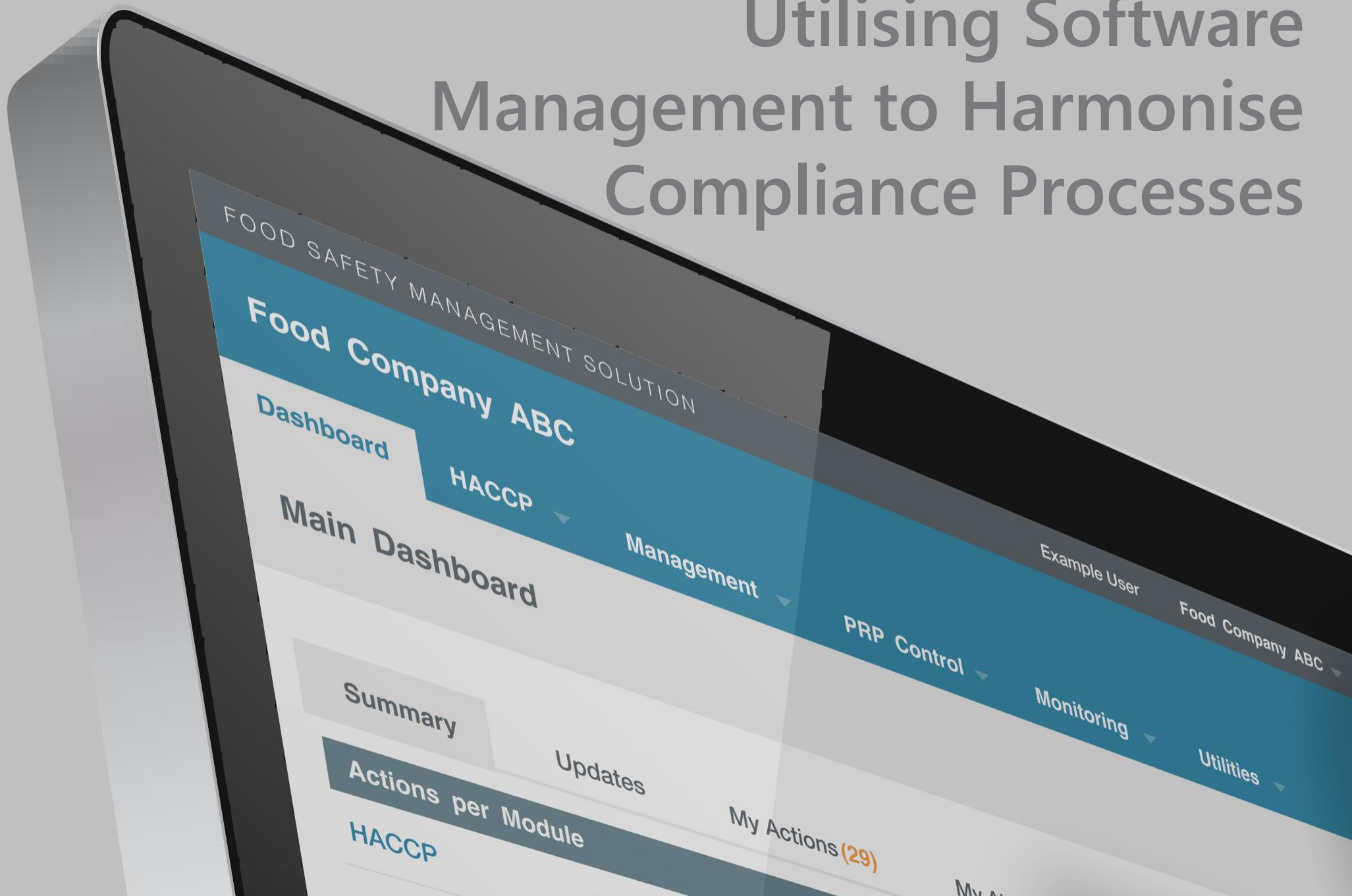
Presentation

Utilising Software Management to Harmonise Compliance Processes



Safefood 360°

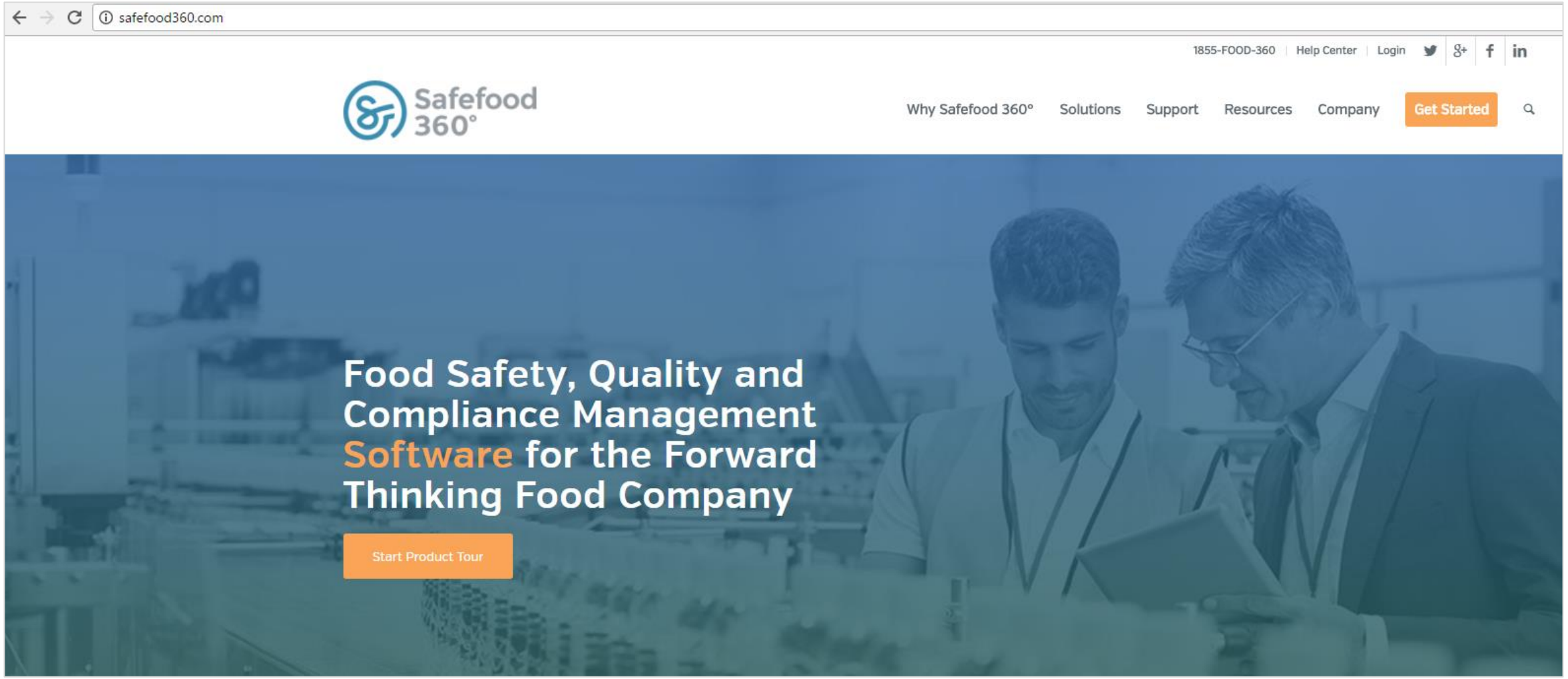
Introduction to Safefood 360

Utilising Software Management to Harmonise Compliance Processes

What is Safefood 360°

Utilising Software Management to Harmonise Compliance Processes

http://safefood360.com/free-resources/



Utilising Software Management to Harmonise Compliance Processes

http://safefood360.com/free-resources/

- Whitepaper

Introduction

Utilising Software Management to Harmonise Compliance Processes

Introduction

The Modern Food Business

- Increasing burden of compliance requirements
- Complexity of the food supply chain
- More demanding regulatory framework

Food Safety and Quality Compliance

- Characterised by a mixed and layered collection of solutions and platforms
- Financial and human resources – maintenance
- Lagged behind other business processes e.g. financial control, stock control, ERP, MRP etc.
