

Track-and-Trace

Are you in control of your product distribution?

Across the globe, drug and food contamination are on the rise. Counterfeit drugs are infiltrating the life sciences industry at such a rapid rate that, by 2010, it is estimated that the market value of all counterfeit drugs in circulation will exceed US\$75B or 15% of the global market¹. Globally, the life sciences industry lost \$90B in revenue in 2007 due to counterfeit drugs.

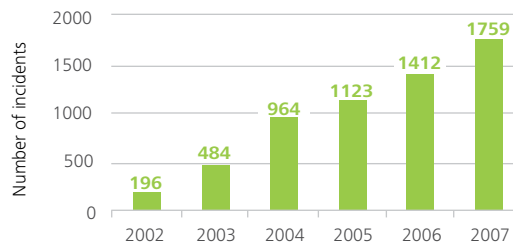
The food industry faces similar threats from contamination and supplier quality control. In 2005, Premier Foods, the United Kingdom's (UK) largest food manufacturer, recalled more than 470 products containing chili powder contaminated by the cancer-causing chemical Sudan 1². The total cost of the recall exceeded £100M, making it the largest food recall in UK history. Most of the cost was associated with the time and effort required to locate all the affected products. In response to these threats, regulators in Canada, the United States (US) and the European Union (EU) ushered in a wave of legislation to improve traceability for food and drugs. Spurred by this legislative push, new traceability technologies and standards have emerged as well.

These trends are taking a toll on both the life sciences and food industries. Aside from the financial cost of product recalls, which can rise into the tens of millions of dollars, the reputational costs can be immeasurable, particularly if death occurs. This underscores the need for consumer businesses to understand how evolving traceability legislation and technology stand to affect their organizations – from the supply chain and beyond. This paper reviews those impacts, and provides a roadmap that can help you determine how to respond.

The costs of counterfeiting and contamination

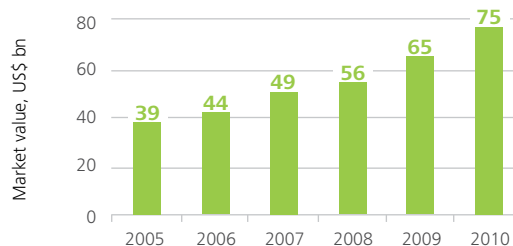
A quick review of recent trends highlights the extent of the contamination challenge. In the **life sciences industry**, incidences of counterfeit drugs increased ninefold from 2002 to 2007³ (see chart). Worldwide, the market value of counterfeit drugs is expected to rise from US\$39B in 2005 to US\$75B by 2010⁴. World Health Organization studies show that nearly one out of two medicines ordered online could be counterfeit⁵, with potentially lethal implications for North American and European markets.

Global drugs safety incidents



Source: "Pharma Regulation – EU, US, Asia", SupplyScan. October 2008

Global value of counterfeit drugs⁶



Source: "Pharma Regulation – EU, US, Asia", SupplyScan. October 2008

In the food industry, food-borne disease and chemical contamination are also on the rise. Between 1998 and 2004, the number of food-borne disease outbreaks doubled in the US, from 44 to 86⁷. According to a 2005 study by the Center for Disease Control, there are approximately 76 million cases of food-borne disease in the US each year, causing about 325,000 hospitalizations and 5,000 deaths⁸. As supply chains become more complex, stretching farther afield into less regulated environments, the potential for contamination and counterfeits rises.

Enter the regulators

As the risks of contamination rise, consumers around the world are demanding corporate and government response. This has impelled legislative bodies to introduce a variety of laws, policies, frameworks and protocols to safeguard the public by improving product traceability (see map).

In the **life sciences industry**, the US and various European countries are leading global efforts to establish a drug traceability framework. Already, 27 states have pedigree requirements, 13 of which are effective today, while California is slated to mandate an electronic pedigree (ePedigree) requirement by 2015. This state action has spurred the Food and Drug Administration (FDA) to develop national standards for drug traceability, which are due for release in January 2010. The US government also introduced the Consumer Product Safety Improvement Act (CPSIA) in 2007, which requires all consumer product manufacturers to fix a tracking label or other permanent mark on all products intended for children 12 and under⁹.

