DNV GL Overview

Global Certification Body, Assessor, and Webinar Sponsor

How to protect yourself with doing documentation right

DNV GL –Your global business assurance partner

Position

One of the world's leading certification bodies

People

12,500 highly skilled specialized employees

10,000

Food and beverage companies partner with us to ensure safety and sustainability of their operations and supply chain

Partnership

with more than 70,000 customers in 187 countries

80,000

Management system (ISO 9001, 14001, 18001, etc.) certificates issued under more than 80 accreditations

2,400

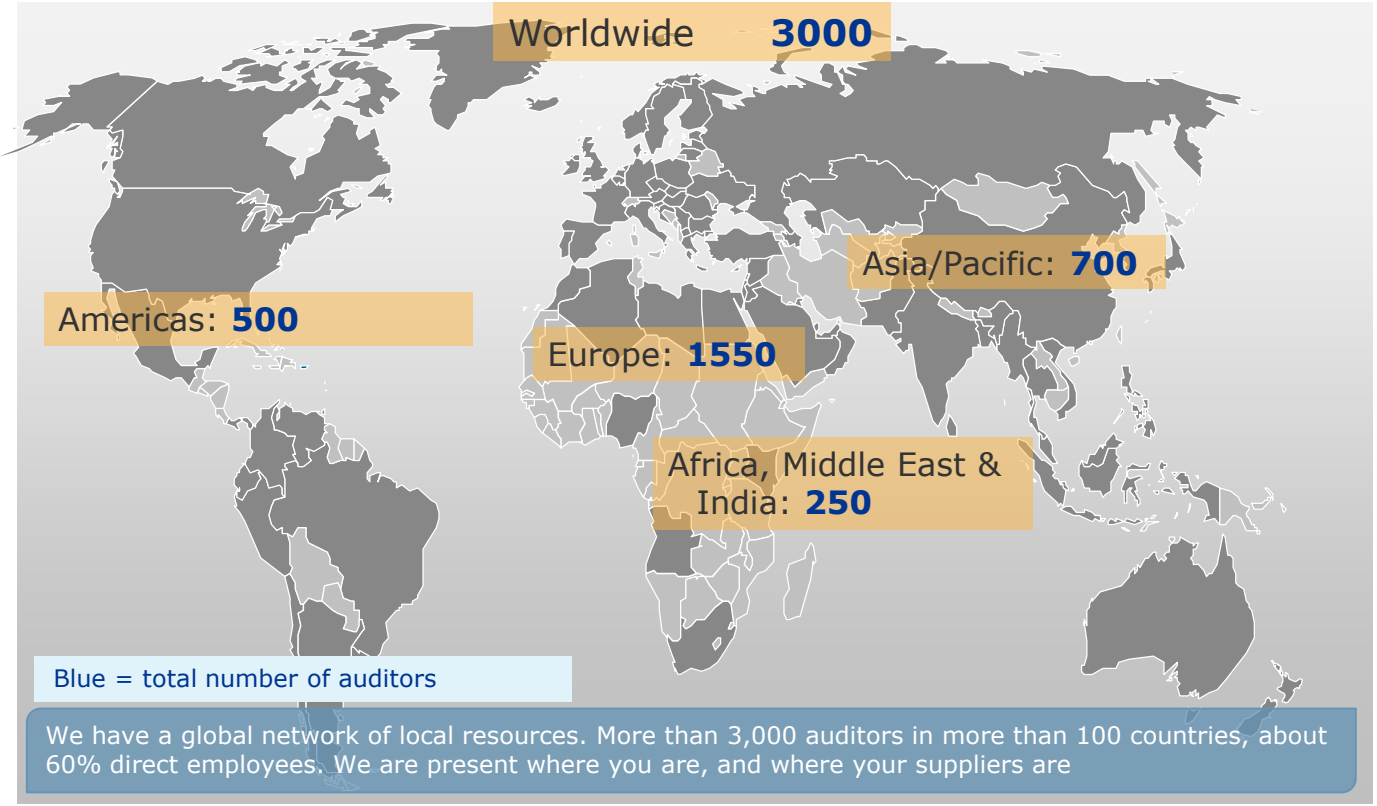
Healthcare organizations trust us to help them improve quality and patient safety

Global Reach – Local Competence - Auditors

Our purpose
To safeguard life, property and the environment

Our vision
A trusted voice to tackle global transformations

Our values
We care. We share. We dare.



