TRACEGAINS

How to Prepare for Onsite Facility Inspections

March 3, 2022

Meet Your Moderator

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Webinar Specialist

TRACEGAINS

Meet Your Speakers

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Sr. Account Executive

TRACEGAINS

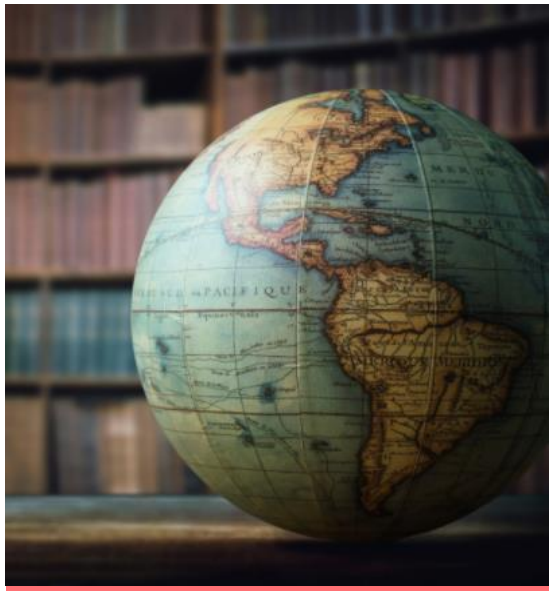
The Return of the FDA:
How to Prepare for On-site Facility Inspections

March 3, 2022

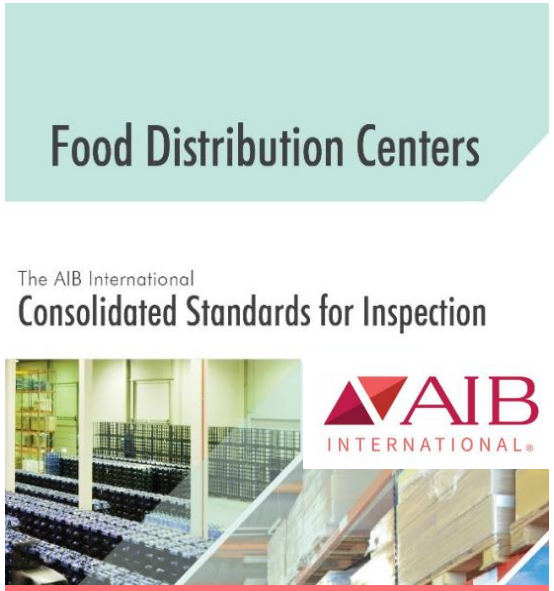
About Us

What Makes Us Different?

