Facilitating FSMA Compliance with Technology

Summary discussions of what companies need to understand about the US Food Safety Modernization Act (FSMA) and how they can leverage technology for compliance.

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GRANTEK

Introduction

When it comes to the Food Safety Modernization Act (FSMA), where do you start? Of the seven rules proposed by the U.S. Food & Drug Administration (FDA) thus far, the majority are hundreds of pages in length and understanding what is required can be confusing. With additional rules still expected to roll out, it can be difficult to plan for the future when so much is unknown. And yet, there is no time to delay-- because the rules are coming, and fast! So far, the FDA has released the following proposed rules, with court-defined dates for finalization:

FDA's FSMA Regulation	Final Rule Deadline
Preventive Controls- Human Food	**Aug 30, 2015**
Preventive Controls- Animal Food	**Aug 30, 2015**
Produce Safety	**October 31, 2015**
3rd Party Accreditation of Auditors	**October 31, 2015**
Sanitary Transport	**March 31, 2016**
Intentional Adulteration/ Food Defense	**May 30, 2016**

Note: Large Businesses have 12 months to comply, Small businesses have 24 months to comply, and very Small Businesses have 36 months to comply with the final rule deadline as per the FDA.

Few know the ins-and-outs of the FDA proposed FSMA rules the way Grantek's own Consulting Group does. And, our analysis is that while the proposed rules may seem complicated, regulatory compliance is well within reach. Grantek offers a comprehensive suite of solutions, starting with understanding your business and identification of opportunities, through to implementation of the hardware and software to get the systems in place to protect your brand and exceed regulatory and customer requirements. While regulatory compliance is a baseline requirement, the ability to concurrently satisfy other business needs helps ease the burden of implementing a change.

This paper offers expert insight into specific aspects of FSMA, offers perspectives on approaches to compliance, and provides examples of solutions deployed by industry leaders.

The Need to Know

Expectations within the food industry are changing, driven by customer requirements and federal regulations. With forthcoming requirements for preventive controls across the FDA-regulated food industry, as well as traceability requirements that enable a rapid, focused response to a potential issue, the food industry is feeling increased pressure to not only do the right thing, but have the documentation to prove it. While few expect the FDA to dictate the specific systems and processes that food manufacturers must use to achieve compliance, industry leaders are looking at how system upgrades will ease the burden of Food Safety Modernization Act (FSMA) requirements and, importantly, protect their brands.

What's your FSMA Readiness?

(a) I've never heard of these things, and I have no idea how to prepare

(b) I'm familiar with the rules but I don't know how they apply to me

(c) I think I can comply with the rules, but my current systems hold me back from doing it well

(d) I've got the technology but I need to figure out what exactly I need for regulatory compliance

(e) I know what to do and I have the right amount of automation and technology to make it happen!

If you chose b, c or d, you're like most companies—read on to learn how to take the next step!

Already, the FDA has the following increased authorities as a result of FSMA:

- Increased records access
- Authority to issue a recall
- Authority to require a certificate in order to import foods
- Require companies to re-register their facilities biennially
- Whistleblower protections
- Increased, risk based frequency of regulatory inspections

Currently, the FDA is in the process of defining requirements around several other FSMA-related authorities as well, such as:

- On-farm food safety requirements
- Food safety plans for FDA registered facilities (both human and animal food)
- Food defense/intentional adulteration
- Transportation requirements
- Responsibilities of importers to verify suppliers

Food Safety in the Future

Historically, within a company, food safety has been the responsibility of the food safety/quality manager, director or similar position. Increasingly, our industry, the government, and your customers recognize that food safety needs to permeate an organization. This is evident through the Global Food Safety Initiative (GFSI) requirements around the demonstration of management commitment, and the HACCP (Hazard Analysis Critical Control Point) requirements to form a multidisciplinary HACCP team.

No longer is food safety (and quality) a silo within a company or a manufacturing facility. Decisions involving food safety influence your entire supply chain, affecting operations and engineering, even having an impact on the brand. Likewise, changes in your operations and approaches to managing the supply chain can have an effect on the safety and quality of your food products, as well as a regulatory impact. Thus, it's critical that a team approach to food safety be established.