We have a global network of local resources. More than 3,000 auditors in more than 100 countries, about 60% direct employees. We are present where you are, and where your suppliers are

How we deliver assurance

Certification & Verification

Results in a certificate or statement of compliance.

Every certification journey starts with standards and their implementation. As an independent third-party, we **check compliance of systems, products and persons to recognised national and international standards**, both generic and **industry specific**.

Assessment

Supports reliable decision making.

For many global brands we **perform audits and assessments** that do not end in a certificate, but rather provide benchmark feedback and critical guidance on **important metrics like corporate responsibility, environmental impact, safety and quality**.

Training

Learning how to improve from a global perspective.

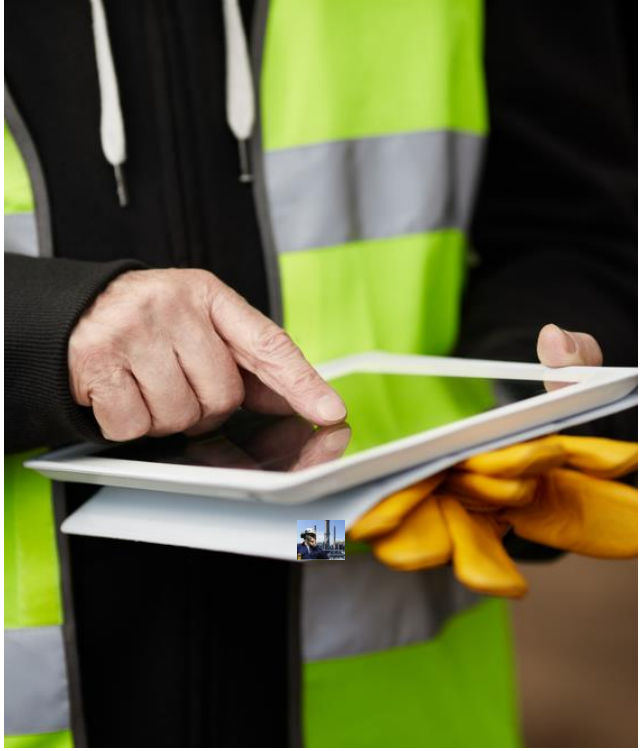
Sustainable performance means having the in-house skills and knowledge to continuously improve. Our worldwide training programs empower customers to self-enhance and constantly adapt to their changing market conditions and customer needs.

DNV GL provides virtual audits

- DNV GL Business Assurance is currently working on livestreaming software to be able to perform assessment audits remotely in the future!

Benefits of remote auditing includes:

- Reduce cost
- Reduced safety risk
- Reduced environmental impact
- Multi-party simultaneous involvement
- Improved mobilisation and delivery time
- Improved planning flexibility
- Reduced operational downtime.



HOW TO PROTECT YOURSELF WITH DOCUMENTATION

Kestrel Tellevate LLC
ELEVATE YOUR BUSINESS

WHO IS KESTREL TELLEVATE LLC?

- Consulting & Advisory Firm
  - Food Safety
    - Compliance, FSMA, FSVP, intentional adulteration, food defense, GFSI, audit readiness, internal audits, supply chain & supplier audits, label review, training, programs development, etc.
  - Environmental, Health & Safety
    - ISO management systems; federal (EPA/OSHA), state, local regulatory compliance
  - Data Management

OBJECTIVES

- Understand how to protect yourself & your company by doing documentation right
- Discuss the many key aspects of preparing food safety & quality documentation for legal compliance
- Discuss strategies for simplifying document & records management

DEVELOPMENT OF DOCUMENTED PROGRAMS

- Documented programs: described in FSMA as “written” within the various rules, and as a key management system component of the Food Safety Plan under FDA
- Document requirements are consistent across most of the food supply chain:
  - Identify applicable requirements
  - Develop compliance programs
  - Ensure documentation is clear and correct
- Adequate program, document management & control requires Preventive Control Qualified Individuals (PCQI) for all key rules:
  - Audit
  - Sanitation
  - Foreign Supplier Verification Program (FSVP)
  - Intentional Adulteration (IA) & Food Defense
  - And more…