100 Years of Food Safety & Quality

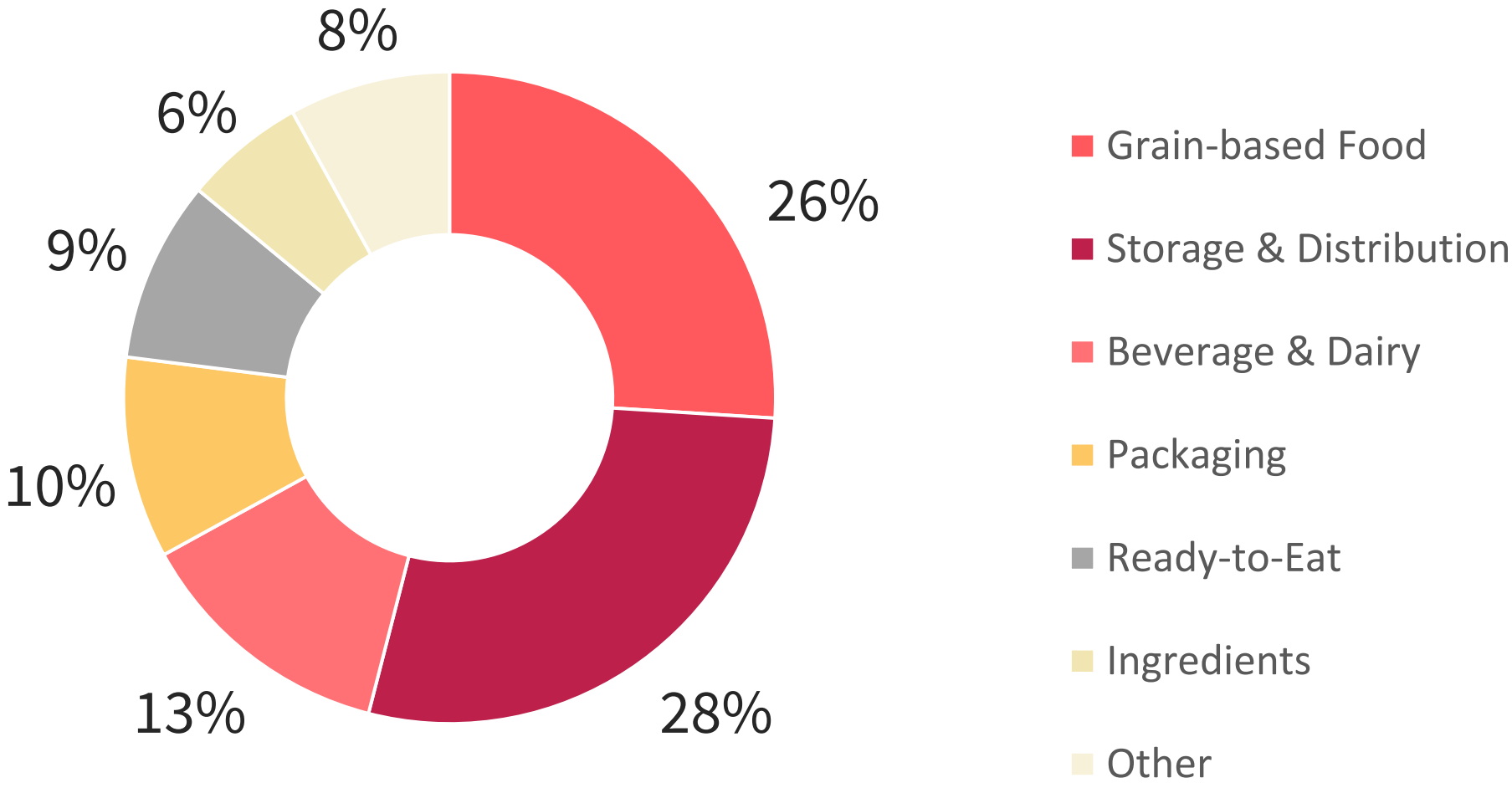


120+ Countries Served



Consolidated Standards

Portfolio


8%
6%
26%
9%
10%
13%
28%
Grain-based Food
Storage & Distribution
Beverage & Dairy
Packaging
Ready-to-Eat
Ingredients
Other

