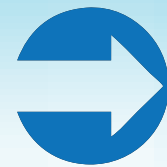




# Methodologies Employed BY OMNEX AROUND THE WORLD



# Methodologies Employed by Omnex Around the World

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Over the past 33 years, Omnex has been involved in the development, implementation and continual improvement of methodologies that are used by organizations worldwide to achieve world-class performance. In fact, these methodologies have been used in the transformation of the Automotive, Aerospace, Transportation, Semiconductor and Service industries.

The methodologies described in this brochure have been developed and innovated by Omnex over the past 33+ years. They are effective in transforming organizations in becoming Lean Organizations employing Effective Leadership Practices resulting in Effective Supply Chains with low PPM External Quality and 100% On-time Delivery. In other words, these methodologies create a more efficient and low-cost world-class organization.

## The methodologies described in this document include:

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- 1.0 Quality/Business Operating System (QOS/BOS)
- 2.0 Phase Gate Risk-Based New Product Development Process
- 3.0 Integrated Management Systems
- 4.0 Quality/Business Management Systems
- 5.0 Environmental Management Systems (ISO 14001) including Social Responsibility (ISO 26000)
- 6.0 Audit Processes and Methods
- 7.0 Effective Problem Solving
- 8.0 Lean and Six Sigma
- 9.0 Functional Safety
- 10.0 Business Excellence
- 11.0 Supply Chain Practices and Outsourcing
- 12.0 Software: Enterprise-wide Integrated Management Systems

Omnex, working with Ford Motor Company, developed the Quality Operating System (QOS) methodology, also known as BOS (Business Operating System). This approach involves a leadership process that aligns customer and interested party expectations (focus) with a disciplined method for managing continual improvement in the performance of the business (See Figure 1). This methodology, once it was adopted by Ford, was deployed throughout its worldwide supplier base in the 1990s. Since that time, Omnex has assisted companies in a wide range of industries in the effective implementation of QOS/BOS systems. The BOS encompasses the entire organization, including the New Product Development and Manufacturing or Service Operations, and is fully aligned with the ISO 9001 architecture of processes and metrics. BOS has evolved to a Context, Interested Party Expectations process that drives the Strategic Objectives of the organization. The objectives help drive organizational KPIs and also the Key Process and Process Measurables of the organization. The KPI driven BOS process helps drive an integrated process for the QMS, EMS, OHSAS, and IT Security management system. In other words, the high level structure defined by the Annex SL by the ISO body.

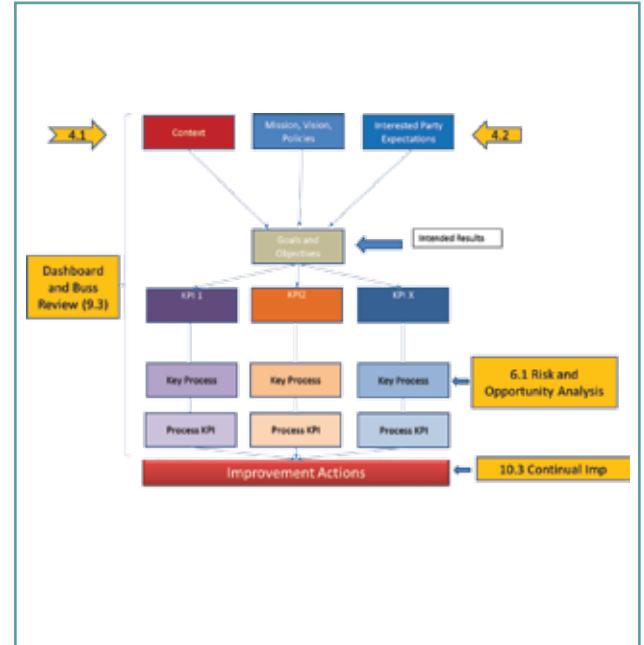


Fig 1 – Customer-Focused Strategy and Alignment of Results to Key Processes & Process Measurables (QOS)

The power of the BOS is the performance improvements driven by improvement teams focused on the process measurables that then drive results in the KPIs.

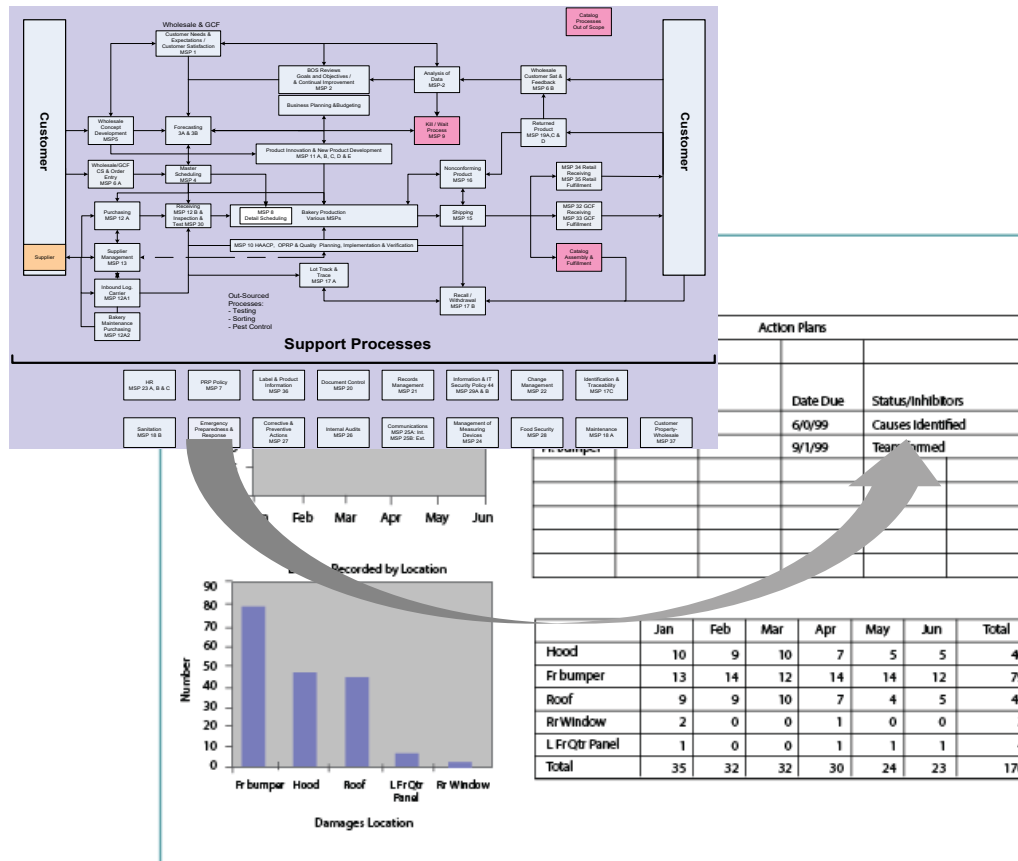


Fig 2 – Disciplined Management Methods – Visual Management – Data Driven Improvement led by Management at all levels. (QOS)

Phase Gate Risk-Based New Product Development uses methods and competencies that introduce preventative risk management techniques into the New Product Development process (See Figure 3). This process begins with requirements management incorporating rigorous risk and feasibility assessment, with analytical disciplines sustained throughout R&D, Development, Manufacturing, and ultimately propagated throughout the Supply Base.

Omnex typically works with organizations to first customize their New Product Development (NPD) process, integrating Phase Gate Risk-Based tools and deliverables management into their existing processes and organizational structures, redefining tasks to enable employees to understand and fulfill their new roles. The updated NPD process, methodologies, deliverables and new roles and responsibilities are then deployed organization-wide and throughout the Supply Base.