For its part, centralized EU regulations governing drug traceability are unlikely in light of the fact that pharmaceutical companies are governed by national policy. Yet, Turkey, Italy and France have already adopted traceability regulations and European consumer demands may push other EU nations to adopt FDA-driven traceability frameworks.

The cost of food contamination

- 2008: Maple Leaf Foods suffered an outbreak of listeriosis in one of its meat plants in Ontario. The outbreak resulted in 21 confirmed cases of illness, four deaths¹⁰, \$27M in legal settlements¹¹ and a severe blow to the company's public image. The company's stock tumbled nearly 40%, wiping out \$580M in market value (August 23 – October 23, 2008).
- 2008: The Peanut Corporation of America suffered a salmonella outbreak which led to 600 illnesses¹², nine deaths and an investigation by the US Senate House Sub-Committee.
- 2007: Menu Foods, a leading pet food manufacturer in North America, announced a recall of 100 brands of pet food¹³. The cause of the contamination was cost-efficient wheat imported from China that had been tainted with melamine. Menu Foods' stock began a one-year slide from nearly \$8 a share to under \$1 (February, 2007 – February 2008).

In the **food industry**, traceability standards in the US are governed by the Public Health Security and Bioterrorism Preparedness Response Act (2002), which requires all domestic and foreign food facilities to register with the FDA and maintain records needed to determine the immediate previous source, and immediate subsequent recipients, of food.

In Europe, EU Regulation 178/2002 (also called the "food law") makes traceability compulsory for all food and feed businesses by compelling producers to label and track food products throughout the supply chain¹⁴. In addition, the EU is funding programs designed to improve traceability by mandating the adoption of a radio frequency identification device (RFID) system.

Additionally, Canada is emerging as a leader in the development of food traceability standards. The Canadian Food Inspection Agency (CFIA) introduced the Canadian Cattle Identification Program (CCIP) in 2001 and the Sheep Identification Program in 2004. The CFIA has begun implementing the National Agriculture and Food Traceability System (NAFTS), which aims to provide timely and relevant traceability information to enhance emergency response and market competitiveness. And in 2006, GS1 Canada released Can-Trace, a set of data standards and requirements for national whole-chain all-product food traceability¹⁵.

