Ensuring Food Safety with Quality Management Software

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FSMA is a First Step Towards Risk-Based, Science-Based Integrated Food Safety & Quality Management

“In a food safety system, decisions about resource allocation need to be made consistently in order to maximize benefits and reduce risks while also considering costs.

Food safety risk managers must consider a wide variety of concerns in their decision making, including the needs and values of diverse stakeholders, the controllability of various risks, the size and vulnerabilities of the populations affected, and economic factors. Although the balancing of diverse risks, benefits and costs is challenging, the lack of a systematic, risk-based approach to facilitate decision making can cause problems ranging from a decrease in public trust to the occurrence of unintended consequences to society, the environment and the marketplace.”

Objectives

You will learn about:

1. Relationships between **standards and guidelines**
   ISO 22000:2015, FSSC 22000, ISO/TS 22002, PRPs, GMPs, and HACCP/HARPC

2. How to **QMS** can ensure consistent and effective processes across sites and processes, and help you make the most of your **CAPA** process

3. Why **internal and supplier communication is critical** for the effectiveness of the quality program

4. What **blockchain** is, and how IBM Food Trust is demonstrating its value and utility right now

5. How to **get started/increase maturity with QMS & FSMS software**
1: Food Safety & Quality

core components, value propositions
“Food **quality** is the extent to which all the established requirements relating to the characteristics of a food are met…

Food **safety** is the extent to which those requirements relating specifically to characteristics or properties that have the potential to be **harmful to health or to cause illness or injury** are met.”


“Classical quality control methods only emphasiz[ing] **hygienic quality** of final products are inadequate to control hazards occurring at early stages of the process.

### Food Protection Risk Matrix

<table>
<thead>
<tr>
<th>Food Quality</th>
<th>Food Fraud</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motivated by economic gain (economically motivated adulteration/counterfeiting)</td>
<td></td>
</tr>
<tr>
<td>Food Safety</td>
<td>Food Defense</td>
</tr>
<tr>
<td>Unintentional</td>
<td>Intentional</td>
</tr>
</tbody>
</table>

The Food Safety Modernization Act (FSMA) Preventive Controls for Human Food (PCHF) Rule **Adds Rigor** to GFSI Recognized Schemes

Things an FSMS can do:
- Establish and maintain a hygienic environment
- Manage preventive controls to reduce nonconformances
- Keep records that detail when activities dictated by those controls were enacted

Things a QMS can do:
- Prevent or reduce recalls
- Reduce defects and variation
- Reduce product loss
- Increase customer satisfaction
- Design and develop new products

**FSMA COMPLIANCE DATES**

From [https://www.lsuagcenter.com/topics/food_health/food/safety/food%20safety%20modernization%20act](https://www.lsuagcenter.com/topics/food_health/food/safety/food%20safety%20modernization%20act)

- Produce Safety Regulation (PS)
- Preventive Controls Human Food (PCOF)
- Preventive Controls Animal Food (PCAF)
- Foreign Supplier Verification Program (FSVP)
- Intentional Adulteration (IA)
- Sanitary Transportation of Food (STF)

**CSPM** = Current Good Manufacturing Practices
**PC** = Preventive Controls
**PMO** = Pasteurized Milk Ordinance

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1. Except for certain provisions concerning written customer assurances. Additional two years to comply with these specific requirements.
2. Except for facilities that only pack and/or hold raw agricultural commodities that are produced and/or handled and shipped. Compliance date for these facilities extended approximately 12 months to match the compliance dates for businesses in the same size categories in the produce safety regulation.
3. Except for facilities that would qualify as a secondary activities farm except that they do not meet the ownership criteria. Compliance date for these facilities extended approximately 2 months to match the compliance dates for businesses in the same size categories in the produce safety regulation.
4. Except for facilities that color raw agricultural commodities. Compliance date for these facilities extended approximately 6 months to match the compliance dates for businesses in the same size categories in the produce safety regulation.
5. Except for facilities solely engaged in the ginning of cotton. Compliance date for these facilities extended approximately 1 months to match the other extension dates that relate to the "farm" definition.
6. Except for the importation of food contact substances. Additional two years to comply with the FSVP requirements.
“Quality assurance has become a **cornerstone of food safety policy** in the food industry [which has] started to implement integrated quality and food safety management systems.”

