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# **EwQIMS** key changes

- By Anthony John, VP Omnex Systems

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EwQIMS Software has recently undergone a major UI/UX change which includes five platforms like NPD/APQP Platform, Electric & Autonomous Vehicle Platform, Quality Management Systems / QHSE (IMS) Software Platform, Supplier Quality Management Platform, and performance management platform.

read more

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# AS13100: Integrating AEQG Customer Requirements with AS9100 and AS9145

- By Dave Watkins, Director International Operations and Craig Thompson, General Manager - Plantech

AS13100 is a new standard to harmonize and simplify supplier quality requirements, supplementing AS9100 (QMS) and AS9145 (APQP/PPAP) developed by the SAE G-22 Aerospace Engine Supplier Quality (AESQ) Technical Committee. As a result of the changes brought about by AS13100, development is more rigorous with increased read more prevention and control strategies and methods to improve product quality. Integrating the requirements of this new standard is considered essential to developing, maintaining, and improving a more effective and

# The Cyber security Standards Landscape & Supply Chain Standards

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- By Chad Kymal, CTO, Omnex Inc.

The cyber threats landscape is constantly evolving. Cyber security is of greater importance to an industry that is the backbone of communications and information exchanges of any kind. The Defense industry has read more adopted the CMMC 2.0 standard and rolled out the updated Cybersecurity requirements of the Department of Defence(DOD). What is the current cyber security standards landscape, and what are industries doing to address this grave danger?

# TIA initiative

- By Chad Kymal, CTO, Omnex Inc.

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The SCS 9001 is a Supply Chain Security Management System. It appears to be the most comprehensive and most specific Supply Chain Security Standard because IT telecommunications are at the center of all organizational infrastructure for both the US and global organizations. The key to understanding SCS 9001 is reflected in the read more architectural model with a summary of the entire standard including security measures (metrics), 10 security domains, supply chain requirements, and some key security processes.



EV/AV Training For: IATF 16949, AIAG-VDA FMEA, ISO 26262, Automotive SPICE, SOTIF, Cybersecurity & Agile APQP!



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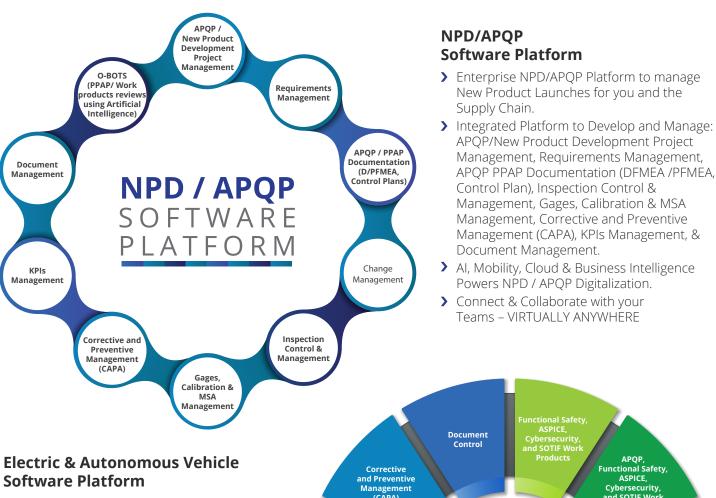
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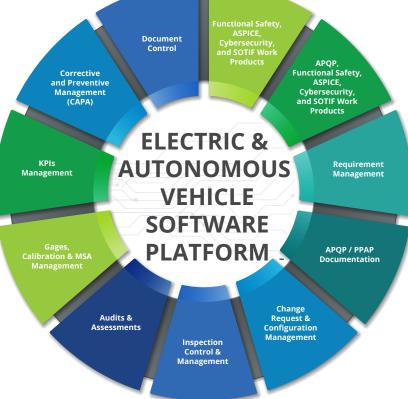


CONTINUED FROM PAGE 1 BY ANTHONY JOHN, VP OMNEX SYSTEMS

EwQIMS Software has recently undergone a major UI/UX change. This change includes the adoption of 5 Platforms



- ➤ Enterprise EV-AV Platform to revolutionize new product development of electrical and autonomous vehicle products for you and the supply chain.
- ➤ Integrated Platform to manage Functional Safety (ISO 26262), Automotive SPICE® (ASPICE®), Cybersecurity (ISO 21434), SOTIF (ISO/FDIS 21448), APQP/New Product Development Project Management, Requirements Management, APQP PPAP Documentation (D/P FMEA, Control Plan), Configuration Management, Change Request Management Inspection Control & Management, Gages, Calibration & MSA Management, Corrective and Preventive Management (CAPA), KPIs Management.
- AI, Mobility, and cloud and business intelligence is powering EV-AV product development Digitalization.





CONTINUED FROM PAGE 3 BY ANTHONY JOHN, VP OMNEX SYSTEMS



# Quality Management Systems / QHSE (IMS) Software Platform

- ➤ Integrated QHSE (quality, environment, health, and safety), social responsibility, and integrated IT security.
- Manage any management system document management, and control, audit management, corrective and preventive action management, customer complaints, gages, calibration, MSA management, continual improvement, KPI management, training, competency management, and Total Productive Maintenance (TPM).
- ➤ AI, Mobility, Cloud, and Business Intelligence are powering digitalization.
- Connect & Collaborate with your Teams VIRTUALLY ANYWHERE

# **Supplier Quality Management Software Platform**

- > The comprehensive supplier management platform allows organizations to manage their suppliers effortlessly by utilizing a central repository of supplier information, including supplier metrics, PPAPs, APQPs, audits, receiving inspections, and SCARs. The benefit of this system is in the ability to implement Plan-Do-Check-ACT (PDCA) in supply chains, with a closed-loop continual improvement process.
- Omnex BOTs (O-BOTs) utilize artificial intelligence, machine learning, and deep learning algorithms to review PPAP documents, including DFMEA, DVP&R, PFMEA, PSW, and dimensional layouts. O-BOTs also use NLP (Natural Language Processing) techniques to review PPAPs.
- Our platform harnesses AI, mobility, cloud, and business intelligence to assist with integrated management systems deployment.
- Connect and collaborate VIRTUALLY ANYWHERE.





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BY ANTHONY JOHN, VP OMNEX SYSTEMS



# Performance Management Software Platform

- Design, Deploy, and Track Organization KPIs: including Supplier KPIs and drive actionable insights.
- Powerful Business Intelligence Platform to visually explore data, quickly spot deficiencies, and augment organization's data drive and the decision-making process.
  - Our Platform Harnesses Al, Mobility, and Cloud & Business Intelligence to enhance Performance Management.
- Connect & Collaborate VIRTUALLY ANYWHERE
- Intuitive User Interfaces to Perform Complex Tasks Quickly & Easily.
- Platform Available in the Cloud and On-Premise.



Configurable landing pages of the 14 modules can be accessed through a single landing page with the most commonly and frequently used action with Zero to Two-Clicks.

