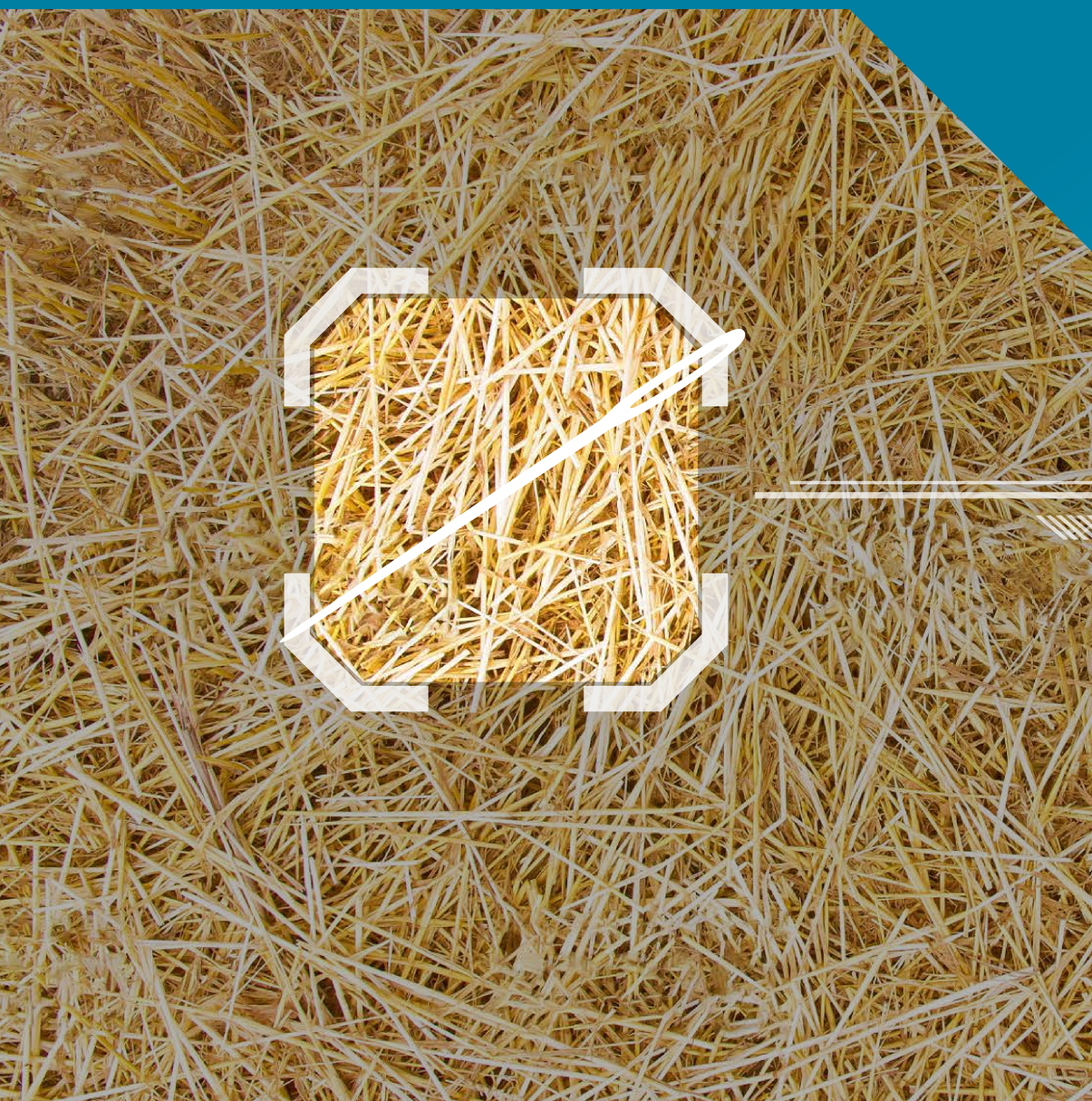
SYSPRO TRACEABILITY

Mitigating the Effects of Product Recalls

IN THE MANUFACTURING AND DISTRIBUTION SECTORS

Systems Advisory Services

SYSPRO™
Say Yes to Next



Facing a recall?
Trace. Isolate. Eliminate. Mitigate.

Implementing a Robust, Reliable Traceability System and Product Recall Plan

Today, the manufacturing industry is truly global; American suppliers use factories in India which source raw materials from southern Africa. The supply chain for just one product or its parts or ingredients has become extremely complex. And with increased complexity comes the increased likelihood of a product recall.

At the least, faulty products or contaminated foods are an inconvenience for unlucky buyers. At worst, they cause injuries, illnesses and even deaths. Recalls have the potential to damage brand reputations and affect bottom lines and share prices, costing millions – and in some cases billions – in litigation and fines, as some of the following examples illustrate.

