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UNDERSTANDING THE CHANGES

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## The AIAG-VDA DFMEA – Understanding the Changes

GM, Ford, and Chrysler had established a not for profit organization, AIAG, in the early 1980's with the mission "To improve its members' competitiveness through a cooperative effort of North American vehicle manufacturers and their suppliers." In the late 1980's, the US Automotive industry suppliers, through auspices of the American Society for Quality (ASQ), approached the VPs of Purchasing for GM, Ford, and Chrysler and explained the burden of multiple standards that were being imposed on

Gregory Gruska, VP, Omnex Systems

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## Information Security – To Hack or Not To Be Hacked APQP

When we think about IT Security, we typically think about the large hacks that were reported in the press. When viewed as a whole, we can understand the magnitude of lost data. (See Table 1.) It is no surprise that these hacks are what comes to mind when we think about information security.

Chad Kymal, CTO, Omnex INC

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

New technologies and an expanded supply chain have increased design and production complexity

Product design in autonomous and electric vehicles requires a product architecture of systems, subsystems, hardware, and software, as well as requirements management and the "Engineering V." Electronics, hardware, and software in the product also necessitate new software standards. Automotive SPICE, a software capability standard required by many OEMs,

Chad Kymal and Dr. Juan Pimentel

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## Waste Management is the New Fashion

Never in the metropolis of Shanghai, a home of 25 million residents, have there been so much enthusiasm, passion and participation around the subject of 'garbage'. Starting from 1 July 2019, the city's lately issued 'Regulation of Shanghai Municipal Household Waste Management' will take effect. Discussions and posts are everywhere on the newspaper, TVs and the Internet including social

Lily Xie, Omnex General Manager China

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# The AIAG-VDA DFMEA – Understanding the Changes

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GREGORY GRUSKA, VP, OMNEX SYSTEMS

the supply base. Not only where there multiple OEM standards, there were 100s of tier one standards as well.

After understanding the problem of multiple standards and the “waste” it represented, the American OEMs, with the Automotive Division of the ASQ, created a Supplier Quality Requirements Task Force or SQRTF who would work on harmonizing GM, Ford, and Chrysler standards. This work would be conducted and disseminated through AIAG. The results of the work was first seen with the release of the Measurement Systems Analysis standard in 1990. It was soon followed by the Statistical Process Control standard in 1991, Production Parts Approval Process and FMEA in 1993, and the APQP and QS 9000 Management Systems standard in 1994. The QS 9000 standard and the five core tools (MSA, SPC, FMEA, PPAP & APQP) helped harmonize the OEM expectations of the US Automotive Industry. Mr. Greg Gruska, one of the writers of this article, was on the writing committees of the MSA, SPC and FMEA manuals.

In 1999, AIAG and VDA worked together to introduce a joint US and German Quality Management System standard, the ISO/TS 16949. In 2002, the Japanese Automobile Manufacturers Association or JAMA joined the AIAG and the VDA to make ISO/TS 16949:2002 the first global Automotive standard. It was important for two reasons. First, it was a global Automotive standard and second, it incorporated ISO 9001:2000, which included Customer Focus and the Process Approach. While the Quality Management System standards between the US and Germans were harmonized the Core Tools (MSA, SPC, FMEA, PPAP and APQP) were still unique. Each of these tools are applied differently with their own specific approaches.

## Same Tool, Different Approaches

The same tool being applied differently caused multiple problems if the same plant or design center supplied both US and German OEMs. Other times, it was two different approaches to New Product Development being applied by the engineering functions of the same company in their US and German Design Centers and Plants. The redundant approaches caused significant non-value added in the supply chain. An automotive industry survey by Deloitte and AIAG in 2015, which included respondents from the German Automobile industry, showed that “suppliers are most concerned with their ability to standardize business processes and systems, while OEMs were concerned with managing customer expectations and relationships.” Scott Sharland, Executive Director of AIAG had this to say – “most OEM purchasing teams have reduced their number of Tier 1 suppliers, favoring larger, more technology-laden companies with global manufacturing capabilities. “These mega-Tier 1s enjoy a more balanced book of business than they did when they were quasi-captive suppliers for one or two OEMs only,” he says, “and as a result, Customer Specific Requirements (CSR) variations from OEM to OEM have quickly driven up compliance complexity and cost.”

David Kneisler, VP of Quality at Dana, points out that “obviously, the OEMs believe quality is not only critical to their business but also a competitive advantage, so there is a need for some Customer-Specific Requirements. Speaking as a tier supplier, however, the complexity of CSRs for Tier 1s is difficult, and the challenge for Tier 2 through Tier N must be incredibly confusing. A standard approach would have significant benefits — we should commonize what could be commonized.”

The study monetized the lack of commonization as costing them “16

workdays annually per site” to meet QMS requirements. They felt that a 40% reduction (\$50,000 value) was possible if the quality expectations were commonized. One of the top three actions in this study was working for common standards with the Verband der Automobilindustrie (VDA) which is the German Automotive Industry’s equivalent to AIAG.

The results of the reduction of the CSRs standards can be seen in the IATF 16949 standard released in Oct of 2016 where the 16 OEMs that made up the International Automotive Task Force (IATF) worked together to reduce their CSRs.

## Why the AIAG-VDA FMEA

The AIAG and VDA began working in 2015 on a joint workgroup made up of individuals from the OEMs and Tier One Suppliers. The idea was to reduce confusion and redundancy that was prevalent in organizations that had to use two different methods. The one in the US was frequently completed using Excel and driven by company personnel. The one in Germany was completed using FMEA software programs and driven by specialized facilitators. Omnex participated in 2013 and 2014 in FMEA forums in Germany where there were discussions on the merits of both approaches. Each method had their pros and cons and a combination was necessary to alleviate the confusion in the large tier ones where both methods were used.

The goal of the workgroup was to develop a single robust, accurate, and improved methodology that satisfied both AIAG and VDA FMEA approaches.

## Where Are We Today?

The new AIAG-VDA FMEA 1st edition was released in November 2017 as a draft by AIAG and a yellow book by VDA for a 90 day commenting period. The draft was available (free) from the respective organizations and

# The AIAG-VDA DFMEA – Understanding the Changes

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readers were encouraged to understand the changes, read the manuals for themselves, and to provide their comments.

The AIAG-VDA FMEA first edition was planned to be released in 2018, but was finally released on June 3, 2019

## A Brief Summary of the New FMEA

The new FMEA adopts a **seven step process** as shown below.

1. Planning and Preparation
2. Structure Analysis
3. Function Analysis
4. Failure Analysis
5. Risk Analysis
6. Optimization
7. Results Documentation

The **FMEA Form** follows Step 2 thru 6 as follows. Some comments on the form:

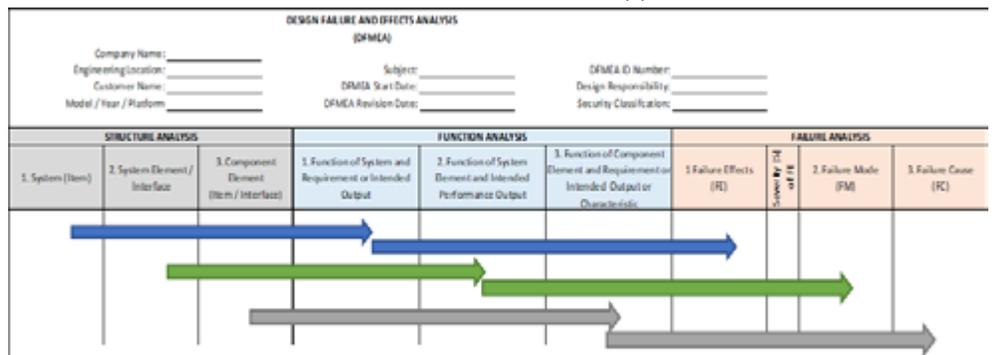
- First, it can be seen that the form has many more columns than previously.
- Second, the first three grouped headings which are structure analysis, function analysis and failure analysis are organized in threes representing the focus element, the higher element and the lower element.
- The fourth grouped heading is the Risk Analysis which shows an absence

develop their FMEAs, software to develop FMEAs will become commonplace with the AIAG-VDA FMEA because it represents a 3 dimensional relationship not easy to capture in an Excel form.

Additionally, it is important to understand there are relationships between the columns in the form as follows:

Simply said, the focus element (the column numbered 2 above) has a function and a requirement and the function/requirement has a failure mode. Similarly the high level element to the left of the focus element has a function and requirement and it has a failure mode. Similarly, the lower level element to the right side of the focus element has a function and requirement and it has a failure mode. The failure mode of the focus element is caused by the failure mode of the lower level element and it results in the failure of the higher level element. The direct use of this relationship between the elements of the Bill of Materials in a system or sub system is probably one of the bigger differences between the AIAG and VDA DFMEA approaches. Now the new AIAG-

STRUCTURE ANALYSIS	1. System (Item)
	2. System Element / Interface
	3. Component Element (Item / Interface)
FUNCTION ANALYSIS	1. Function of System and Requirement or Intended Output
	2. Function of System Element and Intended Performance Output
	3. Function of Component Element and Requirement or Intended Output or Characteristic
FAILURE ANALYSIS	1 Failure Effects (FE)
	Severity (S) of FE
	2. Failure Mode (FM)
	3. Failure Cause (FC)
RISK ANALYSIS	Current Prevention Control (PC) of FC
	Occurrence (O) of FC
	Current Detection Control (DC) of FC or FM
	Detection (D) of FCFM
	AP
	Filter Code
OPTIMIZATION	Prevention Action
	Detection Action
	Responsible Person
	Target Completion Date
	Status: [Untouched, Under Consideration, In Progress, Completed, Discarded]
	Action Taken with Pointer to Evidence
	Completion Date
	Severity
	Occurrence (O)
	Detection
AP	



of the RPN and the introduction of the Action Prioritization step.