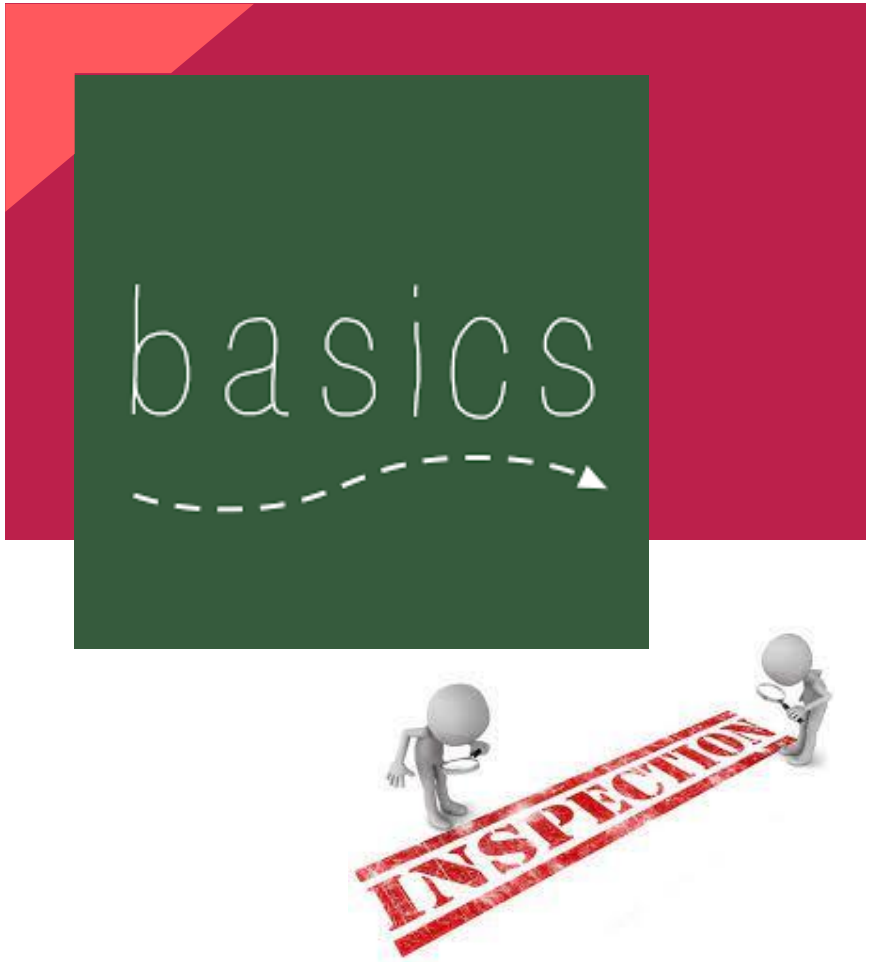
Agenda

The Return of the FDA

- How FDA is prioritizing inspections to address the backlog created by the pandemic
- What may trigger a “for cause” inspection of your facility
- What inspection components may continue to be conducted remotely
- How to prepare your facility and your team for an on-site FDA inspection

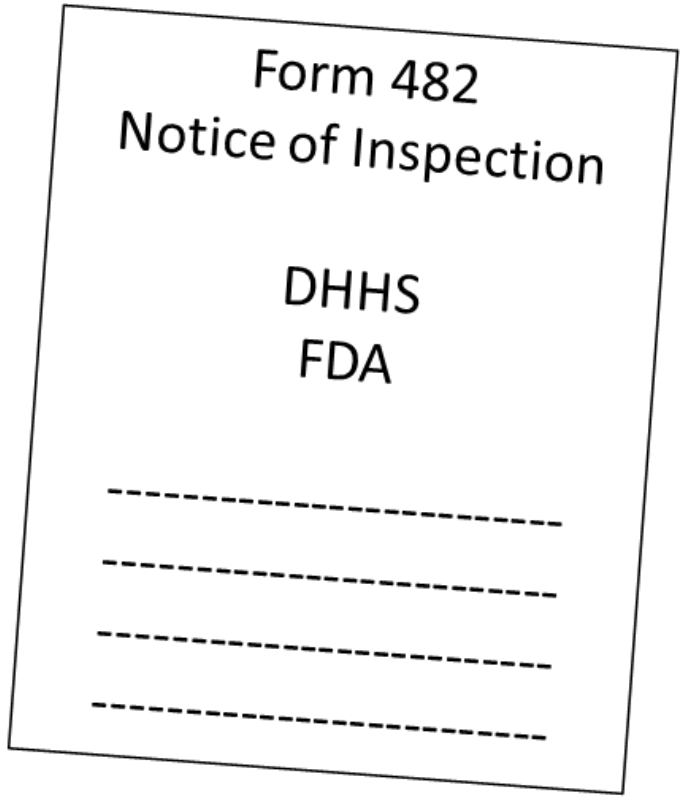
Basics – Types of FDA Inspections

- For Cause
  - Serious manufacturing problems
  - Specific problem or product complaint
- Pre-approval, pre-market, or pre-license
  - Review process to market a new product
  - Primarily Medical devices and Drugs
- Routine surveillance inspections
  - FDA regulated facilities
  - Monitoring CGMP's and other requirements



Basics – FDA Inspections

- Authority to
  - Inspect during normal business hours
  - Take samples
  - Take photos
- Inspector must present
  - Credentials
  - Form 482
- Facility provides
  - Designated, trained escorts



FDA's Response to Pandemic

- March 2020 FDA suspends routine inspections
  - Conducted mission critical inspections, when possible, domestically
- July 2020 resumed routine inspections based on risk
  - Pre-announced
- February 2022 resumed routine inspections
- Leveraged other resources

FDA's Other Resources

- Request for records and other information for review by FDA
- Remote assessments
  - 1,183 remote FSVP inspections as of May 2021
- Leveraging information from other regulatory partners
  - 4,273 human food and 1,295 animal food conducted from March 2020-March 2021
- Sampling and testing
  - Remote document review
  - State and other regulator assistance

Remote Inspections

- Remote Regulatory Assessments of Human and Animal Food Facilities
  - Not considered FDA inspection
  - No FDA-482 issued
  - No FDA-483 issued
  - Can voluntarily participate or may opt out without penalty
- Benefits
  - Decrease on-site inspection time
  - Allows facilities to develop corrective actions before FDA inspections
- FDA selection process
  - Good compliance history
  - Promised corrective actions FDA determined verification through a remote review of records