- Technical compliance is the poor relation of the business process family

Emerging Thinking

- Compliance processes tend to be defined and repetitive
- Contain a high content of non-value adding activities
- Require high level of human input to maintain
- *Lend themselves very well to management software, but…*

Typical Compliance Process

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Typical Compliance Process in a Food Business

Food Safety & Quality Management

Define Compliance Requirement

- Legislation
- Customers
- Global Standards
- Business needs

Implement Process

- Design and develop process which meet the requirement
- Implement processes

Collect Data

- Processes generate data
- Data collection
- Data analysis
- Records

Verify / CAPA

- Confirm you are doing what you say you are doing
- Corrective actions
- Preventive actions

Improvement

- Efficiency
- Validation
- Review

What Are The Problems?

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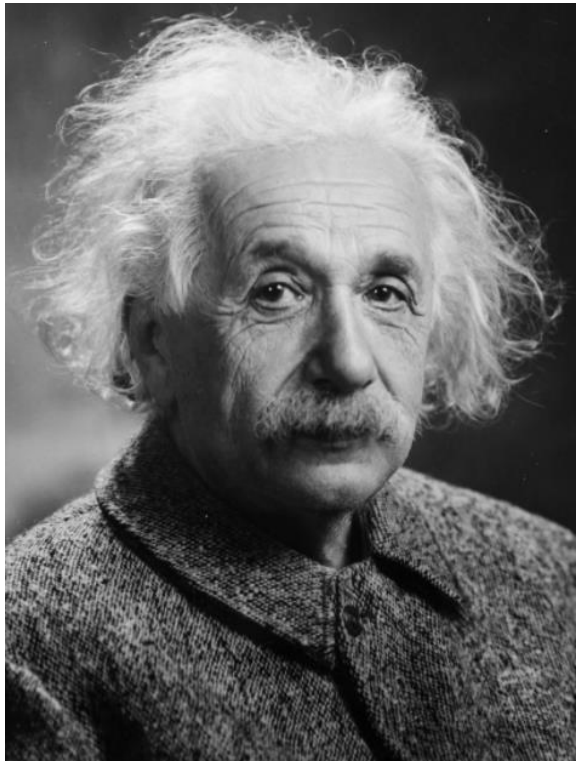
What are the Problems?