- The fifth grouped heading is the Optimization that shows the recommended actions planned and the action taken.

Although the FMEA process was developed so that teams could use the forms to

VDA FMEA has adopted this approach.

the focus element has a function and requirement and it has a failure mode. The failure mode of the focus element is caused by the failure mode of the lower level element and it results in the failure of the higher level element. The direct use

# The AIAG-VDA DFMEA – Understanding the Changes

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of this relationship between the elements of the Bill of Materials in a system or sub system is probably one of the bigger differences between the AIAG and VDA DFMEA approaches. Now the new AIAG-VDA FMEA has adopted this approach.

## What Changed?

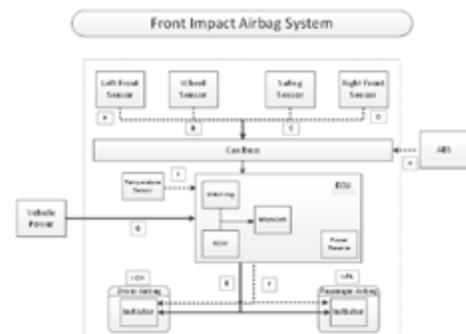
What changed differs in perspective from the existing AIAG and the VDA methods. In this section, we will study these changes first from a VDA approach and then the AIAG approach. We will start with the DFMEA in this paper, while addressing the PFMEA in the next.

### 5Ts

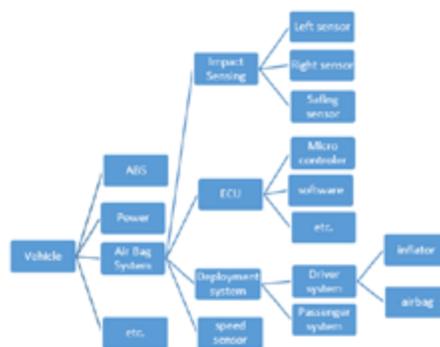
- **FMEA Team**  
– Who needs to be on the team?
- **FMEA Timing**  
– When is this due?
- **FMEA Intent**  
– Why are we here?
- **FMEA Task**  
– What work needs to be done?
- **FMEA Tool**  
– How do we conduct the analysis?

## What Changed in the DFMEA – VDA APPROACH?

The new DFMEA approach now includes a new first step, e.g. “scoping.” The biggest difference is that this step is not the 5Ts / Project Planning but the block or boundary diagram. This diagram is used at the start of each DFMEA in the AIAG approach. See an example of a block diagram below.



The structure analysis is the second step in the New DFMEA. The purpose of structure analysis is to identify and breakdown the design into systems, subsystems, components, and parts for technical risk analysis. In this step, the structure analysis is completed and the focus element is determined. The focus element is the application of the FMEA investigation. See the figure below.



Nothing in the structure analysis has changed. The VDA process follows a multi-tier approach. Frequently, there is a three tier investigation in the focus element, the higher level element and the lower level element. “Why only three levels?” would be the question asked. Are all investigations going to stop at the three levels? Should complex systems not require multiple system and sub system DFMEAs? What is the responsibility of an owner of a system?

Note: The VDA approach often times describes more than three levels, however, VDA teams and facilitators in practice do not go beyond one DMEA and one focus level.

The third step is the function/requirements step. While this step is also not new to the VDA DFMEA, the addition of requirements is. This may be seen as optional by the VDA practitioners, the AIAG methodology specialists may say that the function and requirements will allow us to more

precisely define failure modes. Although Omnex DFMEAs always used functions and requirements, one cannot generalize it for all AIAG DFMEA implementations.

Failure analysis is the fourth step of the process; it identifies the functional loss or degradations when the requirements are not met. In the VDA approach, subsequent analysis is based on the failure modes for all levels of the structure (at least 3). The AIAG approach only requires the failure mode to be described for the focused level. Although identification of the effects and causes of the focused failure mode will use the same logic as the VDA approach, explicit identification of the higher and lower failure modes is not required.

It is here where we see the “old” and “new” approach beginning to merge. Step 4 identifies:

- The effect = the failure mode of the higher level
- The failure mode = the failure mode of the focused level
- The cause = the failure mode of the lower level

If the preliminary work is complete, the relationships among the failure modes of all three levels can be mapped out. In this situation, the VDA approach forces the team to only look at the levels identified and helps them from (erroneously) jumping down levels in their analysis. For example, identifying a part characteristic as the cause when the appropriate cause is the design approach for the component.

In this step we also see the use of the Parameter Diagram. The Parameter Diagram, though not mandatory in the AIAG approach, was used frequently to help understand the relationships of the input to the output, the noise factors that influences the design and the unintended outputs. The

# The AIAG-VDA DFMEA – Understanding the Changes

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Parameter Diagram is a new suggested tool for the VDA DFMEA specialist.

The fifth step in this approach is risk analysis. The approach to identify necessary preventive and detective controls to eliminate, mitigate, or detect causes or failure modes is the same for VDA and AIAG. The difference between the two is the identification of priorities of what should be worked on first. The introduction of Action Priority (AP) tables will require a rethinking of prioritization. In the US, the AIAG approach encouraged teams to consider alternate prioritization schemes and many Omnex customers used this option. The new AIAG-VDA handbook does not appear to allow this flexibility.

The sixth step, optimization, is one of the steps which may be quite different for the VDA format. While recommended actions as a whole was used by the AIAG approach, the new approach focuses on identifying alternative preventive and detection actions. This forces the team to limit their recommendations only to these categories. This approach of preventive and detective actions only may seem limiting to those familiar with the AIAG approach.

The seventh step, Results Documentation, is also new to the VDA facilitator who did not have explicit requirements for the results documentation publication.

## What Changed from the AIAG DFMEA Approach?

### A. Structure Analysis

The biggest change is the structure or bill of materials or the identification of the system, sub system and component required for the new DFMEA.

While, this is not new for the VDA specialists, it is indeed quite different for the AIAG DFMEA specialists. In the AIAG approach, typically the start was a block diagram and

the Parameter diagram. Generally there was not a good understanding of the DFMEA functions vs component functions in the AIAG approach. Often one DFMEA was created that had an assortment of system and component functions.

In the US according to an AIAG survey, most organizations used Excel and developed FMEAs internally without an expert facilitator. The consequence of this structure approach is the need for software to handle the new FMEA process and the need for an expert facilitator. While the AIAG FMEA was not easy, the difficulty level of the AIAG VDA FMEA with the three levels makes an FMEA that much more difficult.

### Conducting an FMEA (AIAG 4<sup>th</sup> edition)

- **Complete necessary prerequisites**
  - Complete a Block Diagram
  - Complete a Parameter Diagram (optionally)
  - Identify and list all the requirements
  - Define the scope of the analysis
- **For each requirement**
  - Identify potential failure modes
- **For each failure mode**
  - Assess potential effects of failures
  - Identify the cause(s)
- **For each cause**
  - Identify what control(s) are/will be in place to prevent or detect the cause or failure mode
  - Identify and implement continual improvement actions

### B. The Seven Step Approach

Although the AIAG approach followed a well-defined series of activities, it was not formalized into “steps” to allow the team greater flexibility of implementation. Although the Seven Steps is a logical sequence, it does require more preliminary analysis and documentation than previously.

### C. Function Analysis

In the AIAG approach and a random set of FMEAs Omnex examined when writing this article showed that often times, the

cause of a failure was not identified at one level below. FMEA teams, jumped down many levels to what they thought was the “real failure.” In the new FMEA, it is very methodical, and the failures will all be one level down. We can say that one of the positive points of identifying the flow down of functional requirements is that the team will find it easier to maintain the proper relationships; e.g., will not “jump” levels when identifying causes. This does, however, have it negative points, like the additional documentation and analysis requirements. What if only one level is conducted or one DFMEA is completed, will the controls go right to the root cause?

There is a second key issue which we think will result in differing “severity” levels. When identifying the effect of a failure mode when the focus level is a component, the three level approach has its shortcomings. If the team only looks at the higher level failure mode as the effect, it is possible to identify the wrong severity. The handbook recognizes this since it include “and/or vehicle end user” in the column heading and directions. This could be difficult when only three levels have been analyzed.

### D. Failure analysis

Since the new approach requires the identification of the failure modes at all three levels before mapping the effect to failure mode to cause relationships, implementing this only using the form without software will be difficult.

### E. Risk analysis

Not much change other than prioritization via RPN vs AP. As mentioned previously, in the AIAG methods, many US companies used both RPN and also prioritization rules of S, SxO, and SxOxD. Omnex recommends that companies still use a combination vs only SxOxD as stated in the new AIAG VDA Manual.