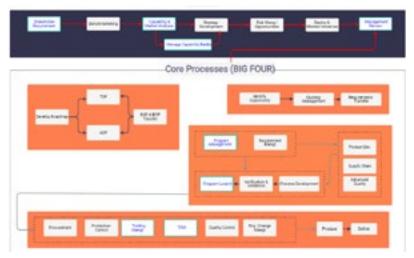
Traditional reports migrated to Configurable Business Intelligence Reports.

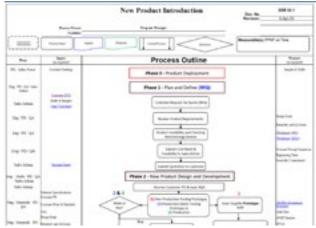
Improvements in UI for consistency, lightweight and better performance.

Integrated Program & Project Management of APQP/NPD, Functional Safety, Automotive SPICE (ASPICE), Cyber Security (CySe), PPAP, and more for both Internal & Suppliers.



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BY ANTHONY JOHN, VP OMNEX SYSTEMS





Customer requirements can be imported to requirements management and such requirements can be allocated to different elements easily.

Requirement's review process is improved to support both internal and external reviewers

APQP/NPD (APQP PPAP Manager Interface) becoming the one-interface connectivity of all the Work Products and APQP Scoring checklist.

Major Strides in Audit Management solution to support Usability, Audit Plans, Mobile Apps (both iOS & Android), VDA Audits, Improvement in LPA.

Document Management to include Online Process Map and Procedure Development Capability. Can create online documents and edit excel files using browser.

Joint development and introduction of new modules into the platform with OEM and major Tier 1 customers – Warranty Management, Configuration Management, Change Management, and Supplier Quality Management Platform

# Launch of EV-AV Software Platform

- Integrated Platform to manage Functional Safety (ISO 26262), Automotive SPICE® (ASPICE®), Cybersecurity (ISO 21434), SOTIF (ISO/FDIS 21448), APQP/New Product Development Project Management, Requirements Management, APQP PPAP Documentation (D/P FMEA, Control Plan), Configuration Management, Change Request Management, Inspection Control & Management, Gages, Calibration & MSA Management, Corrective & Preventive Management (CAPA), and KPI Management

Multipoint Failure integrated with FMEDA and FTA (Fault Tree Analysis).

Improved AIAG-VDA FMEA based on customer and FMEA author's feedback.

Program/Projects to support project estimation, configuration management, improved gate reviews, and change management.

Enhanced printing feature of Gantt chart and developed new feature for stitching of PPAP documents as a single PDF or zip file.

Improvements and changes to performance management platform on BoSS, training, and competency management.





CONTINUED FROM PAGE 1

BY DAVE WATKINS, DIRECTOR INTERNATIONAL OPERATIONS AND CRAIG THOMPSON, GENERAL MANAGER-PLANTECH

efficient QMS.

Developed by the SAE G-22 Aerospace Engine Supplier Quality (AESQ) Technical Committee, AS13100 is an effort to harmonize and simplify supplier quality requirements, supplementing AS9100 (QMS) and AS9145 (APQP/PPAP), while focusing on the specific requirements of Aircraft Engine OEMs. That it may also be adopted as a contractual requirement by other aerospace/defense OEMs and 1st tier organizations is a distinct possibility. There are already indications of this occurring.

The primary intent of this new standard is to help enable suppliers to rigorously improve overall product quality by focusing on the key systems and processes currently deterring consistent aerospace engine product quality. As enhancements to the industry's key standards of AS9100 and AS9145, the recently released AS13100 is designed to reduce defects and waste by enhanced prevention and control strategies and methods. Integrating the requirements of this new standard is considered essential to developing, maintaining, and improving a more effective and efficient QMS and more robust and predictable New Product Development (NPD) processes.

Part of the issue the new standard seeks to address is the proliferation of supplemental requirements not explicitly covered by AS9100 and AS9145, which has proven increasingly onerous and wasteful for the suppliers to the industry.

To summarize, the rationale for AS13100:

- Harmonize and simplify additional Supplier Quality Requirements with AS9100 systems and AS9145 programs
- Create a common set of supplemental requirements for Aerospace Engine Manufacturers and their supply base

- The need to meet Regulatory, Customer, Industry, and Business requirements not covered by AS9100 or AS9145
- Level the playing field, ensure clarity among suppliers and raise the bar for performance in key areas
- Employ a numbering scheme and format that is consistent with AS9100 and AS9145

Since ISO 9001 (the basis for these standards) and AS9100 is (or should be) well known to the industry—as are, to a lesser degree, AS9145 and APQP/PPAP—this article will focus almost exclusively on the new AS13100 requirements, as well as how they fit directly into and apply to, AS9100D and AS9145 requirements.

As one might expect given its scope, AS13100 includes a detailed list of terms and definitions, an extensive list of related documents and standards with, as well, the previously issued AS13XXX series of standards developed by the AESQ Committee, now adapted as and re-issued as Reference Manuals for AS13100 (e.g. RM13004 on PFMEA and Control Plans), each providing examples of acceptable and/or recommended means of compliance. They include methodologies, templates, and case studies applicable to key processes required by the standard.

Fundamentally, AS13100 requires compliance to all of the requirements of ISO 9001, AS9100, and AS9145, as well as additional customer-driven requirements. (Illustrated in Fig. 1) It is the latter we'll be addressing in this discussion. Of course, given the degree of specificity and detail provided in the standard, only the most significant additions can be addressed in a brief article.

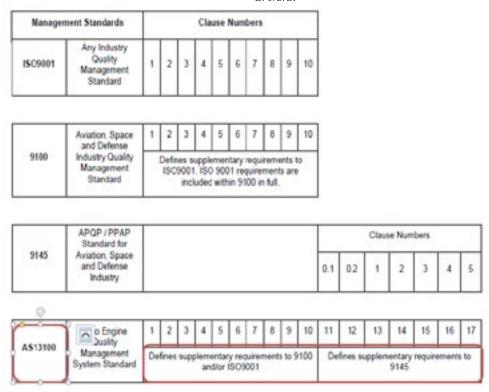


Figure 1





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BY DAVE WATKINS, DIRECTOR INTERNATIONAL OPERATIONS AND CRAIG THOMPSON, GENERAL MANAGER-PLANTECH

# AS13100 SIGNIFICANT ADDITIONAL REQUIREMENTS TO AS9100D

These additional requirements are included in AS1100 Clauses 4-10

#### Clause 4

- 4.3.1 Use of a flow chart in Appendix B to determine which Organizational Type you fall in
- 4.3.5 Includes a requirement for an AS13100 Compliance Self-Assessment
- Does not state a frequency requirement

### Clause 5

- 5.1.1.1 Requires a commitment to address Human Factors
- 5.3.1 Production personnel must be identified as accountable for ensuring product conformity across shifts as necessary

#### Clause 6

- 6.1.3 Requires a Crisis Management and Business Continuity Plan which includes a 3 working day customer notification requirement
- 6.1.3 Must implement a Risk Management Process

# **Clause 7**

- 7.1.5.1.1 Ensure access to a practitioner who has the appropriate experience and demonstrable competence in MSA
- 1. Must use table 3 to determine when to apply the MSA requirements
- 2. There will be a need for a documented MSA process
- 7.1.5.1.3 MSA Acceptance criteria are listed in Table 4
- 7.2.1 Competence requirements extend beyond regular employees to include contract and/or agency personnel