Your Food Safety team should include:

- **Operations**
- **Engineers**
- **Supply Chain**
- **Risk Managers and**
- **Regulatory Compliance**

The Food Safety Modernization Act will revolutionize food safety in the US, and will have a ripple effect across the globe. For the past 50 years, the food industry has been transitioning from a system of reacting to food safety issues toward one where systems are designed to guard against contamination and prevent issues from occurring in the first place. The Hazard Analysis Critical Control Point (HACCP) approach to food safety has been gaining ground over the past several decades, and is required for certain types of food products in the US (seafood, juice, meat and poultry). FMSA will require the breadth of the food industry to build upon HACCP and formalize a comprehensive system to address food safety. When considering the multiple rules that will ultimately be issued to implement FSMA, full implementation will address nearly the entire "farm to fork" spectrum of the supply chain. Standards will be instituted for fresh produce, food processing, transportation, and imports.

Rather than issuing prescriptive, product-specific requirements, the FDA sets the objective and leaves it up to companies to figure out how to get there. While the FDA does not require the use of any specific system, technology, or the use of any degree of automation, it's clear that the FDA wants companies to embrace technology. Therefore, complying with many aspects of the proposed rules will be much easier if firms leverage technology.

Regardless of the approach taken, there are several overarching “ingredients” needed for FSMA compliance that are also critical for your brand protection:

A Rapid Response

Whether it’s recognizing that a process is out of control or providing records to the FDA, companies need to be able to respond rapidly.

Consistency

When considerable effort goes into developing a plan to achieve food safety, the consistent implementation of those policies is critical.

Documentation

The foundational role that documentation will play in demonstrating that food safety is under control—even when a regulator or auditor isn’t looking- can’t be overstated.

Analysis

The food industry currently collects a lot of data. However, bringing the data together to make sense of the bigger picture is often lacking. Trending data gives companies a heads up to anticipate looming issues and can also reveal opportunities to optimize systems and increase efficiency.

Fortunately, most food companies take food safety seriously and continue to look for opportunities to improve what they are doing. While FSMA revolutionizes the FDA’s food safety authorities, an individual company’s path to compliance should be more of an evolution, not a revolution.

The examples provided below demonstrate how Grantek solutions can help companies develop more efficient and effective ways of meeting FDA requirements while also protecting their brand and being viewed as best-in-class. Although these examples are limited in scope and detail, they are illustrative of the possible ways to improve the way you do business, while facilitating regulatory compliance.

Preventive Controls

Preventive controls by definition are controls designed to prevent, eliminate or reduce the known hazard to an acceptable level for safe consumption of food. Under FSMA the FDA will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply. For food facilities the mandatory preventive controls involves:

1) evaluating the hazards that could affect food safety
2) specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards
3) specifying how the facility will monitor these controls to ensure they are working
4) maintaining routine records of the monitoring
5) specifying what actions the facility will take to correct problems that arise. (Final rule due 18 months following enactment)

Moving forward, some activities that have historically been considered cGMP's (current Good Manufacturing Practices) may be updated and modernized, thus falling under Preventive Controls. We will look at this in the section below.

Within the realm of Preventive Controls, process controls are the most familiar. These are the controls that are typically associated with HACCP and are recognized as the critical control points for food safety. With Preventive Controls, the FDA expects that food manufacturers will continue to heavily rely upon process controls. Consistent with what is seen in existing HACCP regulations, the FDA would require that the following approach be followed:

Validation

Whatever process control is selected must work. If a process is being employed, for example, to control for *Salmonella*, the food producer must be able to show that the process will effectively destroy the pathogen. In this example, this means knowing the expected and worst case levels of the pathogen so that the amount of "kill" can be determined. Then, the parameters that will accomplish this reduction need to be tested. This should be done using the food products to which the process will be applied, under the most real-to-life conditions possible, including using the actual equipment that will be used during production. In some cases, scientific studies may already have been published and can be used as a starting point for the validation studies.

Establishment of parameters

The validation studies will help a company establish the conditions needed for an effective process. These could include the specification of factors such as time, temperature, line speed, humidity, antimicrobial concentration, etc. Any change, such as a change in formulation,

processing equipment, etc., should prompt a re-evaluation of the parameters to ensure that the process is still valid. Automated recipe management for equipment and process parameters can help food producers meet this need.

