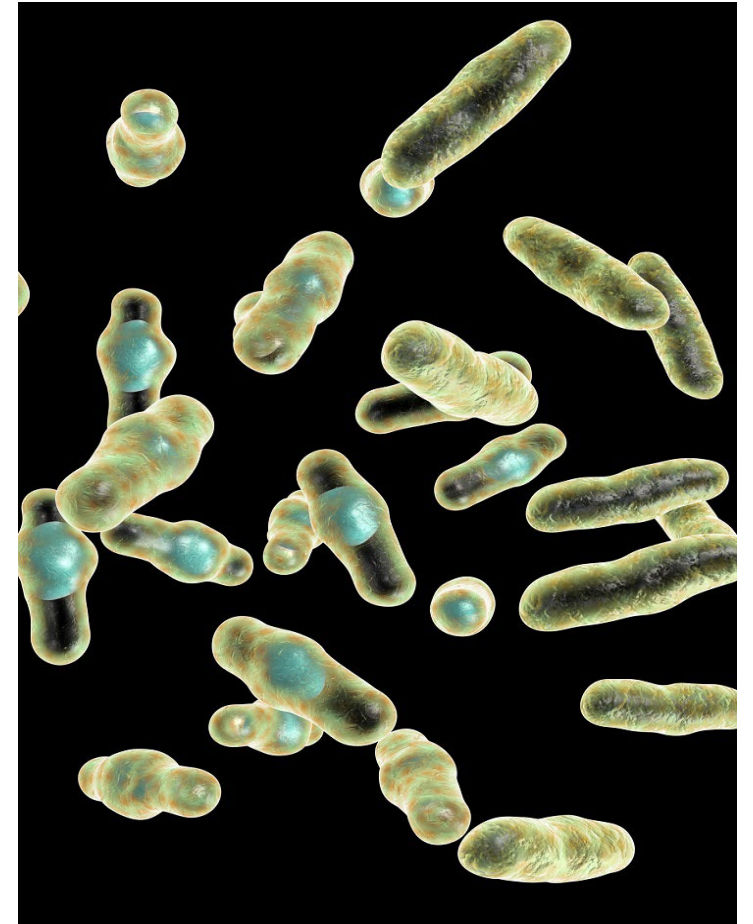
- Inactivates microorganisms by denaturing proteins
- Critical Considerations
  - Set Point Temperature
  - Dwell/Residence Time
  - Batch Size
  - Product Temperature Achieved
  - Product Specifications
    - Moisture Content
    - Density
    - pH
    - Piece Size





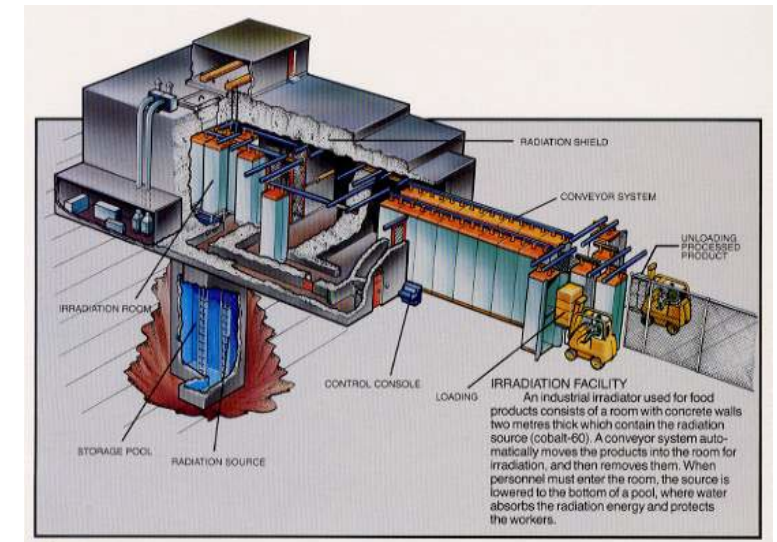
# Cooling Curve

- Determination of risk associated with the product being within the temperature growth range of pathogenic bacteria on its way to refrigerated temperatures
- Specific interest with *Clostridium perfringens*
  - Heat resistant spores
  - Fast doubling time
- Critical Considerations
  - Time from 135°F to 41°F
    - Study needs to replicate the full cooling curve
  - Product Specifications
    - pH, water activity, preservatives, etc.