# The AIAG-VDA DFMEA – Understanding the Changes

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## F. Optimization

With the exception of limiting the recommended action to only preventive and/or detective actions, there has not been much change. This is also a key difference between AIAG and VDA formats. US teams often went beyond just “preventive” and “detective” column improvements and thought outside the box on how to improve the design or how to catch a failure as early as possible. We do not see this strategy being discussed in the new AIAG VDA Manual, e.g. making sure either a preventive or detective technique is applied early in the design life cycle instead of finding the issue in the end. As we know, costs multiply when caught late in the game. vs only SxOxD as stated in the new AIAG VDA Manual.

## G. Results Documentation

Results documentations does not represent a big change for the AIAG FMEA practitioner. Though this was not a formal step, implementing the FMEA recommended actions was a big focus for the AIAG FMEA.

### Beyond the standard – Consequences

The key to understanding the DFMEA and PFMEA is not just the links between these tools but to also the understanding of the linkages among the DFMEA, the test plan, the PFMEA, the Process Flow and Control Plans. The US approach, starting in the 1980s with the advent of the “Process Review” for Omnex and the Dimensional Control Plan for Ford, looked at the linkages between these documents. In the mid-1980s the focus was on manufacturing. Greg Gruska, one of the authors of this article, wrote the Ford DCP (Dimensional Control Plan) standard. At the same time, Chad Kymal, of Omnex, linked the Process flow, PFMEA, and Control Plans to the Work Instruction and brought out the first FMEA software package with linked documents in 1988.

The key challenge in the US will be the domain knowledge in the higher level element (system), focus element (sub system), and the lower level element (component). Generally, the OEM understands the “vehicle system,” and the tier one understands the “sub system”, and the tier two supplier understands the “component.” No single organization understands all three levels. In the US, customers typically never share DFMEAs with tier ones for DFMEA or PFMEA creation. The specialization of knowledge and the evolution of the supply chain asks for structural changes and cooperation between OEM, tier one, and tier two, which is not currently there.

In Germany, many organizations have conducted DFMEAs but have not spent enough time conducting PFMEAs. The linkages between DFMEAs and PFMEAs are clear, but it is unclear if this is there in actual practice in the linkages in the VDA or AIAG approaches.

With the new AIAG-VDA FMEA, because of the highly distributed nature of organizations and supply chains (design centers in USA and Europe, software design in India, hardware in China, manufacturing in Mexico, for example), the linkages between the DFMEA and PFMEA are really not possible without software that helps link them.

### Evolution of Supply Chain and Integration of Development

The new AIAG-VDA method is an evolution of distributed design and extended supply chains. Methodologies, structural changes in the relationships between customer, supplier, and sub supplier, and linkages between DFMEA/DVPR (test plans), Process Flow PFMEA, Control Plans and Shop Floor Documents will cause a “disruptive innovative” wave. OEMs and software will need to link requirements flow down and failure flow down in this extended

distributed environment. There will be a next level of design and quality innovation and improvement with this evolution.

With the product shift globally from gas and diesel vehicles to electric and autonomous cars, the AIAG-VDA structure analysis in the DFMEA may be quite timely.

Join Omnex for a webinar on “Relearning the FMEA: AIAG-VDA FMEA” and for 4 other webinars on the new AIAG-VDA FMEA visit [www.omnexus.com](http://www.omnexus.com) to register for this series.

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*engineering and reliability/safety analysis in both hardware and software development. Greg managed the Quality Engineering Activity at Chevrolet. This group provided benchmarking, quality engineering and statistical support to all divisional and corporate activities and their suppliers. Besides the application of statistics within the design, manufacturing, and support environments, this group was active in the development of new technologies and training in these areas. Greg additionally served as a Divisional and Corporate consultant in Statistical Engineering and Management. He has traveled extensively in assisting engineering, financial, and support staffs and manufacturing plants in the investigation and solution of problems*

# The AIAG-VDA DFMEA – Understanding the Changes

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affecting quality, new product development, product failures and customer satisfaction.

Greg has also been a writing member of the MSA, SPC, FMEA, and EFMEA Manual subcommittees of the American Automotive industry's Supplier Quality Requirements Task Force which is part of the international task force governing TS-16949. Greg is an adjunct professor at Madonna University. He has advanced degrees in mathematics

and engineering from the University of Detroit, Michigan State University and Wayne State University. He was the Deming Memorial Lecturer at the Sheffield Hallam University for the year 2000.

Greg is a charter member of the Greater Detroit Deming Study Group and the W. E. Deming Institute. He is an ASQ certified Quality Engineer, a licensed Professional Engineer (CA - Quality) and a member of

the Board of Examiners of and Judge for the Michigan Quality Leadership Award (1994-2011). Greg is on the writing committee of AIAG on FMEA, a member of the SAE Functional Safety Committee (J2980) and is considered one of the foremost authorities on risk management in the world. He has considerable hardware and software experience in Automotive applications.



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## Layered Process Audits (LPAs)

BY DQS

Layered Process Audits (LPAs) are a useful tool for any management system type (EHS, Quality, Food, etc.). The basics are that different levels of management do manufacturing audits at various frequencies. Typically, the direct supervisor level does an audit of something every day, his or her manager would do one every week, the next level up does one every month, and so on. Even the plant manager would do them at some frequency.

Typically, the layered audit is a checklist document that takes only 10-15 minutes to complete, but it brings focus to whatever management deems important during that time. One of the keys is to keep the questions

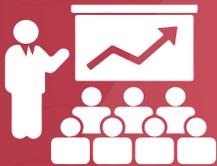
fresh. You don't want to go around every day for months on end asking if the operator at station 10 is qualified. People lose interest and will start pencil whipping the form. The way LPA's should be used is by taking results from customer complaints, internal audits, regulatory findings, etc. and map those into LPA questions.

We tell customers quite often that they can use LPA's to change a culture. This is because you ask the same questions over and over and verify the expected result is happening every day. So, let's say a company wants to start a 5S program (Sort, Set in order, Shine, Standardize, Sustain). Certainly, it takes an initial effort for the first 4 S's, but the Sustain

aspect can be a part of an LPA. You look at it every day to make sure. A common theory is that if you do something for 28 straight days, it becomes a habit. LPA's can drive new habits, and when they're properly designed and implemented, they can offer many valuable benefits, such as reducing customer complaints and lowering rework costs.



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

CONTINUED FROM PAGE 1

BY CHAD KYMAL, CTO, OMNEX INC. AND GREGORY GRUSKA, VP, OMNEX SYSTEMS

has the voice of the customer translated into system architectural requirements, which flow down to system requirements, then to software architecture, next to software requirements, and finally into unit requirements. As the requirements flow down, customers, suppliers, sub suppliers must work closely together because product development of Functional Safety, SOTIF, Cyber Security, and AIAG-VDA FMEA demands linked development.

Organizations in the automotive industry, and other sectors such as steel, plastics, and semiconductors, have been heavily influenced by automotive industry standards and practices like IATF 16949, advanced product quality planning (APQP), failure mode and effects analysis (FMEA), and production parts approval process (PPAP). Excluding the IATF 16949 which is the Automotive Quality Management Systems standard, the others are collectively called “Core Tools” which includes measurement system analysis (MSA) and statistical process control (SPC).

driver warning systems. It is expected that soon, more than 50 percent of a new car’s value will be found in its electronics (i.e., semiconductors) and software (see figure 1).

These new technologies also are resulting in multipoint failures and software-related failures in automobiles. Data show that 15 percent to 50 percent of warranty failures are attributable to software defects (see figure 2). In addition, these new technologies also introduce a significant number of vulnerabilities thus enabling hackers to mount attacks and target vehicle assets. Now, more than ever, it is important to recognize the need for improved product development processes in systems, hardware, and software. Until now, the automotive industry has relied almost exclusively on APQP and other Core Tools.



Figure 2: Software is now to blame for 15 percent of car recalls; many OEMs have reported that up to 50 percent of warranty and recalls are related to software. Functional safety can address these in software and hardware.

change toward autonomous vehicles. GM is applying its “super cruise” in combustion engines, while Tesla is applying its autopilot to electric vehicles.

## The three parallel developments of:

1. Increased electronics and software in automobiles
2. Increased software failures
3. Automobile product shift from ICEs to electric and AVs are requiring new standards and methodologies in automobile vehicle and parts design as well as manufacturing.

Seven standards or methodologies are levers to this shift in automobile design and manufacturing (see figure 3)

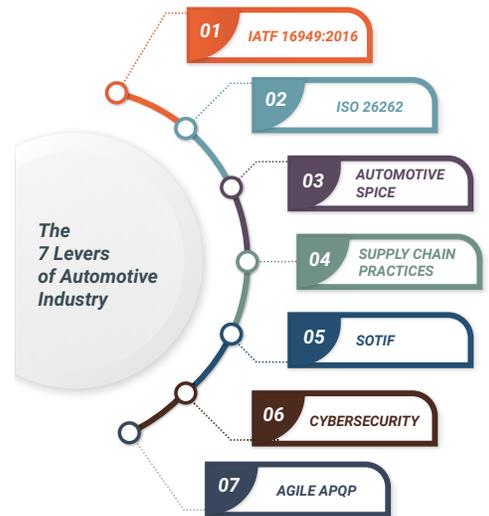


Figure 3: The seven levers of the automotive industry

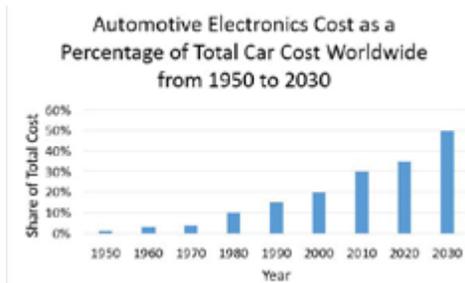


Figure 1: Automotive electronics cost as a percentage of total car cost worldwide from 1950 to 2030. (What is the source of this Figure?)