The technological response

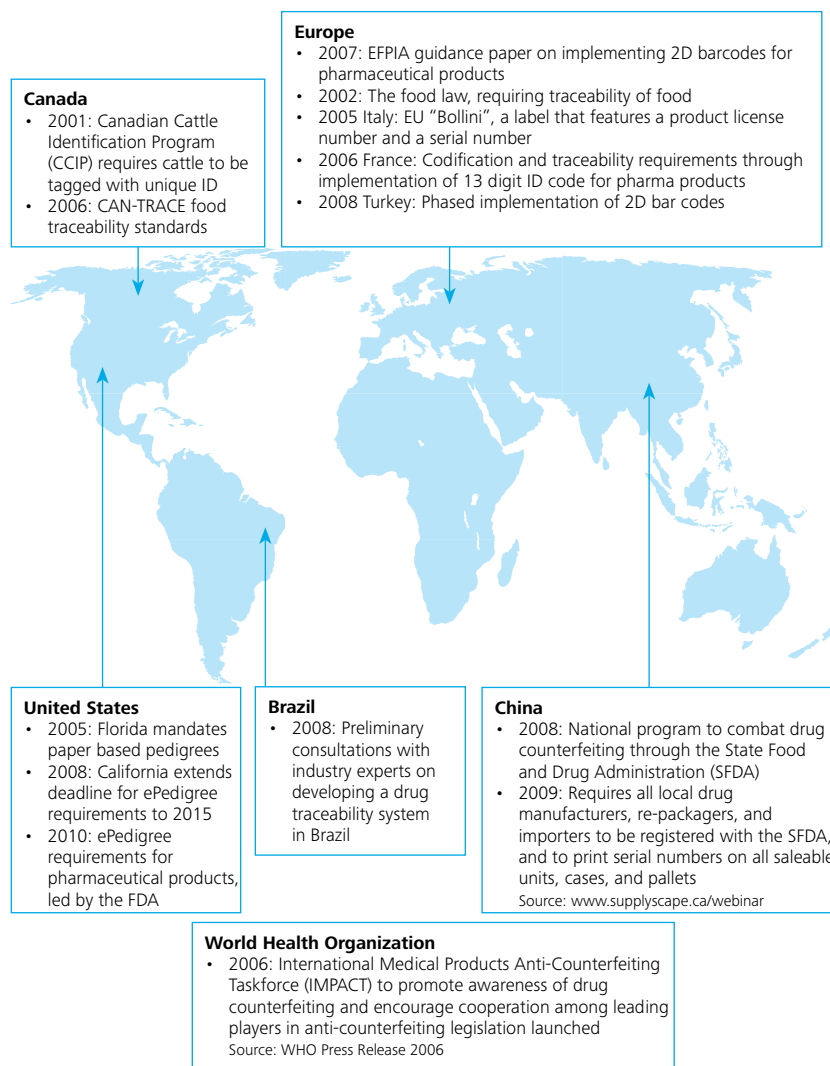
The growth in regulation has led to the development of an entire industry providing technological traceability solutions to consumer businesses. Traceability systems include both hardware (ID tags, printers and scanners) and software components (ePedigree, serialization and track-and-trace). The principal software components are described below:

Software elements of traceability system	Brief description
ePedigree	Used to generate an electronic manifest that contains shipment details, including lot number, serial number and details related to manufacturing, packaging and invoicing.
Serialization	Used to generate unique serial numbers for every unit produced that can be used to trace the product across the supply chain.
Track and trace	Systems that help verify the authenticity of the product based on a unique serial number or lot number printed on the unit packaging.

While there is debate over which technical platforms or standards for traceability systems will prevail, the following four projections are likely:

- **The standard:** Electronic systems will likely prevail over paper-based traceability systems as they offer efficiency and cost advantages, and are currently promoted by both the FDA and European Federation of Pharmaceutical Industries and Associations (EFPIA).
- **The technology:** RFID technology will likely prevail over 2D barcodes due to its advantage in speed, range and storage capacity, as well as its unique ability to scan multiple items at once from any orientation. In addition, the cost of RFID technology is expected to fall to 5 cents per tag.

Map of global life sciences and food traceability regulations



- **The transmission protocol:** XML will likely prevail over EDI as it allows for platform-independent data compression with faster transmission rates. GS1 Health and EPC Global recently developed an ePedigree system built using XML serialization, which has been backed by the FDA.
- **The software:** Large Enterprise Resource Planning (ERP) systems are likely to prevail over best-of-breed traceability solutions as they offer seamless integration with enterprise systems. Major ERP players SAP and Oracle already offer traceability modules as part of their product suites, while smaller best-of-breed track-and-trace firms are likely to be acquired by other ERP vendors.

As these trends show, drug traceability systems are progressing towards a common set of standards, including RFID chips, XML serialization and integration with ERP systems. In the life sciences industry, GS1 Health, along with its subsidiary, EPC Global, is leading the convergence of these standards. In consultation with industry players, these organizations developed a comprehensive set of technology standards for drug traceability systems which were ratified by EPC Global in 2007. While similar standards do not yet exist in the food industry, they are likely to begin emerging over the next few years, taking advantage of the innovations made in life sciences.

New challenges demand new responses

As legislative and technical standards for traceability frameworks evolve in Canada, the US and Europe, both life sciences and food and beverage companies are wondering how these changes will affect their businesses. While there are no hard and fast answers, the table below summarizes the implications organizations will likely experience in four major areas: strategy, supply chain, marketing and technology and people.