Albert Einstein

"If I had an hour to solve a problem, I'd spend 55 minutes thinking about the problem and five minutes thinking about solutions"

Supplier & Material Assessment Process (SQM) - Example

The following are the typical steps conducted a food business under a Supplier Quality Management (SQM) process

Assessment Details
- Details of the Supplier and Material itself

Data Collection
- Questionnaire
- Certificates
- Statements
- Specifications
- Hazard Data

NC & CAPA
- Missing or incomplete data / documents

Risk Assessment (without Controls)
- Based on data collected
- Risk assessment of supplier
- Supplier site
- Ingredients
- Materials
- Criteria Required

Determination of Control
- Appropriate Control Measures are determined
- Decision Trees
- Criteria

Control Planning
- Controls are built out (Verification Programs)

Risk Assessment (with Controls)
- Additional risk assessment following the identified controls to ensure risk is mitigated to an acceptable level

Approval
- Supplier and or Material is approved
- Suppliers List is updated

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Supplier & Material Assessment Process

Problems and Challenges experienced by food businesses when maintaining compliance processes like SQM

Assessment Details
- Time to define data required
- Emails
- Phone calls

Data Collection
- Time and methods to collect the required data?
- Emails
- Portals

NC & CAPA
- Time and methods to obtain missing or incomplete data / documents
- Non-standard data
- Driving of the process, who, when etc

Risk Assessment (without Controls)
- Time and methods to conduct risk assessment
- How to define appropriate models for various suppliers, plants, materials etc.

Determination of Control
- Time and methods to determine controls
- Appropriate models
- Linking to HACCP and PCP plans
- Verification
- Validation

Control Planning
- Time and methods to implement systems, data collection

Risk Assessment (with Controls)
- Time and methods

Approval
- Defining what is approval
- Conditional approval
- Linking to other software systems e.g. ERP
- One version of the truth

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Summary of the Problems

Time
- Time on non-value adding activities
- Emails
- Phone calls
- Site visits

Human Element
- Processes driven by human intervention
- Manual / semi-manual systems
- Errors

Pull, Not Push in Nature
- Systems need to be pulled towards compliance
- When, who, what needs to be done?
- Finding your data

Non-Standardisation
- No clear, verifiable process for all
- Variation from person-to-person or site-to-site

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Summary of the Problems

"Creep"

- Over-time small but accumulated changes in processes lead to major issues
- Cannot be detected without audit

Increased Complexity of Systems

- More compliance demands
- Variations (e.g. geographic, business units)

Lack of Oversight

- Significant time, energy and expenses to determine what is happening now
- Visibility of what is missing, tasks, CAPA's, audits

Lack of Integration

- Multiple and layered solutions
- Manual, semi-manual and automatic

How Utilising Software Management Systems May Help

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Supplier & Material Assessment Process

How utilising software may help to solve problems and improve efficiency

Assessment Details

- Reduces time and errors in collecting and profiling suppliers and materials initially

Data Collection

- Automates the process of collecting and renewing the collection of data and documents
- Drives work via notifications, alerts and escalations

NC & CAPA

- Automates the process of CAPA management and collaboration with suppliers and other parties
- Drives work via notifications, alerts and escalations

Risk Assessment (without Controls)

- Helps to standardise models and criteria for RA
- Central control of models used locally
- Standardise hazard identification and risk rating

Determination of Control

- Standardises appropriate and validated controls for addressing specific risks

Control Planning

- Digital collection of control data for compliance

Risk Assessment (with Controls)

- Best practice for measuring risk mitigation

Approval

- Automatic and real time approved suppliers and materials based on defined business processes
- Reduced consumer and business risk

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How Utilising Software Management Systems Helps

Standardisation

- Define what and how processes are to be completed
- Controlled software platforms
- Drives root cause – systemic failure is always better to drive improvement

Oversight

- Know what is happening – overview and specific
- Real-time dashboards, scorecards

Pushing the Work Required

- Notifications
- Alerts
- Escalations

Current Compliance

- As standards and requirements change, system can be updated quickly

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How Utilising Software Management Systems Helps

Reduction in 'Creep'
- Standard platform
- Change is visible at local level

Analysing & Reports
- Data is quickly analysed to drive compliance every day
- Improvement

Integration
- All modules for compliance
- With other ERP systems

Workflows
- Configurable workflows
- Aligned to compliance and nest practice

Portals
- Supplier / Site Facilities / 3PM
- Internal Auditors

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Benefits

Time
- Reduction in time spent on non-value addicting activities
- Emails, call and visits
- Looking for data, documents and information