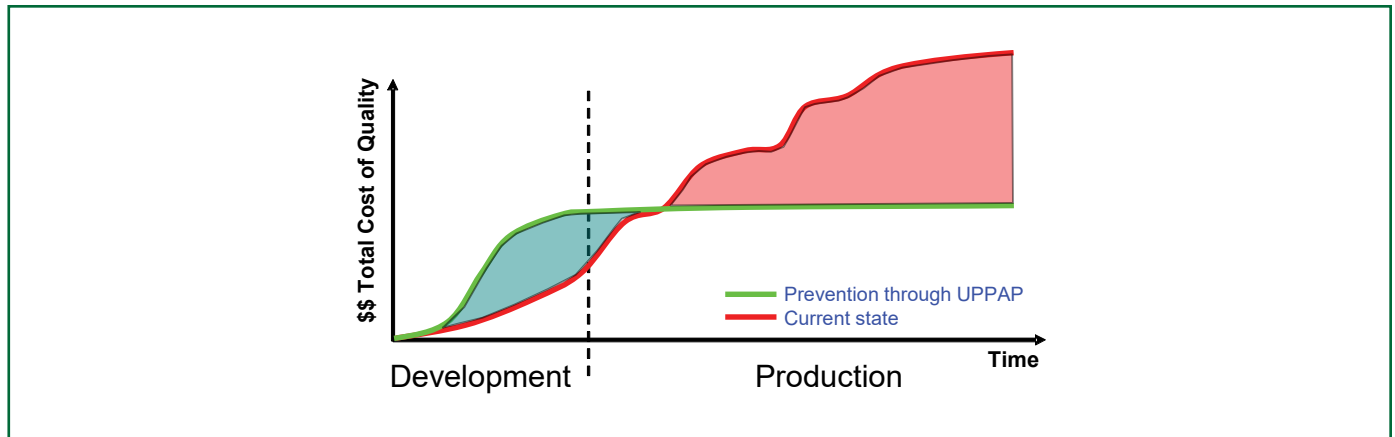


Fig 3 – Prevention is a one-time expense; detection and correction are forever. Thus, effective prevention techniques (Advanced Quality Planning) – save money (Phase Gate Risk Based NPD)

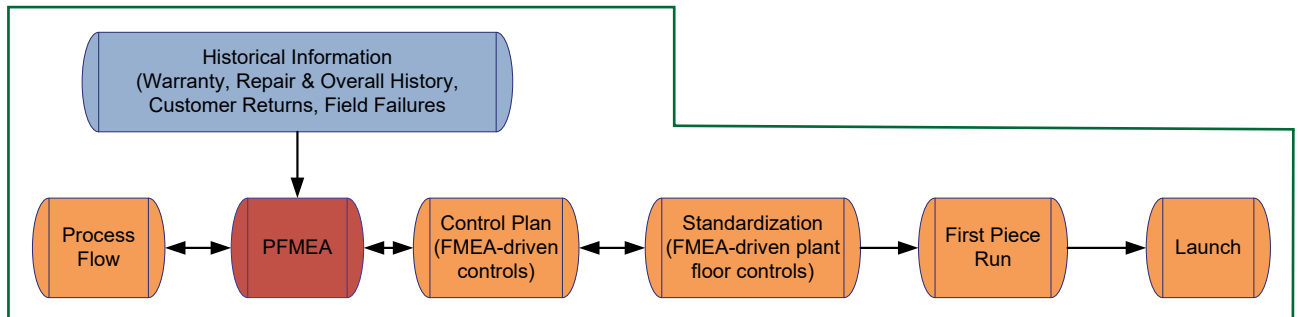


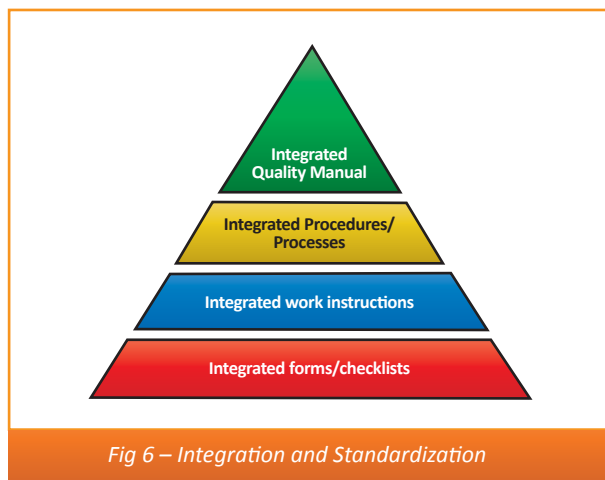
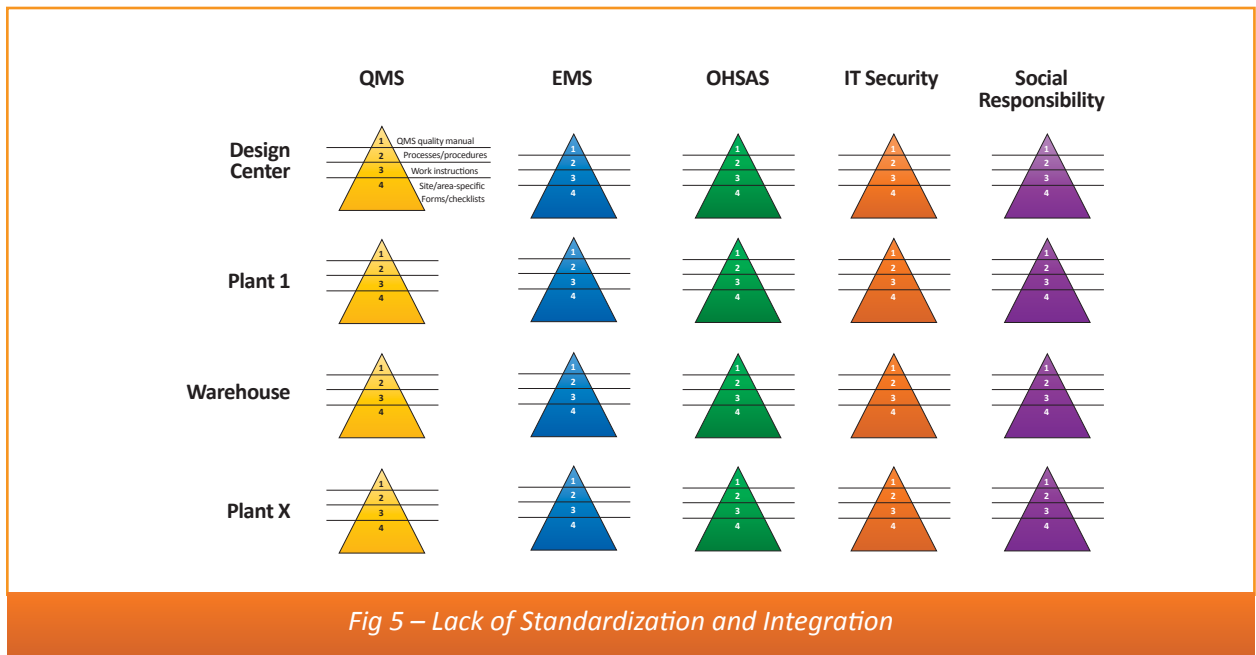
Fig 4 – Risk focused Plant floor Controls (Phase Gate Risk Based NPD)

