

FDA, FSMA & AI:

Navigating Regulation, Data, and Compliance Intelligence

Today's Presenters:

Dr. Ben Miller
The Acheson Group



Dean Brown
SafetyChain
Software



Chris Brandsey
Frame & Flight



FSMAFRIDAY

Monthly Industry News, Updates & Trends for Food, Beverage, & CPG Manufacturers



What is FSMA Fridays?

- ✓ Monthly FSMA Related News
- ✓ Regulation Changes & Updates
- ✓ Industry Trends
- ✓ Q&A with TAG



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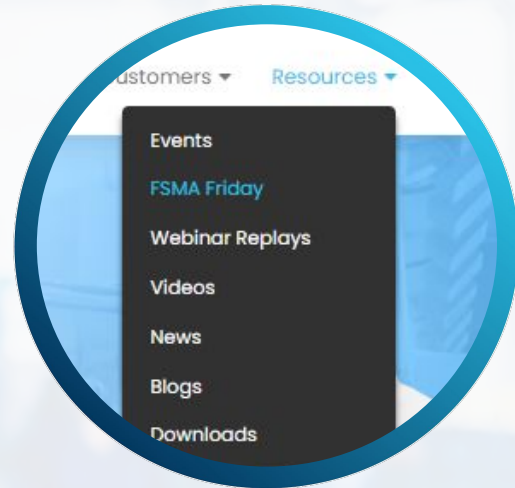
A global food safety and public health consulting group made up of seasoned industry experts.



Award-winning digital plant management platform to visualize plant-wide performance and better control quality, yield & production optimization.

Before We Get Started...

- ✓ Only panelist microphones are on
- ✓ Ask questions! (Q&A at end)
- ✓ Recording link will be shared
- ✓ Audio issues: use call-in number



Watch prior FSMA Friday recordings at [safetychain.com > Resources > FSMA Friday](https://safetychain.com/resources/fsma-friday)

Meet Your FSMA Friday Speakers



Dr. Benjamin Miller

EVP of Regulatory and Scientific Affairs at The Acheson Group. 25 years in food safety, public health, and epidemiology. Ph.D. in Environmental Health, MPH in Epidemiology.



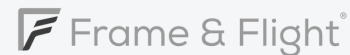
Dean Brown

CEO of SafetyChain Software. Executive background spanning ERP, FinTech, and EdTech with deep expertise in AI, product innovation, and scaling companies in complex markets.



Chris Brandsey

Founder of Frame & Flight. 20+ years across Starbucks, Nestlé, and Google- and BCG-backed ventures. Advised on \$200M+ in technology investment across global manufacturing facilities.



Agenda

01.

Recent Regulatory Updates

02.

Practical FDA Insights

03.

Q&A

04.

Other Resources

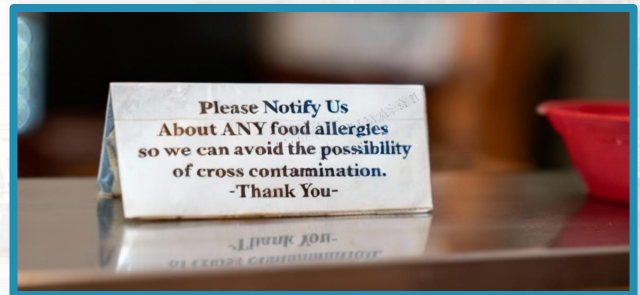
Recent Regulatory Updates Overview

FDA Public Meeting on Lot-Level Traceability

- FDA public meeting on Food Traceability Rule implementation, June 15, 2026; registration required (general by June 14, speakers by June 5), with docket materials to follow.

FDA Issues first Generative AI-related Warning Letter

- Purolea Cosmetics Lab used AI agents to generate drug product specifications, procedures, and master production records without adequate human review, which FDA cited as a violation of 21 CFR 211.22(c) because the firm failed to verify that AI-generated documents were accurate or CGMP-compliant.
- FDA flagged overreliance on AI, noting Purolea skipped required process validation because the AI agent never flagged it as a legal requirement; any AI output used for CGMP activities must be reviewed and cleared by an authorized human representative of the quality unit.



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Poll 1 — Opening

How would you describe your organization's current AI readiness for compliance?



- A** We're actively using AI for compliance today

- B** We're piloting or evaluating AI tools

- C** We have the data foundation, but haven't started

- D** We're not ready — still building the basics

Panelist:
Dr. Miller



You've spent 25 years in food safety and worked directly with FDA on traceability requirements. How well does FSMA actually hold up when AI enters the compliance picture — and where does it start to show its age?



All Panelists

What's the most persistent misconception you encounter when manufacturers start talking about using AI for compliance?



Panelist:
Dr. Miller



You've been on both sides of the regulatory table. Where are you seeing AI usage show up in audits or different things?



Poll 2 — Data Governance

What's the biggest barrier to using AI in your compliance program right now?



- A** Our data is disconnected across systems

- B** We don't have consistent processes across facilities

- C** Leadership hasn't committed to the investment

- D** We don't trust AI outputs enough to act on them

Panelists:
Dean & Chris



SafetyChain operates inside these manufacturing environments daily. When a customer wants to apply AI on top of their existing systems – what do you typically find when you look at what's actually there?