# **Clause 8**

- 8.3.1.1 Design and Development process must comply with AS9145 and AS13100
- 1. Must have a documented Design and Development process
- 2. Must have a single point of contact for the customer on APQP activities
- 8.3.4.4 Create a Verification Strategy outlining the product verification activities to be accomplished
- 8.3.4.5 Design for 'X' (DfX)
- 1. Includes design for Manufacturability, Assemblability, Cost, Weight, and Aftermarket

- 8.5.1.4.3 Requires a Control Plan addressing all product characteristics
- 8.5.1.9 Requires a Documented Operator Self-Verification Program conforming to AS9162

## Clause 9

- 9.1.2.1 Must strive for 100% Product Quality and 100% On-Time Delivery, and have a defined improvement program when not being achieved
- 9.2.3 Internal Audits must conform to Table 9 within the standard for audit frequency based on audit type
  - Special Process audits are to be conducted annually, regardless of NADCAP merit status
- 9.3.2.1 Management Review must be held at least annually (Omnex recommends significantly greater frequency for operational management reviews, e.g. monthly)

## Clause 10

• 10.2.3 Incorporates additional requirements for problem-solving, including instances where suspected nonconformance is observed within the product lifecycle and product design.

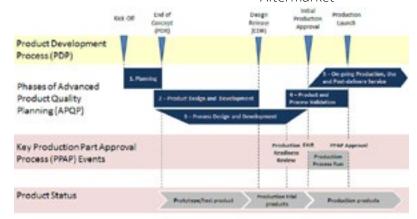


Figure 2: NOTE: In the interest of brevity, AS13100 clauses containing "Reference 9145:11/2016" have not been included in this list.

# AS13100 SIGNIFICANT ADDITIONAL REQUIREMENTS TO AS9145 (APQP&PPAP)

These additional requirements involve AS13100 Clauses 11-21

## Clause 13

 Includes 13.3 Supplemental requirements to determine when all or some of the APQP phases are applicable and thus required

# Clause 16

• 16.1.7 Provides Illustrated guidance on the APQP and PPAP Flow, Timing, and PPAP events.



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BY DAVE WATKINS, DIRECTOR INTERNATIONAL OPERATIONS AND CRAIG THOMPSON, GENERAL MANAGER- PLANTECH

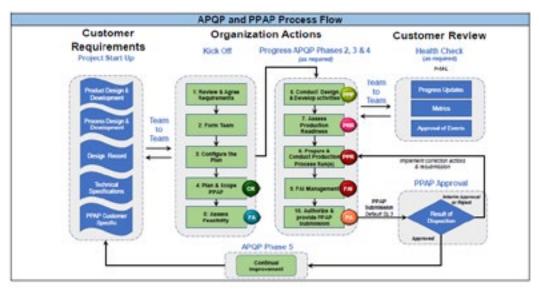


Figure 3: APQP and PPAP flow plan diagram

- 16.4.7 Must use Design FMEA to satisfy Design Risk Analysis
- 16.5.10 shall conduct PFD, PFMEA, and CP for a specific part number
- Family or Group of parts are not allowed unless approved by the customer
- · 16.6.9
- MSA activities are required for the measurement of KC's
- Process Verification of KC's on parts from the significant production (PPAP) run must achieve a Cpk/Ppk index value equal to or greater than 1.33

#### Clause 17

- 17.1.1 Each organization shall define the person(s) responsible for PPAP approval
- I. PPAP Submission Levels are more defined as shown in Table 11 in the standard
- II. Develop the PPAP File and PPAP submission per Table below.

## Clause 18

AESQ SUPPLY CHAIN RISK MANAGEMENT PROCESS (Supplemental)

• Provides a standardized approach to

Table 11 - Submission/retention levels

PPAP			SUBMISSION LEVEL				
NUMBER	AESQ PPAP ELEMENT	SL1	SL 2	SL3	SL 4	SL 5	
1	Design Record	SR	SR	SR	CR	SRW	
2	Design FMEA	RH	RH	SRM	CRIN	SRW	
3	Process flow diagram	R	R	SR	CR	SRW	
4.	Process FMEA	R	R	SR	CR	SRW	
5	Control plan	R	SR	SR	CR	SRW	
6	Measurement System Analysis verification	RH	RH	SRE	CRR	SRW	
7	Initial process capability studies	R	SR	SR	CR	SRW	
8	Packaging, labelling standard, and documentation	R	R	SR	CR	SRW	
9	First Article Inspection	RR	SRR	SRR	CRM	SRW	
10	Customer-specific requirements	R	SR	SR	CR	SRW	
10.1	Dimensional/Nondimensional results	R	SR	SR	CR	SRW	
10.2	Initial manufacturing performance studies	R	R	SR	CR	SRW	
11	PPAP Approval Form (or equivalent)	SR	SR	SR	CR	SR	
23 When sp	nd Manufacture organization only. eoifed by the related MSA Plan (Phase 3 of APQP), lance with 9102.						
1.12	Key/Legend						
S Submit	to customer (or nominated representative).						
R Retain	a record as part of the PPAP file and make available t	to the cust	tomer upor	request.	10		
C Consul	t customer - submission (S) and/or witness (W) may b	e requirer	4				



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BY DAVE WATKINS, DIRECTOR INTERNATIONAL OPERATIONS AND CRAIG THOMPSON, GENERAL MANAGER-PLANTECH

Project-based APQP (Ref. RM13145)

- I. Sourcing Strategy and plan, e.g., Additional sources
- II. Stocking policy, e.g., pull forward inventory, increase levels for periods
- III. Supplier Development strategy, e.g., Technology development, capability improvements of suppliers

IV. Special actions, e.g., Financial, Third Party Inspection

Note: Reference in AS13100: Table 15 – AESQ APQP assurance framework.

#### Clause 19

- Organizations must have a process for reviewing and updating Control Plans throughout the APQP process and when changes to products or processes occur
- The Control Plan must include <u>all</u> <u>dimensional and non-dimensional</u> <u>measurements</u> that are required to occur

#### Clause 20

• 20.1 Key quality tools shown in Figure 4 below are to be applied at the part number level

#### Clause 21

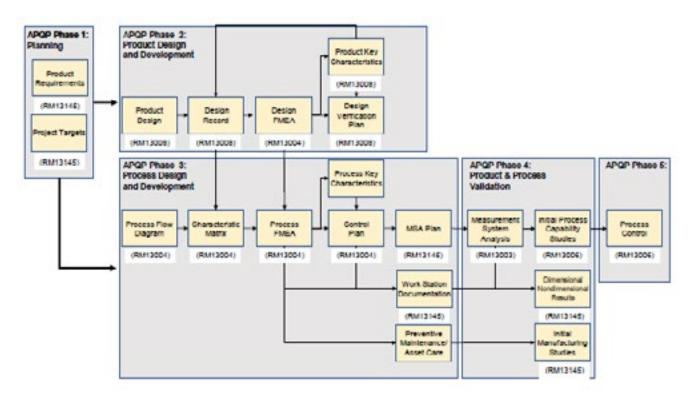


Figure 4: Key Quality Planning Tools (Ref. AS13100 Figure 6)

This clause provides several additional supplemental requirements to Clause 16 Design Development, addressing the requirement for DFMEA as the method for conducting a design risk analysis, timing, ownership, controls in the design process (rather than relying on controls in the production processes), with detailed requirements regarding scope, architecture, expected

outputs (e.g. Design Verification Plan), risk characterization and application of classifications (i.e. Cls and KCs, etc.).