Compliance
- Day to day compliance
- Avoiding the pre-audit frenzy

Improvement
- Getting to the source of issue quickly – root cause
- Improvement part of normal business culture

Efficiency
- Portals save time, cost and failures
- Improvements deployed in a system and real-time way and across the business

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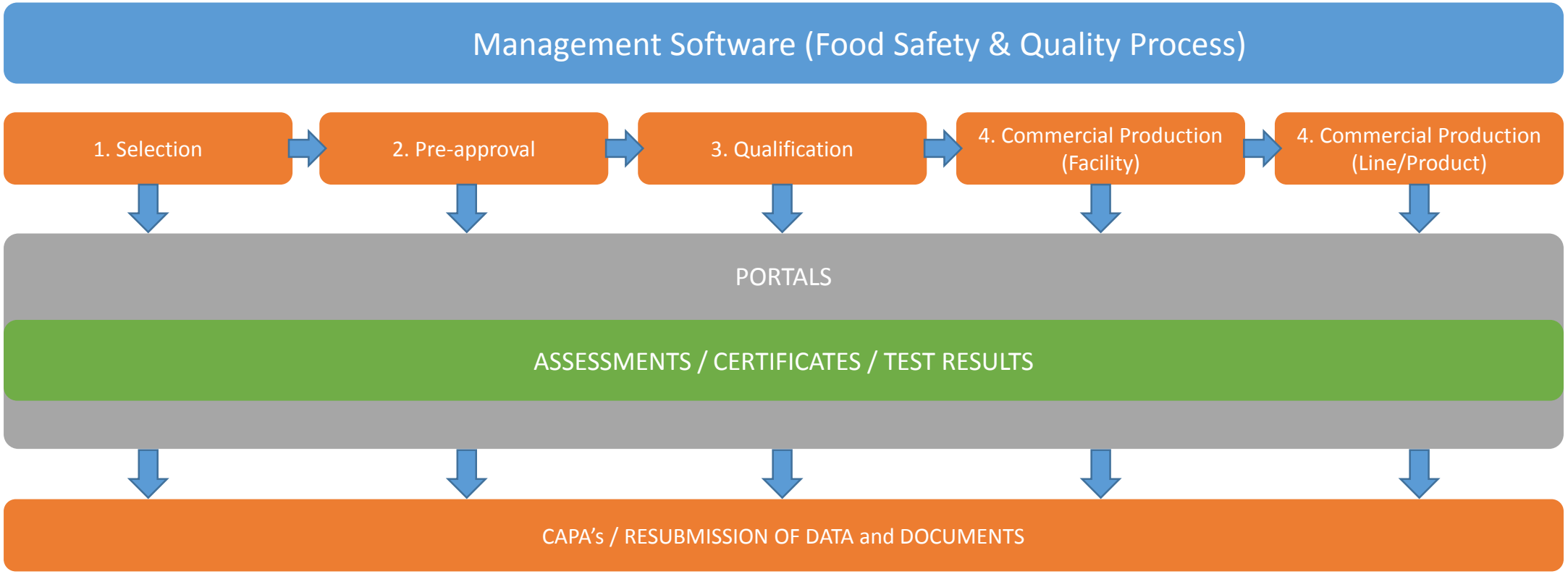
Sample Facility Qualification & Approval Process



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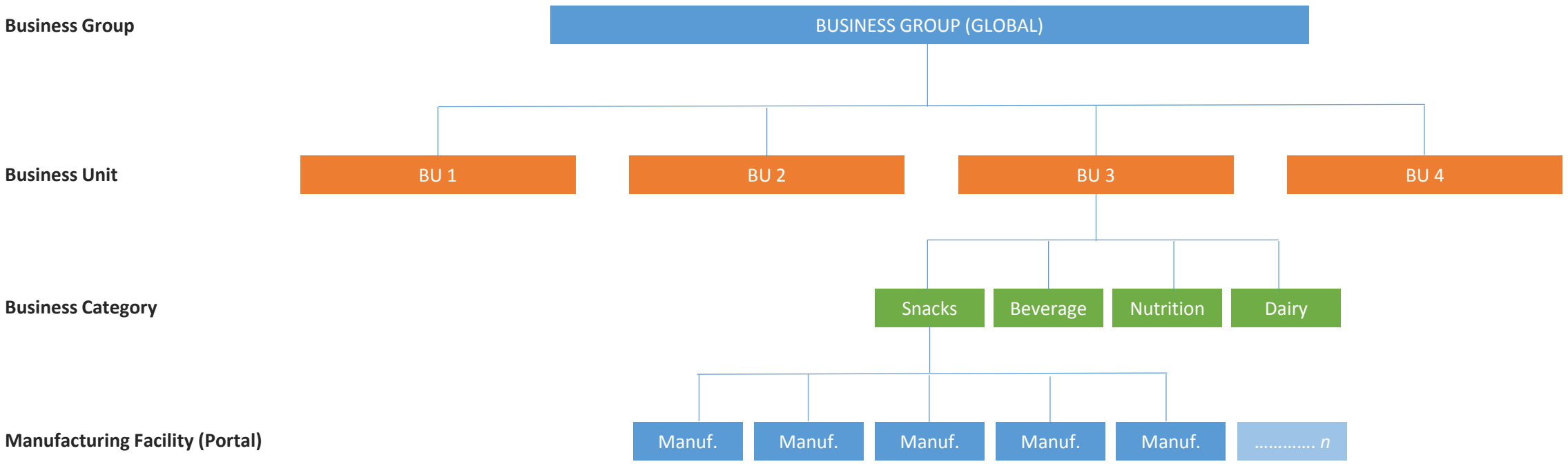
Scaling Software Solution to Meet Your Needs