GFSI ALIGNMENT

- GFSI requires all legal requirements for food compliance be met & documented for certification
- The reciprocal is true with FDA, FSMA, USDA & others:
  - Documented programs that address compliance requirements must be implemented & followed based program requirements & inspected evidence
- Options to align include programs with common use of content/element descriptions under the various programs

ALIGNMENT

- Consider internal application & familiarity with the program layout to the statutes and standards being addressed
  - Arrange document registers according to the purpose and contents, followed by concluding summary
  - Confirm the sections to clarify the intended scope of compliance
  - Indicate what may not apply (as written for what is determined non-applicable as an area of compliance); to support this decision and possible non-compliance.

DOCUMENT MANAGEMENT

- Start the development of a program or update by establishing a management system "register" to:
  - Confirm all required program documented elements
  - Provide a record of development of these programs
- List the content checklist (horizontal) & the status or actions (vertical) on the register
- Maintain document number & version control, including revision date & purpose

PROGRAM REGISTER OF DOCUMENTS

Compliance Content

Numbering/ Document Management	Document/ Program Element Name	Status/ Development	Issued/ Approved	Department	Purpose	Actions
A001	Company Commitment	Complete	Approved	Executive	Program Commitment	Scheduled Review
HR001	Resources	Issue	Pending	HR	Resource Allocation	Implement
A002	Objective for Program	Development	Pending	Management	Compliance Objectives	Develop
G00X	TBD					

DOCUMENT CONTROL

- Process provides a means of confirming that all program elements are established:
  - Content register
  - Food safety Plan & hazard analysis
  - Procedures, cGMPs & PRPs
  - Evidence of implementation (e.g., PCQI qualifications by function, overall training)
  - Corrective actions management, audit & review
  - Related regulatory & industry (GFSI) requirements
  - CAPA, Root cause analysis & documented resolution as recorded
  - Validation of all programs & practices for CI & PDCA
  - Verification & internal approval that all requirements of the specific standard are met
  - **Document & records management as updated and current**

ALIGNMENT OF RELATED STANDARDS

- Maintain the “register” to align & meet content requirements through similar development process:
  - Allows for the content sections of each to be listed & described
  - Each can be confirmed, checked for status & updated using this process
  - Information collaboration provides for both common & unique responsibility for each designated standard
  - Ultimately, this provides for many programs to be shared within the food-compliant management system
  - **To meet requirements all programs must be adequately implemented**

ALIGNMENT MODEL

Description/ Category	FSMA	GFSI	QMS	Customer Requirements
Company Commitment	FSMA Description	GFSI -Section	QMS Scope	Customer Requirements List
Resources	FSMA Description	GFSI - Conformance	QMS Organizational Assignments	Customer Assigned Resources
Objective for Program	FSMA Description	GFSI - Planning	QMS Purpose	Customer Communication and Validation
TBD				

MANAGING STANDARD DETAILS

- Major programs that may require their own sub-register include:
  - HACCP/Hazard Analysis
  - Supplier Qualification
  - Recall/Traceability
  - Preventive Maintenance
  - Internal Audit/CAPA
  - Others, as determined based on importance
  - **Alignment and standardization is the recommended approach!**

MANAGING TRAINING & QUALIFICATIONS

- Proper qualifications must be met for each position to effectively staff & sustain a compliant program
- Without qualified personnel at all functions (FSP, Audit, Sanitation and other):
  - Documented program will likely degrade
  - Implementation will be more difficult or less successful
  - Inspection or audit will not proceed smoothly & likely result in a possible non-conformance
  - FSMA rules for PCQIs will not be met
- Well-developed training program & records must be continually updated to ensure proper management of the organization
- Organizational change may be the most significant issue in food safety compliance **today with the level of qualified resources not readily available and turnover**