# Irradiation Validation

- Uses ionized radiation to damage/destroy microorganisms
- Critical Considerations
  - Irradiation Type
    - Electron Beam
    - Gamma ray
    - X-ray
    - UV-C
  - Total Dosage
  - Product Specifications
    - Moisture Content
    - Density
    - Piece Size
    - Color/Absorption



# Sanitizer Validation

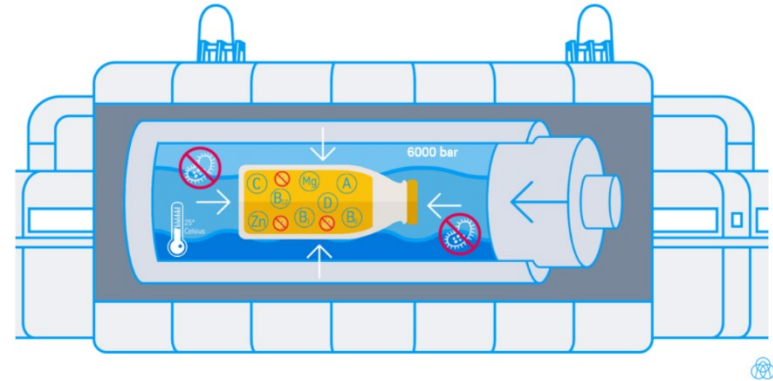
- Chemical inactivation of organisms
- Critical Considerations
  - Sanitizer Type
  - Concentration
  - Exposure Time
  - Mode of Delivery
    - Direction of Spray
    - Volume delivered per unit
    - Mechanical action



# High Pressure Processing

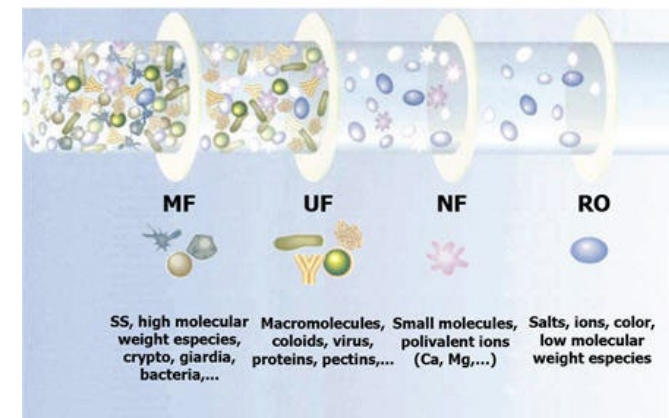
- Using high pressure on the product directly to inactivate organisms
- Critical Considerations
  - Maximum Pressure (87K PSI)
  - Time at Maximum Pressure
  - Come-up/down times
  - Product Specifications
    - Water activity
    - pH
    - Initial product temperature

What is High Pressure Processing (HPP)?



# Microfiltration Validation

- Using filters to physically separate the organism from the product
- Critical Considerations
  - Pore Size(s)
  - Filter material type(s)
  - Product Specifications
    - Suspended Particulates
    - Bactericidal Properties



# Hold Time Validation

- Effectively a challenge study
- Critical Considerations
  - Time
  - Product Specifications
    - pH
    - Moisture Content/water activity
    - Packaging System
    - Any/all other innate properties that can impact bacteriocidal efficacy of the product



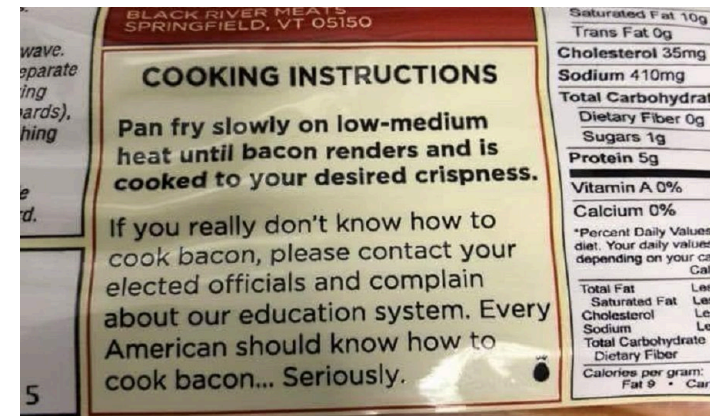
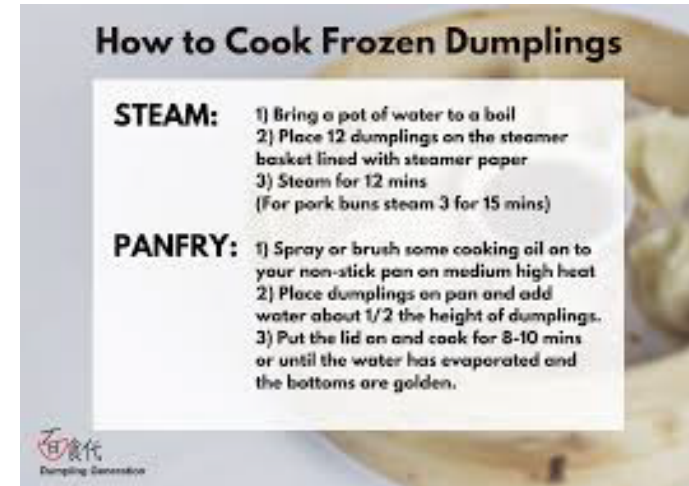
# Curing Validation

- Preservation technique that uses salts to draw moisture out of a food rendering the water potential too low to support growth
- Critical parameters:
  - Duration of curing/drying process
  - Ambient humidity
  - Salt volume used relative product volume or surface area
  - Final moisture/water activity