FDA's Resiliency Roadmap

- March 2020-March 2021 – Mission Critical Inspections
  - Conducted 346 total (320 Human, 26 Animal)
- March 2020-March 2021 – Prioritized Domestic Inspections
  - Conducted 511 total (494 Human, 17 Animal)
- Completed 90% Surveillance Inspections in FY19
  - Pre-pandemic
- Completed 61% Surveillance Inspections FY20
  - Almost 13,000 completed before pandemic
- FY21 planned over 26,000 Surveillance Inspections
  - 2,953 completed as of March 2021

FDA 483 Observations FY2020

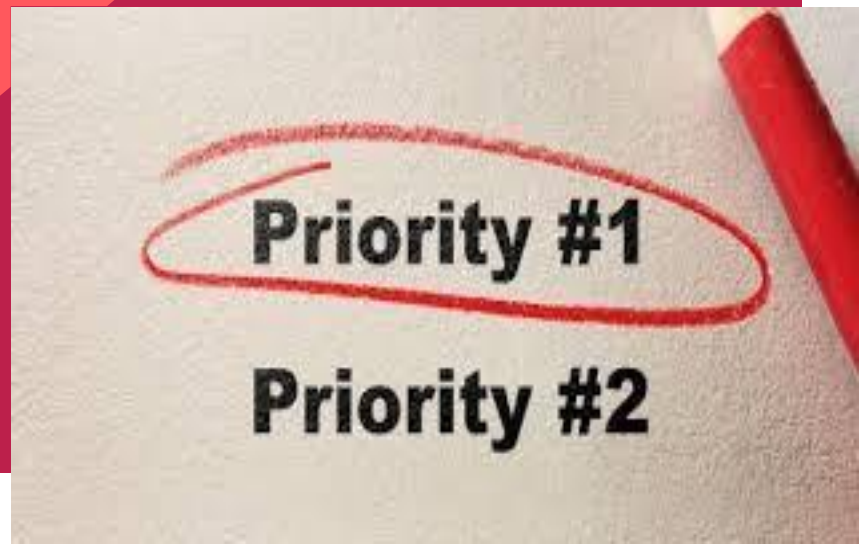
- FY20 October 2019 – September 2020
  - 1,749 FDA 483 forms issued
- Top Five reasons for 483 observations
  - No Foreign Supplier Verification Program (514)
  - Hazard Analysis – Identification of Hazard (104)
  - Pest control issues (98)
  - Manufacturing, Processing, Packing, Holding – Controls (95)
  - Personnel practices (87)

FDA 483 Observations FY2021

- FY21 October 2020 – September 2021
  - 1,751 FDA 483 forms issued
- Top Five reasons for 483 observations
  - No Foreign Supplier Verification Program (796)
  - Pest control issues (88)
  - Manufacturing, Processing, Packing, Holding – Controls (84)
  - Hazard Analysis – Identification of Hazard (83)
  - Written Hazard Analysis (78)

FDA-Moving Forward

- Adapting
  - Remote oversight
  - New tools and resources
- Prioritizing
  - Tier 1-Mission Critical
  - Tier 2-Higher Priority
  - Tier 3-Lower Priority



Preparedness

- Holistic approach to regulatory compliance
- Review and improve regulatory policy
- Back to basics on GMP's
- Training
- Develop, review, or improve internal inspections and audits
- Outside the organization review

Approach to Regulatory Compliance

- Develop list of current requirements
- Review FSMA and key regulations
- Obtain training to gain understanding
- Network
- Develop teams and action plans

Regulatory Policy

- Review for current content
  - Consider FDA's new tools
  - Training
- Add elements
  - Improved CGMP's
  - Record requests
  - Photo Requests
  - Sampling/swabbing
  - Other recording devices
  - FDA Quick Check

Back to Basics

- Food safety culture
  - New Era of Smarter Food Safety
- Sanitation
- GMP's
- General maintenance
- Attention to detail