2: Quality Management for Food Safety

how HACCP/HARPC, ISO 22000, ISO/TS 22002, FSSC 22000, PRPs, GMP & GFSI recognized schemes work together
## GFSI Recognized Schemes

<table>
<thead>
<tr>
<th>Scheme Name</th>
<th>Standard</th>
<th>Date of Recognition</th>
<th>Benchmark Leader</th>
<th>CanadaGAP</th>
<th>AsiaGAP</th>
<th>CanadaGAP</th>
<th>Global Red Meat Standard (GRMS)</th>
<th>PrimusGFS Standard</th>
<th>IFS Logistics Version 1</th>
<th>JFSM</th>
<th>AsiaGAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSSC 22000</td>
<td>Standard: GFSI GFSI-GAP Version 1.2</td>
<td>31/03/2016</td>
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<tr>
<td>SQF Code Ed. 8</td>
<td>Standard: SQF Food Safety Code for Primary Production Version 3.0</td>
<td>10/09/2018</td>
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<tr>
<td>BRC Global Standard for Food Safety</td>
<td>Standard: BRC Global Standard for Food Safety Version 7</td>
<td>05/02/2018</td>
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<tr>
<td>BRC IOP Global Standard for Packaging and Packaging Materials</td>
<td>Standard: BRC IOP Global Standard for Packaging and Packaging Materials and Distribution Version 3</td>
<td>01/05/2018</td>
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<tr>
<td>CanadaGAP</td>
<td>Standard: CanadaGAP Version 3.3</td>
<td>15/03/2018</td>
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<td>Global Aquaculture Alliance</td>
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<tr>
<td>GRS</td>
<td>Standard: PrimusGFS GFSI-GAP Version 3</td>
<td>15/03/2018</td>
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</tr>
<tr>
<td>IFS</td>
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<td>15/09/2018</td>
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<td></td>
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</tr>
</tbody>
</table>

For more information, visit [https://www.mygfsi.com/files/CPO_printable-version_2.pdf](https://www.mygfsi.com/files/CPO_printable-version_2.pdf)

- FSSC 22000
- SQF Code Ed. 8
- BRC Global Standard for Food Safety
- BRC-IOP Global Standard for Packaging and Packaging Materials
- IFS Version 6
- CanadaGAP
- Global Red Meat Standard (GRMS)
- PrimusGFS Standard
- IFS PACsecure Version 1
- IFS Logistics Version 2.1
- JFSM
- AsiaGAP
Incorporation of Quality Management & Continuous Improvement

Guidelines for Food Safety Management Systems

Legally Mandated Requirements for Safety

Antecedents of Safety and Quality

New Mechanisms for Trust & Competitive Advantage

Best Practice

GFSI Recognized Schemes

ISO Standard: ISO22000

Legislation - Food Law

Codex - HACCP Principles - GMP

+ New Science
+ Traceability/Blockchain
+ IFS (QMS+ENV+SR)
+ BRC (FSMS+QMS)
+ SQF Level 3 (HACCP+FSMS+QMS)
+ FSSC 22000 (FSMS)
+ SQF Level 2 (HACCP+FSMS)
+ FDCA (1938)
+ FSMA (2011)
http://www.ecfr.gov
+ PRPs (e.g. ISO 22002)
+ GMPs (e.g. 21 CFR 110)
+ HARBPC (21 CFR 117)
+ SQF Level 1

Source: GFSI: Enhancing Food Safety Through Third Party Certification
Relationship Between EHS, Quality, & Food Safety

EHS role works to keep **WORKERS & THE ENVIRONMENT** safe, without negatively impacting production speed or product quality.