# Cooking Instruction Validation

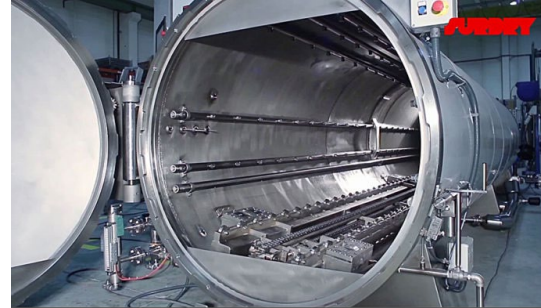
- Raw product is rendered Ready-to-Eat (RTE) via consumers following cook instructions
- Critical parameters:
  - Cook appliance(s)
  - Temp/power settings
  - Duration
  - Internal temperature achieved
  - Product specifications
    - e.g. moisture





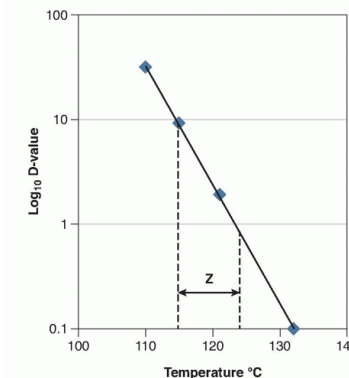
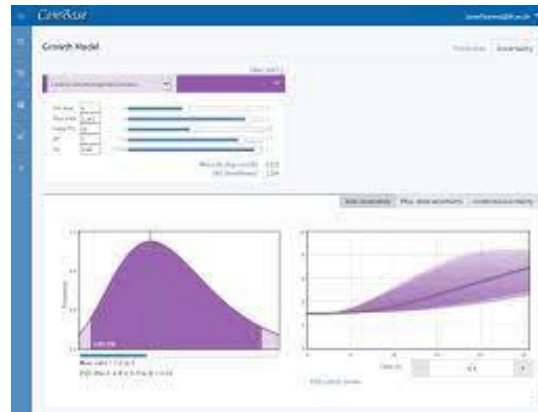
# Commercial Sterility

- Type of processing that renders a product free of organisms that can grow at non-refrigerated temperatures
- More than one means to achieve
  - Retort
  - UHT
  - Microfiltration
- Validation success criteria and standards are more strict and Process Authority highly recommended



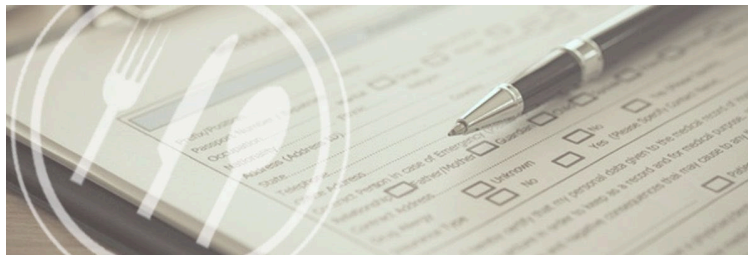
# Process Authority

- In some cases, a Process Authority Letter may be sufficient in lieu of process validation
  - Does require additional supporting data that verification the processing parameters and product specifications
  - Supporting data may also come from modeling data (e.g. Combase), published studies and/or other authoritative sources



# Process Authority

- Can add value even when process validation is required
  - Reducing scope/scale of validation exercise
    - Grouping together like products and processes to reduce the total variations that needed to be evaluated
  - Serving as a 2<sup>nd</sup> opinion on interpretation validation data generated
  - PA letter is an open, living document that can be updated faster and more cost efficiently than repeating a validation study