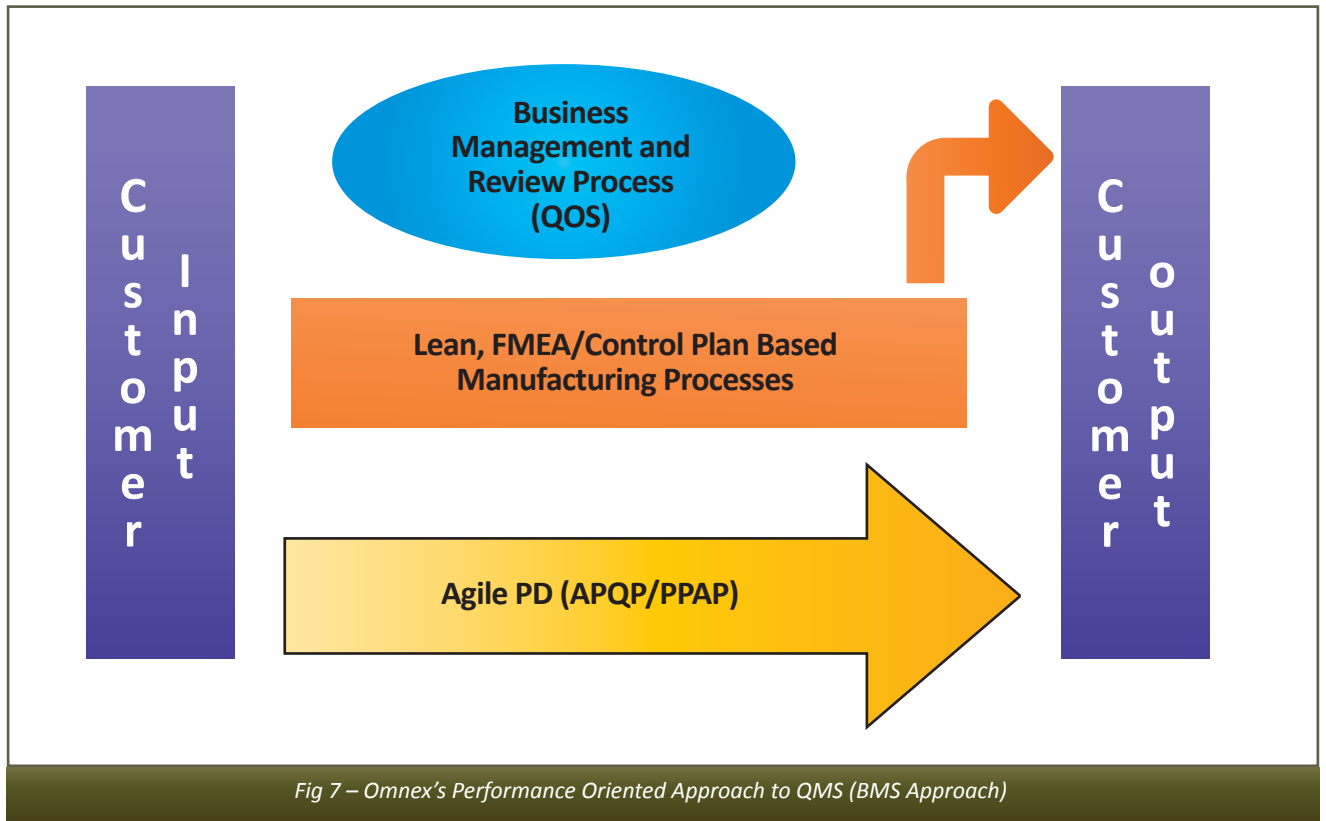


Integrated Management Systems (IMS) combines QMS, EMS, OHSMS and other standards and requirements into a single, integrated management system. IMS fosters the concept that an organization should establish one integrated system that is best for the business rather than creating separate—often duplicate—processes, procedures and documentation systems to satisfy each management standard. IMS creates company-wide processes that, while conforming to various management system standards (e.g., AS9100, IATF 16949, ISO 22000, ISO 9001, ISO 14001, and ISO 45001), establish a system primarily to enable the organization to consistently achieve its business goals.

Omnex recommends integrating QMS +EMS + OHSAS + IT Security + Social Responsibility

Omnex defines IMS as integrated processes, integrated risk and integrated audits





Omnex's approach to QMS/BMS incorporates, documents, and implements the Omnex methodologies (See Figure 7) discussed in this document, including QOS, AGILE Product Development, and Integrated Lean and Six Sigma using cross-functional teams. This approach creates management systems that help organizations reach world-class performance of single-digit PPM and 100% On-time Delivery.

The Omnex approach conceives of the QMS as a Business Management System stressing that the "Q" in "QMS" comprehends the entire business – not simply the "Quality Function" and product conformity. In addition, the business processes defined and documented in the system

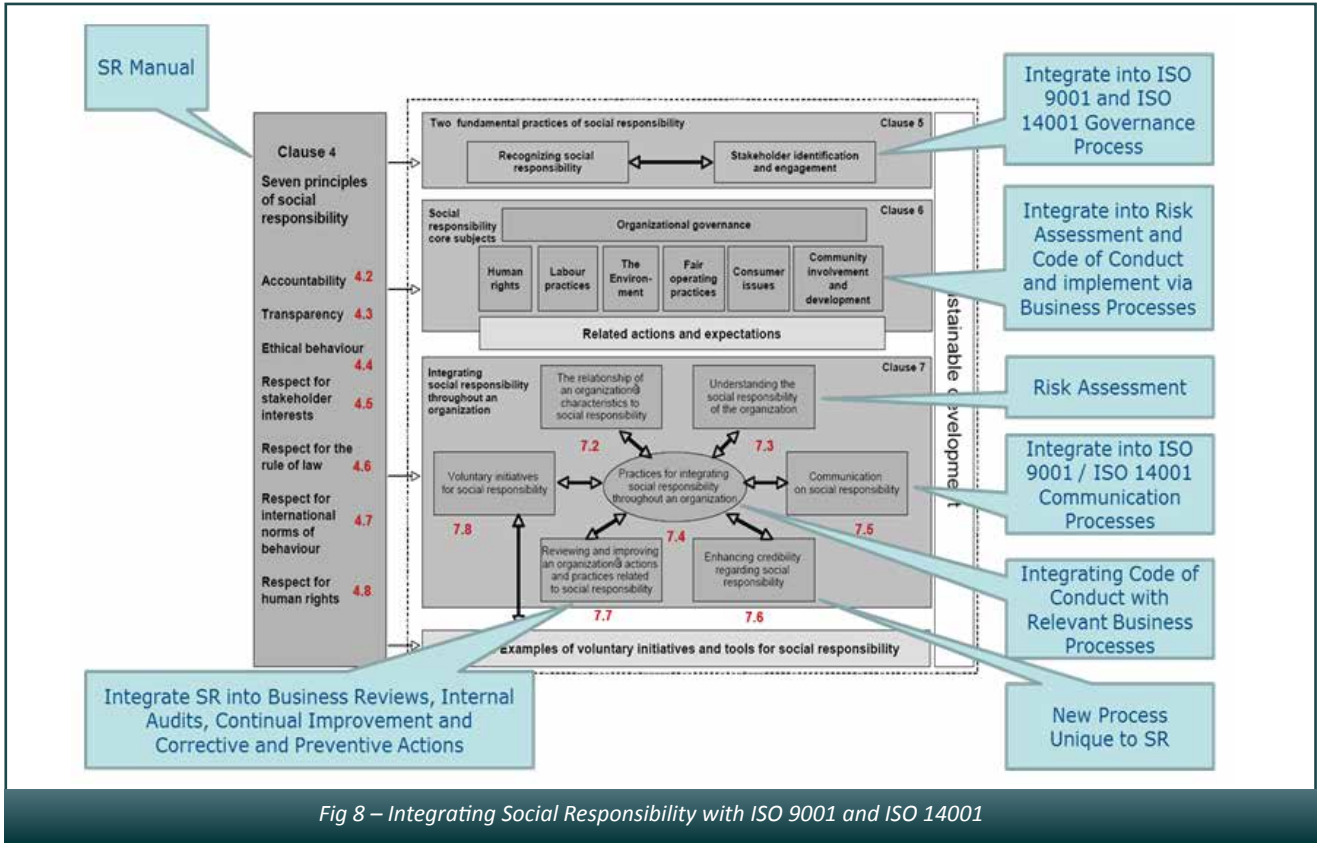


Fig 8 – Integrating Social Responsibility with ISO 9001 and ISO 14001

Omnex’s optimal approach to EMS (ISO 14001) addresses Sustainability, Carbon Footprint Reduction and Social Responsibility (ISO 26000), integrating EMS and QMS with the social responsibility standard as shown in Figure 8 [excerpted from a presentation given by Chad Kymal at the Pathways to Social Responsibility Conference, 2011.] Omnex encourages organizations to build sustainability, reduced carbon footprint, and Social Responsibility (ISO 26000) into their existing QMS and EMS systems.

As discussed in 3.0 Integrated Management Systems, the Omnex approach to integration involves integrated Risk Management, employing the same methodology to combine EMS, OHSMS and Social Responsibility, recognizing that Social Responsibility “has the organization as the focus and concerns the responsibilities of the organization to society and the environment” and also therefore includes “sustainability” and reduction of carbon footprint.



Fig 9 – Integrated Risk Assessment methodology for EMS including Energy, SR, and Sustainability