Monitoring

Once the parameters are set, it is critical that they be monitored. A Historian database can be used to capture these process parameters such as temperature, pressure, time etc. Best in class systems are complete with trending of data and Statistical Process Control (SPC) alarms to give an advance warning if the system is trending out of bounds.

Corrective actions

System failures need to be anticipated, and facilities need to show that they have thought through what could go wrong and have a plan in place to address issues if they occur. When issues do occur, the facility needs to keep records of the event and show that they followed the course of action specified in their food safety plan. In some cases, these types of issues prompt firms to reconsider their approaches and start looking for cost effective solutions to prevent recurrence.

Verification

FDA has proposed a few ways that facilities will need to show that their entire food safety system is working as anticipated. Recordkeeping and documentation, and a review of those records as well as a re-evaluation of the overall food safety plan, would be required.

Examples of Preventative Controls include:

Allergen control

In response to the increasing fraction of the population with food allergies, the FDA and the food industry have cast a spotlight on allergen controls. For facilities that have identified food allergens as hazards that are reasonably likely to occur, the implementation of allergen controls would be required. A solid allergen control program can encompass several different activities, including appropriate sanitation between different allergens as well as runs without allergens, appropriate storage of allergens, and label control and verification.

Did you know that 44% of all the entries to the FDA Reportable Food Registry were due to undeclared allergens?

Supplier verification

In some cases, a facility may not have a means to control a hazard; it might rely on a supplier for control. In this instance, the FDA is expected to propose that supplier controls be enacted in such a way that the receiving facility is assured that their supplier is adequately controlling hazards. While the FDA's exact requirements were not published at the time of this writing, the FDA has verbally confirmed that such a requirement will be proposed.

The proposed Foreign Supplier Verification Rule provides a glimpse into the FDA's thinking. Within that rule, the FDA has proposed that after importers determine which hazards their foreign supplier needs to control, some options to demonstrate control include onsite audits, review of certificates of analysis, testing of the suppliers product, and review of the suppliers food safety records, among others.

The issuance of Certificates of Analysis (CoA's) by suppliers is fairly common within the food industry, however they have little value if a receiving company does not know how to properly review and verify them. A pile of papers in a file cabinet, or emails in a folder, are inadequate to demonstrate that you're using CoA's to control your supplier. The preferred approach is to automate the review of COA's. Implementation of an automated traceability and genealogy system covering raw materials receipt and linking laboratory analysis of raw materials samples to the specific received lots can create a traceable and searchable record that proves control. It can also be used to manage acceptance of raw materials from suppliers.

Transitioning some Current Good Manufacturing Practices (cGMP's) to "Preventive Controls"

The application of cGMP's has been required for many decades; it may seem old hat. Due to FSMA, the FDA has proposed to revise and update cGMP's for human food and require the cGMP's for animal food & feed.

Even facilities that are well versed in GMP's may find that in some instances, they will take on a new role when the Preventive Controls rules are finalized. Briefly, GMP programs that are critical for preventing the occurrence of a specific hazard may now be viewed as a "Preventive Control."

One example of a GMP that may transition to a preventive control is **preventive maintenance**.

According to the FDA, **Preventive Controls** are defined as those risk-based, reasonably appropriate **procedures, practices, and processes** that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to **significantly minimize or prevent the hazards** identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

If preventive maintenance is key to preventing a foreign material from contaminating a product (e.g., the inspection and replacement of screens that may deteriorate), then it should be deemed a preventive control.

Sanitation is another example; having long been an important element of GMP's, it could now be viewed as a Preventive Control in some cases. For example, in the production of ready to eat foods, sanitation of food contact surfaces (including utensils, and even people who may be in contact with the product) are essential to prevent cross contamination. When a facility handles allergens, sanitation may be critical to prevent cross contact as mentioned below.

When specific aspects of sanitation are needed for more than just the maintenance of a clean facility, but are critical to avoid a hazard:

- the sanitation procedures will need to be documented.
- the facility will need to maintain records to demonstrate that sanitation has occurred in accordance with what has been predetermined in the food safety plan and with the frequency specified in the plan.

