



www.omnex.eu

IMPLEMENTATION ROADMAP:  
**EXPECTATIONS FOR SUPPLY CHAIN.  
ELECTRIC AND AUTONOMOUS VEHICLES**



Author:  
**Martin Hettwer**  
PMP CMQOE CQE  
CQA VDA ASPICE  
PSCR.  
Managing Director,  
Omnex Europe GmbH.

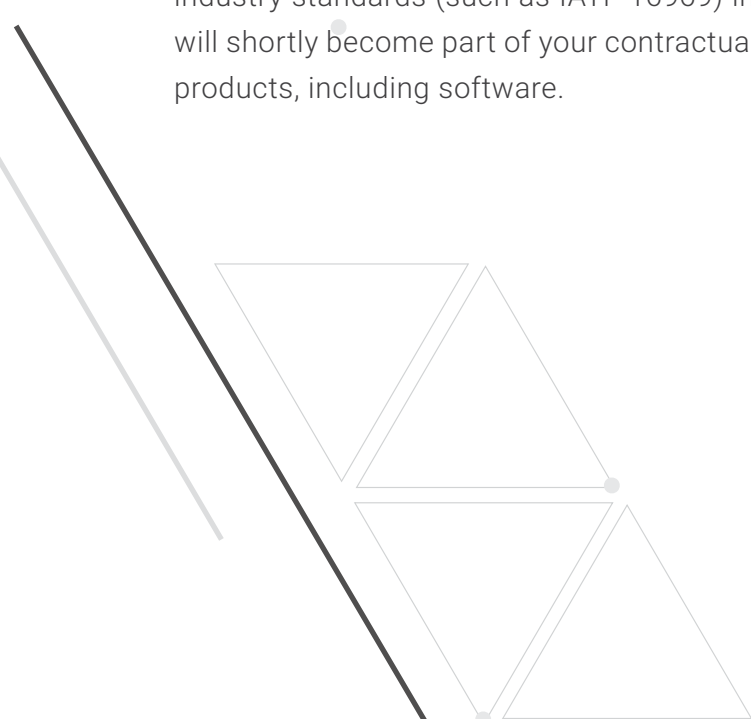


**Omnex Europe GmbH.**

Albrechtstr. 58 12103 Berlin  
Phone: +49 30 61285700 | Email info@omnex.eu



[THE PURPOSE OF THIS PAPER](#) is to provide a clear and concise roadmap for all automotive suppliers so that they may integrate standards, implement systems and processes which are now expected by the industry (OEMs) and their (tier 1-n) customers. Current ISO and industry standards (such as IATF 16969) include real expectations (shall have) and if not today will shortly become part of your contractual obligations required to design, build, and deliver your products, including software.



In his 2013 TEDx talk in Zurich, Switzerland, Nicolas Perony showed us that just because a system is considered complex, it does not necessarily mean it must be complicated. Complexity theory explains that processes having seemingly chaotic independent factors, can spontaneously order themselves into a coherent system and the resulting system will have interacting processes, all following simple individual rules and with their own emergent properties.

Implementing an integrated management system (IMS) for the entire organization is a best practice and is considered to be the most effective way to manage risk, and also to anticipate the unknowns of ever-evolving complex systems. As organizations evolve and mature, they are often bombarded with new expectations from relevant interested parties (e.g. OEMs) to implement industry or sector specific standards such as IATF 16949:2016 and ISO 14001:2015.

As the automotive industry continues to evolve towards fully electric and greater autonomous vehicle production, we often hear automotive suppliers asking: “what do we need to do in order to satisfy interested party expectations?” and “where do we start integrating the new standards listed in the customer Statement of Work (SOW) and purchase contract?” This paper will answer these questions and more.

## Laying down the foundation

Just like constructing a multi-story building, a solid foundation is required, in this case, starting with an effective quality management system. Certification of the organization’s quality management system (QMS) to IATF 16949:2016 is a key objective and is required for all tiered automotive product suppliers. It is important to note that IATF 16949 includes specific clauses for Product Safety (Cl. 4.4.1.2), Risk Analysis (Cl. 6.1.2.1) and Automotive product-related software or automotive products with embedded software (Cl. 8.4.2.3.1).