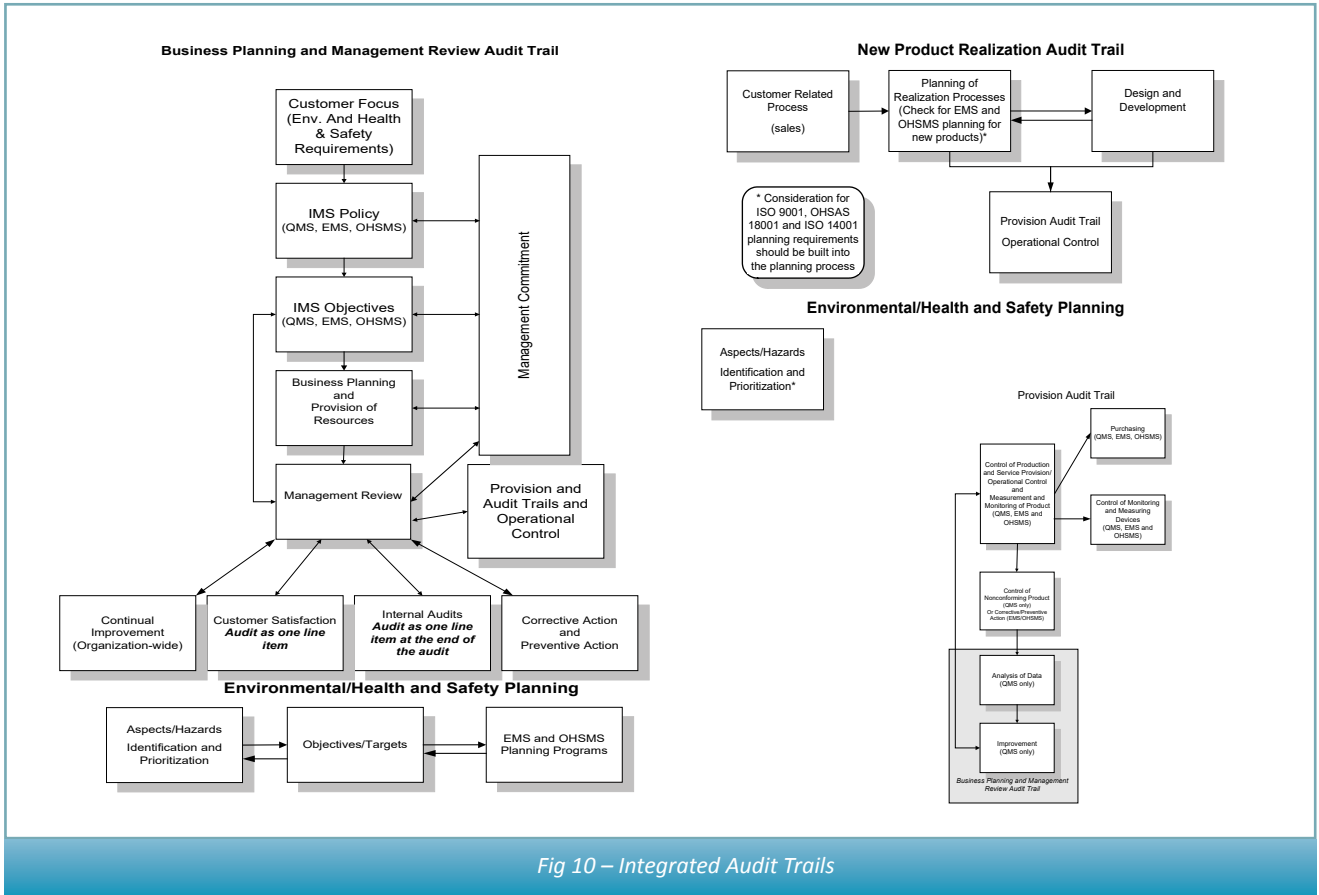


Fig 10 – Integrated Audit Trails

The Business Management System (BMS) and the business processes of an organization must be audited to ensure they are working effectively as defined and, as appropriate, documented. Omnex uses the “process approach” to auditing, including audits focused on business performance.

Omnex’s CTO and Founder, Chad Kymal, conducted the first worldwide witness audit to QS-9000 and has also published five books on audits and audit methodologies. Omnex is the only organization in the world to conduct a certified Lead Auditor Course on auditing Integrated Management Systems.

To ensure audit effectiveness and value to the organization, Omnex’s hallmark approach uses audit trails as shown in Figure 10.

In order to develop well-qualified auditors, Omnex uses a progressive training program from Internal to Lead to Advanced, Integrated auditing. This progression can be seen in Figure 11.

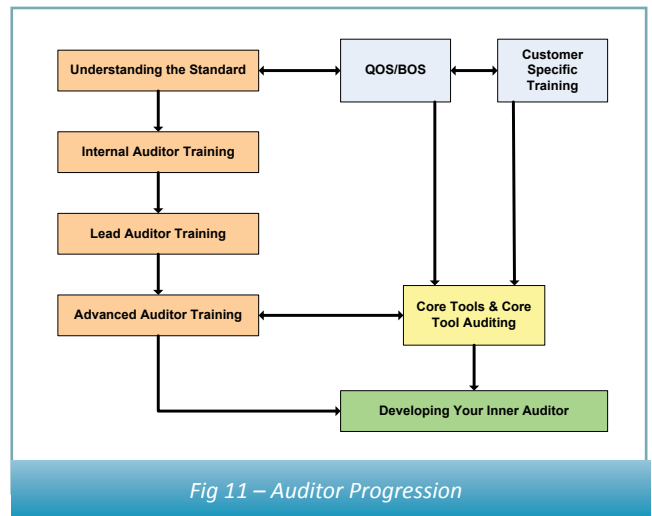


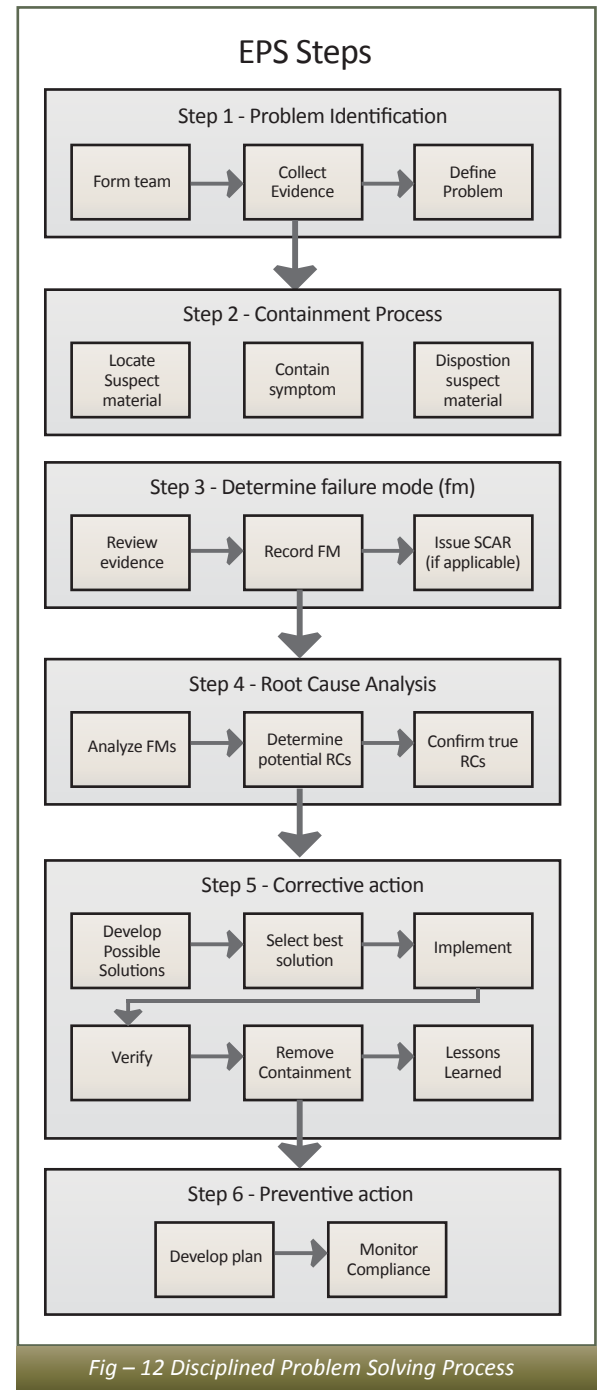
Fig 11 – Auditor Progression

Effective Problem Solving (EPS) is a step-by-step method to go from “identifying a problem” to “effective corrective and preventive actions” to ensure a problem is resolved and does not repeat. Effective Problem Solving is one of the core methodologies, along with Process Review and Six Sigma, used by Omnex to achieve single digit PPMs (product defects) and significant error reduction in organizations.

Effective Problem Solving at Omnex involves the use of a disciplined process (consistent with most of the approaches such as Global 8D, etc.; see Figure 12) that includes: Defining a Problem; Taking Containment Action; Identifying System, Escape, and Occurrence Root Causes; Implementing Corrective Action; and Taking System-wide Preventive Actions. Integrated into this process are a number of tools including FMEA, Cause and Effect Diagrams, Brainstorming, 5 Whys, Is/Is Not, and the Seven Basic Quality Tools.