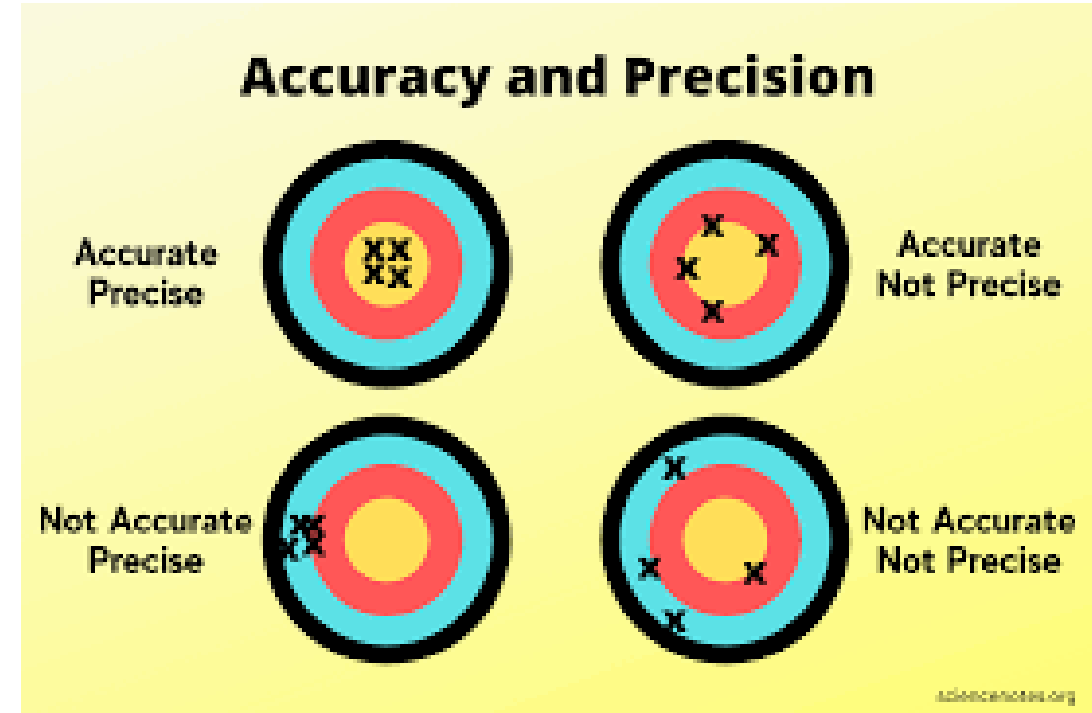
# Best Practices

- Evaluation of ‘worst case” parameters
  - Validation should be performed in a fashion that verifies conditions the least favorable to the inactivation of the organisms
    - Lowest temperature/duration for thermal treatment
    - Largest batch size relative equipment capacity
    - Highest product pH for acid inactivation
    - Lowest water activity for HPP
    - Consumer deviation with a cook procedure



# Best Practices

- Redundancy and Replication and Redundancy
  - Sampling replicates increases accuracy and tests the precision of any individual data point
  - Trial replicates increases accuracy and tests the precision of entire body of data
  - Specific numbers of trials are not usually dictated by regulators
    - “More than one” sets minimum trial replicates at two
- Consideration of inherent variation in the process and product should be given when deciding on number of trials/replicate



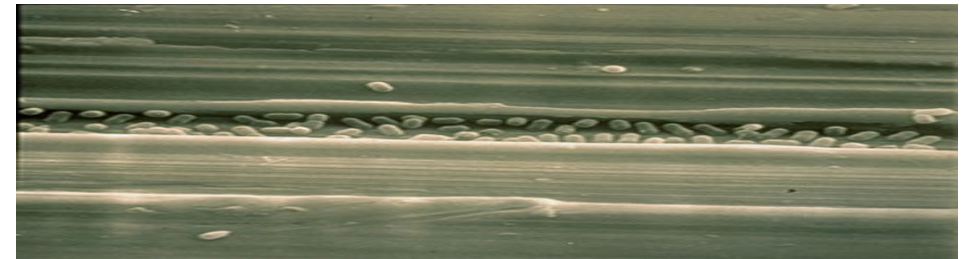
# Best Practices

- Sampling and Trial Replicates
  - Cost-to-Value Determination
    - Cost/point of data generally goes down considerably as you add replicates
    - Does have diminishing returns
  - Ultimately comes down to client
    - Projects are often quoted with multiple variable inputs and their associated costs



# Best Practices

- Schedule a call with all parties before moving to proposal
  - There is always nuance in objectives, requirements and budget
- Caution needs be taken when bringing surrogates in a food manufacturing environment
  - Though benign, it's a lot of bugs
- Include surrogate candidate in lab-based process simulations



# Certified Group Services

- LabPlus
  - Over a dozen qualified project managers across three U.S. locations
  - Wide range of expertise in study design covering the gamut of processing applications, food and beverage categories and regulatory jurisdiction
- EAS Consulting
  - Large stable of Process Authorities and SME who can provide assistance and guidance to a client from process design through full implementation and compliance





# Contact Information

Alex L. Brandt, Ph.D.  
Chief Science Officer  
Food Safety Net Services

[alex.brandt@fsns.com](mailto:alex.brandt@fsns.com)

D: 210-384-5463

C: 210-284-9427

[contractresearch@certifiedgroup.com](mailto:contractresearch@certifiedgroup.com)

**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

# Supplier Compliance

Accelerated sourcing with supplier scorecards and industry intelligence.

## THE PROBLEM

Risk and variability can be hard to spot, and outstanding supplier performance easy to miss.

## WHY IT MATTERS

A single issue can drive huge costs, while tiny trends can hurt over time.

## THE SOLUTION

Score performance, customize templates and automate processes.

## THE TRACEGAINS DIFFERENCE

Real-time information integrated with ingredient specification-level data.