Facing a recall?
Trace. Isolate. Eliminate. Mitigate.

Before You Consider the Price of an Effective Traceability System –

consider the cost of not having one

2.5 Million Devices Recalled

Samsung

The world's largest smartphone maker was forced to discontinue and recall the Galaxy Note 7 after some units started bursting into flames. Samsung was forced to recall 2.5 million of the devices, some of the priciest smartphones on the market, costing the company billions.

31 Million Bottles Recalled

Johnson & Johnson

Known as 'the recall that started them all', seven people in the Chicago area died after ingesting Extra-Strength Tylenol laced with cyanide. Parent company Johnson & Johnson spent more than $100 million on recalling 31 million bottles of its best-selling product.

Faulty Pedal $2 Billion Loss

Toyota

In 2010, a faulty accelerator pedal forced Toyota to recall 4.1 million vehicles sold in the US and Europe. It was the company's second recall in three months, following a recall of 5.3 million cars because poorly fitting floor mats trapped pedals. In total, more than 9 million Toyota cars worldwide were recalled for pedal-related flaws, costing the company an estimated $2 billion.

Declared Bankruptcy

Peanut Corp. of America

In 2009, a salmonella outbreak in an obscure, privately-held peanut processing company in Georgia ended up killing nine people and sickening hundreds of others. More than 3,913 different products from 361 different companies had to be recalled. Major brands such as J.M. Smucker and ConAgra's Peter Pan were unaffected by the recall, but it didn't matter. Wary consumers shunned peanut butter, driving down industrywide sales by 25%. Peanut Corp. declared bankruptcy and went out of business.

30.4 Million Cars Recalled

General Motors

2014 was a year the massive motor manufacturer will never forget. Faulty ignition switches that could shut down the engine without warning, thus disabling power steering, brakes and air bags, were linked to at least 124 deaths and more than twice as many injuries. The defect impelled GM to recall 30.4 million cars worldwide and cost the company an estimated $4.1 billion.

271 Deaths 800 Injuries

Firestone and Ford

Allegedly defective tires installed on Ford SUVs and pickup trucks were linked to 271 deaths and more than 800 injuries in the US alone. Firestone and Ford blamed each other for the tire failures, but ultimately both companies were on the hook. Firestone recalled 6.5 million tires, while Ford recalled and replaced 13 million. The Firestone brand survived the scandal but its 100-year relationship with Ford was severed forever.

Recall Trends

Product recalls are at record numbers and have been growing every year for the past decade. Whether it's in consumer goods, automotive, food and beverage or pharmaceutical industries, the problem is getting worse.

The Effect of Social Media

Social media has become such a potent force that it can have a bottom-line impact on companies that are simply connected to the problem, not responsible for it.

Ripple Effect Drives Larger Product Recalls

The consolidation of the supply chain, with **multiple brands** using the **same supplier**, means that **a single recall can impact whole industries** and **multiple brands.** The recent recall of Takata airbags is thought to have affected some 60 to 70 million units worldwide.

Cyber Recall

New technology brings new risks. Future product recalls are predicted to come from new bases. Motivated by extortion or malicious intent, hackers could change or contaminate a product by controlling machinery. Nanotechnology and 3D printing are two further examples of innovations that could change recall exposures.

The Rise of New Recall Triggers

Undeclared allergens are fast emerging as a primary cause of food recalls. Typically involving such products as nuts, milk and wheat, these recalls can often be the result of **manufacturing error (mislabelling)** or **unintentional cross-contamination.**

Increasing Regulatory Scrutiny

As countries implement stricter product safety laws and oversight, companies which don't comply are likely to be **identified and penalized.**

> Most telling of all, of the roughly 250,000 manufacturing companies in the US, 70-80% currently do not have a product recall policy in place.
>
> **Florian Beerli,**
> *Senior Vice President and Head of the Product Recall Team at Chubb*

Economic Pressures and the Growth of Fraud

Economic pressures continue to bite in many sectors, increasing the risk of human error. Meanwhile, **fraud** and **counterfeiting** have become major issues that have resulted in large recalls.

Toxins in Consumer Products

This is another growing concern, while the incidence of **environmental contamination** is also rising.

> Excellent tracking of products by lot is critical for us. SYSPRO gives us the tools to meet the current and foreseeable HACCP requirements.
>
> **Barbara-Ann O'Brien,**
> *Manager, Bronte Foods*

The Rise of Non-Safety Recalls

Companies increasingly feel obliged to recall products if it emerges that child or slave labor has been used during production in the supply chain or if there are issues around **religious** or ethical designations such as **halaal** or **vegan food**.