A strategic storm

Evolving traceability legislation and technology will significantly affect corporate strategy by forcing companies to acquire traceability systems and capabilities. Organizations will face the strategic choice of outsourcing these new business processes, building up these capabilities internally or acquiring companies that have already developed the necessary skills and invested in traceability systems.

Companies will also have to re-evaluate their relationships with their core business partners, including suppliers, contract manufacturers, packagers, third-party logistic providers (3PLs) and distributors. To meet stringent regulations, companies must assess the benefits of outsourcing to these providers, and consider the advantages of doing business only with partners that adopt compatible traceability systems. Furthermore, companies will need to appropriately allocate the added costs that result from implementing traceability systems across the value chain to all channel partners, so that one party does not bear the entire burden alone.

Major business impacts of implementing traceability systems

Strategy	<p>Operating model</p> <ul style="list-style-type: none"> • Outsource, build or acquire traceability knowledge & infrastructure • Role of contract manufacturers, 3 PL, re-packagers, distributors <p>Risk management</p> <ul style="list-style-type: none"> • Regulatory compliance strategy • Product anti-counterfeit strategy <p>Competitive strategy</p> <ul style="list-style-type: none"> • Contractual agreements with business partners to meet compliance <p>Competitive strategy</p> <ul style="list-style-type: none"> • Product safety, quality messages to shareholders, community and regulators
Supply chain	<p>Supplier management</p> <ul style="list-style-type: none"> • Low cost country sourcing • Vendor development <p>Logistics and warehousing</p> <ul style="list-style-type: none"> • Process changes in receiving, quality inspection, product storage, picking, packaging and shipping • Warehouse equipment and stores layout <p>Manufacturing</p> <ul style="list-style-type: none"> • Quality process and systems • Packaging line modification <p>Product recall management</p> <ul style="list-style-type: none"> • Processes, metrics, compliance
Marketing	<p>Pricing strategy</p> <ul style="list-style-type: none"> • How to share cost with supply chain partners and customers • Assign price increases across portfolio to minimize customer impact <p>Product portfolio</p> <ul style="list-style-type: none"> • Acquisition/ divestment of products to provide competitive advantage • Brand building strategy to promote product safety <p>Sales upside for early adopters</p> <ul style="list-style-type: none"> • Large wins expected from government contracts to supply food/drug
Technology and people	<p>IT strategy</p> <ul style="list-style-type: none"> • Impact on existing systems viz. ERP, WMS, MES, quality management • Implementation of traceability systems including – track & Trace, serialization, electronic Pedigree <p>Training</p> <ul style="list-style-type: none"> • Process & system Training <p>Organizational change</p> <ul style="list-style-type: none"> • Change management with supply chain partners • Internal change management resulting from process change/ work redesign <p>Traceability performance measurement</p>

Finally, organizations will face brand management challenges related to potential product recalls. To mitigate the impact of negative publicity and damage to the brand, companies must adopt robust risk reduction strategies that address public concerns regarding product contamination, counterfeit products and recalls. They must also develop suitable communication strategies to address the concerns of shareholders, the public, local communities and regulators.

Tightening weak links in the supply chain

Supply chains bear the direct impact of traceability initiatives. Because the requirements for traceability in the food and life sciences industries differ, companies will experience different supply chain challenges. While the food industry is concerned with traceability at the lot level – to prevent contamination – the life sciences

industry requires traceability at the unit level, to prevent counterfeiting. Either way, companies should review four major areas when assessing the implications of traceability on their supply chains:

1. Supplier management. In addition to revisiting their low-cost country sourcing strategies, companies in both industries need to redesign their supplier management and vendor development programs to take traceability capabilities and requirements into account.

2. Logistics and warehousing. While existing systems meet traceability requirements in the food industry, life sciences organizations must adapt their Warehouse Management Systems (WMS) and ERP environments to gain the ability to track lot numbers and unique serial numbers. They may also need to invest in specialized hardware such as RFID scanners, printers and tunnels. Regardless of industry, warehouse operations will be affected as companies make the investments required to implement new traceability systems.