COAs (All)  Show Inactive New Filter Reset Import Export

COA Arrival Date	Supplier Lot ID	Supplier/Site Name	Item ID	Item Name	Item Group	COA Status	COA Action	PO Number	PO Date	PO Exp Delivery Date	Receiving Date	Truck Delivery #	Plant
10/7/2022 08:32:18 AM	781185	Basic Ingredients, Inc. - Minneapolis	STG-NS-11	Salt	Flavoring		Accept	579211	10/6/2022	10/27/2022			
10/7/2022 08:32:14 AM	781186	Basic Ingredients, Inc. - Minneapolis	STG-NS-11	Salt	Flavoring	Out Spec	Reject	579215					
9/27/2022 09:51:07 AM	NOI-123	Number One Ingredients, Inc.	TG-KCOA	Egyptian Onion Powder	Raw Materials		Accept						
3/3/2022 03:10:04 PM	K11122	SupplierXYZ	0529	Sucrose, Extra Fine, Bag	Sweetener	Out Spec	Reject	AA3415	1/15/2019	2/20/2019			Denver,
5/23/2019 03:00:57 PM	BI-630	Michael Foods	00A-FLF	Chopped Garlic	Vegetable		Accept				6/8/2019 09:40:00 AM	1234	Location 2
5/23/2019 03:00:23 PM	BI-438	Michael Foods	00A-FLF	Chopped Garlic	Vegetable	Out Spec	Reject	002703	3/1/2019	4/6/2019	4/6/2019 10:00:00 AM	1234	Location 2
5/23/2019 02:59:58 PM	BI-584	Michael Foods	00A-FLF	Chopped Garlic	Vegetable		Accept	000113	3/15/2019	4/20/2019	4/19/2019 03:00:00 PM	73211	Location 1
5/23/2019 02:59:10 PM	BI-999	Basic Ingredients, Inc. - Minneapolis	00A-FLF	Chopped Garlic	Vegetable		Accept				6/3/2019 04:30:00 PM	326	Location 3 (Dock
5/23/2019 02:58:43 PM	BI-464	Basic Ingredients, Inc. - Minneapolis	00A-FLF	Chopped Garlic	Vegetable		Accept	002943	4/3/2019	5/8/2019	5/15/2019 10:14:00 AM	6154	Location 2
5/23/2019 02:58:13 PM	BYCO-412	Byco Food Products	00A-FLF	Chopped Garlic	Vegetable		Accept	000332	3/30/2019	5/5/2019	5/1/2019 08:52:00 AM	63652	Location 2
5/23/2019 02:57:05 PM	BYCO-281	Byco Food Products	00A-FLF	Chopped Garlic	Vegetable		Accept	000456	3/26/2019	5/1/2019	4/29/2019 12:40:00 PM	63652	Location 1
5/23/2019 02:56:11 PM	BYCO-109	Byco Food Products	00A-FLF	Chopped Garlic	Vegetable	Out Spec	Reject	000176	3/22/2019	4/27/2019	4/25/2019 11:00:00 AM	63652	Location 2
5/23/2019 02:55:23 PM	BSC-91	Baking Supplies Central	00A-FLF	Chopped Garlic	Vegetable	Warning	Ask	18945	3/14/2019	4/19/2019	4/20/2019 08:00:00 PM	7571	Location 3 (Dock I
5/23/2019 02:54:39 PM	BSC-949	Baking Supplies Central	00A-FLF	Chopped Garlic	Vegetable		Accept	89305	3/18/2019	4/23/2019	4/26/2019 10:21:00 AM	1257	Location 2
2/8/2019 01:44:20 PM	WBG-141	We Be Gel Inc.	TG-750MG	750mg Softgel	CBD		Accept	10008	3/10/2019	4/15/2019	4/20/2019 04:20:00 PM	3888	Location 3 (Dock
2/8/2019 01:41:38 PM	FA-643	Feeling Alright Inc	TG-750MG	750mg Softgel	CBD		Accept	10006	2/9/2018	3/14/2018	3/4/2019 04:00:00 PM	54343	Location 1
2/8/2019 01:40:33 PM	WBG-258	We Be Gel Inc.	TG-750MG	750mg Softgel	CBD		Accept	10007	2/8/2018	3/13/2018	3/14/2019 09:00:00 AM	98789	Location 1
2/8/2019 01:38:59 PM	FA-687	Feeling Alright Inc	TG-750MG	750mg Softgel	CBD		Accept	10005	2/7/2018	3/12/2018	4/4/2018 07:00:00 AM	54343	Location 1
2/8/2019 01:35:46 PM	WBG-226	We Be Gel Inc.	TG-25MG	25mg Softgel	CBD	Out Spec	Reject	10004	2/6/2018	3/11/2018	3/11/2019 06:00:00 AM	77253	Location 2

Page Size: 50

1

1 - 26 of 26 results in 1 pages

Sections

- 1. Transaction Information
- 2. Shipment and Unloading Information
- 3. Truck Inspection
- 4. Receiving Item Inspection

Documents

### Truck Inspection

This section is for recording TRUCK INSPECTION type information, which will inform the overall statuses above.

PO Req Delivery Date

10/31/2022

Receiving Lot

Trailer\_Truck ID

Trailer Chocked

Truck Padlock

Trailer Seal ID

Lot Number on Container

Driver Name

Blacklight Inspection

Allergen Check

Find the corresponding record in the Items Supplied tab, and confirm a match on all recorded

### Receiving Item Inspection

This section is for recording PRODUCT INSPECTION type information, which will inform the overall statuses above.