Training

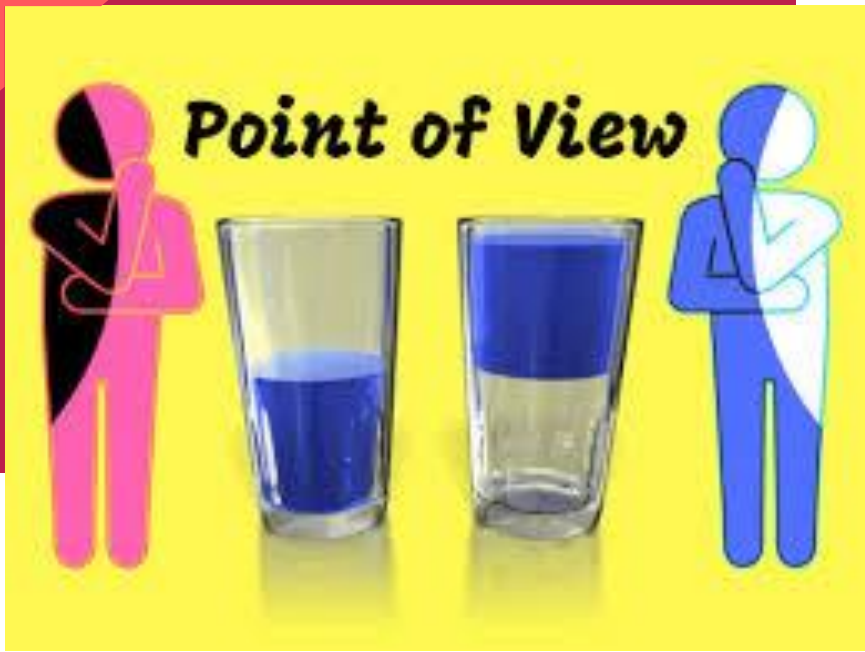
- Four levels of training
  - Gaps due to COVID-19
- Documentation
- Interviews
- Corrective actions

Internal Inspections and Audits

- Review and update
  - Regulatory requirements
  - Top 5 483 Observations
  - Complete corrective actions and amend programs
- Train
  - When procedures are amended
- Complete detailed inspections

Outside the Organization Review

- 3rd party inspections and audits
- Gap assessments
- FDA information
- Consultants



Facilities – Moving Forward

- Understand
  - Time between inspections could be greater
  - New tools utilized by FDA
  - Backlogged inspections will still take place
- Reminders
  - Significant changes due to Covid-19
  - Verify all programs
  - Develop corrective actions from 3rd party audits
- Facts
  - 3rd party audits-more findings and or lower scores during pandemic
  - Employee shortages-training and verification

Summary

The Return of the FDA

- How FDA is prioritizing inspections to address the backlog created by the pandemic
- What may trigger a “for cause” inspection of your facility
- What inspection components may continue to be conducted remotely
- How to prepare your facility and your team for an on-site FDA inspection

Questions

TraceGains Network

Freedom from tracking down suppliers and requesting information or documents

46K+
Supplier Locations

530K+
Items & Ingredients

3M+
Supplier, Item & Ingredient Documents

150+
Standardized Online Forms

130+
Supplier Countries

Digital Transformation – What Companies Want

Bringing People and Information Together to Work Smarter

Research & Development

- Quickly find experimental ingredients & raw materials
- Digitally model ingredient variations to meet product claims before physical testing

Suppliers

- Ensure compliant raw materials & ingredients seamlessly enter the supply-chain with required documentation

Regulatory

- Immediately address claims, labeling issues, and more
- Eliminate downstream delays

Procurement

- Negotiate pricing with Suppliers
- Recommend alternative Suppliers

Quality

- Manage ingredient & Supplier approval processes
- Prequalify new ingredients and suppliers
- Support formula iteration

Our Solution

A Standard, Centralized and Digitized Approach to Controlling the Verification of Materials and Ingredients