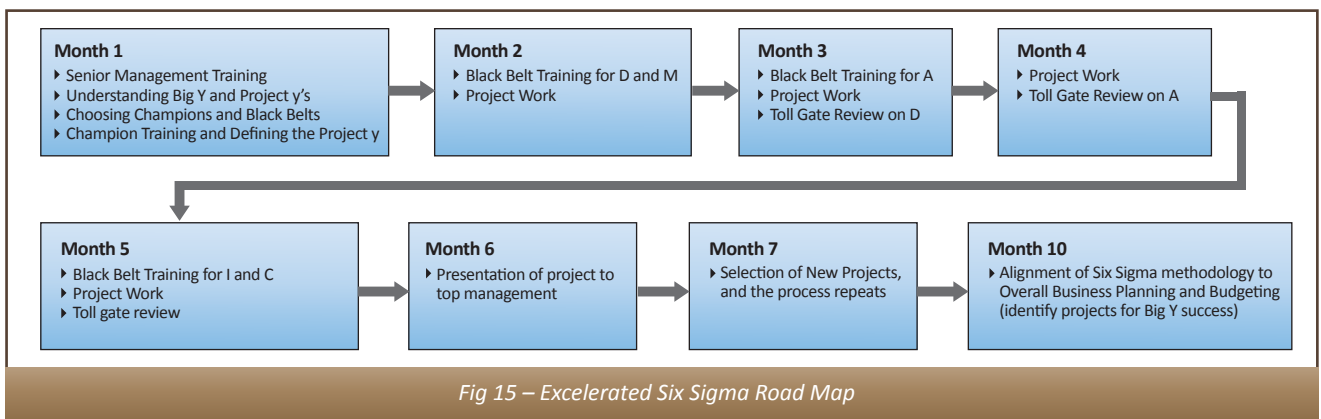
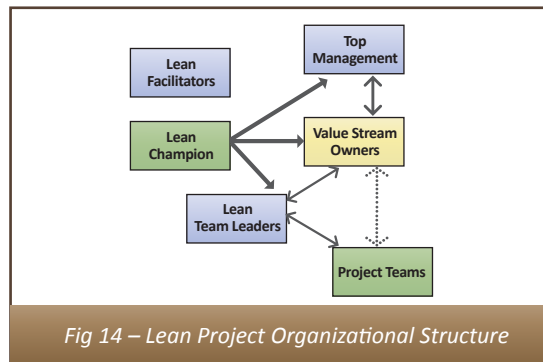
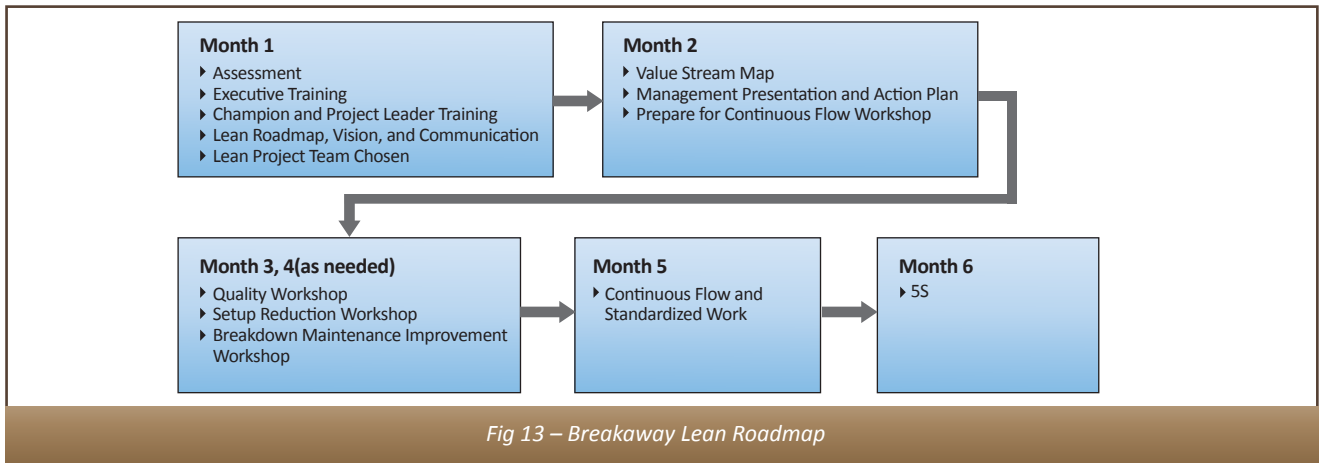
A problem solving culture must cascade throughout the organization starting with top management, through middle management, and finally out to all activities in the organization. Monitoring the effectiveness of this process is a critical Management activity at all levels. Creating and using trained facilitators throughout the organization helps ingrain this competency into the culture of the enterprise.

When internal and external problems are solved there are lessons learned that need to be transferred to the DFMEAs and PFMEAs of the organization. The organization has learned that a product has failed, its root cause, and the corrective and preventive action. This “detection” needs to be transferred to “prevention” ie. link from “problem solving” to the “FMEAs”. See figure below.



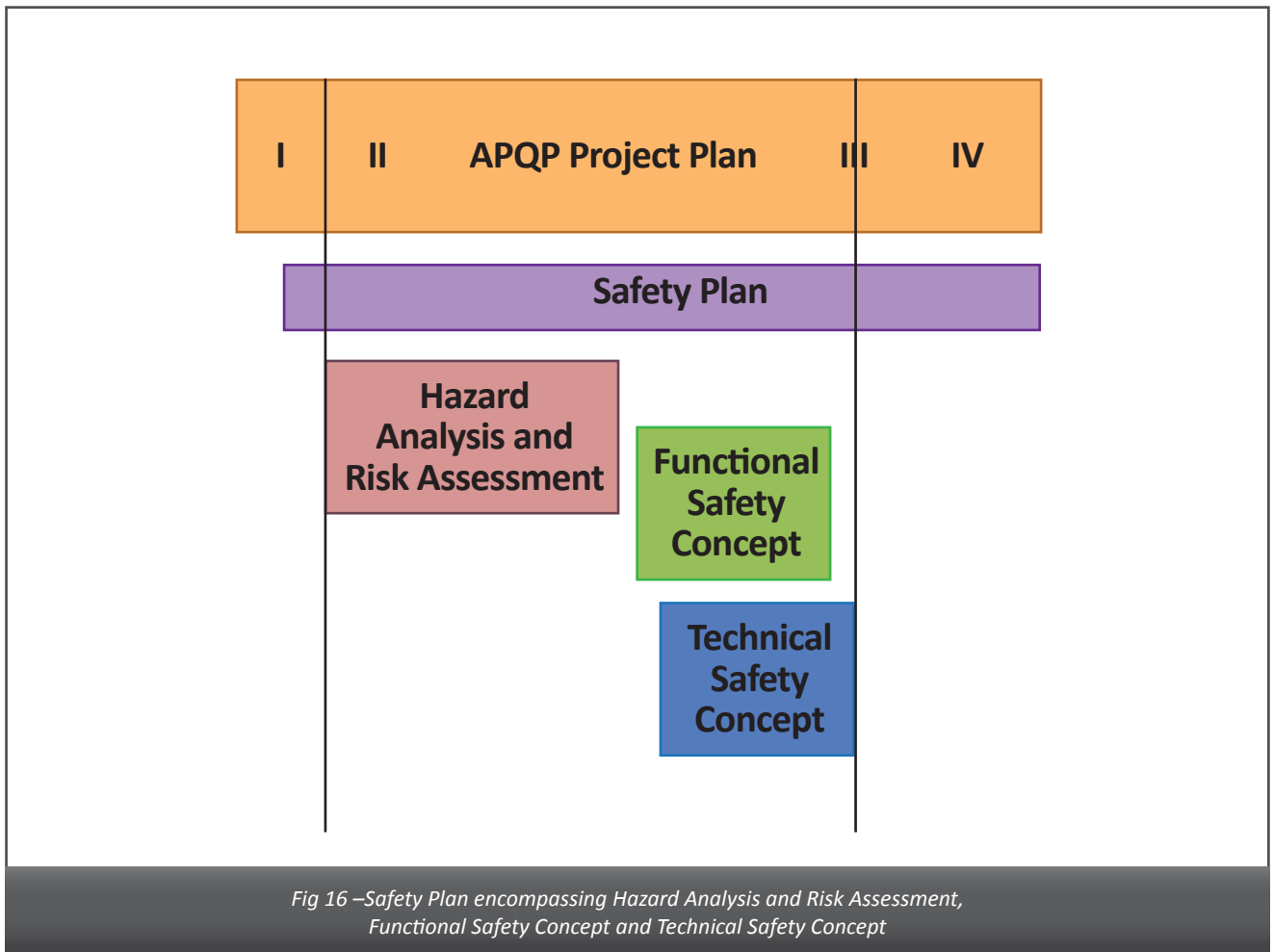
Omnex’s Lean and Six Sigma Methodologies are taught and implemented stand-alone or in an integrated Lean and Six Sigma process. Omnex uses a structured Lean process known as a Breakaway Lean™ and a Six Sigma process called Excelerated Six Sigma™.

Omnex's Breakaway Lean™ approach is a highly structured, results-oriented process that consistently achieves results of 50/50/20, often in the relatively short time frame of six months. 50/50/20 refers to the improvement an organization practicing Breakaway Lean™ (see Figure 13) can expect to achieve – a 50% or more reduction in inventory, 50% increase in throughput, and a 20% reduction in operational costs.



Functional Safety (ISO 26262) is a methodology that ensures safety-related hazards due to malfunctions in Electrical/Electronic Hardware and Software in vehicles are identified early in the development cycle. Related Safety Goals are classified by an Automotive Safety Integrity Levels (ASIL) and the risk prevention methodologies based on these ASILs are employed. The Safety Goals are realized by identifying and cascading Functional and Technical Safety concepts into Hardware and Software Safety Requirements. Safety technical measures, mechanisms and testing processes appropriate for the ASIL level are used to create a safe product. The Work Products of these processes are integrated into the AGILE PD process and culminates in a Safety Case for each Safety Goal.

This methodology can be customized to be applied to products in other industries such as Sensors, Semiconductors or Heavy Equipment. The safety plan encompassing the Hazard and Risk Assessment (HARA), the Functional Safety Concept and Technical Safety Concept is shown in the Figure 16, which is integrated with the Agile PD process. There is no reason the Functional Safety development cannot be integrated into the AGILE PD Sprint team.