RCV Tailing Comment

RCV Total on

RCV Total Thru

RCV Total Weight

RCV Weight

### Images

RECEIVING EVIDENCE

Sections ⚙

- 1. Lot Information
- 2. Testing & Sampling
- 3. COA Scanned Attributes
- 4. QA Scanned Attributes

Documents

### Organoleptic

Flavor

Salty!

Texture

Slightly rough

### Chemical

NaCl (%) ▾

99.9

Sulfate as SO4 (%) ▾

0.22

Water Insolubles (%) ▾

0.0025

### Physical

Bulk Density (#/cu. ft.) ▾

70

Surface Moisture (%) ▾

0.8

### Other

Arsenic (ppm)

10

### Organoleptic

QA\_Flavor

QA\_Texture

### Chemical

QA\_NaCl (%) ▾

QA\_Sulfate as SO4 (%) ▾

QA\_Water Insolubles (%) ▾

### Physical

Bulk Density (#/cu. ft.) ▾

QA\_Surface Moisture (%) ▾

### Other

QA\_Arsenic (ppm)

# Quality Management

Centralized quality control with the power of real-time data.

## THE PROBLEM

Manual and unintegrated quality processes are costly and risky.

## WHY IT MATTERS

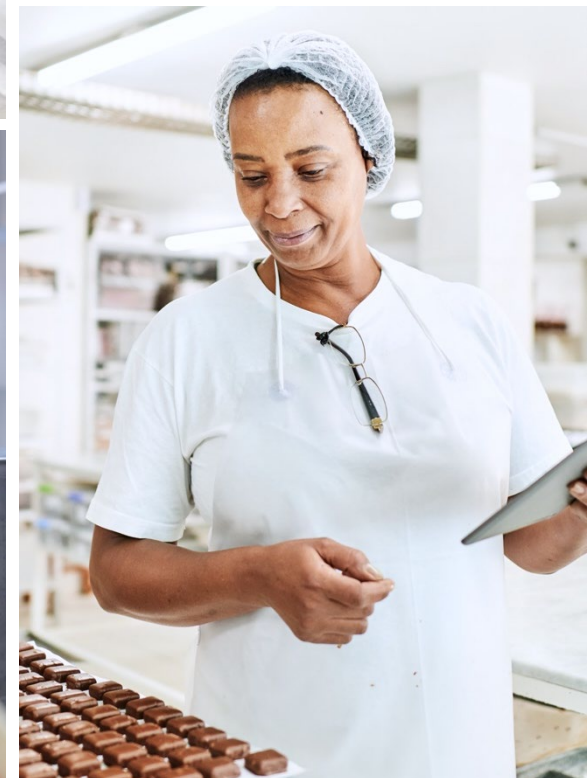
Cost, risk and audit exposure are major concerns for every business.

## THE SOLUTION

Centralize quality and safety plans, data and corrective actions in one system.

## THE TRACEGAINS DIFFERENCE

Leverage industry standard forms, with data flowing throughout the system.





