

# Navigating FDA and FSMA compliance when exporting into the US

Thurs Feb 23<sup>rd</sup> , 2023





#### YOUR MODERATOR

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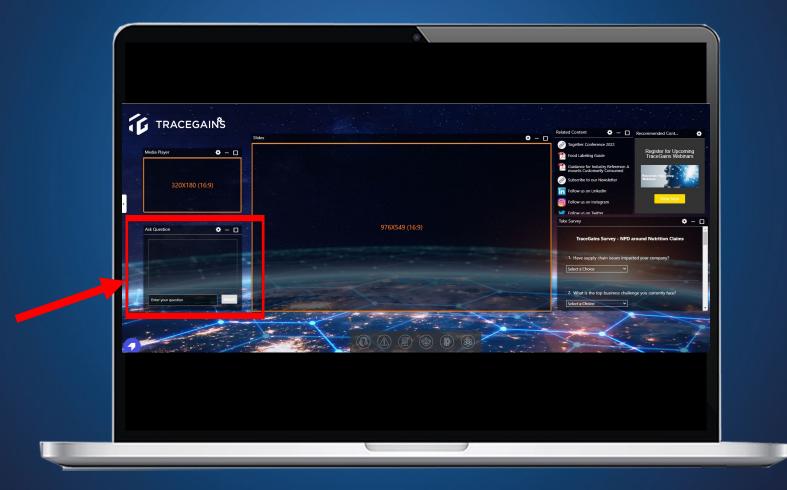


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# We want to hear from you! Please type your questions in the chat box.



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# **About TraceGains**

Together we do more





#### **DISCOVER THE POWER OF NETWORKED**



### WHAT MAKES TRACEGAINS DIFFERENT?

Home of the worlds first Networked Ingredient Marketplace



### **BRIAN RAVITCH**

Consultant | FDA Imports

#### **ANGEL** SUAREZ

Consultant | EAS Consulting Group

#### **DAN** MCGLYNN

YOUR SPEAKERS

Snr Account Executive | TraceGains



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#### **DISCOVER THE POWER OF NETWORKED**



# DAN MCGLYNN Snr Account Executive

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# WHAT DID WE COVER TODAY?

- What is FSMA, the Foreign Supplier Verification Program (FSVP) and System Recognition
- FSVP: Enforcement authorities, who must comply, exemptions, and evaluation and approval of foreign suppliers
- FSVP Regulatory Compliance and seven components of a successful FSVP program
- The layers and process of import refusal and import detention and what to expect at each stage
- Overview of foreign and domestic food safety, importing food and the PREDICT program
- The many moving parts of FDA Alerts

### HOW CAN TRACEGAINS HELP?



# **TraceGains Network**

The global ecosystem built on networked ingredient data

56K+ Supplier Locations 425K+ Items & Ingredients 146+ Supplier Countries

3M+

Supplier, Item & Ingredient Documents 717k Completed Standard Online Forms 53k Counties with Customer Presence



# **TRACEGAINS NETWORK**

The global ecosystem built on networked ingredient data

56K+ Supplier Locations 425K+ Items & Ingredients **146+** Supplier Countries

3M+

Supplier, Item & Ingredient Documents 717k Completed Standard Online Forms 53k Counties with Customer Presence

# **TRACEGAINS** PRODUCT SUITE

R&D / NPD TEAMS

QUALITY and REGULATORY COMPLIANCE TEAMS

#### TRACEGAINS MARKETPLACE

#### NETWORKED FORMULA MANAGEMENT



VALIDATE PRODUCT

SPECIFICATION MANAGEMENT

#### NETWORKED FINISHED GOODS



AUDIT MANAGEMENT

NETWORKED SUPPLIER COMPLIANCE

QUALITY MANAGEMENT

CUSTOMER MANAGEMENT

#### BUILD/MANAGE PRODUCT

CONSUMPTION

CONCEPT

EXPLORE CONCEPT

### **TRACEGAINS** TECHNOLOGY STACK

A network platform drives collaboration across departments and with suppliers and co-manufacturers, automating and digitizing document collection and information exchange across the supply chain.