Quality role works to keep **THE PRODUCT** safe, while managing systematic, repeatable processes that satisfy operations goals (e.g. yield) and product quality requirements (e.g. taste, value).
<table>
<thead>
<tr>
<th>TQM</th>
<th>ISO 9000:2000-QMS</th>
<th>HACCP</th>
<th>ISO 22000-FSMS</th>
</tr>
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<tbody>
<tr>
<td>Focus on customer</td>
<td>Customer focus</td>
<td>Hazard analysis</td>
<td>Customer focus</td>
</tr>
<tr>
<td>Leadership</td>
<td>Leadership</td>
<td>Critical control points (CCPs)</td>
<td>Leadership and teamwork</td>
</tr>
<tr>
<td>Involvement of people</td>
<td>Critical limits</td>
<td>Critical limits</td>
<td>Involvement of people</td>
</tr>
<tr>
<td>Process approach</td>
<td>Monitoring procedures</td>
<td>Monitoring procedures</td>
<td>Process approach and food safety</td>
</tr>
<tr>
<td>System approach to management</td>
<td>Corrective actions</td>
<td>Corrective actions</td>
<td>System approach to management</td>
</tr>
<tr>
<td>Continual improvement</td>
<td>Verification procedures</td>
<td>Verification procedures</td>
<td>Continual improvement</td>
</tr>
<tr>
<td>Factual approach to decision making</td>
<td>Documentation procedures</td>
<td>Documentation procedures</td>
<td>Factual approach to decision making</td>
</tr>
<tr>
<td>Reality approaching</td>
<td></td>
<td></td>
<td>Mutually beneficial supplier relationships</td>
</tr>
<tr>
<td>Cooperation with suppliers</td>
<td></td>
<td></td>
<td>Legislation, regulations</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Science and experience</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Interactive communication</td>
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<td></td>
<td></td>
<td>Interactive communication</td>
</tr>
</tbody>
</table>

Table 1. The Principles of TQM, ISO 9000:2000-QMS, ISO 22000-FSMS and HACCP

Table 2. Some quality processes and prerequisite programs

<table>
<thead>
<tr>
<th>Strategic</th>
<th>Operational</th>
<th>Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>QP.1 Market Research and Customer Relation</td>
<td>QP.6 Product Design</td>
<td>QP.8 Purchasing</td>
</tr>
<tr>
<td>QP.2 Internal Communications</td>
<td>QP.7 Food Manufacturing</td>
<td>QP.9 Internal Audit</td>
</tr>
<tr>
<td>QP.3 Document and record Control</td>
<td>QP.10 Data Analysis</td>
<td>QP.11 Maintenance of measurement’s and process equipments</td>
</tr>
<tr>
<td>QP.4 Planning</td>
<td>QP.12 Calibration of measurement’s equipment</td>
<td></td>
</tr>
<tr>
<td>QP.5 Resources Management</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Q: Quality Process, PR: Pre-requisite

Risk-based thinking is introduced to make better decisions in uncertain environments:

- Reduce frequency of losses
- Reduce likelihood of losses
- Reduce costs of losses
- Improve response time
- Reduce stress
- Increase communication
- Enhance learning
- Capture opportunities for improvement

FSMA Cornerstone is Food Safety Plan (FSP)

HACCP is an internationally recognized standard for hazard analysis to:

- Ensure sanitary conditions for manufacturing, processing, packaging and storage
- Prevent post-process contamination
- Deliver safe, wholesome food with no visible deterioration in quality

HARPC is a FSMA-driven update to HACCP that:

- Adds risk-based thinking and risk management
- Emphasizes the need to continuously monitor and improve GMPs and PRPs

HACCP

Assumes PRPs in place

- Process Controls
  - Cooking, refrigeration
  - Controls during storage or transport
- Biological, Chemical, & Physical Hazards

HARPC

Assumes no PRPs in place

- Supply Chain Controls
- Allergen Controls
  - Cross-contact & labeling
  - Sanitation Controls
- Radiological (e.g. contaminated soil)
- Economically Motivated (e.g. fillers)

GMPs are regulated and PRPs are not; 21 CFR Part 117 specifies required GMPs
Food fraud, under FDA, only addresses hazards that would impact food safety; intentional sabotage by an insider must also be considered
You can refer to all Preventive Controls in your FSP as Critical Control Points
Food Safety Plan Parameters/Values can be categorical (Pass/Fail) – unlike CCPs
Table 4
Hazard analysis of ice cream conducted in the MAZFORD.