Business Excellence (BE) means going beyond the management system standards (e.g., QMS, EMS, and OHSMS) to improve the effectiveness of the overall business infrastructure. If the management systems and process ownership is practiced by middle management, Business Excellence is practiced by top management. BE is a yearly internal assessment process by top management comparing their business processes against world-class benchmarks from the best organizations in the world. Gregory Gruska, Senior Consultant with Omnex, when providing a keynote speech at the 9th World Congress for Total Quality Management, had this to say about the Omnex Business Excellence model – “The Integrated Performance Management model is a systematic approach to performance management focusing on six fundamental

management initiatives. This approach has transformed an enterprise from a ‘good company’ into a world-class organization that deploys and uses ‘best in class’ processes to achieve industry-leading results. .... Such organizations will be able to achieve measurable improvements in revenue, quality, and costs at various milestones throughout the journey.”

Omnex implements and benchmarks the organization against a model broken into six sections. The Omnex approach is illustrated in Figure 17 – Business Excellence Model and Figure 18 – Section 1.0 – Management Systems (one of the six sections of BE model).



Fig 17 – Business Excellence Model in Six Sections

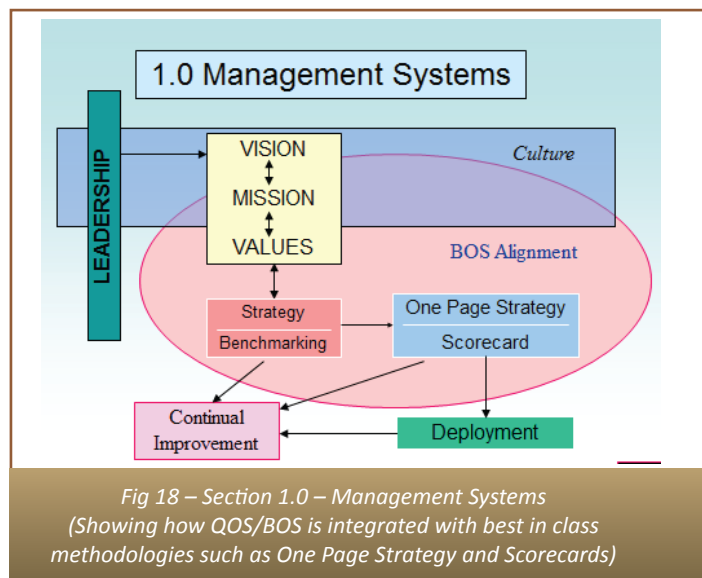


Fig 18 – Section 1.0 – Management Systems (Showing how QOS/BOS is integrated with best in class methodologies such as One Page Strategy and Scorecards)



Omnex has and continues to work with some of the largest organizations in the world—including Ford, Cummins, Mack Truck, Volvo Truck, ABB and others—in helping their suppliers consistently meet the needs of their customers. Omnex helped Ford Motor Company develop and roll-out the QOS process to their entire North American supplier base. Subsequently, Omnex assisted in the roll-out of a combined QOS, APQP and QS-9000 (predecessor to ISO/TS 16949) methodology to Ford and Ford Suppliers in Brazil, Venezuela, Argentina, India, and Thailand. Omnex also helped a JV of Cummins and DFM roll-out ISO/TS 16949, APQP, and the core tools in 1999 and subsequently helped all the DFM plants including their suppliers.

Some of Omnex's most significant successes occurred while working alongside the Semiconductor Assembly Council (SAC) to transform the Semiconductor supply chain in SE Asia into the best in the world. Ron Ramos of Philips Semiconductor and a board member of SAC reported the results of the transformation as follows:

- ▶ Productivity improvements : 10% – 30%
  - Equipment
  - People
- ▶ Yield improvement
  - Subcontractor yields improved to 99.6%
- ▶ Performance to schedule improvement
  - Consistently sustaining 100%
- ▶ Number of customer complaints decreased
  - Up to 15x reduction

Here is a list of projects undertaken by Omnex around the globe: (in no particular order)

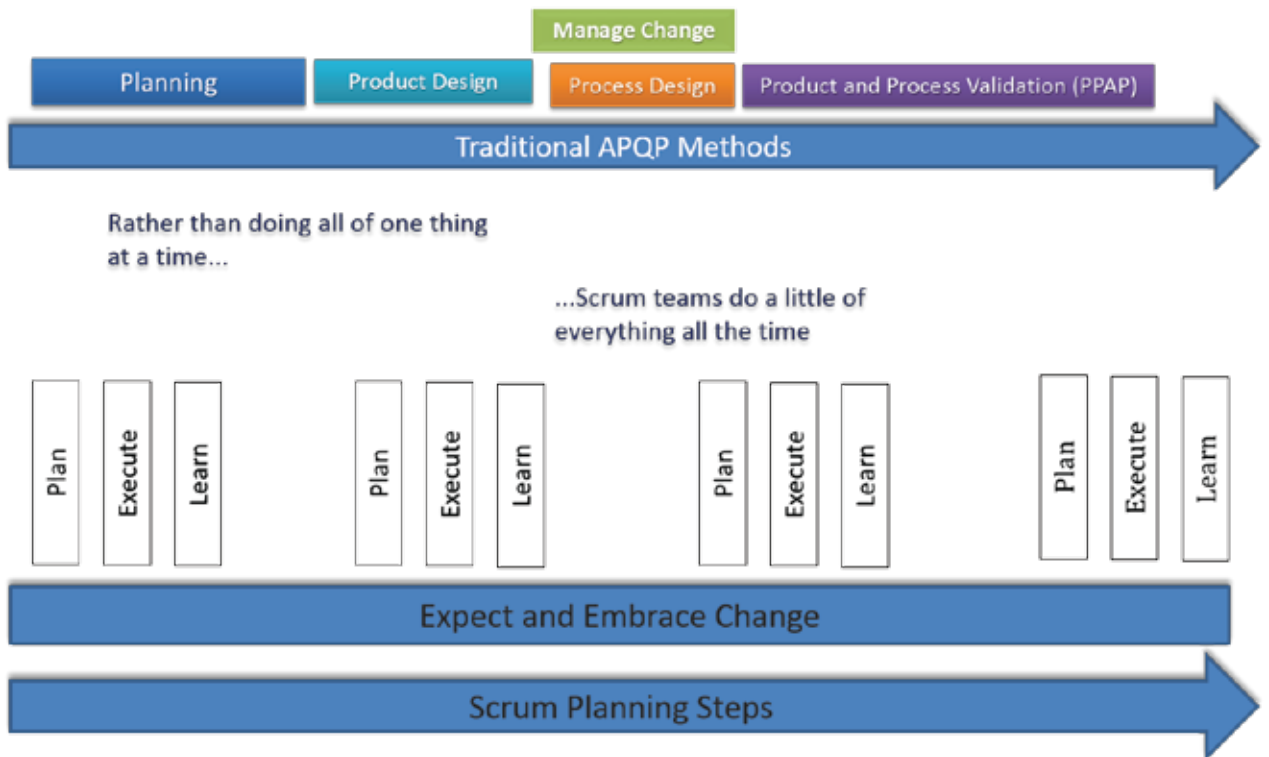
- 1 Conducted APQP, SPC, MSA, and PPAPs for 220 suppliers for a New Car Launch (Indica) for an OEM of Tata Motors in 2000. This car launched with a high quality index and was highly touted in Automotive News in the USA.
- 2 Conducted APQP, SPC, MSA, and PPAPs for 220 suppliers for a New Car Launch (Indica) for an OEM of Tata Motors in 2000. This car launched with a high quality index and was highly touted in Automotive News in the USA.
- 3 Improving the Automotive Supply Chain in North America in consort with AIAG (US-based Automotive

AGILE PD uses methods and competencies that introduce AGILE PD with preventative risk management techniques into the New Product Development process (See Figure 3). This process begins with requirements management incorporating rigorous risk and feasibility assessment, with analytical disciplines sustained throughout R&D, Development, Manufacturing, and ultimately propagated throughout the Supply Base.

Omnex typically works with organizations to first customize their New Product Development (NPD) process, integrating AGILE Risk-Based tools and deliverables management into their existing processes and organizational structures, redefining tasks to enable employees to understand and fulfill their new roles. The updated AGILE PD process, methodologies, deliverables and new roles and responsibilities are then deployed organization-wide and throughout the Supply Base with AGILE coaches from Omnex.

AGILE PD refers to product development methodologies based on iterative & incremental development, where requirements and solutions evolve through collaboration between self-organized cross-functional teams incorporating the methodologies of APQP and PPAP.