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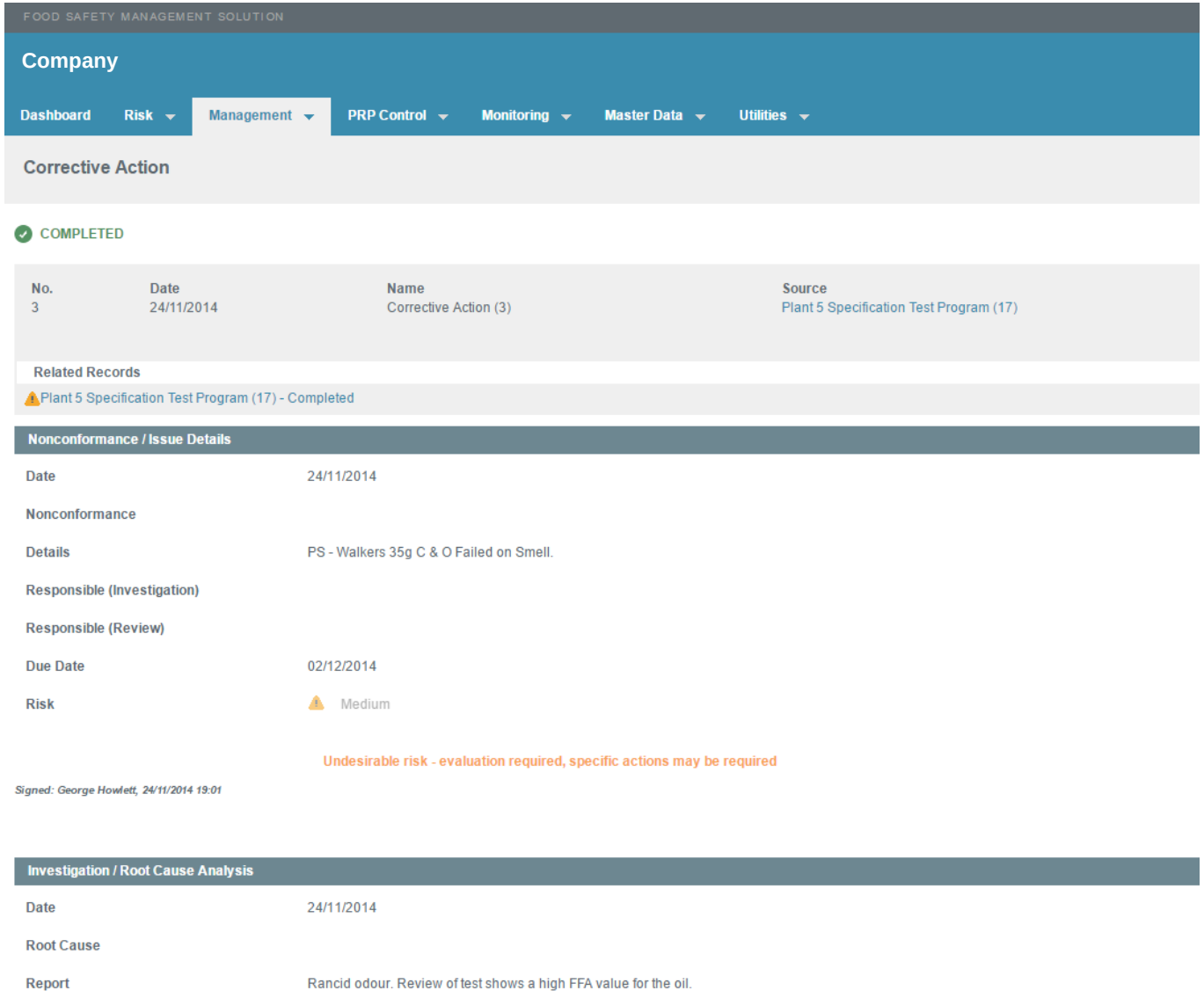
Workflows