<table>
<thead>
<tr>
<th>Process steps</th>
<th>Hazards</th>
<th>Types Causes (5 M’s)</th>
<th>P×S</th>
<th>Preventive measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reception</td>
<td>Physical: foreign bodies (wood, hair, etc.)</td>
<td>C</td>
<td>5</td>
<td>Yes Yes No Yes Yes Visual inspection</td>
</tr>
<tr>
<td>Pasteurization</td>
<td>Biological: pathogenic microorganisms</td>
<td>P</td>
<td>5</td>
<td>Monitoring of time and temperature of pasteurization (80°C/25s)</td>
</tr>
<tr>
<td>Cooling</td>
<td>Biological: pathogenic microorganisms</td>
<td>M</td>
<td>5</td>
<td>Monitoring of temperature and time profile of cooling post-pasteurization (4°C within 1.5 h)</td>
</tr>
<tr>
<td>Flavour and colourant addition</td>
<td>Physical: foreign bodies (hair...)</td>
<td>C</td>
<td>1</td>
<td>Staff hygiene control. Respect cleaning and disinfection programme PRP</td>
</tr>
<tr>
<td>Flavour and colourant addition</td>
<td>Biological: pathogenic microorganisms</td>
<td>C</td>
<td>5</td>
<td>Control of expiry date before use. Staff hygiene control. Respect cleaning and disinfection programme PRP</td>
</tr>
<tr>
<td>Aging</td>
<td>Biological: pathogenic microorganisms</td>
<td>M</td>
<td>5</td>
<td>Monitoring of time and temperature of aging (4°C/24 h)</td>
</tr>
<tr>
<td>Freezing with air incorporation</td>
<td>Chemical: air compressor oil</td>
<td>C</td>
<td>1</td>
<td>Calibration of centrifugal machine and change of de-oiling filter of air compressor periodically PRP</td>
</tr>
<tr>
<td>Packaging/labelling</td>
<td>Chemical: packaging materials substances</td>
<td>C</td>
<td>2</td>
<td>Filtration and sterilization of air incorporated                                    PRP</td>
</tr>
<tr>
<td>Packaging/labelling</td>
<td>Biological: pathogenic microorganisms</td>
<td>C</td>
<td>5</td>
<td>Specifications of packaging materials.                                             PRP</td>
</tr>
<tr>
<td>Packaging/labelling</td>
<td>Physical: foreign bodies (wood, hair, etc.)</td>
<td>C</td>
<td>1</td>
<td>Implementation of GHP. Staff hygiene control. Specifications of packaging materials. Storage in controlled area PRP</td>
</tr>
<tr>
<td>Hardening</td>
<td>Allergens: milk proteins, lactose</td>
<td>C</td>
<td>2</td>
<td>Mention of allergen on label. Staff training and label inspection. PRP</td>
</tr>
<tr>
<td>Hardening</td>
<td>Biological: pathogenic microorganisms</td>
<td>C</td>
<td>5</td>
<td>Regular cleaning and disinfection.                                                 PRP</td>
</tr>
<tr>
<td>Storage of ice cream</td>
<td>Biological: pathogenic microorganisms</td>
<td>M</td>
<td>5</td>
<td>Monitoring of refrigerator temperature (≤ −18°C)</td>
</tr>
<tr>
<td>Transport</td>
<td>Biological: pathogenic microorganisms</td>
<td>M</td>
<td>5</td>
<td>Monitoring of ice cream transport truck temperature (≤ −18°C)</td>
</tr>
</tbody>
</table>

a 5 M’s, Material (raw), Machine (technology), Mother Nature (environment), Man power (physical work), Method (process).
b P, probability.
c S, severity.
d The five questions can be found in Fig. 2.
e Q, Question.
f C, Contamination.
g M, Multiplication.
h P, Persistence.

Is it a CCP, PRP, or oPRP?

A Decision Tree

Fig. 2. Decision tree for HACCP implementation adopted from Hordner et al. (2006).


From https://www.safefood-online.de/en/download.php?id=15
The Process is the Centerpiece

Preventive Controls form the basis of the control plan, from which individual records regarding monitoring requirements are identified.