For suppliers that deliver only software to the automotive industry, ISO 9001:2015 certification is the current expectation for a QMS. All of clause 8.3 Design and development of products and services should be addressed by all suppliers who develop and deliver products; including hardware and or software.

Further, the ISO 9001:2015 includes several important clauses (Cl. 5.1.1) that state: The organizations top management shall demonstrate leadership and commitment with respect to the quality management system by:

- a** Being accountable for the effectiveness of the quality management system
- c** Ensuring the integration of quality management system requirements into the organization's business processes
- d** Promoting the application of the process approach and risk-based thinking

These key clauses are the foundation (the basis) for the development of a fully integrated (business) management system for the entire organization/enterprise

A solid integrated business management system need not be complicated, but all its interacting processes need to be carefully managed by individual process owners with adequate resources, and with the full support of leadership; to ensure the intended outcomes of each process is achieved.

IATF 16949:2016 Cl. 8.3.2.1 Design and development planning is supplemental to ISO 9001:2015 Cl. 8.3.2 which states; 'the organization shall ensure that design and development planning include all affected stakeholders (aka relevant interested parties) using a multidisciplinary approach that typically includes design, manufacturing engineering, quality, production, purchasing, suppliers and maintenance.' Clause 8.3.2.1 also includes the need for;

- (a) project management (for example, Advance Product Quality Planning or VDA-RGA)
- (c) product design risk analysis
- (d) Manufacturing process risk analysis

The AIAG manual - Advance Product Quality Planning and Control Plan provides guidance on using a multidisciplinary approach to product design and development planning, and risk analysis using 'core tools' such as Failure Mode and Effect Analysis (FMEA) and DFM/DFA. All suppliers shall note that (APQP) 'Planning' must begin prior to the Concept Phase of product development. The focus of APQP is prevention and one intended outcome is another core tool – Production Part Approval Process (PPAP).

Advance Product Quality Planning is part of the Concept Phase of development as shown in figure 1 below, **The Integrated Management System implementation roadmap** - As proposed by Omnex.

