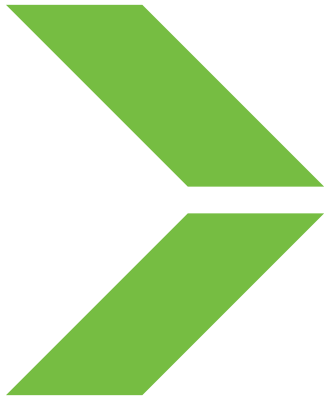




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Recall Preparedness: *Having the Right Tools*

Process manufacturers know that product recalls or recall threats are an inevitable part of business. Manual methods for instituting a recall are no longer sufficient; manufacturers need the ability to start, track, stop and even prevent a recall. New software developments have given manufacturers the ability to identify, notify, remove and replenish any recalled product. Manufacturers that invest in new technology and embrace more effective means for managing product recalls are positioning themselves to successfully make it through.

The definition of a recall is “the request to return a batch or manufacture of a product—most often due to a defect, safety concern or efficiency problem.” Thousands of products produced by process manufacturers are recalled each year. These manufacturers typically include pharmaceuticals, food and beverage and dietary supplements. A recall can occur at any time and may stem from a wide variety of issues including contamination in the process plant or cross-contamination, incomplete tracking of product distribution, improper labeling, underprocessing or inadequate plant safety. Regardless of circumstances, the impact of a prolonged product recall can have tremendous effects on a company brand, supplier, etc.

The Food & Drug Administration (FDA) is permitted to conduct voluntary or controlled product recalls, and they require an extensive list of product information in the event either occurs. Being prepared for a recall is more important than ever before. An Enterprise Resource Planning (ERP) system can be utilized as a tracking tool, and provides the features necessary to meet these requirements and regulations. It has the ability to track finished goods including customers who purchased a particular lot, which orders were produced and where the orders were shipped. An ERP solution also links information to the bill of lading, bill of material and batch tickets. Additionally, it manages all aspects of inventory including: balances, lot numbers, product line information, locations and types of storage division.

A great deal of preparation must go into a recall. You will need to be equipped with the right tools, which include a written recall procedure and an ERP system. A strong communication plan should outline training staff in understanding recalls, how to test the communication plan and how to resolve problems through practice. A written recall policy includes a designated recall coordinator, traceability procedures, regulatory agency/legal counsel’s contact information, sample media and notification letters to retailers, as well as a compiled list of customers.

A communication plan should begin with a list of possible crisis scenarios, an approximation of the likelihood that each could occur and estimate of the potential damages to the company in the event that a crisis arises. You’ll also need to establish a chain of command such as an Emergency Direction, Communications Coordinator, Legal Coordinator, etc. This chain is typically made up of the Human Resources Coordinator, Transportation Coordinator, Financial Coordinator, etc.

Practicing mock recalls can help to significantly save your company money. Due to the high expenditures of a recall, you should anticipate direct recall costs that include: laboratory testing, production stoppage/overtime, penalties and legal fines, post-recall advertising and more. While the direct costs of a recall can seem overwhelming, there are additional indirect costs that you should also be aware of, which include a reduction of sales and profits as a result of a loss in consumer brand loyalty.

There are numerous benefits of an ERP system in terms of mock and actual audits, one of which includes safer food supply and faster tracking during a recall which can prevent illness and death. Additionally, it improves consumer confidence which builds brand loyalty.

An ERP system is also capable of keeping records such as purchase orders, bills of lading, certificates of analysis and shipping documents more accurately. These records are important to retain in an accessible location at the site where the activity occurred. Documentation should be created at the time food is released, received or transported and should be kept for no less than two years. While the FDA does not specify how records should be contained, responsibility falls on the person subject to regulations and must be available within 24 hours if the FDA suspects adulterated food products.

The following are key components of a mock recall:

1. Assign duties
2. Discretely create a scenario to begin the process
3. Second person in command begins procedure
4. Secure emergency site
5. Notify remaining emergency team to begin
6. Simulate recall based on prepared written plan
7. After simulation, review results, make changes where needed and repeat if necessary

The 'technology' of formula management for many companies continues to be Excel spreadsheets, which may not be the best practice. There are product lifecycle management solutions that can not only help manage formulas, but also ensure performance and label requirements, as well as assist in flagging any potential allergens or other contaminants that could result in a recall.

The capability for tracing the source of problem is essential in managing the outcome of a product recall. The technology responsible for tracing the source of a recall must be embedded throughout all aspects of the business and supply chain. Trace capability is a critical insight extending beyond the measure of simply where a finished product ends up. It must provide a complete picture — full visibility from raw materials to individual batches, all the way to the semi-finished or finished products that are supplied to the customer. Steps such as purchasing, manufacturing, shipping and fulfillment are all important for tracing the process throughout the supply chain.

Manufacturers can help decrease the time taken and increase accuracy of locating potential issues by adopting new technologies and modern software systems. Manufacturers that use integrated lot tracking systems can view their products by lot and have the ability to pull only those of potential concern. In comparison, manufacturers that lack this access and visibility are often forced to recall more products (and possibly everything ever produced) than necessary until a source has been identified. Investing in an integrated ERP system can help keep good products on the shelves and lower any costs associated with a recall.

Managing any data, formulas, lot tracking, etc. on spreadsheets is no longer a viable option and should never be considered the last line of defense in suppressing the heat of a product recall. Manufacturers need to embrace technology to address all areas of recall preparedness. Mock exercises and written plans help, but be sure to allow enough time for planning and practice. Only fast response times will remove questionable products from the supply chain and minimize the impact of a recall. Product recalls are not going away, invest in an ERP system, have a plan, test it, make corrections and keep it current – always be prepared.



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