During the last 10 years, a significant number of new technologies have been introduced in automobiles, including autonomous breaking, auto lane change, adaptive cruise control, vision based driver assistance systems, and various sensor-operated

At the same time that these technology and related hardware and software changes are occurring, the automotive industry is shifting from internal combustion engines (ICE) to electric power, and soon, to autonomous vehicles (AV). One can see many different strategies applied around the world. In the United States, for example, Tesla and General Motors are leading the

In this article we will address four of them. The first three are functional safety (ISO 26262); automotive software process improvement and capability determination (SPICE), a maturity model derived from ISO/IEC 15504; and cybersecurity (SAE J3061 and ISO 21434). The fourth addresses the need for technology to manage new-product development (i.e., supply chain

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

CONTINUED FROM PAGE 9

initiatives) within the automotive industry. Automobile design and manufacturing have lengthened their supply chains from system design to include extensive hardware and software links that extend all over the globe, including the United States, Canada, Europe, Mexico, China, and India (see figure 4)



Figure 4: Global automotive supply chains now include extensive hardware and software links.

For more on these standards and the “New Product Development Frameworks: Functional Safety, Automotive SPICE, and Cybersecurity” download the entire paper which is 12 pages long.



## AIAG-VDA FMEA Saw The Light OEM CSR Update on AIAG-VDA FMEA

BY ANTONY JOHN, VP, OMNEX SYSTEMS

The AIAG Quality Summit took place on Oct 2nd and 3rd, 2019, where the much-awaited announcement of the AIAG-VDA FMEA transition was made by the OEMs and CSR. Four OEMs presented their transition plans to AIAG-VDA FMEA 1st edition. Below is a summary of their announcements.

### FCA:

FCA is ready to accept supplier submissions of either AIAG FMEA 4th edition or AIAG-VDA FMEA. FCA is going to encourage suppliers to submit AIAG-VDA FMEA because they see it is new and more active developments will take place to improve FMEA.

### Ford Motor Company:

Ford is internally evaluating and getting trained on the new AIAG-VDA FMEA and its adoption. The AIAG-VDA FMEA supports

Ford’s V-Model. Ford is expecting to have its supply base start with AIAG-VDA in FY2022 programs. Suppliers will be requested to submit AIAG-VDA FMEAs on a per program basis. The Ford Supplier Handbook will be revised in 2020 and will have specifics of AIAG-VDA adoption & transition. Ford acknowledges AIAG-VDA, will continue their support, and recommend the use of DVP&R and Process flows diagrams, which is less emphasized in the current AIAG-VDA FMEA.

### General Motors (GM) Company:

GM is yet to make its transition with AIAG-VDA FMEA. GM is speculating that their Year 2023 calendar programs could have AIAG-VDA FMEA adoption. GM will release its transition plan in its SORs.

### Honda of America

Honda has very clear timelines on the AIAG-VDA adoption. Honda is expecting their suppliers to use AIAG-VDA from 2022 onwards. The presentation included a transition plan and training available for Suppliers.

### OEM’s announced AIAG-VDA neutrality:

- OEMs are going to accept MS Excel or spread sheets/Software-based outputs of AIAG-VDA FMEA
- AIAG-VDA will only apply to newer programs. Suppliers DON’T have to convert their existing FMEA’s to AIAG-VDA FMEA’s
- AIAG-VDA FMEA Training can be taken up from any vendor. There are NO prescribed or recommended vendors

## THE NEW AIAG-VDA FMEA SOLUTION



Automotive Industry  
Action Group



Verband der  
Automobilindustrie



# Information Security – To Hack or Not To Be Hacked

CONTINUED FROM PAGE 1

BY CHAD KYMAL, CTO, OMNEX INC.

Company	Accounts Hacked	Date of Hack
Yahoo	3 billion	Aug. 2013
Marriott	500 million	2014-2018
Yahoo	500 million	Late 2014
Adult FriendFinder	412 million	Oct. 2016
MySpace	360 million	May 2016
Under Armor	150 million	Feb. 2018
Equifax	145.5 million	July 2017
EBay	145 million	May 2014
Target	110 million	Nov. 2013
Heartland Payment Systems	100+ million	May 2008
LinkedIn	100 million	June 2012
Rambler.ru	98 million	Feb. 2012
TJX	94 million	2003-2004
Sony PlayStation Network	77 million	April 2011
JP Morgan Chase	83 million	July 2014
Tumblr	65 million	Feb. 2013
Uber	57 million	Late 2016
Home Depot	53 million	April 2014
Facebook	50 million	July 2017
US Office of Personnel Management (OPM)	22 million	2012-2014
Anthem	78.8 million	Feb. 2015
RSA Security	40 million	Mar. 2011
Adobe	38 million	2014-2015

Source:

“The 18 biggest data breaches of the 21st century” by Taylor Armerding, CSO

“The biggest data breaches of all time, ranked” by Nicolas Rivero, Quartz

The largest hack happened to Yahoo in 2013, can you imagine the effects of 3 billion accounts being hacked? That is approximately 10 times the current US population. The second biggest hack is the attack against Marriot which affected 500 million accounts. The Marriott hack hits especially close to home for me because I use them often and am a top status traveler. The hackers not only have the personal

information of 500 million accounts, but also several credit card numbers. Marriott has yet to acknowledge the issue or provide warning to customers to change their credit card numbers. If you review this list of hacks, we all need to be **really worried**. Look at Yahoo, they first lost 3 billion accts and then another 500 million a year later. It appears that their IT Security team could not measure up to the hackers or that top

management did not provide the impetus and focus inside the organization. We believe there are numerous other hacks that aren't making the news because they are manufacturing and design organizations and aren't affecting the general public.

These external hacks are Cybersecurity issues, defined as “attacks from the internet or as ISO standards call it Cyberspace.” It is worth looking at the definition of a guidance standard in Cybersecurity- ISO 27032 Information technology — Security techniques — Guidelines for cybersecurity. ISO 27032 defines Cybersecurity as: **Cyberspace security** preservation of confidentiality, integrity and availability of information in the Cyberspace. Cyberspace is defined as the “complex environment resulting from the interaction of people, software and services on the Internet by means of technology devices and networks connected to it, which does not exist in any physical form.” Cybersecurity is important, but organizations need to implement Information Security as well. Information Security is the larger issue that contains Cybersecurity as one of its elements. See the diagram below, displaying Information Security and its relationship to Cybersecurity.

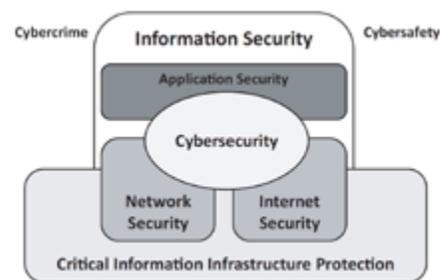


Figure 1 - Relationship between Cybersecurity and other security domains

Information Security standards are the most important standards of our times. Many CEOs have left the topic of Cybersecurity to the CIOs and have not gotten involved themselves. The US Securities and Exchange

# Information Security – To Hack or Not To Be Hacked APQP

CONTINUED FROM PAGE 11

commission issued an interpretive guidance last year to companies that traded on the stock exchange – “Cybersecurity risks pose grave threats to investors, our capital markets, and our country. Whether it is the companies in which investors invest, their accounts with financial services firms, the markets through which they trade, or the infrastructure they count on daily, the investing public and the U.S. economy depend on the security and reliability of information and communications technology, systems, and networks. ... Today, the importance of data management and technology to business is analogous to the importance of electricity and other forms of power in the past century. ... First, this release stresses the importance of maintaining comprehensive policies and procedures related to cybersecurity risks and incidents. Companies are required to establish and maintain appropriate and effective disclosure controls and procedures that enable them to make accurate and timely disclosures of material events, including those related to cybersecurity. Such robust disclosure controls and procedures assist companies in satisfying their disclosure obligations under the federal securities laws.” This guidance makes it clear that implementing ISO 27001 is really not an option but a requirement for publicly traded companies.

## How ISO 27001 Works



Based on high-level structure, identical core text, common terms and core definitions

For those familiar with ISO standards, it is good to know that ISO 27001 follows the High Level Structure of ISO standards. Also, it features the Plan Do Check Act cycle also known as the Deming Cycle. There are key differences in the controls of this standard vs other ISO standards as one would expect. ISO 27001 features two requirements 6.1.2 which requires an Information Security Risk Assessment be performed and 6.1.3 that requires an Information Security Risk treatment. So 6.1 in Risk and Planning will identify the Information Security and Cybersecurity Objectives and also the risk associated with Information Security external and internal threats. The risk treatment section requires the organization to consider 132 risk controls in the Annex A of the standard. More on this later.