## Stated Expectations for the Automotive Industry Partners

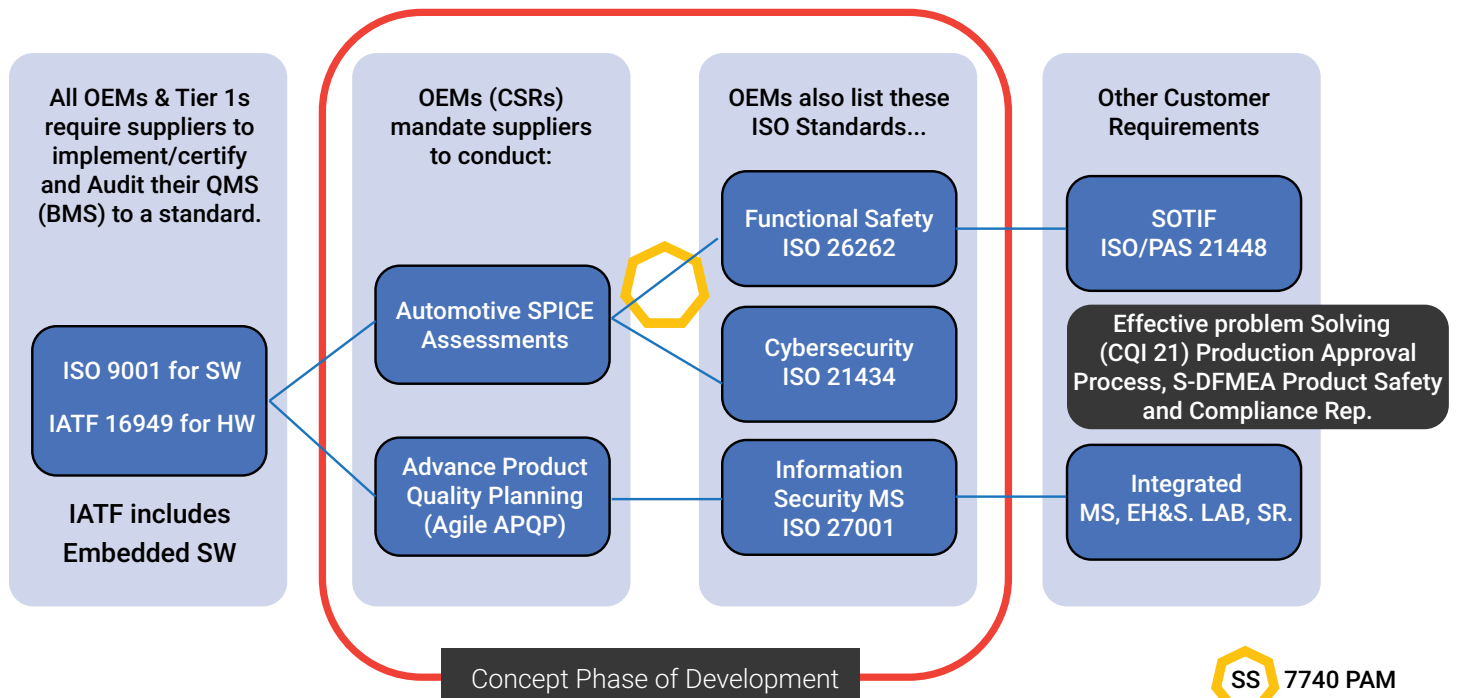


Figure 1. Stated Expectations for the Automotive Industry Partners (IMS implementation Roadmap).

Both IATF 16949 Cl. 8.4.2.3.1 and (Automotive) customer requirements mandate that suppliers are to retain documented information of a software development capability self-assessment. The Automotive SPICE assessment and its PAM conforms to ISO/IEC 33004 and may be used as the basis for conducting a software development process capability (self) assessment. As with APQP, Automotive SPICE assessments are part of the Concept Phase and are used to understand the project (process)

risks before starting and during software development, and V/V testing.

As part of the purchase agreement, contract, or statement of requirements automotive OEMs (and tier 1s) may require their suppliers (providers of externally provided processes, products and services) to integrate into their business management system other sector-specific standards such as but, not limited to:

- ➔ **Functional Safety - Road Vehicles - ISO 26262:2018**
- ➔ **Functional Safety - Road Vehicles - Process Assessment Model – SS 7740:2018 - Swedish Standard**
- ➔ **Cybersecurity Engineering – Road Vehicles - ISO/SAE DIS 21434 (SAE)**
- ➔ **Information Security Management Systems (ISMS) requirements ISO 27001:2013**

Functional Safety for Road Vehicles - ISO 26262:2018 – According to ISO, is intended to be applied to safety-related systems that include one or more electrical and/or electronic (E/E) systems that are installed in series-production road vehicles and intended to address possible hazards caused by malfunctioning behaviour of safety-related E/E systems, including the interactions of these systems.

**Cybersecurity Engineering for Road Vehicles - ISO/SAE DIS 21434 (SAE)** - is the standard that is applied to Cybersecurity Related Systems which includes electric/electronic wired and wireless communication systems installed in production passenger vehicles. If you are a supplier of wired or wireless systems, subsystems including (embedded) software, then you should expect this new standard to become part of your

organizational lexicon. Specific knowledge of potential vulnerabilities and prevention of cybersecurity attacks on your products must be a priority for the organization. Cybersecurity Engineering also begins and resides in the concept phase of development.

**“Unfortunately, for many suppliers the implementation and integration of these (ISO) standards happen much later in the development lifecycle, and only become a priority for leadership once they fail their audit, are subject to major customer complaints, or have astronomically high failure costs and warranty claims.”**

An effective Information Security Management system that is aligned with ISO 27001:2018 may prevent software/cyber-attacks, the theft of intellectual property or sabotage, and many other potential information security risks that organizations may face. The consequences of cyber-attacks can be huge and very costly. Most organizations have some ISMS controls in place to protect them, but how can we ensure those controls are enough? The international reference guidelines for assessing information security controls have just been updated to help

organizations keep their data and system assets secure. Note that IATF 16949:2016 requires Cybersecurity assessments and test as part of contingency planning.