Legislative requirements

To further complicate matters, there are literally hundreds of regulations governing compliance and safety around the world, with each industry sector in each country having its own specific rules and laws which, if broken, result in the product being partially or totally recalled and the possibility of litigation and hefty fines being imposed.

Although many companies think they have measures in place to combat product recalls, the statistics speak for themselves. Until CEOs recognize this and plan for and install a robust traceability system, it will be business as usual for manufacturing companies - in other words, learning their lesson the hard way.

Traceability Checklist

Creating a Robust Traceability System

Traceability is especially challenging because problems can occur at any point along your supply chain, from R&D through materials handling to assembly and shipping. Broken or slow processes can be particularly costly – and even lethal – for suppliers of food, pharmaceuticals, electronics and hi-tech equipment, aerospace and automotive products, medical devices and chemicals.

A traceability system should consist of the following 4 key activities:

1. Define the **SCOPE** of the system
2. **DOCUMENT** the system
3. **REVIEW** the system
4. **TEST** the system

1 Scope

Define the scope before developing the system

- What needs to be put in place to be able to track the entire supply chain?
- Identify elements required to ensure that the system encompasses the full traceability of the product:
  - **Supplier Traceability** – Evaluate the scope required to incorporate traceability of suppliers and their products entering the organization.
  - **Process Traceability** – Evaluate the scope required to incorporate traceability of products through the organization (whether new products are produced or not).
  - **Customer Traceability** – Evaluate the scope required to incorporate traceability of products to the immediate customer.

NOTE: As actionable traceability in your supply chain encompasses the three points above, it's best to bear in mind that:

- Different sectors of the value chain will develop traceability systems that differ in scope.
- In many global companies, communication regarding processes, legislation and production methods between regions is poor or non-existent.
- Problems typically occur where there is no seamless interface between supplier, process and customer.
- Scope becomes a commercial decision – the broader the definition of a batch, the greater the volume of product potentially recalled.

2 Document

The following need to be carefully documented:

- Scope of the traceability system.
- Details of the traceability system.
- Associated operational documentation.
- Arrangements for review.

3 Review

Review the system annually:

- Include a multi-disciplinary team from all functional areas of the organization and senior management.
- Audit the traceability system.
- Identify areas for improvement or non-conformance and address them.
- The review should be signed off by senior management.

4 Test

Review the system annually:

- **Horizontal Check** – This includes an audit of several batches at the same point in the process to ensure that all identification marks and documentation are correct.
- **Vertical Check** – Follow several batches from customer to supplier to ensure all identification marks and documentation are correct.

This is commonly referred to as a mock recall.

Product Recall Checklist

Planning for and Managing Product Recalls

An effective, proactive product recall plan can mean the difference between survival and the loss of the business you have worked hard to create and develop. More often than not, not having a product recall plan in place could have the biggest impact on your company's survival.

Protect Public Health by:

- Informing customers that there is a potentially hazardous product on the market.
- Facilitating the rapid identification and removal of unsafe products from the distribution chain.
- Ensuring that the unsafe products are either destroyed or rendered safe.

The 3 Levels of Product Recall:

Mock Recall

The internal process used by the organization to test its ability to trace where the product was sent, or to test the traceability of the product from the customer to the supplier.

Withdrawal

This is the removal of unsafe products from the distribution chain but does not extend to consumers as they have not bought any product yet. It is initiated when there is a potential risk to public health and the products remain wholly within the distribution chain and has not made it to consumers.

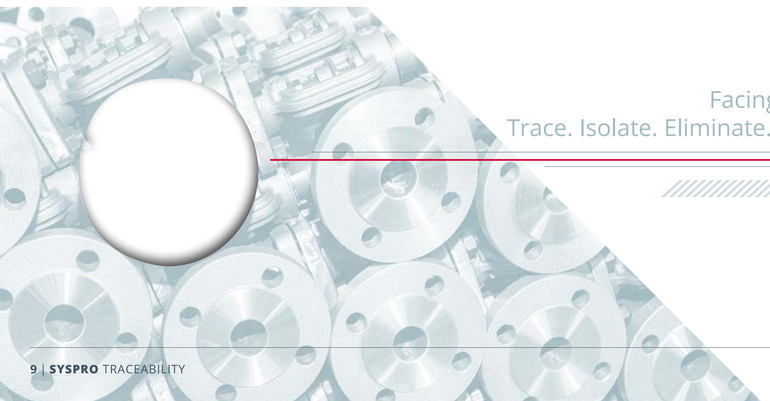
Full Recall

This is the removal of unsafe product from the distribution chain and extends to product sold to consumers. It therefore involves communication with consumers and is initiated when there is a potential risk to public health and the product has already been sold to consumers.