TRAINING MATRIX

Training Requirements	Lead - PCQI	Team	Management	Technical	Operations
Program Development / Management	Full **-FSP -Other**	Provision based on Functional Role	Management Responsibility /Commitment	Technical Requirements Operations, Engineering, Maint.	Job Responsibility/ Operations
Major Program Administration	X	X	X	X	X
Document Management & Control	X	X			
Emergency Management	X		X		
Emergency Response	X	X	X	X	X

AUDIT/INSPECTION READINESS

- Provisions for regulatory audits present potential compliance risks
  - Procedure for unannounced FSMA inspection or audits (customer, GFSI, etc.)
  - Confirmation that all past non-conformances have been properly addressed
    - Non-conformances must be properly determined for more focused “Action” & attention
    - Risk level must be assigned as either corrective action , correction or improvement
    - These must be monitored, addressed & **closed** in an effective manner
    - Corrective actions or corrections resulting from audit/inspection, customer complaint or feedback must be closed, managed, verified & recorded
    - **Conduct Audit/Inspection Readiness!**

EVIDENCE

- Program must provide evidence of meeting compliance at all times:
  - Issues of vulnerabilities & controls within the FSMS must be updated
  - Key programs for food safety management must be audited
  - Compliance must be sustained & subjected to continuous improvement
  - All programs, sites & procedures must be audit-ready 24/365
  - Operations must be verified for production, distribution & release of product
  - **Practice is key to the best level of readiness**

INTERNAL AUDIT SCHEDULE

Topic	Description	Response	Status	Oversight	Validation
Mock Recall	Traceability	ERP	Partial	Escalated	Authorization
Pre-Op	Verification	Sign-offs	Inconsistent	Add Verification Checks	Authorization
Environmental Monitoring	Validation	Sanitation	Verified	Testing	Negative Findings
Sanitation	MSS/MCS/SSOP	Implementation	Verification	Internal Inspection	Verification
All Other	Key Programs	Confirmed	To Requirements	Verified	Validated

NON-CONFORMANCE MONITORING

Non-Conformance	Description	Response	Status	Open	Closed
Sanitation	Inspection	CAPAs	Managing	Until Closed	Verified
Process Control	Audit	Maintained	Validated	Verified	Monitored
Waste Management	Records and Visual Status	Confirmed	Verified	Proper Response	Confirmed
Lot Traceability	Mock Recall	Mock Recall	Completed	Improvements	Inventory Tally
Supplier Program	Qualification	Requirements	Up-to-Date	In Complete	Updates

MANAGEMENT OF CHANGE (MOC)

- Changes must lead to improvements, validation & corrections of systems against non-conformance
- Complete FSP, FSMS & internal documentation – fully implemented & up-do-date
- All changes must be made & recorded as they occur
- New processes, equipment, materials, others must be included
- MOC must be multi-functional & agreed upon
- Key programs (e.g., HACCP, FSP) & procedures must be updated
- **Training must occur prior to or concurrent with the change & recorded**

MANAGEMENT OVERSIGHT

- All reanalysis must be conducted as scheduled with MOC updates properly reported/recorded
  - Determinations of program changes made
  - Changes validated, implement & verified
  - Organization updated based on objectives, job expectations, qualifications & training
- **Conducted under management review as documented**

FSMA RE-ANALYSIS

- FSMA requires procedures & program be reviewed on a prescribed basis: annually, 2 & 3 years, or as changes occur
- Updates as determined by any non-conformance that could lead to food hazard must be documented in 7 days with a revision & update of the program section in 90 days (under FSMA)
- All corrective actions to such issues must be audited, validated & verified
- Under PCQI oversight, all aspects must be managed & changes properly implemented
  - Audit function should verify programs independent from other PCQIs
- **Concurrently GFSI & internal programs are subject to similar requirements**

RE-ANALYSIS

- Must encompass all aspects of the FSP or FSMS, including:
  - Document management
  - Internal audit & records
  - CAPA management & verification, updates
  - Recordkeeping & change updates
  - Management including all market or customer feedback/complaints
  - Response to all market issues or customer feedback/complaints
  - Correction of Internal Audits and NC's
  - Communication with customers or certifiers, as contracted
- **All other elements of the FSP under FSMA and other requirements**