Industry Standards for Data Collaboration

Industry Standard Data

Digitization and Automation

New Product Development Suite

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

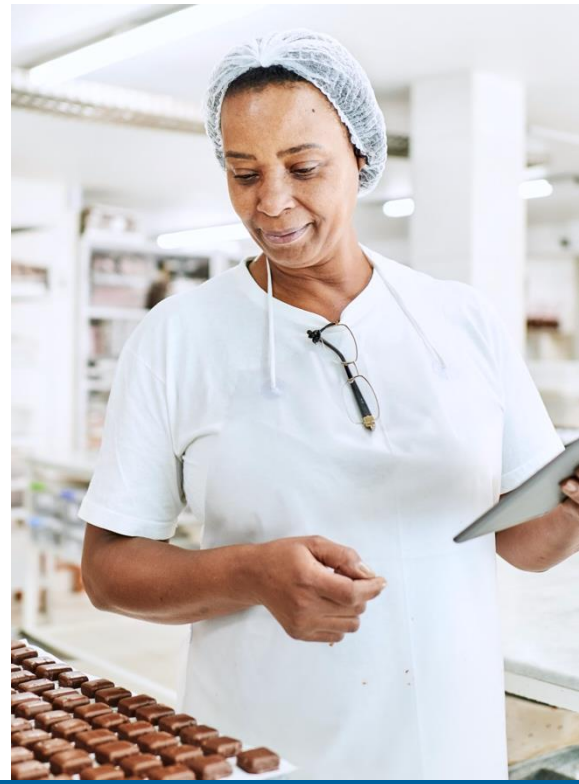
Cost, risk and audit exposure are major concerns for every business.

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.



Audit Management

Automate and streamline the audit process, with actionable data and insights for your business.

THE PROBLEM

Audits are crucial but complex. Outmoded tools introduce error and can hide key data.

WHY IT MATTERS

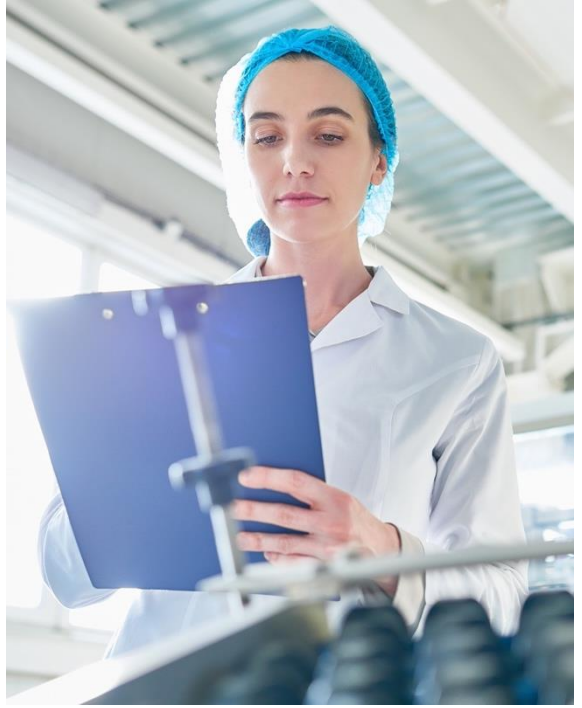
Audits are a big part of your business and create valuable data (if you can find it).

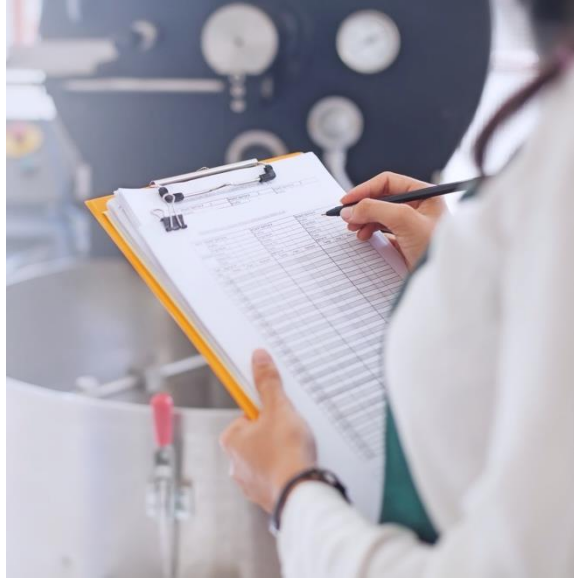
THE SOLUTION

Digitize and automate processes and documents while leveraging unique industry intelligence.

THE TRACEGAINS DIFFERENCE

Leverage TraceGains network to inform and prioritize audit activity.





Value Across the Organization

TraceGains brings people and information together.

- **Single Source of Truth to Identify Items** that are affected by global regulations, such as FSMA §204.
- **Standardized Forms** adapt to KDE requirements via **collaboration** with TAG and TG's Customer Advisory Board.
- **Capture Lot-based Attributes** of materials impacted by regulatory rules. Visibility and control to meet product quality and regulatory compliance requirements.
- **R&D / Procurement** can identify FTL items and its impact on usage in formulations and product marketing.

Live Q&A

Thank You

Plug In. Go Faster.