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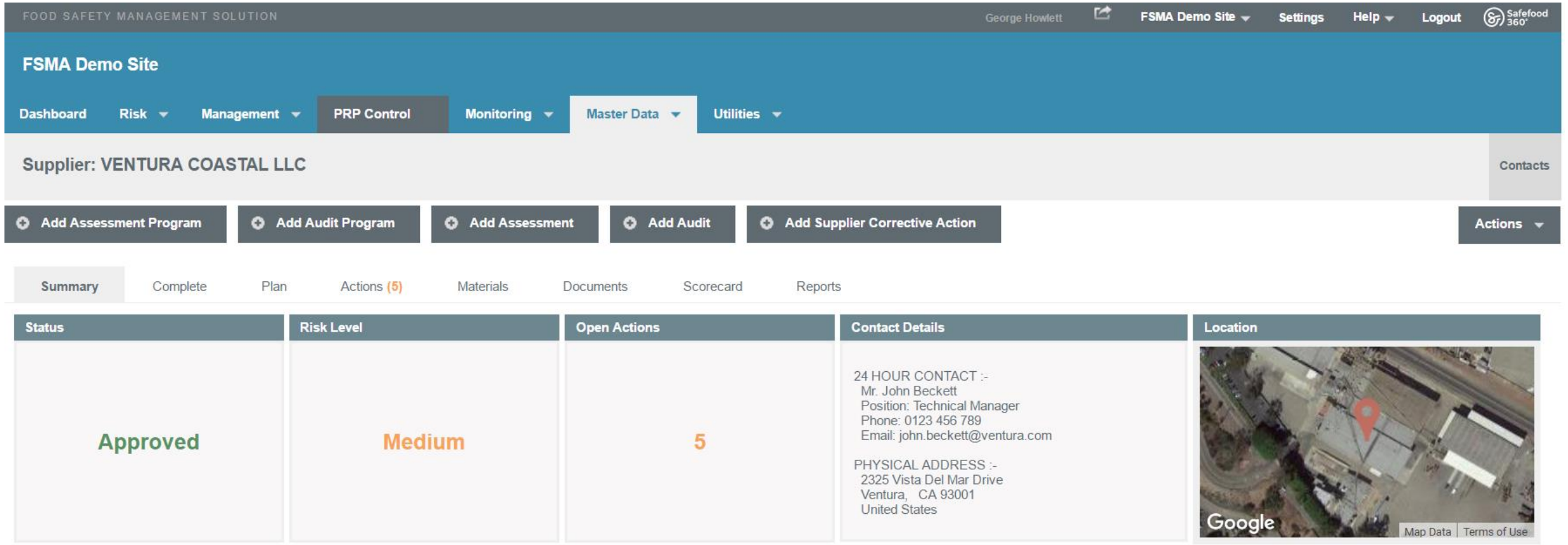
Dashboards



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Scorecards

Summary | Complete | Plan | Actions (5) | Materials | Documents | **Scorecard** | Reports

Report Range	Report Rating	Status	Risk Rating	Portal User
12 Months 22-May-16 to 22-May-17	87.5%	Approved	Medium	Yes

Contact Details

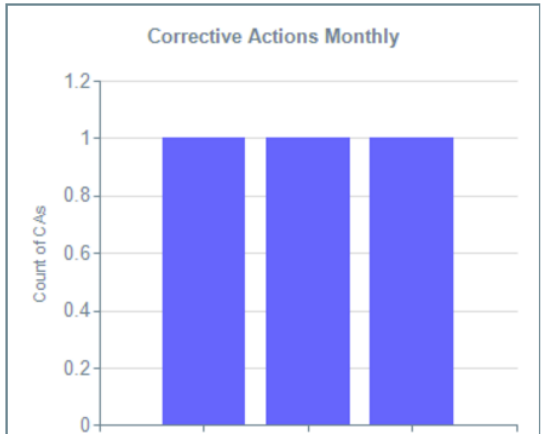
VENTURA COASTAL LLC

Main Contact: John Beckett

2325 Vista Del Mar Drive
Ventura,
United States
United States

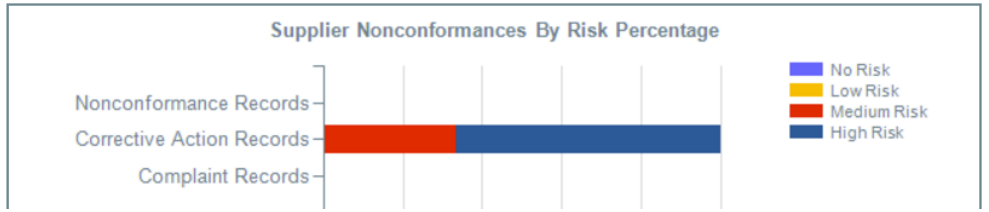
Supplier Rating Details

Category	Count	Fail	Rating %
Receiving	0	0	
Corrective Actions	3		87.0%
Complaints	0		100.0%
Audit	0	0	
Assessment	3	0	100.0%
Certification	0	0	
Actions	8	3	63.0%



Supplier Nonconformances

Record Type	Count	High Risk	Medium Risk	Low Risk	Open
Nonconformance Records	0	0	0	0	0
Corrective Action Records	3	2	1	0	2
Complaint Records	0	0	0	0	0