Information is one of the most valuable assets for any organization, and data breaches can cost heavily in terms of lost business and damage clean up. Thus, rigorous controls should be in place and monitored regularly to keep up with the changing risks.

## Implementation and integration of standards, in the right order

Unfortunately, for many suppliers the implementation and integration of these (ISO) standards happen much later in the development lifecycle, and only becomes a priority for leadership once they fail their audit, are subject to major customer complaints, or have astronomically high failure costs and warranty claims.

Other industries are also susceptible to poor-quality planning and failed designs. Consider the 5.3-billion-dollar loss incurred by Samsung due to improper battery fit in its Galaxy Note 7. Even further, let us never forget what Boeing will eventually payout for the grounding of its entire 737 Max fleet; related to mismanagement of functional safety (software) and the wiring issues found during another FAA audit.

Another customer-driven requirement “newcomer” is ISO/PAS 21448:2019 for Road vehicles – Safety Of The Intended Functionality. The SOTIF standard was written to address the absence of unreasonable risk that arise due to hazards resulting from functional insufficiencies of the intended functionality, or by reasonably foreseeable misuse by persons. This document provides guidance on the applicable design, verification and validation measures needed to achieve SOTIF. However, the new standard does not apply to faults covered by the ISO 26262 series or to hazards directly caused by the system technology.

***Developing new Automotive Systems now requires several fundamental changes in the Product Design processes such as***

1. A deeper consideration of system, sub-system, hardware and software architecture,
2. Adoption of the Engineering V Model, including requirements flow down and linkages between system, sub-system, hardware and software within the supply chain and test flow-up from suppliers,
3. Unique identification and traceability of requirements and test cases,
4. Configuration management for product releases and work products,
5. System FMEA and DVP&R Test Plans need to link/align with sub-system DFMEA and DVP&R including hardware, software FMEAs and Test Plans.
6. Safety ASILs functions and requirements and Security CIL functions and requirements must translate to characteristics controlled via the Process Flow, PFMEA, and Manufacturing Control Plan,
7. Early supplier sourcing documentation (of relevant requirements) must include flow down and flow up from each of the affected tiers in the chain.

Organizations should not forget that automotive OEMs mandate ISO standards and their own customer-specific requirements because of the many competitive advantages these standards provide. However, OEMs and Tier 1s often have further expectations for the implementation of integrated management systems for their supply partners. These expected standards include but, are not limited to:

ISO 45001:2018 Occupational health and safety management systems– Requirements with guidance

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

ISO 14001:2015 Environmental management systems – Requirements with guidance for use

ISO 26000:2010 Social responsibility

Beyond the ISO standards listed above, the automotive industry expects its suppliers and their employees to be proficient and competent with these automotive (core) tools

**(FMEA)**

Failure Mode and Effects Analysis

**(APQP)**

Advance Product Quality Planning and Control Plan

**(PPAP)**

Production Part Approval Process

**(MSA)**

Measurement System Analysis

**(SPC)**

Statistical Process Control

Effective Team Problem Solving – using 8D

VDA Part 3 Process Audits and Part 5 Product Audits

To summarize, the expectations in the automotive industry are changing as rapidly as the expectations of the consumer. What organizations did and what we delivered just two years ago is no longer adequate to remain competitive and stay ahead of the market wants and must-haves. Each of the standards listed in this paper were written to prevent failure and injuries, save money, reduce cost, eliminate waste and non-value-added work, and promote improvement whilst focusing on customer satisfaction. Each standard discussed here is a list of best practices by itself. While organizations and individuals may choose to ignore best practices, often we do so to our own detriment.

Still unsure where to begin or simply want to learn more? Please visit [www.omnex.eu](http://www.omnex.eu) or [www.omnex.com](http://www.omnex.com)

Omnex offers competency focused training and certification (with comprehensive classes led by industry SMEs), consultation with implementation solutions, by the people that actually wrote these standards, and recognized Lead Auditor certification with CEUs for all the standards and core tools given in this paper.



**Omnex Europe GmbH.**

Albrechtstr. 58 12103 Berlin

Phone: +49 30 61285700 | Email [info@omnex.eu](mailto:info@omnex.eu)