Clause 21 also provides detailed requirements for Manufacturing Process development and the use of quality tools (e.g. Process FMEA, MSA, Process Control Plans, Key process characteristics, etc.)

The Challenge of Integration into

# one Quality Management System

Omnex's approach to achieving a seamless, integrated management system is based on processes, their sequence, and interaction to achieve desired results. There are essentially two phases in this approach. First, aligning and integrating the APQP elements into the organization's NPD process defined



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BY DAVE WATKINS, DIRECTOR INTERNATIONAL OPERATIONS AND CRAIG THOMPSON, GENERAL MANAGER-PLANTECH

in the AS9100 system, and then enabling these processes to realize all of the needed deliverables, as illustrated in Figures 5 and 6, below:

With the enhancements brought in by AS13100, development is made more

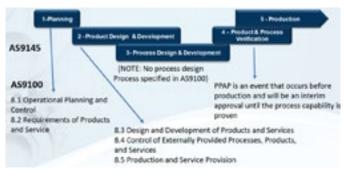


Figure 5: Key Quality Planning Tools (Ref. AS13100 Figure 6)

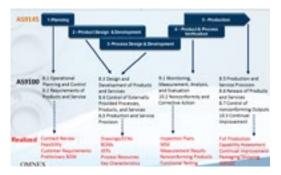


Figure 6: Achieving Desired Outcomes

rigorous by the mandates for DFMEA, DFM, and DFA, more robust by the development of risk-based verification test planning and identification of Critical Items and Key Characteristics. Process design and development are enhanced by the use of the APQP Core Tools and the rigor of PPAP as well as ongoing Continual Improvement.

Overall, the QMS becomes more risk and prevention-oriented, more process-

based, and thus more effective and efficient overall, capable of ensuring all of the Customers' requirements and the entire business plan objectives are met or exceeded.

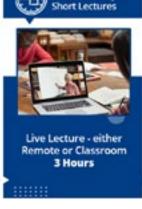
Omnex provides a variety of services and products to support these efforts, including training in systems and Core Tools from Leadership to the shop floor, implementation support, and a software platform integrating all of these

requirements into one user-friendly, web-based solution.

The content of this article with narrative by Craig Thompson can be reviewed in a webinar hosted on <a href="https://www.omnex.com">www.omnex.com</a> entitled: Integrating the New AS13100 Customer Specific Requirements into your AS9100 QMS in conjunction with AS9145

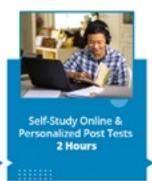
# Virtual Learning & LiveLearn Methodology





45 min. Multiple









# The Cybersecurity Standards Landscape & Supply Chain Standards

CONTINUED FROM PAGE 1 BY CHAD KYMAL, CTO, OMNEX INC.

# Cyber Attacks Are Real

Cybercrimes have risen 600% since the pandemic struck. Ransomware attacks are costing organizations 6 Trillion dollars. On average it took organizations one week to get control over their systems greatly costing them. A new organization fell victim to ransomware every 14 seconds in 2019, and every 11 seconds by 2021 (Source).

These statistics should shock us all. In 2021 one out of 61 organizations were under threat from a Cyber Attack each week. As ransomware becomes more sophisticated this number will likely increase in 2022. (Source). Making things worse is the Solar Winds Orion breach as shown in the next section.

# **Supply Chain Attacks**

The SolarWinds Orion compromise will leave organizations susceptible to supply chain attacks. In this case, a weak supplier will be hacked into to gain

access to their customer.

Attacks of this nature will be more commonplace in the future, leaving industries and large corporations susceptible.

What is the current landscape of cybersecurity standards and what are industries doing in regards to this grave danger? Three industries have taken action to protect not only their assets but also their supply chains – Defense, Automotive, and Telecommunications. Omnex is active in providing training and implementation support for each of these standards.

# US Department of Defense Cyber Security Initiatives

The Defense industry has adopted the CMMC 2.0 standard and rolled out the updated cybersecurity requirements of the Department of Defense (DoD) in November 2021. It is expected to become a contractual requirement for

new project with the DoD. The DoD, however, informs us that it will not become a contractual requirement until they complete the "rulemaking process" which could take 9 to 24 months. The CMMC goal is to -

- Safeguard sensitive information to enable and protect the war fighter
- Dynamically enhance Defense Industrial Base (DIB) cybersecurity to meet evolving threats
- Ensure accountability while minimizing barriers to compliance with DoD requirements
- Contribute towards instilling a collaborative culture of cybersecurity and cyber resilience
- > Maintain public trust through high professional and ethical standards

The CMMC 2.0 has three levels with the three levels of assessment with three levels of practices as shown below.

CMMC Model 2.0		
CIVILVIC IVIOGET 2.0	Model	Assessment
LEVEL 3 Expert	110+ practices based on NIST SP 800-172	Triennial government led assessments
LEVEL 2 Advanced	110 practices Aligned with NIST SP 800-171	Triennial third-party assessments for critical national security information; Annual self-assessment for select programs
LEVEL 1 Foundational	17 practices	Annual self-assessment



# The Cybersecurity Standards Landscape & Supply Chain Standards

CONTINUED FROM PAGE 12 BY CHAD KYMAL, CTO, OMNEX INC.

Level 2 is assessed by contracted third parties sanctioned by the CMMC DoD process. Level 3 is assessed by the US Government and is an additional subset of practices from NIST 800-172 called enhanced security requirements.

The topics of CMMC, as shown below, require an overall information management system to ensure it is managed effectively. It is best integrated with an ISO 9001 Quality management System or with ISO 27001 Information Security Management System.

CHAP	TER ONE INTRODUCTION	1
1.1	PURPOSE AND APPLICABILITY	2
1.2	TARGET AUDIENCE	4
1.3	ORGANIZATION OF THIS SPECIAL PUBLICATION	4
CHAP	TER TWO THE FUNDAMENTALS	5
2.1	BASIC ASSUMPTIONS	5
2.2	DEVELOPMENT OF SECURITY REQUIREMENTS	6
CHAP	TER THREE THE REQUIREMENTS	9
3.1	ACCESS CONTROL	10
3.2	AWARENESS AND TRAINING	16
	AUDIT AND ACCOUNTABILITY	
3.4	CONFIGURATION MANAGEMENT	
3.5	the state of the s	
3.6	INCIDENT RESPONSE	
3.7	MAINTENANCE	27
3.8		
3.9	PERSONNEL SECURITY	31
3.1	0 PHYSICAL PROTECTION	
3.1	* '''2'''''''''''''''''''''''''''''''''	
	2 SECURITY ASSESSMENT	
3.1	3 SYSTEM AND COMMUNICATIONS PROTECTION	36
3.1	4 SYSTEM AND INFORMATION INTEGRITY	40

# Automotive Industry Cybersecurity Initiatives

The German OEMs, under the auspices of the VDA, have launched a Trusted Information Security Assessment Exchange or TISAX. TISAX has started appearing in the OEMs purchase orders for both software services and manufacturing organizations.