In 6.2 of the standard, ISO 27001 requires the organization to identify the Information Security Objectives and develop plans to achieve them. Under 8.0 Operations, the standard requires the organization to implement the plans developed in 6.1 and 6.2, conduct regular Information Security Assessment (8.2) and implement the Information Security risk treatment plan created in 6.1.3.



Annex A – Information Security Controls

Annex A is broken down into 14 areas of control categories with a 132 individual controls. The expectation is that each of the areas are considered and covered. If it is not, there needs to be justification for the reason it is not. The assessment, the risk treatment plan and then the implementation needs to cover each of these areas. This is also where the NIST programs can integrate with ISO 27001.

The NIST Special Publication 800-53 provides a catalog of security controls for all U.S. federal information systems except those related to national security. It is published by the National Institute of Standards and Technology (NIST), which is a non-regulatory agency of the United States Department of Commerce. The NIST standards are quickly becoming mandatory requirements to supply to the federal government. US law specifies a minimum information security requirements for information systems used by the federal government. This in turn refers to NIST Special Publication 800-53 as the mandatory minimum controls that federal agencies must implement.

## Role of Top Management

Clause 5.0 of ISO 27001 explains that top management is accountable for Information Security (5.0) and that the Information Security processes need to be integrated into the organization’s business processes or in other words the “process approach or the process map.” As expected, the objectives, the progress towards objectives, the effectiveness of the controls and other metrics are reviewed in the management or business reviews that are led by top management. It is crucial that top management understand their important role in governance of Information Security and Cybersecurity.

## Where do we go from here?

It is very important to understand that

# Information Security – To Hack or Not To Be Hacked APQP

CONTINUED FROM PAGE 12

understanding the risks from Information Security and Cybersecurity starts with the leadership of the organization. The SEC has made it very clear that if you are a publicly traded company then you will need to develop policies and procedures that deal with Cybersecurity risk. A good place to start is ISO 27001 with its well defined requirements and process methodology. Additionally, ISO 27001 integrates well with the Quality Management System of the organization.

The company board needs to get involved and provide oversight and responsibilities to this effort. The SEC guidance has asked for

a description of how the board administers the risk oversight. ISO 27001 requires both internal audits, and external audits. Like the Sarbanes-Oxley Act (SOX), the system should be regularly tested by the assessors who test the process. Also, vulnerability and penetrating tests with hired external parties need to become a regular practices for organizations. Organizations should not only be focusing on external parties, ISO 27001 management systems should also focus on internal attacks and the general availability of information.

Implementing ISO 27001 and getting a 3rd Party certificate is not enough.

Cybersecurity and Information Security require continual monitoring and upgrades of the organization's defense. Technology is constantly changing and requires IT security teams to constantly update processes and technologies.

As a place to start, Omnex recommends that top management be provided an Executive Overview along with their board. Join Quality Digest and Omnex's Founder and CTO in this webinar to hear how to implement a robust Cybersecurity and Information Security program.



# Waste Management is the New Fashion

CONTINUED FROM PAGE 1

media platforms like WeChat, WeiBo and Douyi, demonstrating the public's eagerness to learn about how to sort out trash correctly. According to the new Regulation, waste will be collected separately under four categories, namely recyclables, hazardous waste, 'wet'/kitchen and 'dry'/other waste. Individuals and businesses that fail to follow it are liable to fines. The regulation also bans hotels and caterers from offering one-off products such as toothbrushes, shower caps and chopsticks. All the courier companies should use digital orders and environment-friendly materials for packaging. Government and public institutions are not allowed to use disposable cups in the office and should give priority in purchasing commodities made from recycled materials. Waste management is listed as one performance indicator for officials. Shanghai has the similar amount of population of Australia. Each day over 25,000 tons of garbage is produced in the city, posing serious threats to the environment and increasingly challenging the city's capacity for waste management. Most of the trash was treated at the city's landfills or incinerators. The city aims to have 35% of its

waste recycled by the end of 2020. Beijing, Guangzhou and Hangzhou all have similar regulations in place in recent years. Putting into perspectives, the total population of the above-mentioned four cities is more than that of the United Kingdom, with the 2018 GDP more than the sum of Russia.

Among all hurra and cheers, please allow me to turn the spotlight to a vast yet almost invisible network of people- the rag and bone man or the informal garbage collectors. On bustling streets in China, you often see men or women ride their tricycles, carrying a huge amount of boxes cleverly bounded together and offering door-to-door collection services for all kinds of domestic castoff, ranging from second-hand furniture, electronics, cartons, cans, glasses and plastic bottles. Before the government's law enforcement, they offer the most effective way for waste management, recycling 90% of recyclables. This rate is much higher than any developed countries. It's said even in the city of Beijing alone, there are 150,000 of them. Most of them are the aged, poor and homeless. They rely on picking up and selling recyclables to earn a living and raise family. With systemic

consolidation and innovation, the informal waste collectors could drive the future of recycling. Yet they commonly suffer the lack of social recognition and material assurance such as the lowest income guarantee and medical insurance.

Policies, public education and community engagement are just one of the many levers of change for China to lead on waste management. At the end of last year, President Xi said 'Garbage classification is the new fashion'. Neglected and despised by many in many cultures, the sector needs to be revitalized and transformed. It holds key to tackle UN's Sustainability Development Goals challenges including inequality, poverty alleviation, climate change, urbanization and women empowerment. Furthermore, it offers huge opportunities for many. Entrepreneurs, investors, start-ups, governments, social workers, low-income earners, digital tech pioneers all have a role to play to generate jobs, create prosperity and bolster circularity in the waste economy. There are no 'waste' in nature. Imagine if the whole world could come up with all the technologies and solutions to recycle every stream and close the loop of waste.

# THE POWER OF ONE

A SINGLE SOLUTION PROVIDER FOR ALL YOUR QUALITY NEEDS

## CONSULTING SOLUTIONS



**ISO 9001 ISO 14001**  
**IATF 16949 AS9100 ISO 13485**  
**ISO 45001 FSSC 22000**

1 COMPANY

5 SERVICES

16 GLOBAL OFFICES

3 ENTERPRISE SOFTWARE SOLUTIONS

1000s of GLOBAL CUSTOMERS

WRITING COMMITTEE MEMBER FOR MANY STANDARDS

600+ EMPLOYEES WORKING IN 30 COUNTRIES

100 CONSULTING PROGRAMS

TRAINED MORE THAN 500,000 INDIVIDUALS

33+ YEARS OF PROVIDING COMPREHENSIVE SOLUTIONS IN QUALITY & BUSINESS MANAGEMENT SYSTEMS.

WORKS WITH 7 OF THE TOP 10 AUTOMAKERS, 70 OF THE TOP 100 AUTO COMPONENT MAKERS, AND THE LARGEST ELECTRONICS/ SEMI-CONDUCTOR COMPANIES WORLDWIDE.

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OMNEX

## Food Safety Management System FSSC 22000

- Understanding and Documenting FSSC 22000
- FSSC 22000 Internal Auditor Training
- FSSC 22000 Lead Auditor Training

Omnex can assist with  
Implementation Support  
and Assessments

OMNEX  
SYSTEMS

## Food Safety QMS Software

### Key Features

Common Across the Suite

-  Enterprise-wide web based system focused on Quality and Integrated Management Systems
-  Manage multiple facilities through single window approach
-  Integrated with e-mail notification with Outlook, Reminder & Escalation services.
-  Support for multi-language and multi-date formats
-  Out of the Box fully integrated solutions



### Why Omnex Enterprise Solutions



#### Configuration

Our out-of-the-box solution is fully configurable and ready to deploy.



#### Comprehensive

Our solutions have both the breadth and depth of Omnex knowledge in the APQP and Management System space.