Agile Scrum VS. APQP/PPAP



Software-enabled processes can help standardize and integrate processes in the organization. Processes need to be kept simple and easy to use for it to be adopted in an organization.

What is EwQIMS? The Enterprise-wide Integrated Management Systems (EwQIMS) is a web-based solution to the Challenge of the Enterprise – Multi-Site, Multi-Language, and Multi-Cultural with Multiple Standards, Audits and Risk Management. It is the solution set to the problems faced by an Enterprise with multiple design centers, sales offices, manufacturing plants and customers far-flung across the globe.

- ▶ The enterprise faces multiple standards and compliance requirements with lack of consistency (of standards, processes, audits, risk management, problem solving) across the Enterprise
- ▶ No central access for quality data
  - Outdated systems, non-complaint software
  - Systems Incompatibility – Integration needs
- ▶ Process Inefficiencies
  - Little or no knowledge transfer or best practices between facilities
  - No common nomenclature for quality metrics (including audit nonconformities)
  - No integration in quality and business planning efforts (audit practices)
- ▶ Lack of flexibility and functionality in current practices

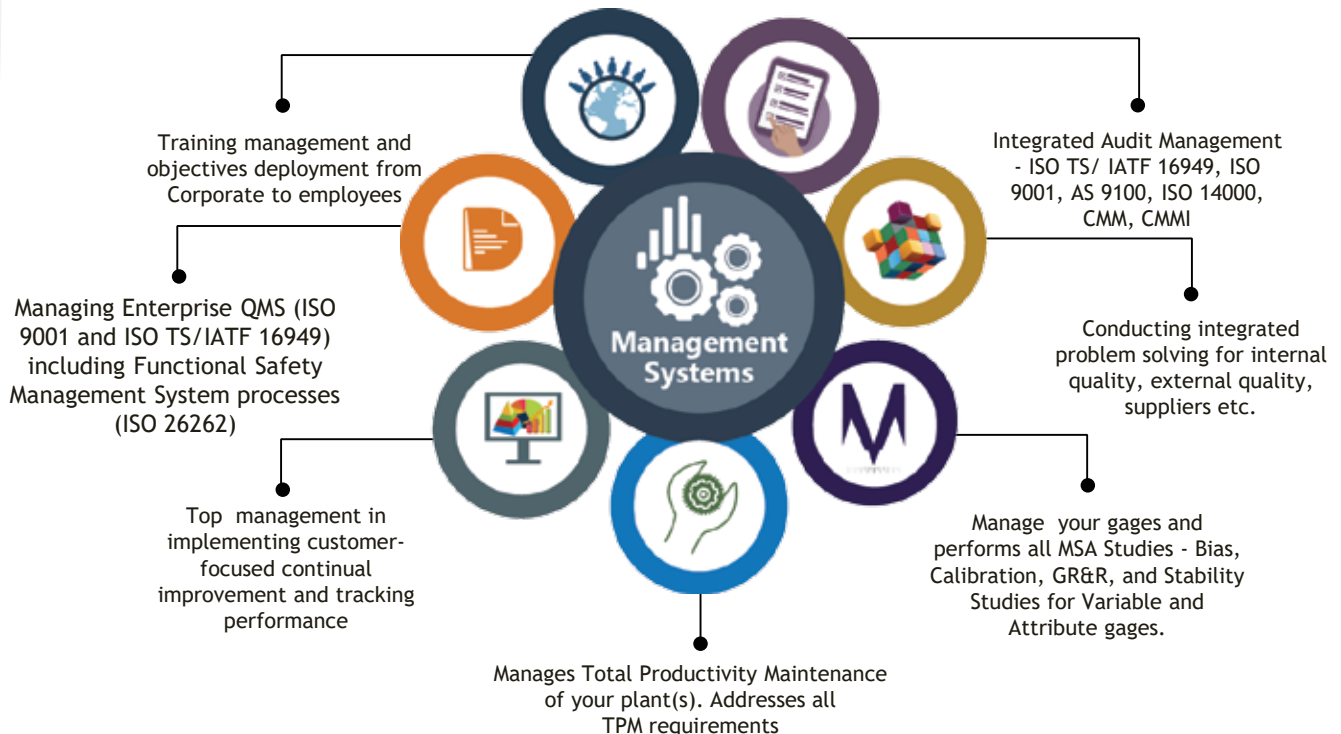
### Enterprise wide Quality Integrated Management System



### Enterprise APQP Solution



### Enterprise Integrated Management Systems



### Supplier Quality Management Suite



### Enterprise-wide Quality Integrated Management System and Enterprise Functional Safety

**APQP/PPAP MANAGER**  
equipment lifecycle

**Requirement Flowdown**  
equipment lifecycle

**AQuA pro**  
product realization software

**Document pro**  
document management software

**Audit pro**  
audit management software

**MSA pro**  
measurement system analysis

**Inspection Control**  
quality control inspection

**Problem solver**  
manage your problems and incidents

**TPM pro**  
equipment maintenance

**HR pro**  
performance objectives

**BOSS**  
continual improvement

**Functional Safety**  
functional safety

- Managing integrated APQP/PPAPs, Safety Plans, and Safety Cases for organization and suppliers
- Manage your Voice of Customer & Requirements through out the System, Sub-System & Components – functions, requirements, and characteristics
- Linked DFMEA, Test Plans, Process Flow, PFMEA, Control Plans and Work Instructions by Product and Process Families
- Managing Enterprise QMS (ISO 9001 and ISO TS/IATF 16949) including Functional Safety Management System processes (ISO 26262)
- Integrated Audit Management - ISO TS/ IATF 16949, ISO 9001, AS9100, ISO 14000, CMM, CMMI
- Manage your gages and performs all MSA Studies - Bias, Calibration, GR&R, and Stability Studies for Variable and Attribute gages.
- Manage your In-Process, Incoming/Receiving & Outgoing/Final inspections
- Conducting integrated problem solving for internal quality, external quality, suppliers etc.
- Manages Total Productivity Maintenance of your plant(s). Addresses all TPM requirements
- Training management and objectives deployment from Corporate to employees
- Top management in implementing customer-focused continual improvement and tracking performance
- Manufacturing Controls and Traceability of ASILs to Control Plan, Inspection Plans, and Inspection Sheets



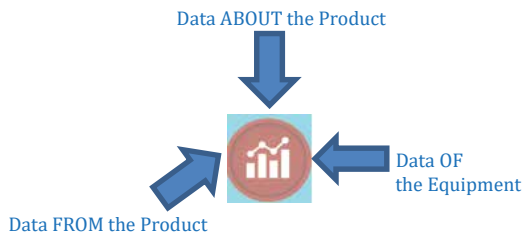
Digitalization of NPD are all Programs, all projects, and supplier submission all on the web. All documents and all submissions are Digital allowing the organization to know the status of the project and program at all times.

Digitalization goes further using BOTs and AI to intelligently gather information about projects and to ensure quality, ontime, and cost risks are brought to the attention of teams or project leads.

Omnex Digitalization projects work for both AGILE PD and also traditional phase gate new product development processes.



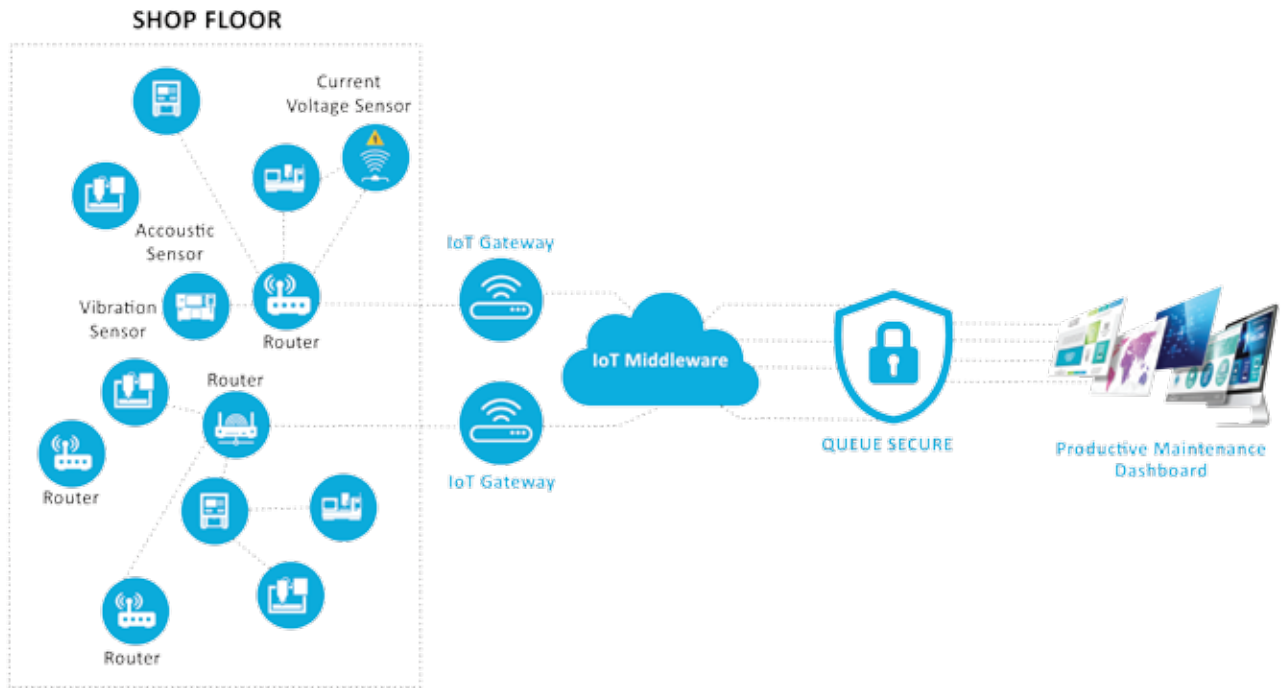
Omnex Product Development 4.0 Store



- ▶ Analysis of Connected Products
- ▶ Product Performance Monitoring.
- ▶ Operational Efficiency
- ▶ Focus on ROI & KPIS

Big data & Analysis...