Panelist:
Chris



You've directed over \$200M in technology investment across hundreds of facilities at organizations like Starbucks and Nestlé. What distinguishes the companies that make AI work from those that invest significantly and see little return?



Panelist:
Dean



Implementing AI in a compliance environment requires a level of trust that doesn't come automatically. How do you build that trust internally – across QA, operations, and leadership – before it gets stress-tested by a real situation?



Poll 3 — Practical Implementation

Where does the most resistance to AI adoption come from in your organization?



A Plant floor operators

B QA / food safety teams

C Operations or plant management

D Senior leadership / finance

Panelist:
Chris



When a food or beverage company engages Frame & Flight with AI for compliance on the agenda – what does a realistic readiness assessment look like in the first 90 days? Could you share more about the type of AI projects you've worked on?



Panelist:
Chris



What's a pattern you keep encountering — a technology investment that was well-intentioned but didn't deliver? What's the early signal that things are heading that direction?



All Panelists

You've scaled companies across ERP, FinTech, and now food manufacturing technology. When it comes to AI adoption, who in the org are most resistance to AI or technology in general? How have you seen people overcome these detractors?



All Panelists

Where do you see AI have real application in Food and Bev manufacturing?



Panelist:
Dean



A lot of manufacturers are still running paper-based or semi-digital systems on the plant floor. Is AI a realistic conversation for them right now, or is there foundational work that has to happen first?



Panelists:
Dean & Chris



There's no shortage of AI vendors making bold claims in this space right now. How should a procurement or operations team evaluate those claims critically before committing?



Panelists:
Dean & Chris



Leadership teams often want a clear ROI before committing to AI investment. What's a credible way to build that business case in a food manufacturing context – and what metrics actually matter?



Poll 4 — ROI & Accountability

If an AI tool gave your team a compliance recommendation that turned out to be wrong, who do you think should be accountable?



A Us; same as any tool we rely on

B The AI vendor, if the system was flawed

C Shared: depends on the validation process

D The regulator needs to define this first

All Panelists

Beyond compliance, where do you see AI creating the most tangible operational value in food and beverage manufacturing – the use cases that pay for themselves quickly enough to justify the investment?



Panelists:

Dr. Miller & Chris



AI tools can produce incorrect outputs, outdated regulatory references, flawed recommendations, model drift. How should manufacturers approach validating the tools they're relying on for compliance-critical decisions?



All Panelists

If an AI-generated recommendation turns out to be wrong and an incident follows, where does responsibility sit? Is this a question the industry needs formal guidance on before AI adoption can scale with confidence?



Panelist:
Dr. Miller



FSMA was designed around preventive controls and hazard analysis. Does AI genuinely strengthen that framework, or does it risk creating a false sense of security if manufacturers treat it as a compliance shortcut?



All Panelists

Food safety culture has always been about people as much as process. Does AI strengthen that culture or does it risk creating distance between workers and the outcomes they're responsible for?



Panelist:
Chris



You've worked inside organizations like Starbucks and Nestlé where scale and complexity are significant. How do you align a global workforce around a new technology without losing the institutional knowledge that already exists on the plant floor?



Panelist:

?

Is AI going to replace my job?



Panelist:
Dr. Miller



Where do you see FDA's position on AI-assisted compliance heading over the next several years: formal guidance, increased scrutiny, or continued ambiguity?



Panelists:
Dean & Chris



Between what SafetyChain is building and what Frame & Flight is seeing across global manufacturers, what should companies be prioritizing now so they're not scrambling to catch up?



All Panelists

For a manufacturer doing the right things operationally but not yet engaged with AI for compliance, where is the right place to begin?



Panelist:
Dr. Miller



FSMA 204 requires a level of data granularity many manufacturers are still working toward. How much does that gap limit what AI can realistically deliver for food safety risk management right now?



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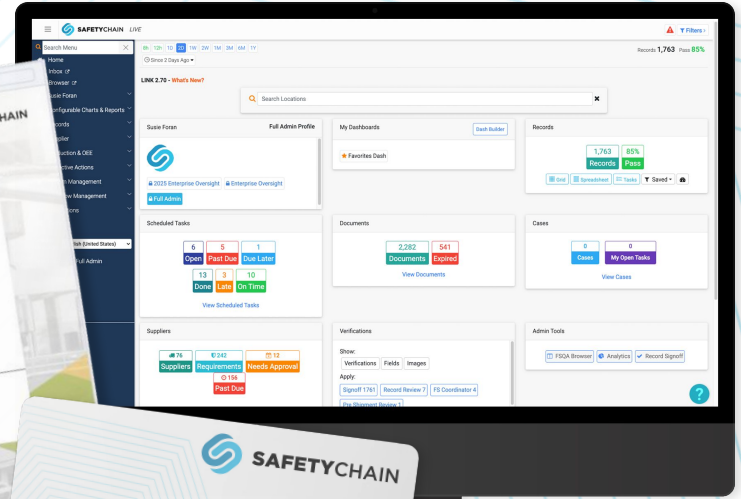
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Questions?



Food & Beverage Manufacturing

Benchmark Survey & Report



safetychain.com/solutions/manufacturing-benchmark-report

Join us in May



Friday
May 29



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