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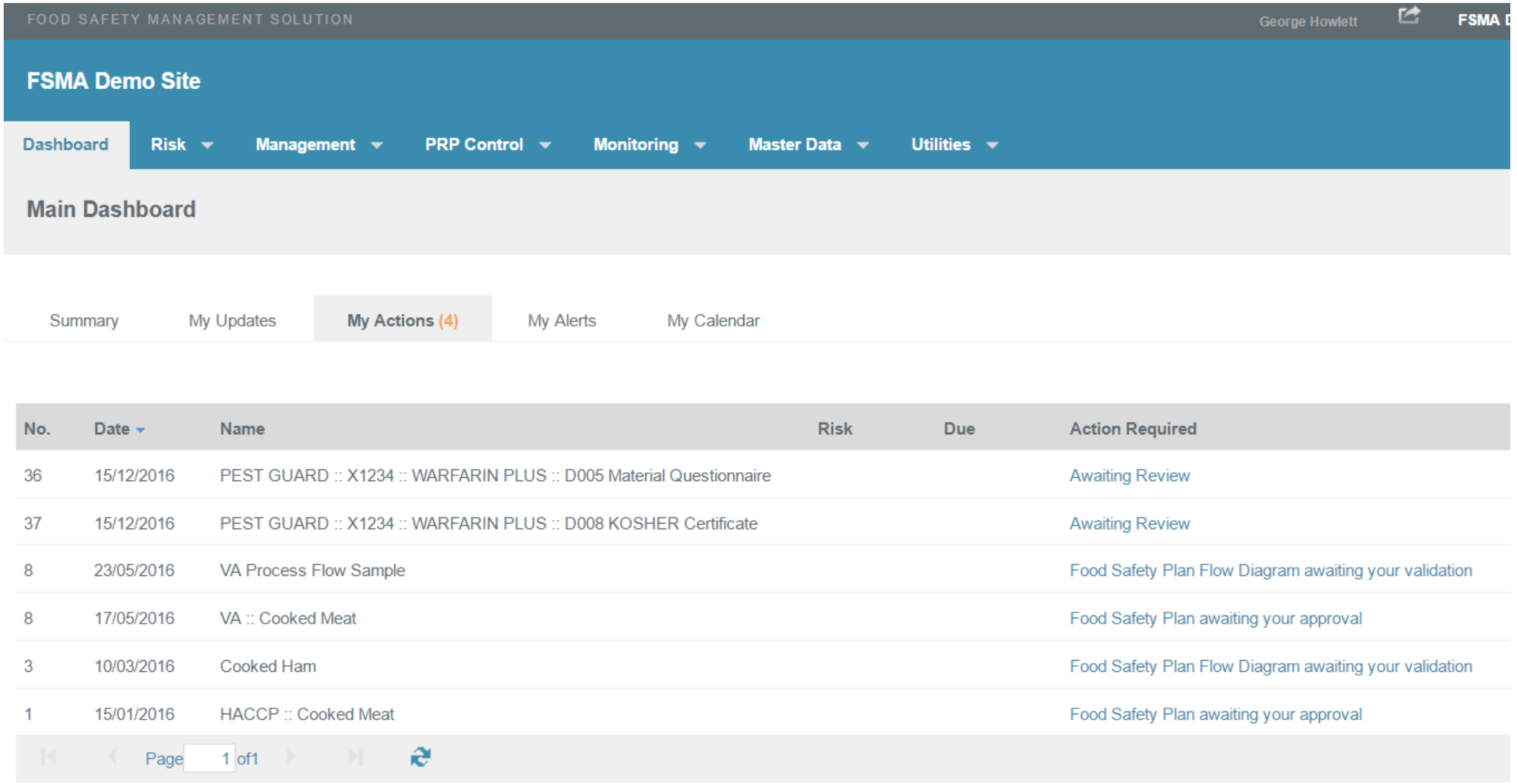
Actions



No.	Date	Name	Risk	Due	Action Required
36	15/12/2016	PEST GUARD :: X1234 :: WARFARIN PLUS :: D005 Material Questionnaire			Awaiting Review
37	15/12/2016	PEST GUARD :: X1234 :: WARFARIN PLUS :: D008 KOSHER Certificate			Awaiting Review
8	23/05/2016	VA Process Flow Sample			Food Safety Plan Flow Diagram awaiting your validation
8	17/05/2016	VA :: Cooked Meat			Food Safety Plan awaiting your approval
3	10/03/2016	Cooked Ham			Food Safety Plan Flow Diagram awaiting your validation
1	15/01/2016	HACCP :: Cooked Meat			Food Safety Plan awaiting your approval