Traceability can be assured by examining all steps of the process and devising a recordkeeping process that incorporates all factors from PCs.

(Traceability does not span full supply chain)
FMEA Can Be Used to Identify PCs

Table 4
Abstract of HACCP plan with integrated FMEA preventive actions

<table>
<thead>
<tr>
<th>Phase</th>
<th>Hazard</th>
<th>FMEA preventive actions</th>
<th>HACCP control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wafer cooling</td>
<td>Anomalous aspect (colour, shape, etc.)</td>
<td>Operative instructions about cooling parameters and controls</td>
<td>Visual inspection by group lead</td>
</tr>
<tr>
<td>Primary packaging</td>
<td>Incorrect propriety of stamped data</td>
<td>Definition of stamp life and periodical substitution</td>
<td>Visual inspection by group lead</td>
</tr>
<tr>
<td></td>
<td>(shelf-life, special information)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary packaging</td>
<td>Inadequate package shape and integrity</td>
<td>Preventive control of integrity and position of wrapping paper reel</td>
<td>Visual inspection by group lead</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Operative instructions of wrapping paper calibration</td>
<td></td>
</tr>
</tbody>
</table>
“HACCP areas posing the greatest risk to food safety were verification, recordkeeping and correction action. Nonconformities were found in HACCP systems which worked for several years. This raises the question whether food producers who implemented HACCP system really guarantee complete food safety… incorporation of FMEA within the verification procedure of HACCP system may be a convenient tool for better food safety assurance.”

3: Importance of Communication

maintaining transparency and visibility across organizational boundaries in the supply chain can prevent errors & disasters
“An on-site audit [requires gathering up-to-date information,] communication of results and [sharing] observations among team members and with the auditee.”

“QMS can reduce the appearance of defective products… improve internal communication, increase customer’s satisfaction, and therefore [market share, increasing] opportunities for expansion in new markets.”

Quality Events indicate that quality & food safety goals are not being met and action is needed.

- Nonconforming product
- Incidents/near misses
- Customer complaints
- Recalls/warranty calls
- Deviations (from SOP)
- Out-of-control Action Plans
- Industry-specific events (e.g. recalls)

Flowchart:

- Serious or systematic?
  - yes → CAPA
  - not really → containment
Quality Controls

to prevent or correct unwanted or unexpected change →
stability and consistency

• Calibrations
• Maintenance
• Inspections
• Allergen & sanitation controls
• Supply chain controls
• Process validation
• Mistake-proofing
• In-situ process monitoring
• Environment monitoring
• Professional testing/competency assessment
• Training programs and reminders
• Corrective actions taken
• Information security/network security
Corrective Actions are the Core

Many different kinds of corrective actions are required to maintain food safety and quality, while continuously improving:

- Supplier CAR
- Customer CAR
- CAR for nonconforming product
- CAR for deviation(s) from process
- CAR for inadequate PRP
- CAR for allergen or sanitation issue
- CAR for supply chain controls
- CAR for inadequate/ineffective CCP/PC
- Internal Audit CAR
- Supplier Audit CAR

Table 4.8 Activities through which top management shall ensure the improvement of the system and examples of those activities

<table>
<thead>
<tr>
<th>Activities</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>Ensure that there is sufficient external information available to update the FSMS. Guarantee that issues that have an impact on food safety are communicated with personnel.</td>
</tr>
<tr>
<td>Management review</td>
<td>The output of the FSMS performance evaluation should include decisions for its improvement. New food safety objectives and updated food safety policy.</td>
</tr>
<tr>
<td>Internal audits</td>
<td>Results from internal audits shall be discussed in the management review or even force the management to take immediate action (corrections or corrective actions) related to the identification of nonconformities.</td>
</tr>
<tr>
<td>Evaluation of individual verification results</td>
<td>Review of the training plan or PRP(s) found necessary after results of the verification activities.</td>
</tr>
<tr>
<td>Analysis of results of verification activities</td>
<td>Take action after identifying a trend that can generate potentially unsafe products.</td>
</tr>
<tr>
<td>Validation of the combinations of control measures</td>
<td>Change control measures or define new combinations when validation fails to prove its effectiveness.</td>
</tr>
<tr>
<td><strong>Corrective actions</strong></td>
<td>Take actions to eliminate the cause of a nonconformity and guarantee that the problem is not repeated in the future.</td>
</tr>
</tbody>
</table>


Figure 4.8 Management review input information and output decisions.
“An accurate and complete transmission of information between the food chain and external stakeholders will ensure, in a more efficient way, the identification and control of all relevant risks to food safety.”

