






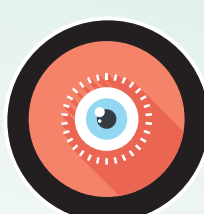
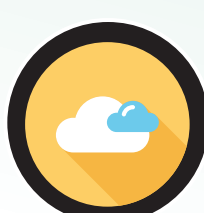
THE ROAD TO FSMA SECTION 204(d) COMPLIANCE

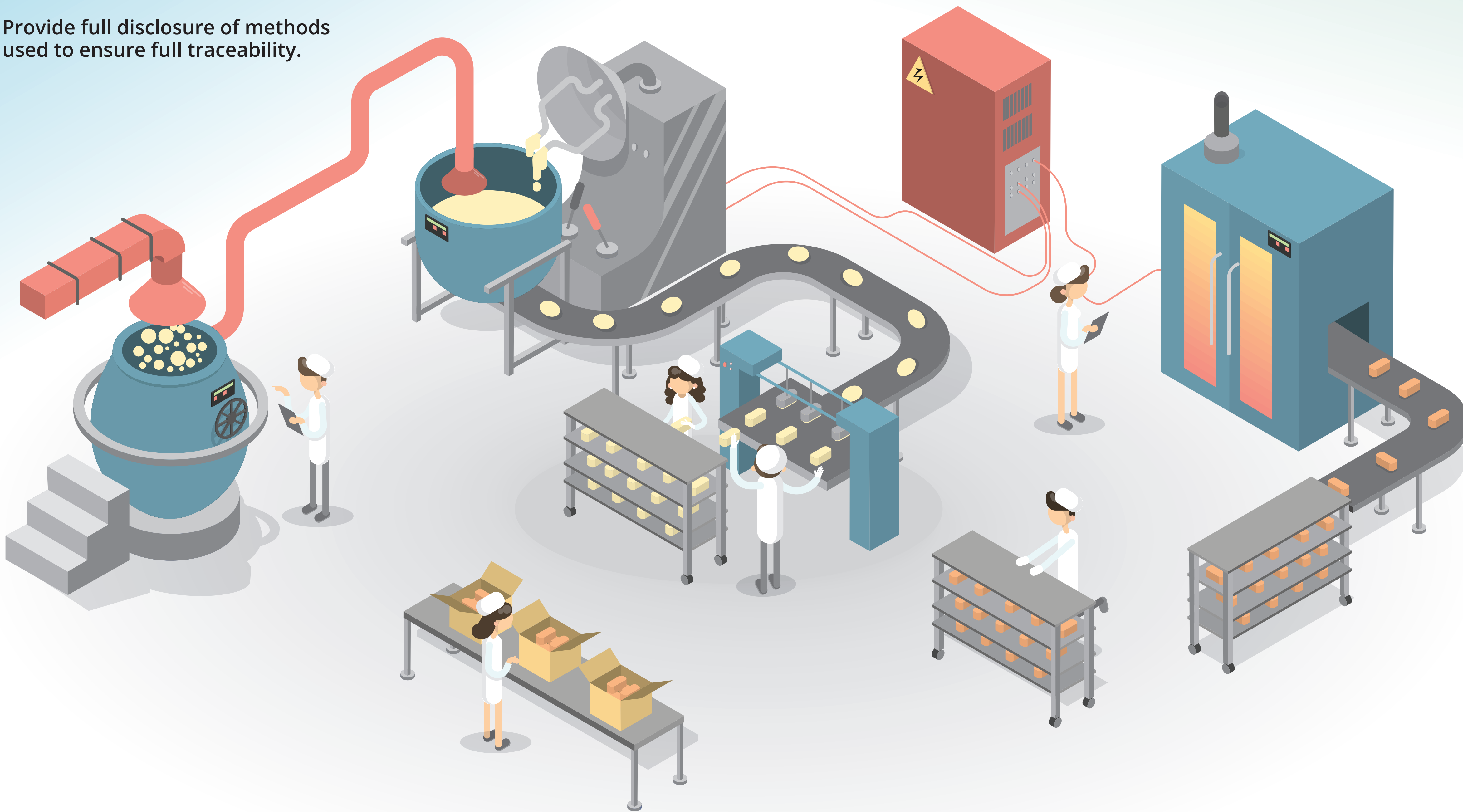
By July 20th 2028, all food manufacturers must be fully compliant with Section 204(d) of the FSMA (Food Safety Modernization Act). The final rule is a key component of the FDA's (Food and Drug Administration's) New Era of Smarter Food Safety Blueprint. Deploying an effective MES (Manufacturing Execution System) such as Plex, by Rockwell Automation is imperative to ensure compliance, avoid disruption, and optimize operations.

WHAT ARE THE FSMA SECTION 204(d) REQUIREMENTS:

-  Provide information to the FDA within 24 hours of a request, either paper or electronic. An electronic sortable spreadsheet is required during an outbreak, product recall, or public health threat.
-  Maintain records containing Key Data Elements (KDEs) associated with Critical Tracking Events (CTEs).
-  End to End Traceability: Support for CTEs (and KDEs) from receiving through any number of production transformation steps all the way to shipping, inventory adjustments and physical count changes.
-  Provide full disclosure of methods used to ensure full traceability.

WHAT MANUFACTURERS MUST CONSIDER:

-  Leverage a system that supports real-time tracking of manufacturing processes and lot usage, providing a foundation for FSMA Section 204(d) reporting compliance.
-  Establish full traceability and visibility within the four walls of the manufacturing plant for Food Traceability List (FTL) items including all CTE's and KDE's, and one up/one down traceability to suppliers and customers.
-  Utilize a centralized system that provides a single source of truth and lot traceability information for all company personnel and auditors.



PLEX SMART MANUFACTURING PLATFORM LOT TRACKING & TRACEABILITY REPORTING TO ENABLE:



Regulatory Compliance

Identification of items on the FTL.

Support for KDEs (and CTEs) through any number of production transformation steps (shipping, receiving, inventory adjustments, and physical count changes).

Mass balance & quantity reconciliation for forward trace of received goods.



Risk Reduction

Product recall support: Reduced risk and cost of recalls via precise containment of suspect inventory and minimization of recall scope.

Centralized, cloud-based system accessible from any location.



Recall Management

Real-time records of all lot traceability events supporting forward and backward trace from origin to destination and vice versa.

Instant access to historical and current traceability data for all FTL goods to support streamlined auditing.

Ability for food manufacturers to demonstrate fast and powerful trace capabilities with full FSMA Section 204(d) compliance to retain existing retail customers and attract new ones.

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