7 Stages of a Product Recall:

1 Develop the Policy

All manufacturing businesses should have a Product Recall Policy which states the objective of the plan and the organization's commitment to providing the necessary resources to remove unsafe products from the market.



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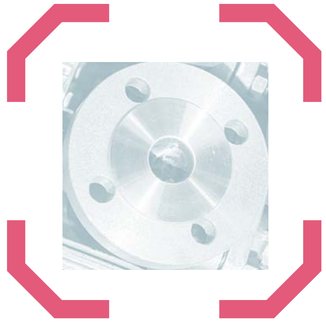


2 Develop the Plan

- A documented procedure designed to ensure professional, efficient and effective removal of unsafe products from the market.
- Requires a multi-disciplinary recall team to develop the plan with a contact list including all details such as roles and responsibilities, decision trees and full details of the plan.

Recall Co-ordinator	**Owner/CEO**
Distribution	1. Stop all distribution of questionable material and arrange for return of product to collection points. 2. Prepare inventory and distribution status of product showing where, when, to whom and quantity shipped.
Production and Quality Assurance	1. Prepare batch identification. 2. Halt production of product if related problem. 3. Investigate cause of problem, check all records.
Consumer Affairs	1. Prepare response for customers. 2. Answer all customer queries.
Accounting	1. Set up stock reconciliation system to determine cost of recall.
Legal Counsel	1. Handle legal implications.
Public Relations	1. Handle press releases – all media.
Technical	1. Obtain batch identification and samples. 2. Obtain product analysis to determine if pick-up or destruction necessary. 3. Consult with regulatory agencies if a recall is required.
Marketing	1. Notify sales managers and brokers. 2. Arrange for pick-up at retail levels. 3. Arrange for proper credit to be given.
Regional Sales Managers	1. Aid in contacting customers. 2. Assist in product pick-up and delivery of credit notes.

3 Test the Plan

Regularly review the plan for errors, at least annually.

- Use mock recalls to test traceability but also have unannounced trial runs to test the whole plan.
- Check for frequency of validation in line with the relevant regulations.
- Once validation is complete, a full review of every aspect of the process needs to be carried out with the relevant team members.
- The recall plan must be well practiced so companies are ready when a real product recall happens.

4 Notify and Initiate

Notify the distribution chain to stop product distribution, retail sale or any other use.

- Isolate and contain unsafe products outside the control of the organization.
- Supply all relevant information.
- Communicate with all external and internal stakeholders:
  - Trade communication – telephone for speed, followed by email.
  - Press release – TV, radio and paid advertisements if necessary.

5 Manage the Recall

The management of a product recall should be driven by the plan.

- There is a high probability that the information gathered in the early stages of an investigation will be flawed.
- Gather the information first-hand.
- Minimum information required: product name, description, batch codes involved, quantity of material implicated, distribution details, any product sold to customers and nature of defect.
- Identify all potentially unsafe products.
- Document the process.

> With Lot Traceability, we know exactly which lots were shipped to each customer, and our warehouse employees can fulfill orders from cases that are not in danger of being outdated. In addition, thanks to SYSPRO, we can now do a mock recall in less than 30 minutes.
>
> **Norman Shung,**
> *Chief Financial Officer,*
> *Basic Grains Products*