- Share information about food safety throughout the food chain and inside the organization
- Inform the Food Safety Team (FST) of any change that may compromise food safety
- Provide faster update(s) and distribution of new documentation, [provides automatic] evidence of [changes]…

4: Emerging Technologies for Traceability

how IBM Food Trust has demonstrated that Hyperledger blockchain can add value in this industry
Traceability


**Fig. 1.** Drivers for traceability of food supply chain.
Blockchain Depends on Hashing

- Convert an object to a sequence of letters and numbers from which you can’t recover the original object
- Lots of hashing algorithms:
  - MD5, SHA1, CRC32, SHA256, SHA512, XXHASH32, MURMUR32
- Goal is to “minimize collisions”

```r
> phrase <- "Here is my password"
> digest(phrase, "crc32")
[1] "61835063"
> digest(phrase, "murmur32")
[1] "611907fc"
> digest(phrase, "md5")
[1] "6303034c25d4e1763f2dd30341ddb0d5"
```
Hash My Cat

> kitty <- readJPEG("kitty.jpg")
> digest(kitty, "sha256")

[1]
"dcd239ba6a09080eb61b7310a5428753f63d05ae2b282bf81dc0182f7552f60d"
Hash My Cat
Small changes in an object ➔

Large change in a hash ➔

“Break” a blockchain

```perl
> digest(kitty, "sha256")
[1]
"dcd239ba6a09080eb61b7310a5428753f63d05ae2b282bf81dc0182f7552f60d"

> digest(kitty2, "sha256")
[1]
"dcd239ba6a09080eb61b7310a5428753f63d05ae2b282bf81dc0182f7552f60d"

> digest(kitty3, "sha256")
[1]
"fe5791ee490693d7d7b25379278b2374c3ada25c76aec5f3aa17e7e8b184362"

> digest(kitty4, "sha256")
[1]
"dcd239ba6a09080eb61b7310a5428753f63d05ae2b282bf81dc0182f7552f60d"
```
Blockchain Data Structure

Blockchain Value Propositions

- Immutable record of peer-to-peer transactions
- Relief from a central authority
- Transparent recordkeeping
- Private channels to protect data privacy
- Immediately auditable

Requires modeling:
- Participants
- Assets
- Transactions
- Conditions for Transactions ("Smart Contracts")
“… in the end it is all about how organizational insights and knowledge are turned into strategic insights and advantage.”

-- Harry Hertz, Director Emeritus Baldrige Performance Excellence Program
5: Advancing Your EHSQ Maturity with Software

moving to the next level
<table>
<thead>
<tr>
<th>Information Management Tools</th>
<th>Streamlined, Centralized, Web-Based Management System</th>
<th>Word Processor, Spreadsheets, Sharepoint (or equivalent)</th>
<th>Paper</th>
<th>Little to No Documentation (no defined system)</th>
<th>Food Safety Management System (FSMS)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Somewhat Prepared (adopt a FSMS)</td>
<td>Unprepared</td>
<td>Very Unprepared</td>
<td>Extremely Unprepared</td>
<td>No Food Safety Management System</td>
</tr>
<tr>
<td></td>
<td>Somewhat Prepared (adopt a FSMS)</td>
<td>Unprepared</td>
<td>Unprepared</td>
<td>Somewhat Prepared</td>
<td>Ad Hoc System Partial Structure</td>
</tr>
<tr>
<td></td>
<td>Very Well-Prepared</td>
<td>Somewhat Prepared</td>
<td>Somewhat Prepared</td>
<td>Meets Minimum Standard</td>
<td>SQF Level 1 &amp; 2 HACCP-based Methodology</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Somewhat Prepared</td>
<td>Somewhat Prepared</td>
<td>SQF Level 3 or equivalent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