TISAX requires an Information Security Management System and 67 controls as shown below. While there is significant overlap with Annex A controls, there are many standalone items as well. The TISAX includes additional areas of prototype controls and data protection or privacy requirements.

	series
5	16
N/A	22
N/A	(4) GDPR
ata (secure	e) GDPR
	N/A N/A



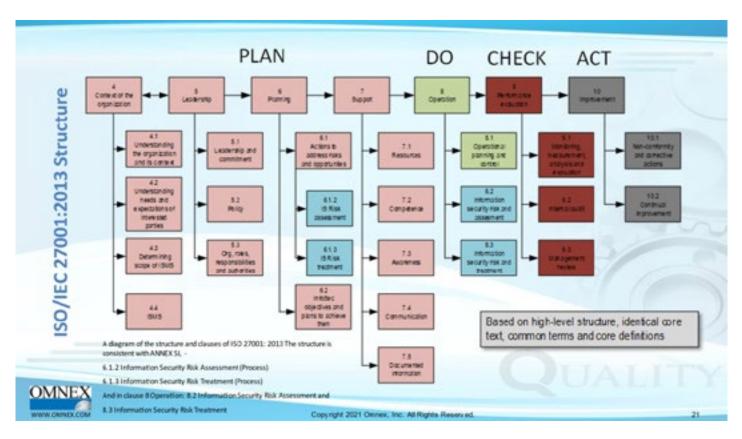
# The Cybersecurity Standards Landscape & Supply Chain Standards

CONTINUED FROM PAGE 13 BY CHAD KYMAL, CTO, OMNEX INC.

TISAX focuses on the controls and ISO 27001 ISMS provides the overall management system with the PDCA cycle

to ensure it is effective. The controls for TISAX have been added into the Annex A controls of ISO 27001. The ISO 27001

requirements are shown below:



# **Telecommuncations Industry**

The Telecommunications Industry Association (TIA) represents the entire supply chain of companies that build and support communications technologies and information networks. This industry implemented in 1999 a standard called TL 9000 for their supply bases from the network infrastructure provider to the service providers are included as a part of this standard.

Cybersecurity is that much more important to an industry that is the

backbone of communications and information exchanges of any kind. Considering the security challenges from the integrator to the component supplier, the TIA Quest has adopted a cybersecurity supply standard SCS 9001. For more on the SCS 9001, see page 16 of the newsletter.

This article does not cover the product cybersecurity standards prevalent in the industry such as ISO 21434 for Automotive Cybersecurity or UNECE or WP 29 an initiative by the UN

on Automotive regulations that are having a major impact on Automotive Cybersecurity.

Contact Omnex for more information on any of these standards including training, gap analysis, and or implementation.



# **Public Training & Onsite Training Available**



# IATF 16949

Understanding Internal Auditor, Lead Auditor and Manufacturing Process Auditor

# **Core Tools**

APQP, DFMEA, PFMEA, Control Plans, PPAP, SPC and MSA

# **Quality Management System Series**

Executive Overview, Understanding, Internal Auditor, Lead Auditor, Manufacturing Process Auditor, Supplier Auditor, Transition Training

**Automotive SPICE / ISO 26262 / AIAG / VDA FMEA** 

#### **Core Tools**

APQP, DFMEA, PFMEA, Control Plans, PPAP, SPC and MSA

ISO 45001 / CQI / CSR / Effective Problem Solving / **Problem Solving using 8D** 

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# TIA initiative

CONTINUED FROM PAGE 1 BY CHAD KYMAL, CTO, OMNEX INC.

The SCS 9001 is a Supply Chain Security Management System. Security here refers to both Information Security and Product Security. In other words, the security of the IT Assets in the organization and the security of the products designed and manufactured. When the SCS 9001 standard references "security" it is referring to "Supply Chain Security." This means the SCS 9001 standard is a supply chain standard for the Telecommunications Industry as a whole.

The SCS 9001 security standard is similar to the efforts of the German Automakers who adopted TISAX (Trusted Information Security Assessment Exchange) for the supply chain of the German OEMs such as Volkswagen, Audi, and Daimler. It is also

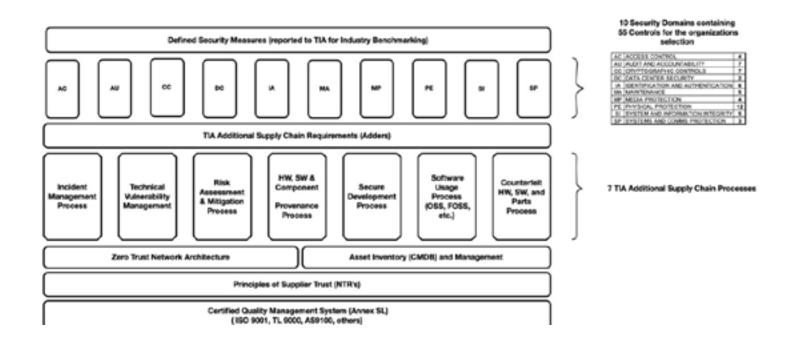
similar to the CMMC standards adopted by the Department of Defense (DoD) which are based on NIST standards for cybersecurity controls. Other industries are sure to follow suit due to large risks to both organizations and products posed by both internal and external actors with malicious intent.

The SCS 9001 standard appears to be the most comprehensive and most specific supply chain security standard because IT Telecommunications are at the center of all organizational infrastructure for both the US and global organizations. The standard builds on ISO 9001 adding specific requirements and controls for design, development, production, operations, and service for IT and Telecommunications suppliers. In

addition, it specifies measurements for companies to help monitor and evaluate the effectiveness of supply chain security management systems and improvement programs.

The key to understanding SCS 9001 is reflected in the architectural model shown below. While it appears somewhat complicated, it is simply a summary of the entire standard including security measures (metrics), 10 security domains, supply chain requirements, and some key security processes.

This standard builds on certain foundational ideas of Zero Trust Network Architecture, asset inventory and management, Supplier Trust, and an ISO 9001 based Quality Management System.



Omnex helps train and implement both IT Infrastructure (assets) and Product Cybersecurity standards. Generally, they are two different standards, for example, ISO 27001 or CMMC for IT Infrastructure

and ISO 21434 for Automotive Product Security or the UNECE or WP 29 for Product Security. In SCS 9001, both of these areas are integrated very effectively into one standard.

This standard addresses the increased risks inherent in the Telecommunications Industry but could be expanded to any business situation where attacks are as much a threat as they are in this



# TIA initiative

CONTINUED FROM PAGE 16 BY CHAD KYMAL, CTO, OMNEX INC.

industry. This is a comprehensive, indepth information security system that leaves little to chance. While all of these systems show controls to be determined by what the company perceives the risks to be, in the SCS 9001 system, these controls are required to be robust, fully implemented and demonstrably effective.