All Collection ▾

Filter Reset Export

Collection Time ▾	QM Program	Product	Lot ID	Tech Responsible	Status	Workflow	CAR Needed?	Days Since Collect	Timely Verification	Verify OK?	Verified By	Verified Date	Scheduled
5/11/2022 03:59:52 AM	Maintenance Verification - Servicing Equipment	Dulce de Leche	12345		Out Spec ▾	Awaiting Collection	No	99					Kettle Room (PS)
5/11/2022 12:29:55 AM	Metal Detector CCP (PS)	Dulce de Leche	12345		Out Spec ▾	Awaiting Collection	No	99					Kettle Room (PS)
5/10/2022 09:04:33 AM	Maintenance Verification - Servicing Equipment			Jason Mueller	Out Spec ▾	Collected	Yes	100					No Associated Ta
5/10/2022 08:40:54 AM	Metal Detector CCP (PS)	Icing	TG-321	Jason Mueller	Out Spec ▾	Collected	Yes	100					No Associated Ta
5/10/2022 08:23:42 AM	Metal Detector CCP (PS)	Icing	TG-321	Jason Mueller		Collected	No	100					No Associated Ta
3/25/2022 01:30:10 PM	Metal Detector - Retail (AFB)	Medalion	43210	Jason Mueller	Out Spec ▾	Collected	No	146					No Associated Ta
3/25/2022 01:27:35 PM	Metal Detector - Retail (AFB)	Beef mince	1234	Jason Mueller		Collected	No	146					No Associated Ta
3/7/2022 03:24:58 PM	Metal Detector Control Program	032022 Release Test	032022 Release Test	Tech 1	Out Spec ▾	Collected	No	164	Yes	Yes	me	3/7/2022 12:00:00 AM	032022 Release
9/30/2021 11:50:04 AM	Mill Operations (Chickpeas)		1234	Tech 2	Out Spec ▾	Collected	No	322					No Associated Ta
3/26/2021 11:49:52 AM	Maintenance Verification - Building Structure	N/A	N/A		Out Spec ▾	Awaiting Collection	No	510					Maintenance (Da
3/26/2021 11:49:51 AM	Maintenance Verification - Servicing Equipment	N/A	N/A		Out Spec ▾	Awaiting Collection	No	510					Maintenance (Da
3/25/2021 11:50:26 AM	Maintenance Verification - Building Structure	N/A	N/A	Tech 3	Out Spec ▾	Collected	No	511	No	Yes	Ruben Galbraith	8/5/2021 03:45:00 PM	Maintenance (Da
3/25/2021 11:50:25 AM	Maintenance Verification - Servicing Equipment	N/A	N/A		Out Spec ▾	Awaiting Collection	No	511					Maintenance (Da
3/18/2021 11:10:14 PM	Finished Product Verification	123	123	Dave Scott	Out Spec ▾	Collected	No	518					No Associated Ta
3/18/2021 09:40:42 PM	Finished Product Verification	123	123	Dave Scott		Collected	No	518					No Associated Ta
12/2/2020 01:53:16 PM	Pre-Op Sanitation Check	N/A	N/A	Jason Mueller	Out Spec ▾	Collected	No	624					Sanitation (Daily
12/2/2020 01:53:14 PM	Pest Control	N/A	N/A	Tech 1		Collected	No	624	No	Yes	Ruben Galbraith	2/9/2022 01:55:04 PM	Sanitation (Daily
10/19/2020 01:18:52 PM	MF-Analytical	Blood Builder	45678	Ruben Galbraith		Collected	No	668	No	No	Ruben Galbraith	3/2/2021 08:40:00 AM	BB: Monday Pro
10/19/2020 01:18:51 PM	MF-Friability	Blood Builder	45678	Ruben Galbraith	Out Spec ▾	Collected	No	668					BB: Monday Pro
10/19/2020 01:18:50 PM	MF-Disintegration	Blood Builder	45678	Ruben Galbraith		Collected	No	668					BB: Monday Pro
10/19/2020 01:18:16 PM	MF-Sensory	Blood Builder	45678	Ruben Galbraith		Collected	No	668					BB: Monday Pro
10/18/2020 06:20:52 PM	MF-Analytical	Blood Builder	34567	Ruben Galbraith	Out Spec ▾	Collected	No	669	Yes	No	Ruben Galbraith	10/19/2020 10:12:00 AM	BB: Sunday Prod
10/18/2020 06:20:51 PM	MF-Friability	Blood Builder	34567	Leah Johnston	Warning ▾	Collected	No	669	Yes	No	Leah Johnston	10/19/2020 10:07:00 AM	BB: Sunday Prod