6 Close

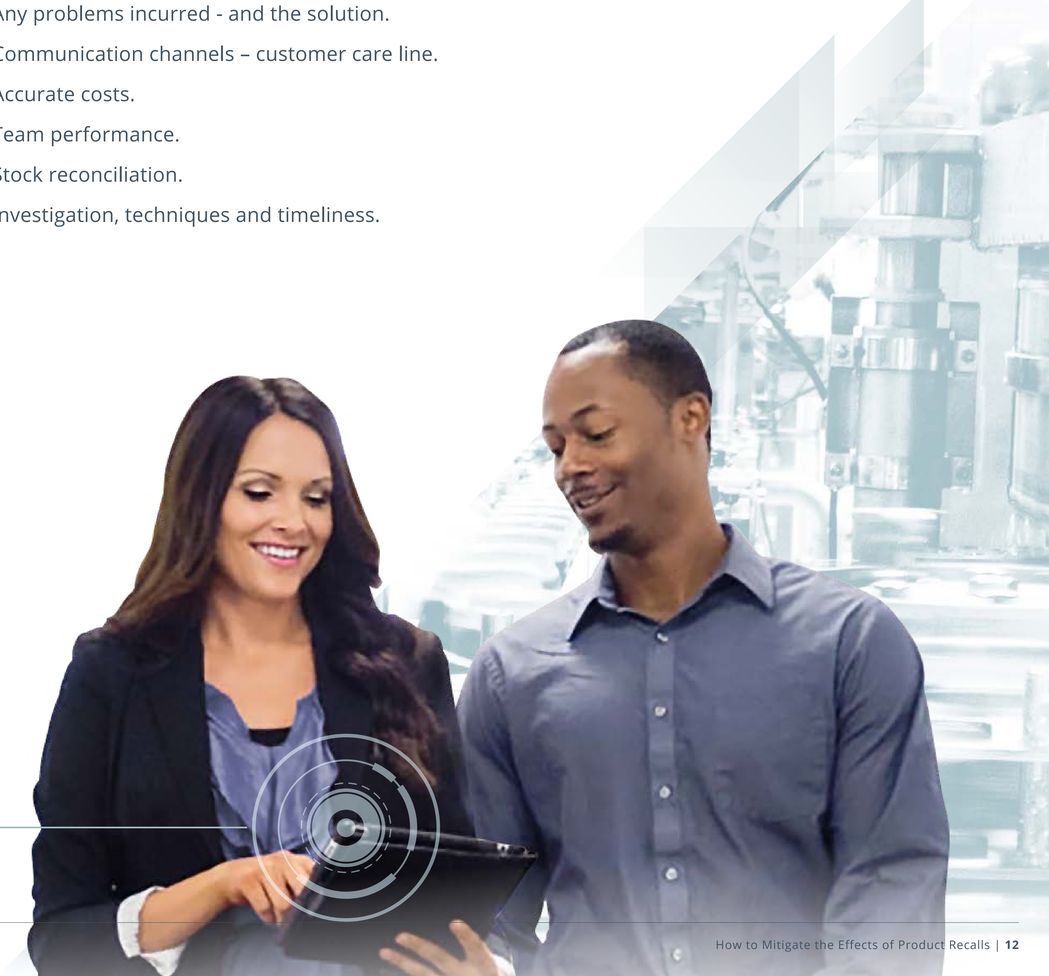
Formally close off the recall when the following has been completed:

- All defective product has been accounted for, the nature of the defect or hazard identified and remedied, and the risk fully mitigated.
- The defective batch sorted.
- Consider new pallets, labels and packaging.
- Include quantity, disposal certificates, decisions and actions taken, as well as future actions to improve the process, and archive.
- Account for all stock – including stock destroyed by the customer.
- Return all stock to one site where it can be easily counted and monitored.
- An off-site warehouse is suggested so that the affected stock can be separated from the good stock.
- Verify the accuracy of the recordkeeping.
- Decisions have been taken and the product has been recovered if possible.

7 Review and Amend

After a product recall, the business should review the process and amend the plan where necessary:

- Did the plan drive the process?
- How effective was it?
- Any problems incurred - and the solution.
- Communication channels – customer care line.
- Accurate costs.
- Team performance.
- Stock reconciliation.
- Investigation, techniques and timeliness.



ERP Checklist

Navigating the complexity of a recall becomes simpler when you're able to act quickly.

The ideal ERP solution should provide a traceability system that offers full visibility throughout the value chain to ensure quality and continued compliance with regulatory requirements. It should provide the ability to trace, identify, isolate, report, quarantine and place affected products on hold quickly and with minimum disruption.

Before (Preparation and Optimization)

1 Supplier Management and Purchase Control

Benefit:

Enable greater visibility, compliance and quality control in the procurement and supplier selection process.

Why SYSPRO:

Request for Quote

- ☑ Suppliers can respond directly to RFQs online.

Supply Chain Portal

- ☑ Enables joint decision-making on suppliers and automatic selection of approved suppliers.

Preferred Suppliers

- ☑ Allows you to capture and maintain predetermined sourcing policies to facilitate the selection of recommended and pre-approved suppliers during the purchasing cycle.

2 Engineering Change Control (ECC)

Benefit:

Engineering Change Control (ECC) is crucial to quality control and is a requirement for ISO and QS certification.

Why SYSPRO:

Engineering Change Control

- ☑ Helps you improve the management of engineering changes to your products and/or associated data by enforcing controls in product design.
- ☑ Provides detailed audit reports of all transactions, including all historical changes and the operator performing the change to meet compliance requirements.

3 Monitor Customer Complaints

Benefit:

Customer Complaints provides visibility into product defects, which may be non-compliant. It also highlights any areas requiring swift intervention and pinpoints the cost of quality measures.

Why SYSPRO:

Customer Complaints System

- ☑ Allows for the capturing, management and effective resolution of customer complaints.