The importance of a Rapid Response

Without question, FSMA and the FDA place great value on the prevention of food safety issues. Realistically, however, problems will occur occasionally and the food supply chain must be well positioned to rapidly respond in a targeted fashion. A rapid response serves several purposes that benefit both food companies as well as consumers. Specifically, a rapid, accurate response can achieve the following:

- Reduce the number of consumers exposed to a potentially hazardous product
- Limit the amount of product subject to a recall
- Maintain consumer confidence in the food system
- Reduce the amount of time that an issue is in the media
- Prevent/Minimize loss of customer confidence in the brand

An example of this is the Impact of 2006 Spinach Outbreak:

One of the main enablers of a rapid, accurate response is a strong traceability system. This encompasses traceability within the four walls of a facility, as well as the "handshake" with supply chain partners that allows food products to be traced throughout their life cycle.

The FDA has not yet proposed regulations to improve the traceability of FDA regulated foods, although basic recordkeeping requirements have been on the books since 2005. The current traceability requirements are commonly referred to as "one forward/one back" meaning that anyone who manufactures, processes, packs or holds food must know the immediate previous supplier of a product, as well as the immediate subsequent recipient. Manufacturers/processors are meant to record lot numbers of ingredients and relate them to the lot numbers of finished manufactured products. Surprisingly, this process is still often done via handwritten batch logs, which are subject to issues of legibility and errors and can be difficult to access and query in a timely fashion.

With an automated traceability and genealogy system, all batches of product that passed through a vessel known to have been the source of contamination may be immediately identified by direct query. It is also possible to identify the downstream vessels and packaging equipment that were used by the contaminated batches. In this way, a focused product

quarantine or recall may be made, catching the product before it leaves the plant or limiting the scope of the recall below the typical "all product made in a specific plant during a specific time period." Limiting the scope of a recall depends on high confidence in the data and a rapid ability to query that data.

The importance of Consistency

While a rapid response to food safety issues is critical, equally important is the prevention of issues in the first place. Food safety plans driven by the FDA's regulations require a significant investment of time and effort to create. But the value in a food safety plan lies in its consistent implementation.

That implementation includes several key elements:

- Consistency in ingredients and process
- Consistent handling of Critical Tracking Events (CTE's) and Key Data Elements (KDE's)
- Consistent data collection from people, the environment, and the process
- Consistent sanitation and product changeover protocols

A lack of consistency can enable the conditions in which foodborne pathogens are introduced or escape the facility. For example, failure to ensure that meat is cooked to a proper temperature may result in pathogens surviving the cooking process. Additionally, failure to ensure proper sanitation between product runs may allow cross-contamination of allergens or pathogens.

Technology may be deployed to facilitate consistency in the process and by people performing any actions in relation to the process. Modern information and control systems can perform automated recipe management by storing the process set points such as temperatures, speeds, and feed rates for any product and deploying those set points at the beginning of a production run. Likewise, standard operating procedures (SOP's) may be enforced by means of electronic checklists which must be completed prior to starting or stopping the process, or any steps within the process. It is also possible to record deviations from any regular setting or practice for the purpose of offline analysis and tie-back with the production record for a specific lot of product.

The importance of Analysis

Understanding when a food production process is in control or trending out of control requires making sense of the volumes of data produced by a typical manufacturing environment. Measuring the values associated with production, including mix times, material thickness, cook times, temperatures, etc. can be useful for understanding how well the process is being executed. Layering in tools such as Statistical Process Control (SPC), can help to automatically identify a process that is trending out of control, so that adjustments may be made before unsafe or out-of-compliance product is permitted to travel further though the production or packaging process.

Additionally, analysis of the data collected during manufacturing may provide insight into the reasons for equipment failure or stoppages. For example, correlated significant downtime from a particular shift with the length of time an upstream process has been run may lead to process improvements that keep a production plant running at a higher efficiency, leading to a lower cost per unit for each product produced.

The importance of Documentation

Getting and keeping control of food safety in a production environment helps reduce the possibility of dangerous and expensive food safety issues. However, with increasing regulation, it is not enough to have control; it is also necessary to be able to prove control. A food producer facing an audit by the FDA must be able to produce accurate records enabling the auditor to verify that food is being produced safely. Additionally, in the event of a food safety incident, accurate records will provide the forensic evidence needed to ensure a comprehensive and appropriate response to the incident.