For example, the mobile device policy has 18 requirements with the last one on Bring Your Device (BYOD) having this to say –

"If the organization allows BYOD, a BYOD policy shall be stated. This policy shall include

 The device and eligibility requirements to allow for BYOD usage,

- 2. The BYOD is included in the organization's inventory of all mobile devices,
- 3. Clarifying language for the expectation of privacy, requirements for litigation, e-discovery, and legal holds.
- 4. Stating the expectations regarding the loss of non-company data in the case that a wipe of the device is required,
- 5. Where applicable, a requirement to perform backups of data; identified methods for data backup
- 6. The systems and servers allowed for use or access on a BYOD-enabled device, and
- That BYOD devices shall be made available for inspection or update."

The level of detail provided in this standard will help organizations implement and auditors audit specific requirements. It will also provide great comfort to the OEMs and the general public to develop trust in Telecommunications products that follow SCS 9001. SCS 9001 can be seen as a gatekeeper to enable suppliers to provide trustworthy products or services to the Telecommunications Industry. As you can imagine, a product or service that is not certified to SCS 9001 could introduce a vulnerable weak link to the network or product supplied.





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# APQP/PPAP Document









#### OMNEX NEWS FROM AROUND THE WORLD

#### **OMNEX US NEWS**

# Omnex IMS - Certification for ISO 27001

• Omnex has an Integrated Management System that includes prior certifications for ISO 9001, ISO 14001, ISO 45001, and conformance to ISO 26000. We are pleased to announce that in early November we achieved certification for ISO 27001, (IT Security).

# Omnex License Agreement for Automotive SPICE®

- Omnex is pleased to announce that earlier this year we finalized a licensing agreement with VDA-QMC for the use of the Automotive SPICE® and Automotive SPICE® terminology and logo
- · Omnex has been leading the way in providing services and solutions to our clients in the Electric and Autonomous Automotive industry, and this agreement with VDA-QMC is another important step in Omnex being a leader that our clients rely on. We value and respect the impact of VDA-QMC on the global automotive industry, and so we look forward to working with them in the years to come on Automotive SPICE® and other vital products and services to remain on the cutting edge of quality and continual improvement

# Omnex - Customer Satisfaction, (Live Learn, Personalized Learning, E-Learning, And Virtual Training)

 With the impact of COVID-19 in 2020-21, Omnex took the lead in being able to continue to offer our products

- and services to clients, while maintaining our focus on customer satisfaction, and health and safety. Omnex quickly adapted our training, auditing, implementation, and software services to virtual platforms like Zoom, Microsoft Teams, and WebEx, and went further by rolling out our personalized learning platform, Live Learn
- This platform allows Omnex to offer clients a training course virtually that focuses on learning objectives and competencies while incorporating a 3-3-2 structure that consists of a combination of self-study, live instruction, and quizzes/testing
- Omnex stresses the importance of our client feedback and so we are happy to report that we are achieving, and exceeding, our goals for training course evaluations
- We review client feedback on a weekly and quarterly basis, since we take every compliment and concern seriously and strive to enhance the services and products we provide to our customers

#### **New Omnex Website Launched**

 Omnex has improved our website(s), which we introduced earlier this year.
 We wanted to make the website more user-friendly so clients could easily find information on training courses, our products, and services, as well as webinars, whitepapers, and knowledge from our team of highly qualified subject matter experts  We strongly invite you to explore our new website, www.omnex.com, and we welcome your input as always

## Want to Work for Omnex?

- Omnex developed a new website earlier this year that allows potential applicants to quickly examine current Omnex positions and submit all of their pertinent information (including their resume and experience)
- Omnex is a global company that is always seeking highly qualified candidates for different positions. For that reason, we encourage all candidates to visit our website and fill out their profiles for consideration for all current and future positions. Visit the careers section of our website, careers.omnex.com/ users/jobs

#### **OMNEX EUROPE NEWS**

## **Germany Snapshot**

- The pandemic has paralyzed social and economic development. As vaccination rates rise, life is beginning to return back to normal. Consumer consumption is on the upswing once more, and the manufacturing is also rising. However, everything appears to be moving at a slower pace than usual, and some people are waiting with bated breath for the pandemic infection numbers to rise in the coming winter
- Supply chains in the EU are slow and unpredictable, and electronic chips are in short supply across the board. Energy costs are continuing to rise, and the entire economy is hesitant to make long-term decisions



#### OMNEX NEWS FROM AROUND THE WORLD

# Germany After the September 26 Election

- The new government is due to take office in December. The coalition of Social Democrats, Greens, and Liberals want to form a government of progress. The primary goals are
  - Alternative energy supply
  - Climate protection through technical development, not restrictions
  - Sustainability throughout the entire product life cycle
  - Digitization of all areas of life: Administration, education, communication, trade, and production

# Germany in the Future

- The German and European automotive industries will continue to create, manufacture, and sell great, luxurious, and faster cars regardless of how society and the economy (re) develop. The new coalition government has made assurances that there will continue to be no speed limit on Germany's super-highways, even after almost a hundred years!
- Our customers expect us to accompany them into this future, first on the road to the electrification of car traffic, then on the road to self-driving vehicles. Omnex experts have a lot of work to do in a market that is finally developing a new dynamic

# **OMNEX ASIA NEWS**

#### India

 A contract was signed with a leading European OEM to run their Quality School workshop with a long-term competency development strategy. Omnex will engage with the OEM Quality School to increase the competency of over 3,000 of

- their employees through the end of 2022
- Omnex implemented a thirdparty inspection program for leading OEMs, covering internal and supplier firewall inspections. The project covered over 20 supplier locations, and over 100 quality inspectors worked onsite
- Omnex is pleased to announce that nine leading Tier 1 companies have renewed their yearly training contracts with us. We have trained over 9,500 workers of these companies in tailored programs over the last several years. Over 2,000 employees have trained annually from Omnex's long-term accounts
- In 2021, Omnex India completed a large ISO 9001 Implementation for Maharashtra State Pollution Control Board at 15 Regional offices and 30 subregional offices and ISO 17025 implementation at their head office, making MPCB one of the leading Governmental Pollution Control boards adopting Best in Class practices, including a fully automated Online SOP access IT Tool for ease of access. We continue to assist MPCB on the Sustenance of the systems and **Compliance Audits**
- Omnex also launched the Automotive Core Tools qualification and Auditing Methods program, which drew over 1,500 participants from top Tier 1 organizations, and completed Functional Safety Level 1 certification programs for 200 specialists in Asia
- Numerous methodologies and contracts were implemented including IATF 16949, ISO 45001, ASPICE, ISO 17025, MMOG, ISO 50001, ISO 26262 Functional Safety. Some of the clients with whom we are continuing to work include MRF Tyres, Indian Air Force, JSW Group, Bharat Forge,

- Philips, TATA Motors, Daimler India, VOLVO, Bharat Electronics, etc
- Four OEMs and 18 Tier 1
   Automotive companies signed
   up for Enterprise Automation of
   QHSE and APQP Solutions. More
   than 8,000 employees from the
   industry will now use EwQIMS
- For further information, please contact us at omnexindia@omnex.com