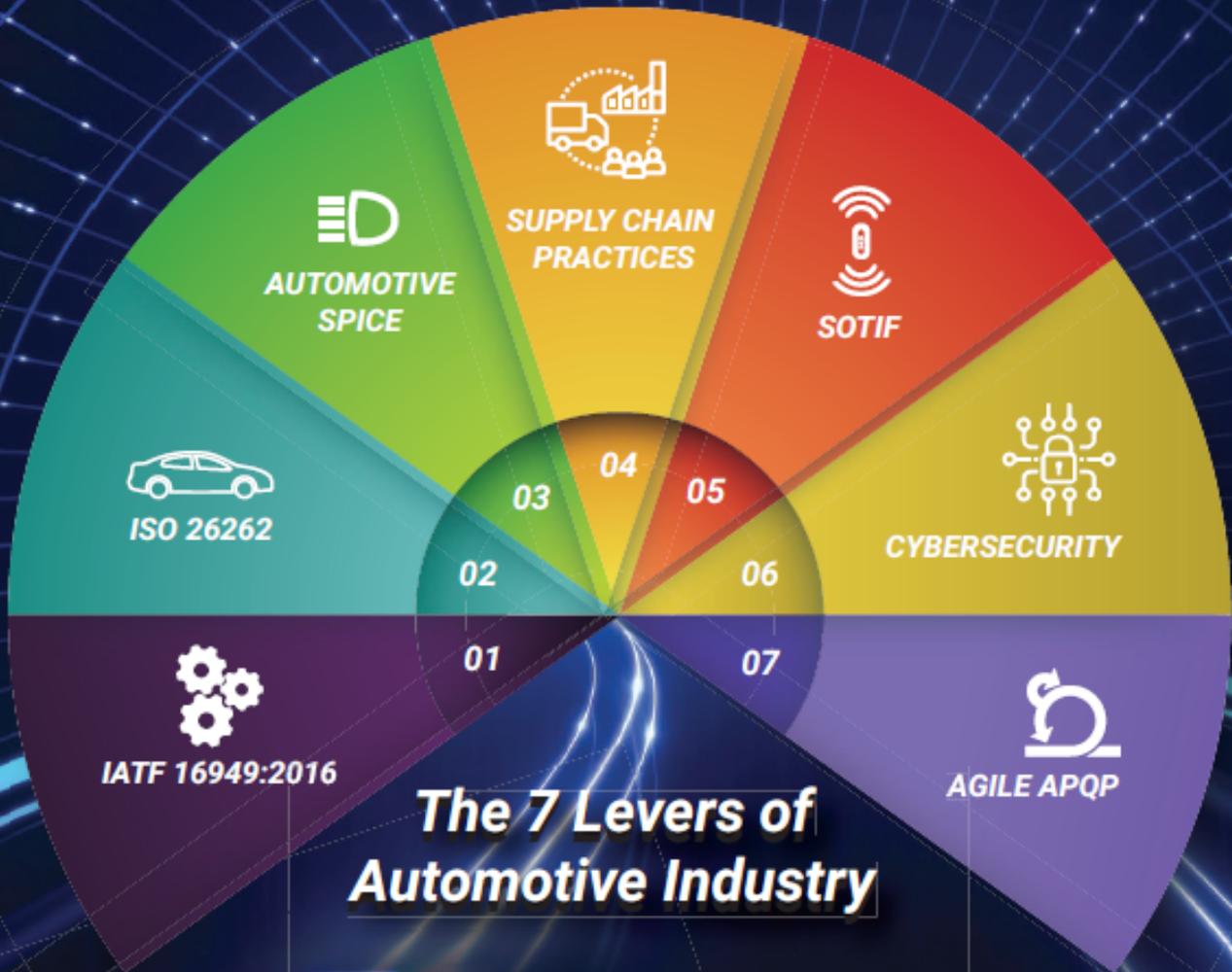


#### Convenient

Our user-friendly interfaces reduce learning curves.

# OMNEX THE POWER OF ONE

A SINGLE SOLUTION PROVIDER FOR  
IATF 16949, ISO 26262, ASPICE, SUPPLY CHAIN PRACTICES,  
SOTIF, CYBERSECURITY & AGILE APQP



## The 7 Levers of Automotive Industry



CONSULTING



TRAINING



SOFTWARE



STAFFING



E-LEARNING



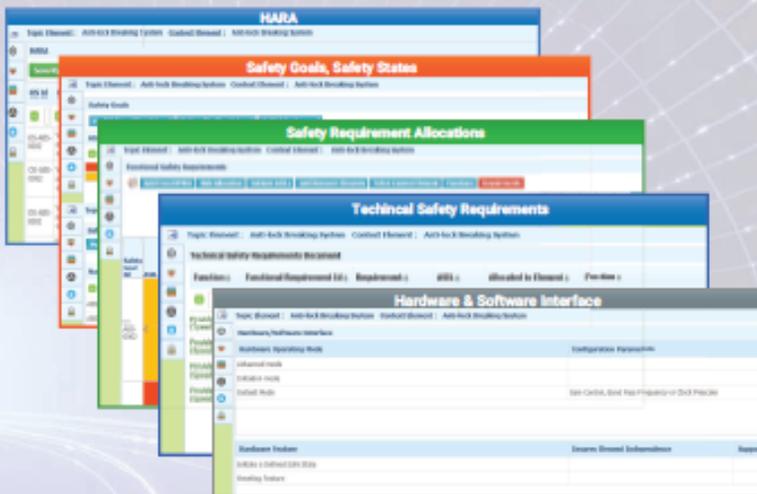
## Enterprise APQP & Functional Safety Software

### Features:

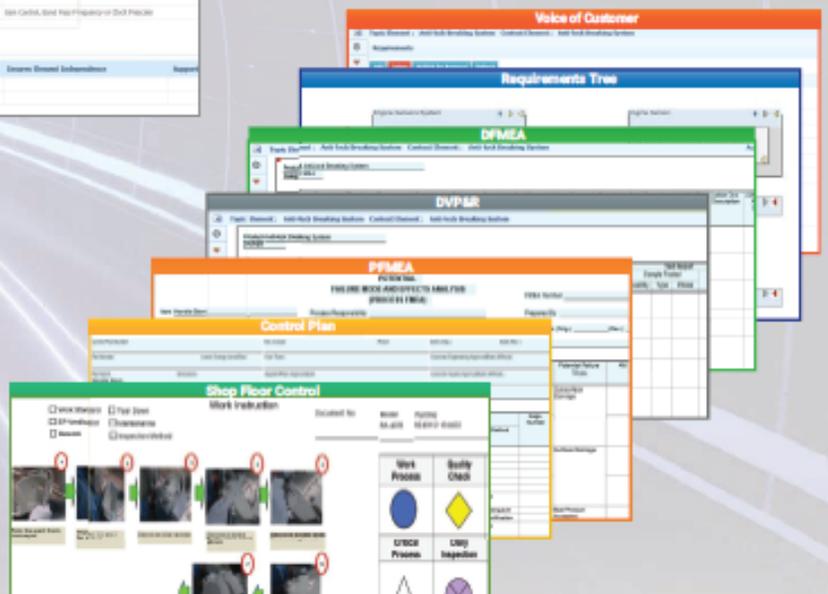
- ✿ Voice of Customer
- ✿ Item Definition
- ✿ HARA & ASIL
- ✿ Safety Goals & Requirements
- ✿ Allocation & HSI
- ✿ Safety Plan

*All work products linked together...*

### Functional Safety Document



### APQP/PPAP Document



US NEWS

- On October 2-3, Omnex was a Platinum Sponsor for AIAG's Quality Summit in Novi, Michigan. The Automotive Industry Action Group (AIAG) is a not-for-profit trade association where professionals from member companies – including automakers, suppliers of all sizes, manufacturers, service providers, academia, and government – work collaboratively to streamline industry processes via global standards development & harmonized business practices. The AIAG Quality Summit is one of the most important automotive industry events of the year with presentations from AIAG, FCA, Volvo, IAOB, Autoliv and more
- On October 15-16, Omnex Cybersecurity Expert, Dr. Juan Pimentel gave a presentation covering "A Cybersecurity Protection Framework to Support Dubai's Self-Driving Transport Strategy" for the Dubai World Congress For Self-Driving Transport. This 2-day conference's goal was to bring together experts in the field of self-driving technology to enhance and accelerate the adoption of self-driving technology globally and contribute to the realization of the vision of His Highness Sheikh Mohammed bin Rashid al Maktoum, Vice President and Prime Minister of the UAE and Ruler of Dubai, to make 25% of all trips in Dubai smart and driverless by 2030
- On March 26-27, Omnex's Functional Safety Champion, Greg Gruska gave a presentation on the fundamentals and reasoning for Integrating ISO 26262, SOTIF, Cybersecurity, ASPICE and ISO 26262 for the 9th Annual IQPC ISO 26262 Conference located in Munich, Germany. The goal of this conference was to discuss the need in for robust system engineering and moving forward from a component-based engineering towards systems thinking that can tackle the complexity of electrification, autonomy and new mobility features. This was the first conference where the ratified standard will be presented by WG members of ISO/TC22/SC32 within the ISO 26262:2018
- On May 6-9, Omnex exhibited at Food Safety Summit in Rosemont, IL. The Food Safety Summit is a solution-based conference and expo designed to meet the educational and informational needs of the entire food industry. The Summit provides a 3-day comprehensive

educational program to learn from subject matter experts, trainers, exchange ideas and find solutions to your current job challenges

- On March 27-29, Omnex Cybersecurity Expert, Dr. Juan Pimentel gave a presentation covering "Novel Threats in the Modern Vehicle" for IQPC's 2019 Automotive Cybersecurity Summit. This summit featured key influencers and decision makers from OEMs, Tier 1's, Disruptors, and other external transport industries with the knowledge to help navigate the most critical opportunities and challenges for vehicle cybersecurity to include ECU security, over the air updates (OTAs), V2V/V2I communications, securing embedded systems, and much more
- On March 6-8, Omnex CTO, Chad Kymal gave a presentation covering "Global Health and Safety Standard – ISO 45001:2018" for the Ohio Safety Congress & Expo. For three days, OSC19 provided world-class workplace safety and health education, in-depth workshops, live demonstrations and much more
- On May 5, Omnex exhibited at the AIAG / AAMA Southern Quality Summit in Birmingham, AL. The annual Southern Automotive Quality Summit is a unique collaboration between the Alabama Automotive Manufacturer's Association (AAMA) and the Automotive Industry Action Group (AIAG). This event showcased the southern automotive industry's commitment to world-class quality and attracts technical professionals and leaders seeking to improve their organizations' quality processes, systems and performance. The theme of the 2019 event was "Engaging Your Workforce in Quality"

KEY STAFF ADDITIONS

Omnex is pleased to announce key staff additions to our team of experts.