## Software Support for Food Safety & Quality

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Application Type</th>
<th>Tasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Control &amp; Training Management</td>
<td>Document Control &amp; Training Management</td>
<td>Always know which SOPs and work instructions are current, manage review and approval paths, make sure your PCQI(s) have up-to-date qualifications (21 CFR 117.8), see which staff need to be updated</td>
</tr>
<tr>
<td>Internal Audits</td>
<td>Audit &amp; Inspection Management</td>
<td>Maintain checklists for ensuring PRPs/GMPs are met, manage and monitor inspections, monitor allergens, monitor process controls (e.g. cooking), keep track of receiving and loading</td>
</tr>
<tr>
<td>Maintain HACCP/HARPC Controls &amp; Records</td>
<td>Process Hazard Analysis; Control Plan; Monitoring &amp; Measurement</td>
<td>Identify process steps, hazards, and control plans; record calibration, maintenance, inspection, and preventive controls tasks</td>
</tr>
<tr>
<td>Manage Nonconformances &amp; Complaints</td>
<td>Nonconformance Reporting (NCR); Customer Complaints</td>
<td>Track customer, internal, and supplier corrective nonconformances &amp; complaints; automatically escalate according to rules &amp; remind people when tasks and actions are upcoming or overdue</td>
</tr>
<tr>
<td>Manage Corrective Actions &amp; Corrections</td>
<td>Corrective and Preventive Action (CAPA)</td>
<td>Track customer, internal, and supplier corrective actions and identify trends and patterns; keep track of minor (non-event) Corrections</td>
</tr>
<tr>
<td>Supplier Preventive Controls</td>
<td>Supplier Relationship Mgmt, Supplier CAPA</td>
<td>See which suppliers have failed audits, expired documents, or corrective actions that need attention; provide supplier portals</td>
</tr>
<tr>
<td>Change Management</td>
<td>Management of Change (MoC)</td>
<td>Keep track of improvements and adjustments to processes and preventive controls; validation, verification, continuous improvement</td>
</tr>
</tbody>
</table>
Step 1: Computerization & Connectivity

Step 2: Visibility & Transparency

Step 3: Predictive Capability

Step 4: Adaptability & Self-Learning
Step 1: Computerization & Connectivity

Step 2: Visibility & Transparency

Step 3: Predictive Capability

Step 4: Adaptability & Self-Learning
Sonduren Fanarredha
Sr. Product Marketing Manager, Quality & Supplier
Moderator

INTELEX
Challenges Now & in the Future

1. **Siloed data is insufficient** to identify trends and make informed decisions using real time insights within the organization and its supplier ecosystem.

2. Ensuring all operations are in **Compliance** with ever changing standards, industry requirements and regulations.

3. **Reduced Productivity** due to disparate systems and lack of integration between processes in the organization and through suppliers.

4. Difficult to build a **Culture of Quality** without the right tools and partners.

*Source: Intelex Quality Survey December 2016*
Intelex is the leader in EHSQ software

Most organizations begin their EHSQ journey with the objective of compliance in mind. Intelex helps you achieve more than compliance and cost avoidance by accelerating your EHSQ maturity progression, leading to business transformation.
The Intelex Platform

The most powerful EHSQ platform on the market, it provides a robust and secure backbone to the Intelex system and the core management functionality upon which all Intelex solutions are built.

The Intelex Platform comes complete with the following components standard with every implementation:

<table>
<thead>
<tr>
<th>Mobile &amp; Offline Capability</th>
<th>Business Intelligence &amp; Analytics</th>
<th>Translation Workbench</th>
<th>Document Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>EHSQ Community</td>
<td>API Access</td>
<td>Root Cause Analysis</td>
<td>Communications Management</td>
</tr>
<tr>
<td>Meetings Management</td>
<td>Audit Trail</td>
<td>Electronic Signatures</td>
<td>Single Sign On (SSO)</td>
</tr>
<tr>
<td>Data Import Tool</td>
<td>Navigator</td>
<td>Image Mapping</td>
<td>Support &amp; Learning Portal</td>
</tr>
</tbody>
</table>
Intelex QMS & Platform
Modernize and simplify your QMS

Alliance
Leverage the power of Engagement and Collaboration to unlock the full potential of your QMS

Integrated QMS
Integrated EHSQ solution to connect applications across our platform for a fully automated and tailored experience

Rich Reporting
Use preformatted and custom reports, graphs and scorecards for at-a-glance insights on all aspects of your business.