CAR Needed Filter Reset Export

<input type="checkbox"/>	QM Program	Collection Time	Status	Workflow	Tech Responsible	CAR Needed?	Days Since Collect	Timely Verification	Verify OK?	Verified By	Verified Date	Scheduled Task Name	Tab
<input type="checkbox"/>	Maintenance Verification - Servicing Equipment	5/10/2022 09:04:33 AM	Out Spec	Collected	Jason Mueller	Yes	100					No Associated Task	PreRequisite
<input type="checkbox"/>	Metal Detector CCP (PS)	5/10/2022 08:40:54 AM	Out Spec	Collected	Jason Mueller	Yes	100					No Associated Task	Controls
<input type="checkbox"/>	Lot Code Control Program	12/4/2019 12:42:00 PM	Out Spec	Collected	Tech 2	Yes	988	Yes	Yes	Ruben Galbraith	12/4/2019 11:46:00 AM	Thawing Procedure - Wednesday	Controls
<input type="checkbox"/>	Lot Code Control Program	11/27/2019 01:08:25 PM	Out Spec	Collected	Tech 3	Yes	995	Yes	Yes	Ruben Galbraith	11/27/2019 11:09:00 AM	No Associated Task	Controls
<input type="checkbox"/>	Lot Code Control Program	11/19/2019 12:21:26 PM	Out Spec	Collected	Tech 2	Yes	1003	No	Yes	Ruben Galbraith	9/27/2021 11:58:14 AM	Thawing Procedure - Tuesday	Controls
<input type="checkbox"/>	Temperature Control Program	11/19/2019 12:21:25 PM	Out Spec	Collected	Tech 2	Yes	1003	Yes	Yes	Ruben	11/19/2019 10:28:00 AM	Thawing Procedure - Tuesday	Controls
<input type="checkbox"/>	Customer Complaint Log	11/19/2019 10:33:35 AM		Collected	Tech 2	Yes	1003	Yes	Yes	Larry Ladhands	11/19/2019 09:38:00 AM	No Associated Task	Misc Logs
<input type="checkbox"/>	Customer Complaint Log	11/18/2019 01:41:25 PM		Collected	Ruben Galbraith	Yes	1004	Yes	Yes	Larry Ladhands	11/18/2019 12:46:00 PM	No Associated Task	Misc Logs
<input type="checkbox"/>	Customer Complaint Log	11/18/2019 09:55:30 AM		Collected	Tech 3	Yes	1004	Yes	Yes	Larry Ladhands	11/1/2019 12:00:00 AM	No Associated Task	Misc Logs
<input type="checkbox"/>	Pre-Op Sanitation Check	10/25/2019 01:29:53 AM	Out Spec	Collected	Tech 2	Yes	1028					Prod Line 3 - Sour Dough	PreRequisite
<input type="checkbox"/>	Lactose Bag Weight Log	2/27/2019 10:31:46 AM	Out Spec	Collected	Tech 1	Yes	1268	No	Yes	Jason Mueller	1/15/2020 02:00:00 PM	No Associated Task	Misc Logs
<input type="checkbox"/>	Metal Detector Control Program	2/14/2019 01:34:13 PM	Out Spec	Collected	Tech 2	Yes	1281	No	Yes	David Scott	3/27/2020 06:00:00 PM	No Associated Task	Controls
<input type="checkbox"/>	Pre-Op Sanitation Check	12/10/2018 10:38:24 AM	Out Spec	Collected	Tech 1	Yes	1347	No	Yes	Ruben	10/24/2019 01:44:00 PM	No Associated Task	PreRequisite
<input type="checkbox"/>	Pre-Op Sanitation Check	8/9/2018 12:55:16 PM	Out Spec	Collected	Tech 2	Yes	1470	No	Yes	David Scott	3/27/2020 06:00:00 PM	No Associated Task	PreRequisite
<input type="checkbox"/>	Pest Control	3/29/2018 09:39:49 AM		Collected	Tech 2	Yes	1603	No	Yes	David Scott	3/27/2020 06:00:00 PM	Prod Line 1 - Whole Wheat Bread (1)	PreRequisite
<input type="checkbox"/>	Magnet Control Program	2/13/2018 06:28:04 PM	Out Spec	Collected	Tech 1	Yes	1647	No	Yes	Ruben Galbraith	6/29/2018 10:00:00 AM	No Associated Task	Controls
<input type="checkbox"/>	Scale Verification - Large Scale	2/13/2018 06:16:24 PM	Warning	Collected	Tech 3	Yes	1647	No	Yes	Ruben Galbraith	6/29/2018 10:00:00 AM	No Associated Task	PreRequisite
<input type="checkbox"/>	Bacon - #3459	2/8/2018 11:18:49 AM	Out Spec	Collected	Tech 3	Yes	1652	No	Yes	Jason Mueller	7/4/2018 09:00:00 AM	No Associated Task	Controls
<input type="checkbox"/>	Pre-Op Sanitation Check	2/6/2018 11:18:33 PM	Out Spec	Collected	Tech 1	Yes	1654	No	Yes	Jason Mueller	9/6/2018 11:00:00 AM	No Associated Task	PreRequisite
<input type="checkbox"/>	Line Downtime Log	1/30/2018 12:33:11 PM	Warning	Collected	Tech 2	Yes	1661	No	Yes	David Scott	4/20/2019 01:00:00 PM	No Associated Task	Misc Logs
<input type="checkbox"/>	Weight Control Program	1/9/2018 04:58:53 PM	Out Spec	Collected	Tech 3	Yes	1682	No	Yes	Ruben Galbraith	3/9/2018 02:00:00 PM	Prod Line 1 - 88Q001 08212017	Controls
<input type="checkbox"/>	Magnet Control Program	11/27/2017 11:36:32 AM	Out Spec	Collected	Tech 1	Yes	1725	No	Yes	Ruben Galbraith	9/28/2018 12:00:00 PM	No Associated Task	Controls
<input type="checkbox"/>	Product Donation Rework Waste Log	11/22/2017 02:15:55 AM	Out Spec	Collected	Tech 1	Yes	1730	No	Yes	Ruben Galbraith	9/28/2018 12:00:00 PM	No Associated Task	Misc Logs

View Preship & Signoff

View Data Collection

View CARS

Save



Audit Trail

Cancel

Sections

- 1. RECORD REVIEW
- 2. CAR & COLLECTION STATUS
- 3. GENERAL INFO
- 4. DATA COLLECTION

Documents

### RECORD REVIEW

\* Verification OK? ▾

Yes

No

\* Date of Review ▾

11/19/2019 10:28:00 AM

\* Reviewed By ▾

Ruben

Additional Notes/Comments

I'm going to officially have a CAR

Days since Data Collection

1003

Record verified within 7 days of Data Collection?

Yes

### CAR & COLLECTION STATUS

If additional Corrective Actions must be taken, press Create CAR button at top of page

This will elevate the record to a formal CAR and create a record on CARS tab

Was a Corrective Action Needed?

Yes

Please describe the Issue and Corrective Action(s) performed

Heat lamp!

Workflow

Collected

Status

Out Spec

Created By

Task Scheduler Service

Updated By

ruben.galbraith@tracegains.com

### GENERAL INFO

QM Program

Temperature Control Program

Scheduled Collection Time

### DATA COLLECTION

\* 1 - Temperature Result (°F) - Freezer Removal ▾

31

\* 2 - Temperature Result (°F) - 30 Minute Check ▾

31

## 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