- Vui Kiong (VK) Chong has joined Omnex as a consultant, trainer, and assessor who has extensive experience in software process improvement (ASPICE), and Functional Safety (IEC

61508, ISO 26262), providing strategic guidance, trainings and objective assessment on various projects

VK is an iNTACS certified assessor who has performed numerous assessments in accordance to Automotive SPICE. Additionally, he also holds certification as a Certified Functional Safety Expert (CFSE), and Certified Professional for Requirement Engineering (CPRE)



- Dr. Juan Pimentel joined Omnex earlier this summer as a consultant/trainer, and will specialize in the area of Cybersecurity. He has extensive Engineering, Safety and Cybersecurity experience, and recently retired as a Professor of Electrical and Computer Engineering at Kettering University. His knowledge and experience includes applied research, product development, safety and cybersecurity assessment and assurance

He has participated and continues to participate on various IEEE, SAE, and ISO standards, and is on the SAE Vehicle Electrical Hardware Security Task Force and on the SAE/ISO 21434 automotive cybersecurity standard task force. On September 5-6, 2019, Omnex China was invited to participate in AUTOMOMOUS VEHICLE World Congress in Shanghai. Omnex CTO Chad Kymal and Dr. Juan Pimentel were invited as a key speakers at this forum.



- Mary Rowzee joined Omnex a consultant and will specialize in the areas of ISO 26262, SOTIF, and AIAG-VDA FMEA. She has extensive experience and achievements in Quality Systems development, implementation and auditing to ISO 9000 series and IATF 16949 standards; Six Sigma Black Belt Problem Solving and Advance Quality

NEWS FROM OMNEX AROUND THE WORLD

Tools including: Design and Process FMEA, Design and Process Verification and Test Planning, Complex Statistical Analyses and Reliability Prediction, Modelling and Risk Reduction. Mary is also a writing member of AIAG-VDA FMEA 1st edition and the Core Tools Guidelines: SPC 2nd edition, MSA 4th edition, EFMEA 1st edition, PPAP 4th edition and APQP 2nd edition, and the SAE J1739 Standards team

**OMNEX TO HOST A CONFERENCE ON ELECTRIC AND AUTONOMOUS VEHICLES ON DECEMBER 16, 2019**

As many of our clients are well aware, the Automobile Industry is at a crucial juncture. Many OEMs, including General Motors and Volkswagen, have announced a strategic shift away from manufacturing internal combustion engines and diesel to making electric vehicles. It has become clear that the future of the Automobile Industry lies in electric and autonomous vehicles/cars. At Omnex, we have been on the leading edge of these changes. Omnex experts have actively participated in developing and writing many of the standards that will have an enormous impact on all of our futures.

To explore and discuss these changes and their potential effects on the industry, Omnex is hosting a one day conference on Monday, December 16, 2019 in Ann Arbor, MI for selected guests. The agenda will include key presentations from our team of experts on Electric and Autonomous Vehicles, including Functional Safety ISO 26262, Cybersecurity, Automotive SPICE, and IATF 16949:2016. The topics being considered at this conference will address the standards and the initiatives that will need to take place in automobile organizations.

Omnex is hosting this conference to better prepare organizations in adapting to these enormous changes in the Automobile Industry. There are only a limited number of spaces available for this conference, and so if you have an interest in attending, please contact Omnex at (734) 761-4940.

**OMNEX ANNOUNCES PREFERRED CERTIFICATION BODY STATUS FOR DQS INC**

Omnex is pleased to announce the addition of DQS Inc. as a preferred management systems Certification Body. DQS is an independent ANAB

accredited global Certification Body with proven competence and experience in multiple standards and industries. The assessment, evaluation, and certification of management systems, processes, and organizations are the key services provided by DQS. As such, DQS management will periodically contribute to our newsletter and customer events. We will be happy to introduce our customers that are interested in further information to their customer support team for more information. Our collaboration with DQS will allow both organizations to better help serve the expanding requirements and business objectives of our clients. While we note this preference, we do clarify that DQS is fully independent from Omnex. Omnex works with a number of certification bodies and this announcement does not preclude Omnex from working closely with any other certification bodies.

**PLANTECH-OMNEX ANNOUNCES PARTNERSHIP WITH PPAPANDAUDITS.COM**

Plantech-Omnex division is excited to announce a new partnership with PPAPandaudits.com. This partnership brings together PPAPandaudits.com's "innovation engine" and Omnex's 30 year history, global reach, and extensive experience with PPAP and Audits respectively. PPAPandaudits.com, powered by EwQIMS™, is an automated solution to customer's PPAP and Auditing needs. PPAPandaudits and Plantech-Omnex will work together to provide performance improvements in the form of staffing, PPAP support, and 3rd party audits

PPAPandaudits.com and Plantech-Omnex is a unique network of quality and supplier quality professionals who have been working with automotive and non-automotive companies worldwide. Together they have worked in supply base optimization in USA, Canada, Europe, China, India, and South East Asia, conducting PPAP or First Article for large as well as medium and small suppliers.

Through combined resources, Omnex-Plantech and PPAPandaudits.com have world renowned consultants who have had the experience of working with both small and large program launches. These consultants have worked with suppliers in diverse industries with different needs. Their combined resources have the experience of completing

over 25,000 PPAPs and supplier audits across the world.

- Outsourcing the supplier development activities to an external consultant is not a new initiative. The critical components in this process are time and finding experts who are reliable, have subject matter expertise as well as SQE experience. Our consultants include Quality and Supply Chain professionals with over 20 years hands on experience in the field. These professionals, most of them Lead Auditors in various standards, have helped many OEMs and Tier 1 companies develop Supplier PPAPs, and conduct audits globally. For more information and how we can help you with your PPAPs or Audits write us at [info@ppapandaudits.com](mailto:info@ppapandaudits.com).

**CHINA NEWS**



- On September 20, 2019, Omnex China was invited to participate in Gasgoo Symposium on Automotive and Environment



- Omnex China helps Fujian Mercedes-

NEWS FROM OMNEX AROUND THE WORLD

Benz introduce the new AIAG-VDA FMEA to their team.



- On September 5-6, 2019, Omnex China was invited to participate in AUTOMOMOUS VEHICLE World Congress in Shanghai. Omnex CTO Chad Kymal and Dr. Juan Pimentel were invited as a key speakers at this forum.



- On September 4, 2019 Omnex China held a webinar on EV-AV on the future of E-Mobility Industry.



- Dr. Juan Pimentel was invited to speak at SAE-AWC 2019 Automated Vehicle Security & Safety Technology Forum on 28 - 30 August 2019.



- Linli Xie, General Manager, Sustainability of Omnex China, was invited to speak at GF's Asia Pacific Sustainability Conference in Beijing on 17-18 September 2019.



- Linli Xie, General Manager, Sustainability of Omnex China, was invited to attend the 2nd UK-China Plastic Industry Circular Economy Forum held on 21 September 2019. The forum is organized by British Consulate-General Shanghai and guest speakers include Chris Wood, HM Consul-General of British Consulate-General Shanghai, Hengqiu Xu, Director-General, Anhui Department of Ecology and Environment, Dr. Nanqing Jiang, Secretary General, China Plastics Reuse and Recycling Association and Neal Carlin, Head of Climate Change and Environment, British Embassy Beijing.



- On September 16, 2019, Robert Liao,

general manager of Omnex south China, accepted the invitation from Mercedes-Benz to train their SQE and suppliers to the new AIAG-VDA FMEA. The training received high praise and positive feedback from the students.

OMNEX EUROPE NEWS



- 2019 has been a pinnacle year of sweeping changes across Europe and by extension the rest of the world. New technologies, new advances in transportation and shifting focus towards product and system safety has opened many doors for organizations now competing for new business, and their future sustainability.

- Omnex Europe recognized as far back as 2014 that the pending changes in many common industry standards would lead to a significant knowledge vacuum for many of our clients and their suppliers. Whether the business is Aerospace, Automobiles, Medical Devices, Food Safety, Semi-conductors or literally on rails. Changes are a part of our unique world.

- When ISO 9001:2015 was released, this latest standard opened the eyes of many producers to need for improvement integrated management systems and business processes to manage their legal requirements, system and product safety and compliance, information security and sustainability.

- Over the past five years Omnex Europe has become a key source of reliable information for our clients and students who now need to understand, navigate the latest standards and implement processes to manage the intentions provided the writers of those industry standards.

- Everyday our subject matter experts field dozens of questions and collaborates with new and existing clients on matters concerning:

1. Implementing integrated management systems and then auditing to respective management system standards.
2. Functional systems and product safety, and compliance to legal requirements.

NEWS FROM OMNEX AROUND THE WORLD

- 3. Prevention of potential failures in both product and process design.
- 4. Changing requirements for software and hardware development.
- 5. Knowledge and Information management, data security and requirements flow-down.
- Everyday our subject matter experts field dozens of questions and collaborates with new and existing clients on matters concerning:

Visit us at [www.omnex.eu](http://www.omnex.eu) or follow us on LinkedIn. All questions and enquiries are welcome.