3. Manufacturing. While adherence to Good Manufacturing Processes (GMP) will limit manufacturing implications in the life sciences industry, food and beverage companies need to maintain and improve their quality management systems to ensure the capture of raw material information.

4. Product recall management. As traceability systems are deployed throughout the organization, the product recall process can be greatly improved. Companies will have more product visibility throughout the supply chain, and will be able to identify affected products at the source more rapidly than before. In turn, this will enable more efficient identification of affected products downstream, typically the most critical and time-intensive step in recalling products.

Preventing marketing mayhem

Both life sciences and food organizations face tough decisions regarding their overall marketing strategies. Primarily, they must decide whether to absorb the increased costs of compliance or pass these costs downstream to customers and final consumers. Large organizations with strong brands will find this easier to do, as their margins are higher than smaller generic or no-label manufacturers.

In addition to pricing, companies must also determine how to distribute additional costs across their product portfolio while staying competitive. Again, large companies with a broad product portfolio across various price ranges will likely find this easier than smaller organizations with more focused product lines.

Major technology system & impacts of implementing traceability

Type	System	Life sciences		Food	
Enterprise	ERP	<ul style="list-style-type: none"> Capture of item serial # Requirements to interface with devices like RFID printers and scanners 	HI	<ul style="list-style-type: none"> Capture of item batch/lot # 	HI
	Warehouse management system	<ul style="list-style-type: none"> Capture of item serial # 	HI	<ul style="list-style-type: none"> Minimal expected impact to current systems 	LOW
	Manufacturing execution system	<ul style="list-style-type: none"> Minimal expected impact to current systems 	LOW	<ul style="list-style-type: none"> Traceability and lot genealogy features to be built into system 	MED
	Packaging systems	<ul style="list-style-type: none"> Capture of item serial # through RFID or 2D bar code Capture of item – case – pallet aggregation information Printing 2D bar code/writing RFID info on each item – case – pallet 	HI	<ul style="list-style-type: none"> Printing 2D bar code/writing RFID info on each case – pallet 	HI
	Quality systems	<ul style="list-style-type: none"> Minimal expected impact to current systems 		<ul style="list-style-type: none"> System to provide additional features like alerts, online monitoring, incidence management etc. 	
Traceability	ePedigree	<ul style="list-style-type: none"> System to generate electronic documents for manufacturing, packaging, invoicing, transportation and receiving at an item – serial level 	HI	<ul style="list-style-type: none"> System to generate documents providing country of origin, farm of origin, manufacturing, packaging, invoicing and transportation at a case – lot level 	HI
	Serialization	<ul style="list-style-type: none"> Ability to produce unique serial # for every item 	MED	<ul style="list-style-type: none"> Minimal expected impact to current systems 	LOW
	Track & trace	<ul style="list-style-type: none"> Ability to authenticate serial # on demand 	HI	<ul style="list-style-type: none"> Ability to authenticate batch # on demand 	MED

Finally, companies will face both challenges and opportunities in managing and building their brand equity. By adopting traceability systems early and communicating this effectively to consumers, companies can establish themselves as leading players in product safety, a growing and significant trend in both the life sciences and food industries.

Technology and the people who use it

To comply with new traceability requirements, companies must invest in new technologies and systems. Implementation costs for these systems will vary depending on the size and complexity of the organization, as well as the industry and value-chain segment in which it operates. The table below can help you assess the potential complexities related to your implementation.