#### **Omnex Middle-East**

- The Middle East office of Omnex has assisted several large US and European Aerospace and Automotive companies with their Asia Supply Chain strategies
- Key implementations include onsite supplier development in line with IATF 16949, AS9100, and AS9145 Systems, continuous improvement assessments, and continual monitoring of suppliers in Asia
- Omnex's local Subject Matter Experts in the Asia Pacific region monitor and improve, using weekly targeted measures, Process performance, Production PPM, Process run@ rates Final Stages of finalizing an MOU with a Saudi Arabian organization focused on Lab Quality Management and ISO 17025. This MOU will involve Omnex providing relevant pieces of training to clients in Saudi Arabia and other parts of the Middle East, operator skill mapping, and breakdown analysis to overcome the risks of overseas travel from pandemics
- Omnex seeks to serve the training and consulting needs of enterprises across the Middle East in the areas of Supplier Management, Production Process Improvement, and Strategic Operations Consulting, including Automation and Digitalization, thanks to strong links with local organizations



# OMNEX TRAINING OFFERINGS FOR 2022

# **TISAX**

ISO/IEC 27001:2013 and VDA ISA TISAX Internal Auditor Training for Information Security Management Systems

ISO/IEC 27001:2013 and VDA ISA TISAX Lead Auditor Training for Information Security Management Systems

Understanding the Requirements of ISO/IEC 27001:2013 and VDA ISA TISAX for Information Security Management Systems

# Cybersecurity

Cybersecurity Maturity Model
Certification (CMMC) and ISO/
IEC 27001:2013 Internal Auditor
Training for Information Security
Management Systems (ISMS)

Understanding the Requirements of Cybersecurity Maturity Model Certification (CMMC) and ISO/ IEC 27001:2013 for Information Security Management Systems

Cybersecurity Maturity Model
Certification (CMMC) and ISO/
IEC 27001:2013 Internal Auditor
Training for Information Security
Management Systems (ISMS)

Preparing a Cybersecurity Case

SAE J3061 and ISO/SAE 21434:2021 Automotive Cybersecurity Auditing and Assessment Certification

SAE J3061 and ISO/SAE 21434:2021 Automotive Cybersecurity Certification

SAE J3061 and ISO/SAE
21434:2021 Conducting a
Cybersecurity FMEA and
Vulnerability Analysis Testing for
Systems, Hardware and Software

SAE J3061 and ISO/SAE 21434:2021 Cybersecurity Engineering Defense & Protection Against Attacks

SAE J3061 and ISO/SAE 21434:2021 Cybersecurity Threat Analysis and Risk Assessment (TARA)

Understanding the Requirements of Cybersecurity Maturity Model Certification (CMMC) and ISO/ IEC 27001:2013 for Information Security Management Systems

WP.29, ISO21434, and VDA CSMS - Automotive Cybersecurity Management Systems

Introduction to Systems
Engineering: A Safety and
Cybersecurity Perspective

# Information Security Management Series

ISO/IEC 27001:2013 Internal Auditor Training for Information Security Management Systems

ISO/IEC 27001:2013 Lead Auditor Training for Information Security Management System

<u>Understanding the Requirements</u> of ISO/IEC 27001:2013 for <u>Information Security Management</u> <u>Systems</u>

#### Automotive SPICE®

Automotive SPICE® and ISO 26262 Executive Overview

intacs Certified Competent
Assessor (Automotive SPICE® V3.1)

intacs Certified Provisional
Assessor (Automotive SPICE® V3.1)

Internal Quality Assurance
Practitioners of Automotive
SPICE®

Mechanical Engineering Plug-Infor Automotive SPICE®

Understanding Automotive SPICE® including integration with ISO 26262 and IATF 16949

Understanding PRM/PAM. Hardware Engineering Processes and Integration with Automotive SPICE®

Writing Effective Requirements and Test Cases for Automotive Software Performance Improvement and Capability Determination (Automotive SPICE®) and HWE PRM/PAM

Writing Effective Requirements, Test Cases and Hardware/ Software Interface (HSI) for ISO 26262:2018 and Automotive SPICE®

#### **SOTIF**

Introduction to Autonomous and Electric Vehicles: A Functional Safety, SOTIF, and Cybersecurity Perspective

Overview to ISO/PAS 21448:2019 (SOTIF)

# ISO 26262 Series

ISO 26262 Functional Safety Overview for Functional Safety Engineers and Managers

ISO 26262:2018 Automotive Functional Safety Certification

ISO 26262:2018 Automotive Functional Safety Certification with Motorcycle Focus ISO 26262:2018 Automotive Functional Safety Certification with Truck & Bus Focus

ISO 26262:2018 Functional Safety Certification for Functional Safety Managers and Program Managers

## IATF 16949:2016 Series

IATF 16949:2016 Internal Auditor Training for Automotive Quality Management Systems

IATF 16949:2016 Lead Auditor Training for Automotive Quality Management Systems

IATF 16949:2016 Supplier Auditor Training for Automotive Quality Management System

Understanding the Requirements of IATF 16949:2016 Automotive Quality Management Systems

# **Agile APQP**

Agile APQP with Lean Product Development Overview

Agile APQP Overview - Advanced Product Quality Planning

# **Aerospace and Defense**

AS9100D Internal Auditor
Training for Aerospace Quality
Management Systems

AS9100D Lead Auditor Training for Aerospace Quality Management Systems

Understanding and Documenting AS9100D Quality Management Systems

AS9110C Internal Auditor Training

**AS9110C Lead Auditor Training** 

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# OMNEX TRAINING OFFERINGS FOR 2022

Understanding and Documenting AS9110C Quality Management Systems

AS9145 with Design FMEA (DFMEA) and Process FMEA (PFMEA) for Aviation, Space and Defense Organizations

<u>Understanding AS9145 - APQP</u> and PPAP for Aviation, Space and <u>Defense Organizations</u>

# Automotive and Production/ Manufacturing Core Tools

<u>Understanding Core Tools:</u> Statistical Process Control (SPC)

AIAG-VDA DFMEA (SFMEA and DFMEA) for Practitioners and Facilitators

AIAG-VDA Process FMEA and. Control Plans for Practitioners and Facilitators

Manufacturing Process
Development using PFMEA.
(Process Flow, PFMEA, Control.
Plan, Part & Process Approval)

Product Development using
SFMEA, DFMEA and Associated
Tools

<u>Understanding Core Tools - APQP</u> & PPAP

<u>Understanding Core Tools -</u>
<u>Measurement Systems Analysis</u>
(MSA)

<u>Understanding Core Tools -</u> <u>Statistical Process Control (SPC)</u>

Understanding Core Tools (APQP/ PPAP, DFMEA, DVP&R, SPC and MSA) Following the AIAG-VDA FMEA 1st Edition Methodology Understanding Core Tools (APQP/ PPAP, DFMEA, DVP&R, SPC and MSA) Following the AIAG FMEA 4th Edition Methodology

Understanding Core Tools (APQP/ PPAP, PFMEA, Control Plans, SPC and MSA) Following the AIAG FMEA 4th Edition Methodology

Understanding Core Tools (APQP/ PPAP, PFMEA, Control Plans, SPC and MSA) Following the AIAG-VDA FMEA 1st Edition Methodology

# Integrated Management Systems Series

Integrated Management Systems

- Internal Auditor Training (ISO
9001 and/or IATF 16949, ISO
14001 and ISO 45001)

Integrated Management Systems – Lead Auditor Training (ISO 9001 and/or IATF 16949, ISO 14001 and ISO 45001).