**OMNEX INDIA NEWS**



- Omnex supports Tata Motors in PPAPs development for new vehicle launch



- Hyundai signs Omnex to implement ISO 14001 and 45001 in Chennai plant
- Omnex and Daimler India sign up Annual training contract for yet another year. The successful training cooperation between Daimler India and Omnex is going on for several years now
- Omnex signs up major contract with a large Indian Tier1 company with significant presence worldwide (65 plants) to revamp their Internal Business Excellence Model, Supplier development manual, and Quality systems improvement projects for their India based plants. Omnex has been working with the company for many years for training workshops which is now extended to a Skill and Competency based development workshop
- Omnex helps a Bangalore based Lager Tier 1 Automotive/ Aerospace supplier for total restructuring of their plant operations, starting with basic shop floor implementation to a 3 year strategy project management

- Omnex completes Lead Auditor training for more than 100 Professionals in India and also has completed DFSS workshop for over 60 people
- Omnex completes successful implementation of various standards, including IATF 16949, ISO 17025, and other standards for 11 more companies in India, including a leading Govt. of India Defense organization

**OMNEX THAILAND NEWS**



- Omnex successfully completed the implementation of EWQIMS- QHSE Solution for Mitsubishi Turbo, Thailand



- Omnex successfully completed ISO 26262 Functional Safety Certification program for Delta Electronics Thailand
- Omnex completed implementations of ISO 17025/ NABL and IATF 16949 for 3 companies in Thailand
- Omnex extends training workshops for Hana electronics, APCB and Panasonic for various training programs.

**OMNEX DUBAI NEWS**



- Dr. Juan Pimental speaking on Cybersecurity and Omnex's AM-MOS framework for EV-AV at the Dubai self driving congress. Great participation from Dubai Government and RTA.
- Omnex Dubai has assisted an Oil & Gas client in Dubai with their

implementation of IATF 16949:2016 by providing internal auditor and automotive core tools training as well as consulting on the revision of documentation.

- Omnex Dubai supports Ras-Al-Khaima Airport for their strategic expansion plan by completing a Lean Six Sigma based passenger convenience & efficiency study.
- Omnex extends support to 2 major customers- Saudi based Natpet Schulman and Guardian glass in RAK for their process improvements and shop floor practices.
- Omnex QHSE client JIC awarded Arabia Corporate Social Responsibility Award -2019

# OMNEX 2020 TRAINING COURSES



## Aerospace and Defense

AS9100D Internal Auditor Training  
(Exemplar Global-certified training provider)

AS9100D Lead Auditor Training  
(Exemplar Global-certified training provider)

Understanding and Documenting AS9100D Quality Management Systems  
(Exemplar Global-certified training provider)

## Automotive and Production/ Manufacturing Core Tools

SAE J3061 and ISO 21434:2019 Automotive Cybersecurity Certification

Understanding Core Tools - (APQP, PPAP, DFMEA, DVP&R, PFMEA, Control Plan, SPC and MSA)

Understanding Core Tools - APQP & PPAP

Understanding Core Tools - DFMEA & DVP&R

Understanding Core Tools - Measurement Systems Analysis (MSA)

Understanding Core Tools - PFMEA & Control Plan

Understanding Core Tools - Statistical Process Control (SPC)

## AIAG-VDA FMEA

AIAG-VDA DFMEA for Practitioners and Facilitators

AIAG-VDA PFMEA for Practitioners and Facilitators

Understanding AIAG-VDA FMEA for Managers and Implementers

Understanding AIAG-VDA DFMEA for Design and Project Team Members

Understanding AIAG-VDA PFMEA for Design and Project Team Members

AIAG-VDA FMEA Understanding, Implications and Strategy - Executive Overview

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

AIAG-VDA FMEA for Managers and Implementers – Implementation Training

AIAG-VDA FMEA Understanding, Implications, and Strategy Executive Overview

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

AIAG-VDA MSR

## Agile APQP

Agile APQP Overview in Product Development Innovation

Agile APQP with Lean Product Development Overview

## IATF 16949 Automotive Quality Management Systems

Transitioning to IATF 16949:2016

IATF 16949:2016 Executive Overview

IATF 16949:2016 Role of Top

## Management

Understanding the Requirements of IATF 16949:2016 (Certified and Non-Certified options)

IATF 16949:2016 Internal Auditor (Certified and Non-Certified options)

IATF 16949:2016 Lead Auditor (Certified and Non-Certified options)

IATF 16949:2016 Second Party (Supplier Auditor) Training (Certified and Non-Certified options)

IATF 16949:2016 Manufacturing Process Auditor Training (Certified and Non-Certified options)

IATF 16949:2016 Product Auditor Training (Certified and Non-Certified options)

Understanding, Documenting and Implementing IATF 16949:2016

OEM CSRs: presentations for BMW, FCA, Ford, GM, Honda, VW

Implementing MMOG with IATF 16949

IATF 16949 Employee Awareness

IATF 16949:2016 Role of Process Owners

Legal and Regulatory Requirements for IATF 16949:2016

## 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)

## ISM

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

ISO/IEC 27001:2013 Lead Auditor Training for Information Security Management Systems  
(Exemplar Global-certified training provider)

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

## ISO 13485:2016 Series

ISO 13485:2016 Internal Auditor Training  
(Exemplar Global-certified training provider)

ISO 13485:2016 Lead Auditor Training  
(Exemplar Global-certified training provider)

Understanding and Documenting ISO 13485:2016  
(Exemplar Global-certified training provider)

## ISO 14001:2015 Series

ISO 14001:2015 Internal Auditor Training for Environmental Management Systems  
(Exemplar Global-certified training provider)

ISO 14001:2015 Lead Auditor Training for Environmental Management Systems  
(Exemplar Global-certified training provider)

Understanding the Requirements of ISO 14001:2015 Environmental

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# OMNEX 2020 TRAINING COURSES



Management Systems  
*(Exemplar Global-certified training provider)*

## ISO 26262:2018 Functional Safety

ISO 26262:2018 Functional Safety Auditing and Assessment

Automotive Functional Safety ISO 26262:2018 Certification

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

Overview to ISO 26262 for Executive Overview

ISO 26262 Functional Safety Overview for Functional Safety Engineers and Managers

Automotive Functional Safety ISO 26262:2018 Certification for Trucks and Buses

Automotive Functional Safety ISO 26262:2018 Certification for Motorcycles

Preparing a Safety Case for ISO 26262:2018

Writing Effective Requirements, Test Cases and Hardware/Software Interface (HIS) for ISO 26262:2018

Functional Safety Level 2 Certification (Engineers)

Functional Safety Program Manager - Level II

ISO 26262 for Semiconductor (including ISO/PAS 19451:2016)

## Automotive SPICE & SOTIF

Automotive Functional Safety ISO 26262:2018 Certification

Automotive SPICE and ISO 26262 Executive Overview

Conducting Internal and Supplier (Second Party) Audits to Automotive SPICE

Implementing ASPICE in an AGILE Development

Overview to ISO/PAS 21448:2019 (SOTIF)

## Cybersecurity (ISO/SAE 21434)

SAE J3061 and ISO/SAE 21434 Cybersecurity Engineering Executive Overview

SAE J3061 and ISO/SAE 21434 Cybersecurity Engineering Overview for Engineers and Managers

SAE J3061 and ISO/SAE 21434 Cybersecurity Engineering Certification

ISO/SAE 21434 Cybersecurity Engineering Auditing and Assessment

Conducting a Threat and Risk Analysis (TARA) and Threat Tree Analysis (TTA) for Cybersecurity Engineering

Conducting a Cybersecurity FMEA and Vulnerability Analysis Testing for Systems, Hardware and Software

Cybersecurity Engineering Defense and Protection Against Attacks

Preparing a Safety Case for Cybersecurity

Writing Effective Requirements, Test Cases and Hardware/Software Interface (HSI) for Cybersecurity

## ISO 45001:2018

ISO 45001:2018 Internal Auditor Training for Health & Safety Management Systems  
*(Exemplar Global-certified training provider)*

ISO 45001:2018 Lead Auditor Training for Health and Safety Management Systems  
*(Exemplar Global-certified training provider)*

Understanding the Requirements of ISO 45001:2018 for Health & Safety Management Systems  
*(Exemplar Global-certified training provider)*

## ISO 9001:2015 Series

ISO 9001:2015 Internal Auditor Training for Quality Management Systems  
*(Exemplar Global-certified training provider)*

ISO 9001:2015 Lead Auditor Training for Quality Management Systems  
*(Exemplar Global-certified training provider)*

Understanding the Requirements of ISO 9001:2015 Quality Management Systems  
*(Exemplar Global-certified training provider)*

## 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 Systems

## MDSAP Course

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

## OMNEX USA

Ann Arbor, MI  
Huntsville, AL  
Seattle, WA  
Chicago, IL  
Greenville, SC  
Houston, TX  
Irvine, CA  
Minneapolis, MN  
Nashville, TN  
Los Angeles, CA  
San Jose, CA

## CANADA

Mississauga, ON

## MEXICO

Mexico City, MX



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Global

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# 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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