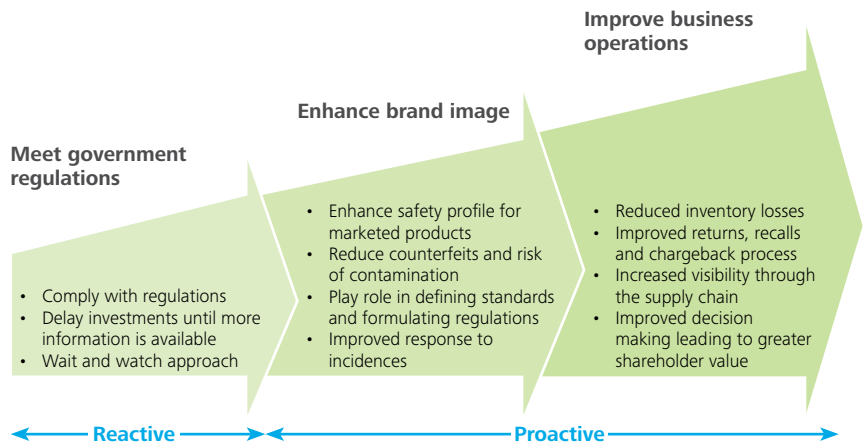
No matter how extensive your technological shifts may be, one thing is clear: The adoption of new systems will lead to process changes, and these must be accompanied by suitable training and communication programs. In addition to reviewing your employees' roles and various departmental organizational structures, you may need additional resources to strengthen both your regulatory compliance and quality monitoring functions.

Time to move beyond compliance

Given the growing uncertainty around traceability regulation and technology, some business leaders are concerned about implementing traceability systems in advance of "final" regulatory guidelines. Many are waiting for the uncertainty to clear before making the investments required in research and development, pilot projects and technology platforms.

This hesitation is a mistake. While traceability regulations have not been set in stone, the brand and operational implications of inaction are high. As the diagram below illustrates, taking a proactive value-based approach to implementing traceability systems can deliver broad benefits beyond compliance.

Find value beyond meeting regulations



Thanks to these advantages, leading organizations are taking a proactive approach by:

- Understanding upcoming compliance requirements and meeting them early
- Enhancing their brand image by playing a role in setting standards and helping governments formulate regulations
- Conducting pilot programs to better understand traceability technology and new process requirements
- Leveraging the new technology to improve operational efficiency and quality management standards

From an efficiency perspective, traceability systems can reduce the time it takes to process returns, improve pick accuracy and lower product expiry and obsolescence. Even more significantly, traceability systems can help you better identify, organize, track and follow up on recalled products, no matter where they may be located. By identifying the exact scope of a recall and the affected customers, you do more than enhance the safety profile for your products. You also gain the ability to reduce counterfeits and speed up recalls, ultimately limiting the negative effects of contamination.

Your traceability roadmap

Taking a proactive approach makes good business sense for most organizations. The key to a successful implementation is the development of a roadmap that builds in opportunities to change course as legislation and technologies shift. While you may not need to implement a traceability program immediately, a roadmap can help you prioritize investments in traceability over time, and demonstrate your long-term traceability plans to regulators and other stakeholders.

In building this roadmap, it is important to answer the following questions:

- How mature is your industry, and where do you stand relative to other players?
- What are the risks facing your industry, and how severe are they?
- How aware is your organization of the latest regulatory changes, and are you taking part in influencing the legislative process?
- Do you have a pilot program to test new traceability technologies as they are developed?
- Are you playing a part in assisting your industry to define technology standards?

After answering those questions, the following diagram can help you map out the development of your traceability roadmap.

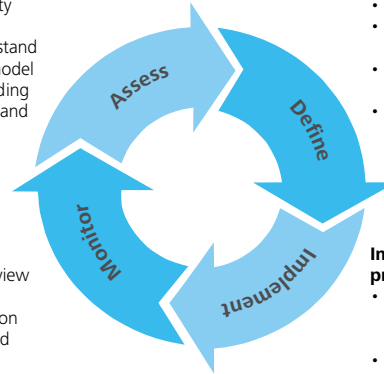
Process for developing a traceability program roadmap

Assess current state

- Assess current traceability preparedness
- Understand where you stand in terms of a maturity model
- Assess current risk including impact on brand image and company value