Mobile
Streamlined and simple user interface on mobile to put Intelex into the hands of people that matter most

Power of Cloud
Our cloud based EHSQ solution provides quick implementation time and cost savings

Intelex is the only EHSQ software with a truly integrated quality management system to help you manage the breadth of your business
What leading companies do differently from the rest

% of respondents (n = 2,135)

Ensure digital strategy is aligned with corporate strategy

Exercise high level of strategic response to digital change in:

- Products, distribution: 86 Winners, 11 Others
- Eco-systems: 78 Winners, 11 Others
- Processes: 80 Winners, 21 Others
- Supply chains: 70 Winners, 22 Others

Avoid pitfalls in organization and culture

- Have siloed mind-sets and behavior: 9 Winners, 38 Others
- Lack a common culture across business units: 10 Winners, 24 Others
- Lack a common view of their customers across the organization: 16 Winners, 24 Others

Transform to Survive

McKinsey & Company
Angelica Lauriano - Panelist
Senior Account Executive – Food & Beverage
Intelex Technologies
Angelica.Lauriano@Intelex.com
LinkedIn: Angelica Lauriano
760-500-8066
Food Safety & Quality Management Software
Easy Data Entry Mobile App

Access Intelex, any time, any place

All the power of Intelex in your pocket

Capture EHSQ data in the moment

Personalized tasks and insights
New Inspection

Questions

1. Have you identified your core business processes and associated systems?

2. Do you have a documented quality policy and defined how it is reviewed?

   - NA
   - Yes
   - No

3. Do you have a quality manual that covers the requirements of ISO 22000?

4. Have all staff who can affect quality been trained in the requirements of ISO 22000?

5. Are there appropriate records for training, skills and qualifications?

6. Does the work environment meet all regulations and guidance in ISO 22000?

7. Are there appropriate systems to record non-conformances and their causes?

8. Are there systems in place to ensure that additional training has been provided where appropriate?

9. Have you reviewed your own internal audit procedure and made any necessary adjustments?

10. Have you reviewed the standard operating procedures and made any necessary adjustments?
BRC Audit - Findings

Critical Findings by BRC Clause

Location: Corporate

Tuesday, October 17, 2017 11:04:02 AM (UTC-05:00) Eastern Time (US & Canada) by Jeremy Mawson
Critical Findings by BRC

Clause

Open Audits | Average Audit Score | Open Findings | # of Critical Findings (last 30 Days)
---|---|---|---
6 | 69.88% | 11 | 14

BRC Audit Scores by Location

- Atlanta Plant: 80.79%
- Chicago Plant: 89.47%
- Greenville Plant: 68.42%
- Savannah Plant: 91.23%
- Toronto Plant: 84.21%

Audit Findings by Criticality

- Minor: 4
- Major: 3
- Critical: 14
Established in 1992
Over 1,300 global customers
Over 1.6 million users and counting
Peer reviewed as best managed company
Over 520 awesome employees
Leaders in the community locally and globally
Awards & Recognition

INTELEX

BEST MANAGED COMPANIES
GREAT PLACE TO WORK
PROFIT 500
SME
CANADA'S TOP SMALL & MEDIUM EMPLOYERS
Technology fast 50
Deloitte
GREEN 30
2013
The Green 30
By Ann Hebb

AON
BEST EMPLOYER
PLATINUM | CANADA | 2016
BEST SMALL & MEDIUM ORGANIZATIONS

GREAT PLACE TO WORK
FOR WOMEN

GREAT PLACE TO WORK
BEST SMALL AND MEDIUM EMPLOYERS IN CANADA

Bracham 300
2016 Edition
Canada's Top ICT Companies

LEADERSHIP ORGANIZATION 2015
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