VALIDATION

- Validation process for compliance level of programs, including reassessment with updated protocols
  - FDA FSMA & GFSI requirements
  - CAPA monitoring
  - Temporary oversight measures for any situation not completely resolved or pending final program verification
  - Root cause analysis - documented, validated & recorded
  - PDCA continuous improvement, as recorded
- **All Current and up-to-date**

CONTINUOUS IMPROVEMENT (CI)

- Sustained CI & documented proof of an effective PDCA process
  - Improvements are an imperative for effective compliance assessment process
  - Meet all requirements at all times
  - Sustained improvement process
  - Root cause analysis program
  - Records responsibility and the implementation process
  - Corrective Actions and MOC
  - **Monitored to Close**

HARMONIZATION

- Harmonization of program assessment & appropriate records of all programs & information required
  - Social responsibility
  - EHS
  - SMETA
  - Fair trade
  - Fraud
  - Banned materials/minerals
  - May be required as part of customer or company requirements
  - Other Objectives as Determined

RECORDS

- Detailed list of records for compliance must be available at all times:
  - Document register
  - Responsibilities & expectations
  - Qualifications
  - Approved materials, suppliers & product specifications
  - CAPA
  - Audit & verifications
  - Ultimately all program elements
  - **Forms, completed and verified**

RECORDS

- Documented evidence of administrative-level updates, corrective actions & communication
  - Supporting evidence of meeting all requirements
  - Listing of CAPAs & status to close
  - Resource issues & continuing problem areas
  - Any key findings reported to management recorded as effectively resolved & verified
  - Justifications from management for change, resources or support
  - Records must be maintained & available as the key focus of inspection
  - **All issues included, closed and audited**

SIMPLIFY DOCUMENT/RECORDS MANAGEMENT

- Leverage available information technology
- Validation process of data
- **All systems information must be backed up for inspections**
  - 2 years of product manufacturing records or as long as the product may be in commerce
  - Organization must determine the record retention program for food compliance records
  - Legal authorities stress less is better than more; however, incomplete information may be subjected to investigation

SIMPLIFY DOCUMENT/RECORDS MANAGEMENT

- System documentation must be validated – leverage information technology to simplify process
- Backup & protection of food safety compliance records reduces legal liability:
  - Records of approving products & materials
  - Test records
  - Calibration records of all testing & processing equipment
  - Processing
  - Lot traceability
  - Non-conformity & control of materials not meeting food compliance
- **Information audit and edit process**

ENTERPRISE RISK VALIDATION

- Overall strategy & plan established & communicated:
  - All key program requirements & content
  - Program verification & enterprise risk
  - Planning & justification
  - Resolution of all issues
  - Validation of all justification
  - Internal or other audit process
  - **Updated objectives – As determined**

ALIGNED SYSTEMS

- Aligned systems for multiple jurisdictions of compliance to GFSI, FDA, USDA, international & contracted requirements
- Common systems elements – provide for stronger program implementation
- Risk assessments including:
  - General food compliance
  - EHS & other regulatory requirements
  - Social responsibility
  - Fair trade
  - SMETA
  - Other
- Implementation evidence
- **Records management**

QUALIFIED PERSONNEL RESPONSIBILITIES

- QI - Qualified Individual responsible for all determined requirements
  - Vetting & confirming qualified personnel
  - Role & qualification requirements
  - Experience, education & certifications
  - Training & updated certifications
  - Proper training & records for all levels of the organization
  - QI focus levels under FSMA/GFSI
    - audit,
    - sanitation,
    - food defense
    - IA,
    - FSVP, etc. (i.e. PC/CCP Management)

SUMMARY—KEY POINTS

- Complete program register of all required documents
- Document management & control
- Validation & verification by internal audit & reanalysis
- Management of Change (MOC)
- CAPA or corrections implementation
- Continuous Improvement (CI) & root cause analysis
- Commissioning & pre-op integrity
- Organization, PCQI & training
- Audit & inspection records for readiness review

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ELEVATE YOUR BUSINESS

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We are here to help to achieve your certification goals!

Thank you!

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