4 Lot and Serial Traceability

Benefit:

For an industry like Food and Beverage, lot traceability is a must to comply with Food Safety Management Systems and Legislation. It enables you to maximize quality control by tracking products, materials and processes as well as by facilitating effective recalls.

Why SYSPRO:

Lot Traceability

- ☑ Allows you to track materials from receipt right through to delivery of the product to the customer, as well as at any level in-between.
- ☑ Provides the ability to trace a lot or batch through the entire value chain from raw material receiving to dispatch.
- ☑ Enables you to trace a unique item with a serial number through the value chain.

5 Mock Recall (Testing)

Benefit:

Regularly performing mock recalls will enable you to test and continually improve on the effectiveness and robustness of your traceability system, thereby increasing the likelihood of a quicker time to completion in the event of an actual product recall.

Why SYSPRO:

Mock Recall Capability

- ☑ Tests the Supplier/Process/Customer Traceability system.
- ☑ Verifies that the product traceability process is effective and can be carried out within the required time limit.
- ☑ All mock recall data is stored for compliance reasons as well as traceability audits.

6 Reporting

Benefit:

Compliance with regulatory bodies.

Why SYSPRO:

Mock Recall Capability

- ☑ Provides detailed audit ECC reports.
- ☑ Mock recall reports can be easily extracted in the recall process and supplied to auditors to meet regulatory compliance requirements.
- ☑ An audit trail of a customer complaint is available.

During (Recalls)

1 Product Recall

Benefit:

Perform a full product recall quickly and efficiently by rapidly identifying and retrieving potentially defective goods from customers using the organization's Product Recall system.

Why SYSPRO:

Mock Recall Capability

- ☑ Is a full traceability system and gives instant access to all of the critical information required to track a suspect product throughout the value chain.
- ☑ It supplies the necessary information to identify, isolate and action the activities that need to occur within the predetermined recall time limit.

2 Trace Suspect Items

Benefit:

Ensure that any products produced and packaged on the premises are traceable back to the ingredients, components and primary packaging. With quick and easy access to all of the key product information recorded in the purchase, production, packaging, sale, distribution and delivery of a product, you can swiftly trace and quarantine stock which is defective, be it spoiled, damaged, hazardous or of inferior quality.

Why SYSPRO:

Lot Traceability

- ☑ Enables you to maximize quality control by tracking products, materials and processes, as well as by facilitating effective recalls.
- ☑ Additional traceability for lots can be added for easy identification.

Product Recall

- ☑ You are able to interrogate the system for affected products using any combination of data available.
- ☑ Assists in identifying the scope of the product recall by specifying affected customers, sales orders and jobs. It will also identify suspect items, original purchase orders and suppliers.
- ☑ Provides visibility throughout the product recall process, including the status of a product recall and detailed information of products that have been included or are in quarantine.

3 Quarantine and Place Products on Hold

Benefit:

Prevents suspect items from being allocated to a job, invoiced or dispatched until the inspection process has been completed.

Why SYSPRO:

Product Recall

- ☑ Helps identify, track and isolate suspect items.
- ☑ Once located internally, the item is quarantined and issuing of that item is blocked.
- ☑ Allows you to scrap affected items that are defective and release unaffected items back into inventory.

4 Customer Returns

Benefit:

Optimize customer service and safeguard customer relationships with timely responses to customer requests to return products.

Why SYSPRO:

Return Merchandise Authorization (RMA)

- ☑ Enables you to rapidly process customer returns and the resulting corrective actions such as receipting, exchanges, cross-shipments, repairs, scrap and credits as well as charges for returns and restocking activities.

5 Supplier Returns

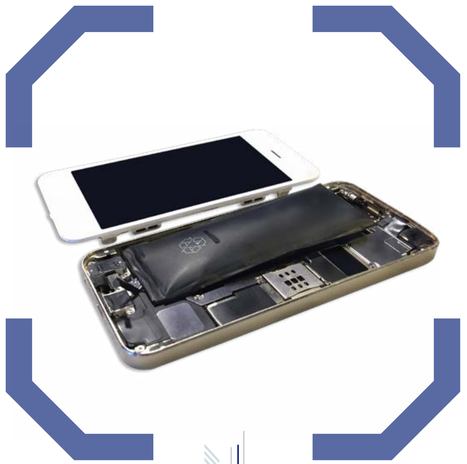
Benefit:

Facilitate the swift and simple return of goods or services to suppliers as a result of defects or other reasons for dissatisfaction.

Why SYSPRO:

Return to Supplier

- ☑ Provides the ability to return defective goods immediately, isolating and removing them from any process.
- ☑ Provides complete visibility of returned inventory throughout the returns process and improves the associated record-keeping or document management.