### TPM Predictive Maintenance - Listen to your machines

- ▶ Traditional Preventive Maintenance embraces a Time-Based approach.
  - This consumes unnecessary Resources.
  - Disrupts Equilibrium of Stable Assets.

Reports say:

**18%**

Only 18% of Machines have age / time based failures.

**82%**

82% of Machines Failure appear Random.

3 Source: ARC view, Optimize Asset Performance with Industrial IoT and Analytics, August 2015

### Predict & Prevent

- ▶ Condition-Based maintenance coupled with IOT to monitor Machine Conditions & Trigger Preventive maintenance actions.
- ▶ Monitor & Analyze Machines Real-time.
- ▶ Intervene at the Right-time instead of scheduled Time-based Maintenance.
- ▶ Prioritize & Optimize Resources.

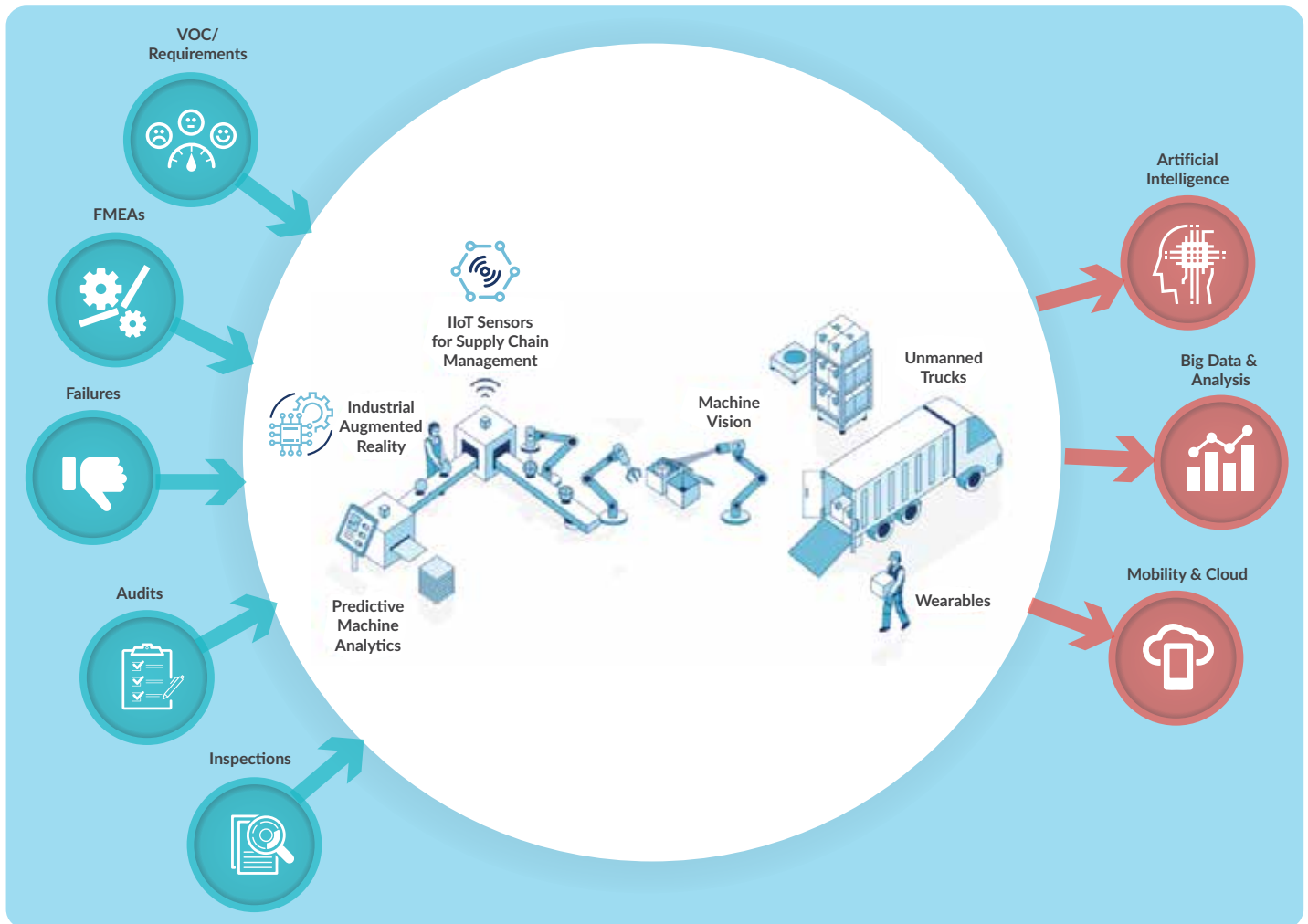


Traditional Preventive Maintenance embraces Gages & Human Inspection.



### Cognitive Inspection

- ▶ Automate Inspection Processes, Accurately identifying defects and significantly reducing manual inspections.
- ▶ Higher quality Inspection using Machine Visions & Cognitive classification achieve accurate Product Inspections.
- ▶ Central Management of Inspection through out the Organization.
- ▶ Lower production costs & Scrap rate reduction.
- ▶ Flexibility in managing Production.



- 1 Pull Systems via IIOT Sensors Supply Chain Mgmt
- 2 Unmanned optimized part movement within cells
- 3 Visual Factory and including LCD Screen
- 4 Mistake proofed unmanned machining and assembly centers
- 5 100% Uptime and zero changeover time
- 6 Parts identification and movement tracked
- 7 Balanced lines and flexible flows
- 8 Robotic flexible assembly cells with automated inspection
- 9 EwQIMS, and IIOT Framework for TPM and Inspection Control

Omnex helps transform manufacturing plants with the latest technologies using Omnex's EwQIMS software, Omnex IIOT solutions, IIOT Supply Chain pull systems linking the customer and the supply chain. Work with Omnex to ensure 100% On Time, automated 100% Inspection, Net Zero- Net Positive, IIOT TPM, and unmanned part movement.



Omnex offers two types of assistance using our training, hands-on workshops and expert advice. The first involves using our experience to guide and mentor the implementation and to help make the right choices at the right time (e.g., how to integrate various elements of management systems; crafting an effective and useful Quality Manual; the power of dynamically linking DFMEA, PFMEA & Control Plans). Typically, these opportunities only arise once, at specific points in the implementation process, and we think the likelihood of success is best when aided by a veteran and experienced organization that has completed many management system implementations.

The second involves access to the specific competencies of people in the various processes. Whether conducting APQP or Management Reviews, certain types of skills can be cultivated and then left in place by Omnex. This is the idea of “teaching how to fish versus fishing for you”. Omnex processes and methods help people in the organization learn competencies identified in our Book of Knowledge for APQP/Core Tools (broken into design competencies and process/manufacturing competencies), systems/auditing, problem solving, and QOS/leadership/reviews/continual improvement. These are imparted by working with people across the organization, including training workshops, and implementation assistance—pledging that Omnex will transfer valuable skills and knowledge to our customers.

Omnex possesses these capabilities to an extraordinary degree and will fully engage them to support and assist organizations. We typically begin our engagement with a Discovery Analysis to understand the current situation, specific problems, current status and the organizational structure. We study the processes and methods, and then conduct an assessment including data analysis to create a situation specific plan and/or a short and long term plan.

Omnex is interested in finding a few good organizations to partner with in order to create world-class organizations that can use the 25 year knowledge and methodologies we have developed over the last few years. These techniques have proven their worth over time as effective and results-oriented. For more on each of the methodologies cited in this document, see the Omnex Resource Center on our website or contact us to receive more information and or a meeting with one of our Principals worldwide.



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