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Models

Criteria	Risk Value (R)	Uncertainty (U)	Total (R+U)	Attach / Link	Report
GFSI Certified (or equivalent)	Yes (0)	Excellent (0)	0	Attach / Link	Certificate supplied
COAs or COCs are provided	Yes (0)	Excellent (0)	0	Attach / Link	Certificates supplied
Likelihood of Adulteration	Low (1)	Fair (3)	4	Attach / Link	Full packed and enclosed
Import Alerts	3 (5)	Excellent (0)	5	Attach / Link	Three recorded in the last 12 months. Source FDA
Urgent Health/Safety Recalls 2010-Current	1 (5)	Excellent (0)	5	Attach / Link	One recorded in the last 12 months. Source FDA
Additional Allergens are Present in the Supplier's Facility	No (0)	Excellent (0)	0	Attach / Link	None identified
Annual Volume of Purchased Materials (Converted to Pounds)	> 150,000 (3)	Excellent (0)	3	Attach / Link	Data provided by procurement
Is the Product Ready To Eat (RTE)/Temperature Controlled	RTE /no temp. control req. (2)	Good (1)	3	Attach / Link	Product category definition
Quantity and Intended Consumer	Consumed in large ...(3)	Good (1)	4	Attach / Link	Consumer survey report 2012
	10	5	Medium 24	Undesirable risk - evaluation required, specific actions required	

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Analysis

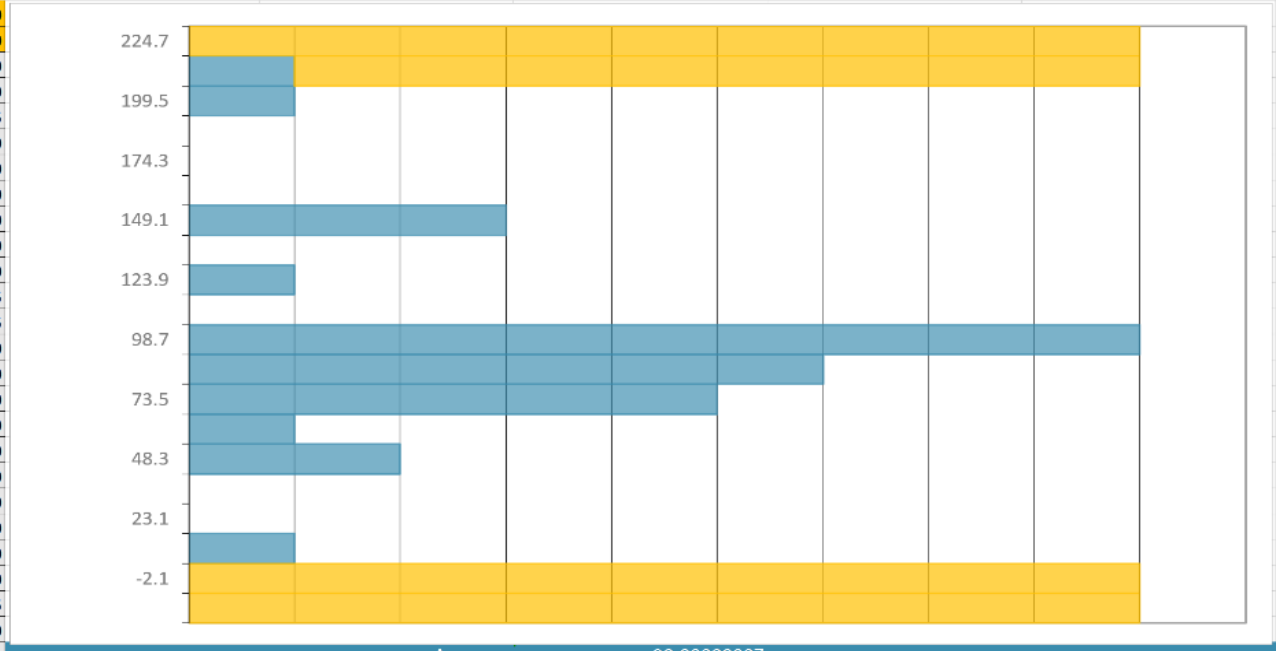
Cleaning Validation - Process Capability Study

General Details:

Date:		**Cleaning SSOP:**		**Criteria:**	
Line No:		**Hazard:**		**Addition variables:**	
Product / Group:		**Risk:**			

Capability Study:

Criteria Maximum:	200
Criteria Minimum:	0
Date 1	50
Date 2	60
Date 3	75
Date 4	100
Date 5	150
Date 6	200
Date 7	210
Date 8	10
Date 9	50
Date 10	75
Date 11	75
Date 12	80
Date 13	70
Date 14	150
Date 15	150
Date 16	100
Date 17	100
Date 18	100
Date 19	100
Date 20	100
Date 21	100
Date 22	75
Date 23	80
Date 24	80
Date 25	80
Date 26	80
Date 27	80
Date 28	120
Date 29	100
Date 30	100



Average:	96.66666667		
Standard Deviation:	41.59188692		
Upper 3 Sigma Value:	221.4423274	"# of Sigmas Capability":	2.3
Lower 3 Sigma Value:	-28.10899409	2-tail PPM "Traditional":	20116.31901
Cp Index:	0.801438353	1-tail PPM "Traditional":	10058.15951
Cpk:	0.774723741	PPM "w/1.5 Sigma Shift":	204921.138

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Report

Thank You