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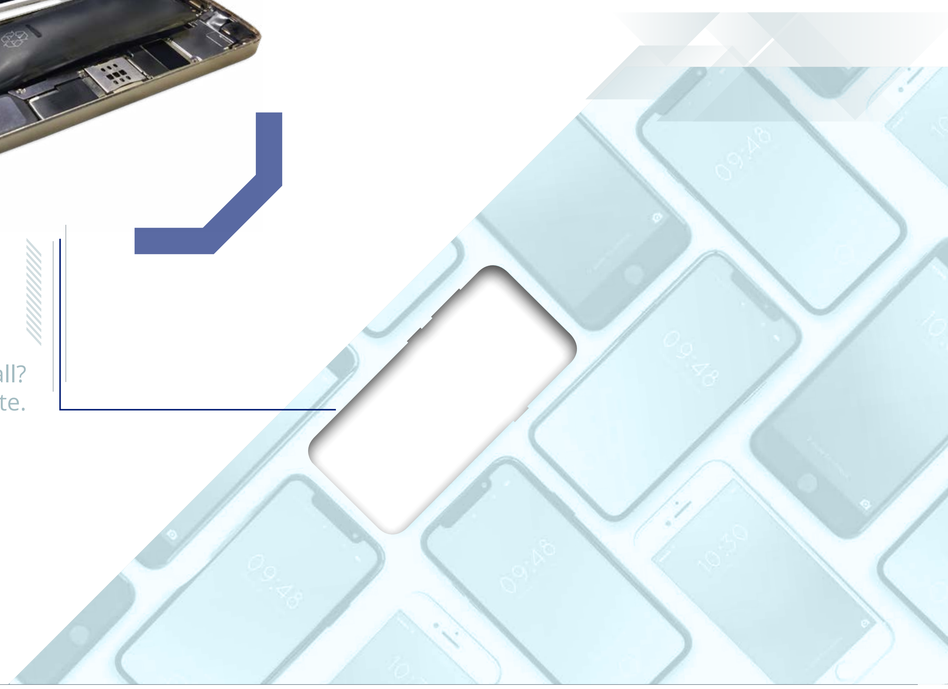


6 Reporting

Benefit:

Improve governance and drive compliance with regulatory bodies.

Why SYSPRO:

- ☑ Built to support your Quality and Food Safety systems, enabling you to develop and maintain your full traceability and recall system policies, plans and procedures, improving internal governance and driving compliance.
- ☑ Provides quarantine, customer quarantine, recall and customer recall reports.
- ☑ An audit trail of a customer complaint is available.
- ☑ Keeps a record of all supplier returns as well as open status.

7 Contact Management for Affected Customers

Benefit:

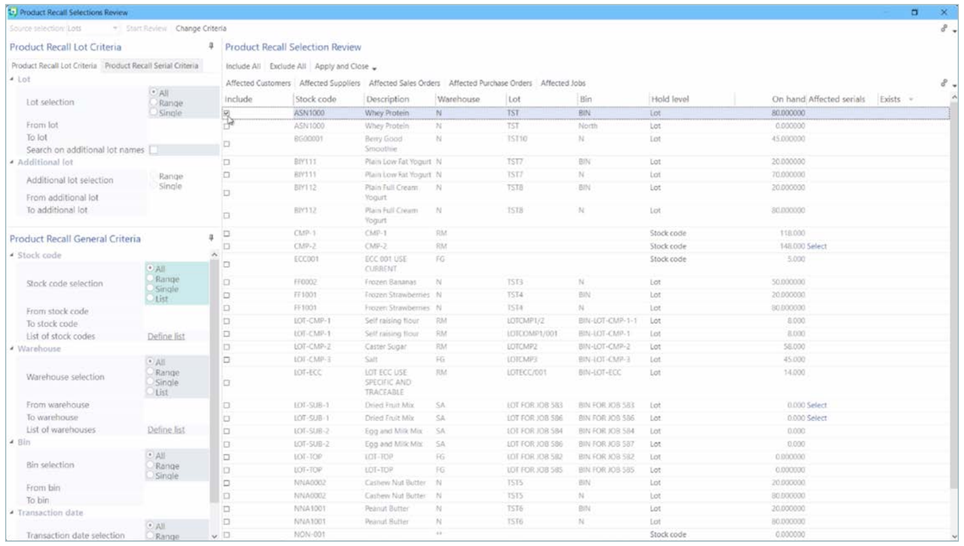
Visibility of the communications (or activities) that occur between the touchpoints of organizations facilitates proactive intervention by management, improves relationships and eliminates duplication of effort.

With early identification of a defect and the ability to quickly communicate with affected customers, you can minimize the damage of a recall.