Although handwritten records are the easiest to implement, they are prone to error, may contain gaps in recordkeeping, and they can be cumbersome to store. Additionally, in the event of an incident, it can take significant time to trace through hundreds or thousands of paper, handwritten records to understand the forward and backward genealogy of a product. Technology can provide solutions to these issues.

Modern information technology systems can automatically record critical process variables, such as temperatures, pressures, and process times in efficient, time-stamped historical data stores called process historians. These historical records may be related to traceability records and records of the equipment and personnel responsible for making each batch or lot of product through modern Manufacturing Operations Management (MOM) systems. Additionally, quality data from Laboratory Information Systems (LIMS) may be related to the

genealogy records to create a master history record for each lot produced. Since these systems are often integrated directly to the controls systems running the equipment and to the business systems, it is possible to ensure the required data will be captured in real time, as the process is completed, without imposing a significant burden on the people running the process.

Traceability

Although regulations have not yet been proposed, FDA has taken several steps specified by FSMA to examine traceability. Notably, FDA worked through the Institute of Food Technologists to conduct several product tracing pilots aimed at exploring effective approaches to improve the accuracy and speed with which system-wide traceability could be achieved. IFT provided FDA with 10 recommendations, which are discussed in a comprehensive report. In short, IFT recommended:

1. Establishing a uniform set of recordkeeping requirements for all FDA-regulated foods and not permit exemptions to recordkeeping requirements based on risk classification.

2. Requiring firms that manufacture, process, pack, transport, distribute, receive, hold, or import food to identify and maintain records of CTEs (Critical Tracking Events) and KDEs (Key Data Elements) as determined by FDA.

3. Requiring each member of the food supply chain to develop, document, and exercise a product-tracing plan.

4. Encouraging current industry-led initiatives and issue an Advance Notice of Proposed Rulemaking or use other similar mechanisms to seek stakeholder input.

5. Clear, consistent, and articulate communication to industry of the information it needs to conduct product-tracing investigations.

6. Development of standardized electronic mechanisms for the reporting and acquiring of CTEs and KDEs during product tracing investigations.

7. Accepting summarized CTE and KDE data that are submitted through standardized reporting mechanisms and initiate investigations based on such data.

8. Request more than one level of tracing data, if available.

9. Considering adopting a technology platform that would allow efficient aggregation and analysis of data submitted in response to a request from regulatory officials. The technology platform should be accessible to other regulatory entities.

10. Coordination of trace back investigations and development of response protocols between state and local health and regulatory agencies, using existing commissioning and credentialing processes. In addition, FDA should formalize the use of industry subject matter experts in product tracing investigations.

As the recommendations are evaluated, it becomes apparent that leveraging technology to manage traceability data is the way of the future. The complexity of the supply chain, and the need to link data as food traverses the globe, demands that data be available electronically. IFT recognized that for some firms the transition to a fully electronic system for data capture may be a revolution and encouraged intermediate, evolutionary steps companies could take to improve upon their current approaches.

So what is your current state of traceability? IFT has developed a financial calculator to help companies understand the ROI of traceability. According to IFT, companies generally fit into one of these categories:

- No systematic traceability

- Paper based
  Manual paper-based records of the source, transformation, aggregation, destination, and other associated information

- Basic electronic
  Computerized record keeping of the source, transformation, aggregation, destination, and other associated information

- Integrated hardware
  Integrated hardware (e.g. bar codes and readers, RFID tags and scanners) implemented to capture the source, transformation, aggregation, destination, and other associated information

Because traceability is something that relies on all players within a production system, the global landscape cannot be ignored. The availability of technology, including communications systems, in the developing world has resulted in the development of some very sophisticated traceability systems. In developing countries, budding food companies are not bound to legacy systems, which provides the opportunity to build modern traceability approaches into their businesses from the beginning.