# ISO 13485:2016 Series

ISO 13485:2016 Internal Auditor Training

ISO 13485:2016 Lead Auditor Training

<u>Understanding and Documenting</u> <u>ISO 13485:2016</u>

# **MDSAP Course**

Internal Auditor Training Based on ISO 13485:2016 and International MDSAP Audit Model

Lead Auditor Training Based on ISO 13485:2016 and International MDSAP Audit Model Understanding the Requirements of ISO 13485:2016 and International MDSAP Audit Model

## ISO 14001:2015 Series

ISO 14001:2015 Internal Auditor Training for Environmental Management Systems

ISO 14001:2015 Lead Auditor Training for Environmental Management Systems

<u>Understanding the Requirements</u> of ISO 14001:2015

## ISO 45001:2018

ISO 45001:2018 Internal Auditor Training for Health & Safety Management Systems

ISO 45001:2018 Lead Auditor Training for Health and Safety Management Systems

Understanding the Requirements of ISO 45001:2018 for Health & Safety Management Systems

# ISO 9001:2015 Series

ISO 9001:2015 Internal Auditor Training for Quality Management Systems

ISO 9001:2015 Lead Auditor Training for Quality Management Systems

<u>Understanding the Requirements</u> of ISO 9001:2015 Quality <u>Management Systems</u>

# ISO/IEC 17025:2017 Series

ISO/IEC 17025:2017 Internal
Auditor Training for Laboratory
Management Systems

ISO/IEC 17025:2017 Lead
Auditor Training for Laboratory
Management Systems

Understanding the Requirements of ISO/IEC 17025:2017 for Laboratory Management System

# ISO 14971 Series

Understanding ISO 14971:2019
Application of Risk Management
to Medical Devices

ISO 14971 Application of Risk Management to Medical Devices Overview

ISO 14971 Application of Risk Management to Medical Devices -PFMEA Overview

ISO 14971 Application of Risk Management to Medical Devices -DFMEA Overview

ISO 14971:2019 Application of Risk Management to Medical Devices Including DFMEA and PFMEA

#### **R&D Series**

Design of Experiments (DOE)

Geometric Dimensioning & Tolerence(GD&T) (ASME Y14.5-2009)

Geometric Dimensioning & Tolerence(GD&T) Gage Design

Tolerance Stack-Up Analysis (GD&T Application)

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# OMNEX TRAINING OFFERINGS FOR 2022

# Teams and Problem Solving Series

**Design of Experiments (DOE)** 

**Effective Problem Solving** 

<u>Problem Solving – Employing the</u> <u>8D Methodology</u>

Statistical Process Control (SPC) and Associated Tools

## **VDA Series**

Conducting Process Audits to VDA 6.3

Conducting Product Audits to VDA 6.5

<u>Understanding VDA 6.3</u>

<u>Understanding VDA 6.3 Process</u> <u>Audits</u>

**VDA 6.3 Executive Overview** 

Product Integrity for the
Product Safety & Conformance
Representative (PSCR)

Omnex is not presently a VDA licensee. If the VDA auditor "card" is required by a customer for their suppliers' auditors, attendees should confirm with a licensed provider if they can take the official exam after this course. Omnex auditor certification is the technical equivalent of the VDA (6.3) training. Many customers do not require the VDA auditor credential.

# **OMNEX AMERICAS**

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Irvine, CA

Minneapolis, MN

Nashville, TN

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# CANADA

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#### **MEXICO**

Mexico City, MX





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# Omnex 2021 Whitepapers and Webinars

Stay up to date with your industry. Omnex experts share findings over a variety of industries and standards in our resource center.

# **WHITEPAPERS**

Integrated Management Systems
- Updated to the latest standard
changes including ISO 9001:2015,
ISO 14001:2015 and ISO 45001:2018

by Chad Kymal, Gregory
 Gruska, Dan Reid

Considerations of Functional
Safety, Automotive SPICE®, and
Cybersecurity in Automotive
New Product Development

- by Chad Kymal, Dr.Juan Pimentel

<u>ISO 45001 – Occupational Health</u> <u>& Safety Management System</u>

- by Kumar Sivan

Agile APQP Overview in Product Development Innovation

- by Michael Popenas

<u>US Govt (solarwinds) breach:</u>
A warning of the perils to
critical infrastructures

- by Dr.Juan Pimentel

Integrating FMEAs, FMEDAs, and Fault Trees for Functional Safety

- by Greg Gruska and Chad Kymal

<u>Digitalization of New</u> <u>Product Development</u>

- by Chad Kymal, Antony John

# **WEBINARS**

Cybersecurity in Aerospace

Integrating Automotive SPICE® and Functional Safety into your New Product Development Planning and Requirements Management

PPAP Reviews - Man vs. Machine

Best Practices for Quality Assurance in Automotive SPICE ®

TISAX – An Automotive Industry
Cybersecurity Requirement

Integrating the New AS13100
Customer Specific Requirements
into your AS9100 Quality
Management System

<u>Successful Implementation of</u>
APQP & PPAP using Digitalization

Cybersecurity Maturity Model
Certification (CMMC) – A Government
and an Industry Priority

FMEA, FMEDA, and FTA
Using Multipoint FMEAs with

Collaborative Software Platform

Top Management's Responsibility for Risk Management in Medical Device Manufacturing (The Requirements of ISO 14971:2019)

Automotive Cybersecurity - Making Sense of a Complex Landscape

SAE J1739 FMEA – The Updated FMEA Standard

IATF 16949 Update - Automotive SPICE®, TISAX, ACMS, VDA PPAP and Other News

Becoming familiar with IEC/
ISO 62304 Software Life Cycle
Processes for Medical Devices

<u>Conducting Virtual APQP Program</u> <u>Assessments on Suppliers</u> Information Security Management:
An Industry Priority (ISO 27001)

PPAP reviews powered by Artificial Intelligence

Exclusive session discussing
EV-AV (Electric & Autonomous
Vehicle) Strategies for Executive
Management and Leadership

Overview of ISO 13485 for Medical Devices

<u>Challenges and Best Practices</u> <u>Implementing Automotive SPICE®</u>

Successful Implementation of AS9145 using Digitalization

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# **OMNEX GROUP**

Omnex and its group companies bring to you cutting edge business improvement practices, tools & methods that increase your competitiveness in the world market.















# **BUILDING WORLDWIDE BUSINESS EXCELLENCE**



# Who in the world is OMNEX?

Our global clients will tell you. We've implemented management systems for many of the world's top companies.



ISO 9001 & IATF 16949 | AS9100D | ISO 26262 | ISO 14001 | ISO 45001 | ISO 50001 | FSSC 22000 | ISO 13485 | APQP | Risk Management | Lean Enterprise



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