Why SYSPRO:

Contact Management

- ☑ Allows you to define and manage a rich set of information about the people with whom you do business, as well as the individuals within your organization.
- ☑ Allows you to record and track activities against contacts in a centralized environment.



Why SYSPRO ERP?

Navigating the complexity of a recall becomes simpler when you're able to act quickly.

What sets SYSPRO ERP apart is its ability to effectively quarantine or place products on hold as well as to trace backwards and forwards, report on affected products, deal with customer complaints and effect returns. As part of the full ERP system, SYSPRO offers a traceability system which minimizes risk before a recall and mitigates damage during a recall, when time is of the essence.

While most business systems provide a one-size-fits-all traceability solution, or a plug-in or add-on to an existing system, SYSPRO ERP is industry-built to enable specific manufacturing sectors to trace each individual component, part or ingredient that makes up a product, whenever and wherever it is in the world.

A fully integrated traceability system enables SYSPRO ERP to trace, identify and report on the position of a product in the supply chain in real time. And with built-in product recall and mock recall capabilities, SYSPRO offers one centralized system to take actionable steps to minimize the impact of issues or recalls.

SYSPRO ERP improves governance and drives compliance to mitigate the risk and minimize the impact of recalls.

What Our Customers Say

AEROSUD

Aerosud Holdings employs 680 employees and manufactures an average of 2000 parts and assemblies a day for more than 20 international customers, including Airbus, Boeing Commercial Aircraft, BAE Systems, AgustaWestland Helicopters and Spirit Aerosystems. Faced with exponential growth, an average of 4000 parts requiring individual invoices and delivery documentation and customer processes which varied greatly, Aerosud recognized the need for a solution to effectively and efficiently manage its supply chain and inventory. SYSPRO was implemented across all the companies in the group, integrating seamlessly with its business processes and providing a multi-dimensional view of the business. In addition, SYSPRO integrated with Aerosud's Product Lifecycle Management solution.

Gorant CHOCOLATIER Quality. Family. Tradition.

"Before [SYSPRO], we did everything manually - everything from spreadsheets to handwritten delivery notes to our customers - and it took a lot of labor to do that. In addition, if we were ever faced with a recall, it would have taken us a great deal of time to trace where those finished products went" says Gorant Chocolatier Purchasing Manager, Mary Ann Yerage.

Based on its requirements for fast, effective implementation and a fully-integrated ERP system, Gorant Chocolatier selected SYSPRO ERP. As an FDA-regulated company, Gorant needed the SYSPRO Lot Traceability module to track the history and future of every ingredient coming into its facility.

"We chose SYSPRO for two main reasons: The first was that SYSPRO is very well known in the food industry for its Lot Traceability modules, which is something we need. The second was the Fast Track Implementation program, and a quick implementation was a requirement for us."

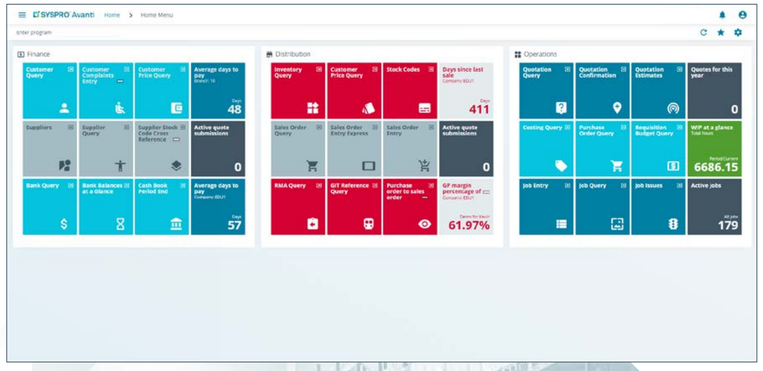
> We have complete visibility of production and traceability via SYSPRO and are able to make crucial manufacturing management decisions quickly.
>
> **Geoff Youds,**
> *Plant Manager, Piolax.*

About SYSPRO

SYSPRO is a single-source, easy-to-implement Enterprise Resource Planning solution designed to minimize business complexity. Our purpose is to provide actionable insights that support daily decision-making, cut costs, streamline processes and improve productivity and outcomes. What sets us apart is our 40-year track record of specialization in the manufacturing and distribution sectors, our simplified approach to technology and our passionate commitment to the success of our partners and our customers.

Because SYSPRO ERP is modular, it allows you to choose the functionality you need now - and to easily add to it as and when your business needs to change. Because we value the relationship above the transaction, we give you a fully informed opportunity to determine the level of service you require.

We believe the value we add is not about our product, but rather about our thorough understanding of how your business works. We call it the SYSPRO experience.



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