Act Now to Prepare for FSMA

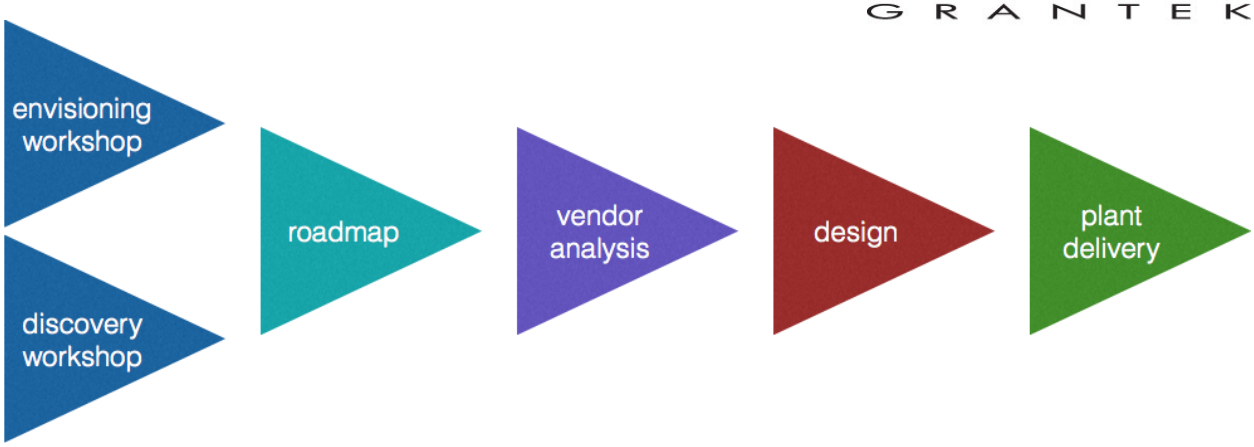
Within a year, FDA is expected to release final rules requiring preventive controls—both for human food as well as animal food. Larger companies will need to be in full compliance a year later. This provides the time needed for companies to evaluate how best to modify their current approaches and systems to achieve compliance.

Between now and the point when compliance is required, companies should identify a multidisciplinary team to read the proposed rules and assess the impact on the company. By working through the process described in the next section, firms can develop a strategic plan to address any needs and plan for any capital expenditures required.

Evolving to Compliance

Grantek believes that the path to compliance is one of evolution, not revolution. Given that the development and maintenance of a strong food safety system requires the support of a multi-disciplinary, inter-departmental team, considerations around enhancements should also include this diverse team—both internally, as well as with the consultants and vendors that aid in developing an approach to move forward. This means partnering with food safety experts, process engineers, and IT professionals

There is a general approach that should be followed when embarking on any new project. As shown in the figure below, Grantek is able to assess where you are and what you need, and objectively provide options to meet FDA objectives in a way that make sense for your company. Grantek is also able to be there with you through every step of implementation.



Discovery / Envisioning

Knowing where you are today and where you need to go to achieve your FSMA objectives is the foundation of a successful plan. Grantek consultants can work with you to understand your baseline environment from a people, process and technology perspective. Grantek can also help you define your future state requirements.

Perform a Gap Analysis

With an understanding of your "as-is," or current state and your desired "to-be," or future state, Grantek consultants can create a clear analysis of the gaps that need to be addressed in order to meet your requirements.

Develop the Business Case

With a clear understanding of the gaps, Grantek consultants can work with you to develop a sound business case around each opportunity, enabling you to understand the size of the opportunities and the required capital to make progress toward achieving your FSMA objectives.

Create the Road Map for Solutions

A clear campaign of one or more executable projects forms the road map that will guide you to your desired future state. Grantek has deep experience implementing projects of this type, and can help you understand the precise steps you need to realize your vision from the plant floor controls through your business systems.

Select Vendors

Selecting the technology that fits your organization is a crucial step in the process. Grantek's consultants have a deep understanding of the technologies available from various vendors, and know the industry standards. Grantek can help you design and execute an appropriate, standards-based vendor selection process so you'll be able to select the right solution with confidence.

Deliver the End Solution

Implementing your plan is essential to meeting your FSMA objectives and realizing the business value from your investment. Grantek's skilled and capable engineers, with deep experience in Manufacturing Information Technology, process control, and electrical engineering, can help you make the vision a reality, whether for a single plant or a worldwide rollout. Typically, Grantek starts with a pilot project or plant, and then deliver the proven solution throughout your enterprise.

Conclusion

FSMA is coming, and change is just around the corner. For some companies, this change will be prompted by FSMA; for others, the change will result from the desire to “up their game” and remain best in class. Regardless of the driver, leading companies are continually on the lookout for ways to enhance their operations while maintaining profitability.

Regulatory compliance is not optional. You need a blueprint for success. Let’s get started on building your future state.