Management With Market PlaceManagementComplianceManagementManagementManagementManagementManagementQualify & Source Procure new suppliers, items, or ingredients, and automatically collect and manage qualityAuthor, Publish & Maintain Centralize spec management and single platform to easily create, publish, andMonitor & Monitor & Monitor & Monitor in complianceMonitor & Management Compliance Monitor incoming collect and manage qualityMonitor a Monitor a Automate ComplianceMonitor & Monitor & Automate Compliance Monitor incoming collect and manage qualityMonitor a Monitor a Automate Const in compliance Monitor in compliance Monitor incoming real-time plant floor insight toContinuous Improvement Automate and streamline the entire audit process, scheduling, conducting, andMonitor Incompliance Monitor Incompliance Monitor incompliance Monitor incompliance Monitor incompliance Monitor incompliance Monitor incompliance Monitor incompliance Monitor incompliance Monitor incompliance management floor insight toMonitor & Automate Continuous Improvement Automate and streamline the entire audit process, scheduling, conducting, andMonitor Incompliance Monitor with advanced recipe and formulation management complianceMonitor & Automate Constructor advance frecipe and formulation management conducting, andMonitor Incompliance advanced recipe and formulation management conducting, andMonitor Incompliance advanced recipe and formulation management conducting, andMonitor Incompliance <th><b>H</b></th> <th>X</th> <th><math>\checkmark</math></th> <th>2</th> <th></th> <th><b>Å</b></th> <th></th> <th><math>\mathbf{R}</math></th>	<b>H</b>	X	$\checkmark$	2		<b>Å</b>		$\mathbf{R}$
SourceMaintainAutomateAutomateImprovementInnovateReceiveCollaboraProcure newCentralize specmanagement andComplianceAutomateAutomateDrive productautomatic alertsPostOnce®suppliers, items, ormanagement andversion control in aMonitor incomingAnalyze qualitystreamline theinnovation withfor key ingredientsPostOnce®automaticallysingle platform toour supply chainsafety data, forprocess,and formulationaid formulationyou to sharcollect andeasily create,in real-time, toprevent foodfloor insight toconducting, andcapabilities toand emergingwith all cus	Management						Scanning	Customer Manager
suppliermaterial and finished goods specs.supply chain disruptions and keep suppliers onimprovement, automaticallyaudits within a single platform.research and 	Source Procure new suppliers, items, or ingredients, and automatically collect and manage quality and regulatory supplier	Maintain Centralize spec management and version control in a single platform to easily create, publish, and update raw material and finished goods	Automate Compliance Monitor incoming COAs throughout your supply chain in real-time, to prevent food safety issues and supply chain disruptions and keep suppliers on	Automate Compliance Analyze quality control and food safety data, for real-time plant floor insight to drive continuous improvement, automatically generate CARs as	Improvement Automate and streamline the entire audit process, scheduling, conducting, and tracking internal audits within a	Innovate Drive product innovation with advanced recipe and formulation management capabilities to accelerate research and development and	Receive automatic alerts for key ingredients and formulas, and daily system updates on new and emerging issues to make it easy to manage	<b>Connect &amp;</b> <b>Collaborate</b> PostOnce® technology allows you to share information, documentation, with all customers at once, avoiding the manual process of responding individually.



# **TraceGains Supplier Manager**

A software solution to manage your FSMA & FSVP requirements – as well as you global GFSI standards

Form FSVP Assessment Form Risk Group Animal Protein		Attributes
FS	SVP Assessment Form	TRACEGAINS
Supplier: Demo Supplier		
Location: Demo Location		
Location Address: TraceGains Inc.: 10385 Westmoor D	r Building 5, Suite 200, Westminster, CO 80021	
Item: Demo Item ID		
Supplier Item ID: Demo Item ID		
*Effective Date		
*Expiration Date		
Please answer the questions below for the ingredient/if red asterisk.*	tem populated on this document. Add comments where additional	information is necessary. Required fields indicated with a
Initial Supplier Assessment		
	tion Program (FSVP) Supply Chain Control Verification Supplier Loc oker / distributor or actual receiving location i.e. "customer"] Or Pre tion "customer"]	

### NETWORKED INGREDIENTS MARKETPLACE

With the world's first and only Networked Ingredients Marketplace, you can search for any ingredient you might need and make sure they are FDA compliant.

Instantly get details on suppliers, download documents, and send requests through TraceGains network.

# A LOOK INSIDE **Trace Gains Gather**\*\*



#### Send Request

# WIN A GIFT CARD...

Take our survey and be entered to win a £25 gift card!

# LIVE Q&A

Type your questions into the chat box!



# **THANK YOU**

Together we do more.