Monitor environment

- Scan environment to review latest developments in technology and regulation
- Monitor competition and other industry trends



Define traceability strategy

- Develop future state vision
- Understand opportunity for improvement
- Develop business case to evaluate benefits and costs
- Suitably change existing strategy based on environment trends

Implement traceability program

- Develop traceability project plan with milestones and timelines
- Develop pilot projects on traceability
- Implement select traceability projects

Of course, developing a traceability program and strategy can be complex, which is why it is important to work with industry specialists capable of helping you:

- Assess your supply chain risks and develop strategies to secure them, including ePedigree and serialization projects.
- Determine the implications of traceability on your corporate strategy, supply chain, human capital and technology integration processes.
- Select and implement appropriate technologies, including ERP software.
- Assess, develop and implement an industry-specific RFID Strategy.

At Deloitte, our practitioners take a multi-functional approach to your challenges, bringing resources to bear across a vast range of national and global practice areas, including our Value Chain practice, Consulting services and Technology practice. The diagram below sets out some of these capabilities.

A clearer road ahead

In the life sciences and food industries, change is inevitable. Products, supplier markets and consumer demands evolve rapidly, as do threats related to counterfeiting and product contamination. Against this backdrop, it is only natural for regulators to respond by adopting policies, frameworks and laws to track the movement of these essential products.

While the current frenzy of legislative and technological activity in the traceability arena presents an ambiguous landscape to business leaders, clear patterns are emerging. Chief among them is the impending push towards an electronic, RFID-based traceability standard in the life sciences industry. As the FDA leads the way, other jurisdictions will likely follow suit. And as standards in the food industry continue to develop, they will likely align with those in life sciences.

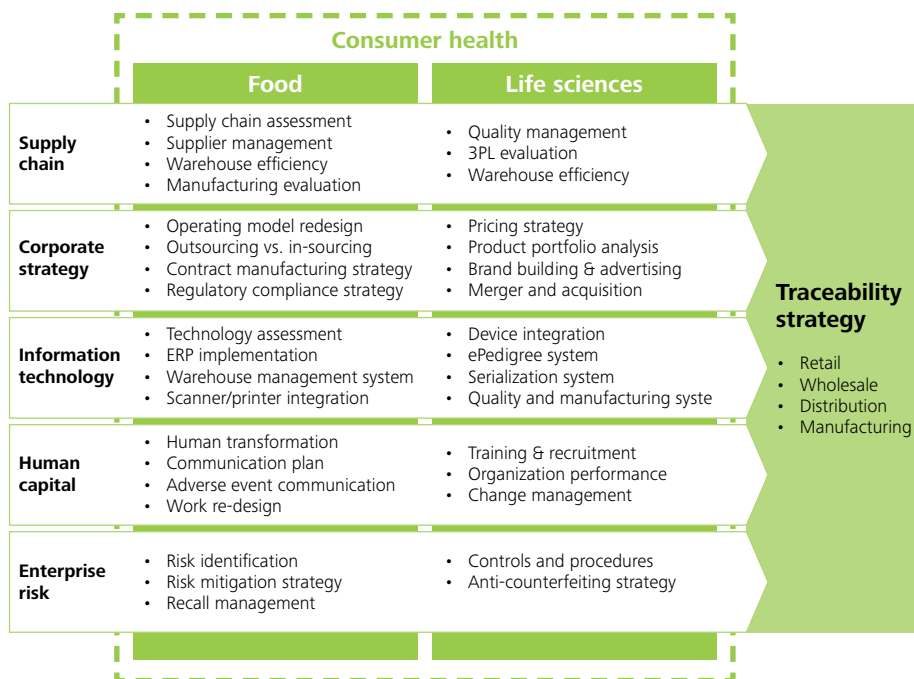
From this perspective, it becomes evident that organizations will benefit by proactively adopting traceability systems. This approach will not only help you achieve regulatory compliance, but will also position you to improve your brand image, operational efficiency and, above all, consumer safety.

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