

Product Lifecycle Management Integrated with Core Tools



ISOQualitas.PLM® is a comprehensive software that integrates all Product Lifecycle Management activities, from Advanced Product Quality Planning (APQP), through the Production Parts Approval Process (PAPP/VDA2) to manufacturing, according to global automotive industry standards.

ISOQualitas.PLM® is a powerful tool that allows your company to comply with the requirements of IATF-16949 standard, and the reference manuals APQP 3rd Edition, Control Plan 1st Edition, PAPP 4th Edition, FMEA - AIAG/VDA 1st Edition, SPC 2nd Edition, MSA 4th Edition, VDA2 6th Edition, and other specific requirements of the global automotive industry. In addition ISOQualitas.PLM® increases the performance and collaboration of team members during the product lifecycle.

Advantages and Benefits



All requirements in just one software

ISOQualitas.PLM® addresses all automotive requirements through integrated functions in the planning and control of activities throughout the product life cycle. The implementation of the software is simple and fast, with a maintenance investment that is very accessible to all sizes of companies. Project data is maintained in modules, and users benefit from an easy-to-use interface with full visibility into the activities of all ongoing projects.



Eliminate consistency errors

All product and process data is fully integrated, which ensures that engineering information is connected on the shop floor.
ISOQualitas.PLM®
automatically analyzes the consistency of product characteristics, process parameters, operations, and all documents and reports to ensure the reliability of information throughout the entire product lifecycle.



Constant updating of requirements

ISOQualitas keeps all its systems up to date on the latest versions of the various standards and requirements of the automotive industry, which ensures that all our customers always meet the demands of the sector. The current version includes the following Manuals:

- FMEA AIAG-VDA 1st Edition
- APQP 3rd. Edition
- Control Plan 1st Edition.



Powerful planning tools

All planned activities, such as APQP, FMEAs, Global 8D and others, are centralized in a single planning, management and control tool with automatic notifications and alerts to ensure compliance with established deadlines and real-time information on the evolution of each project in progress.

Elevating quality and productivity and going beyond the Core Tools

Project Planning and Management

Product Development

Process Development Process Validation Production

Feedback and Continous Improvement



Quick and simple setup

The installation and configuration of ISOQualitas.PLM® is simple and fast, as it requires only a small investment of time and resources and parameterization of some modules, such as:

- · Company information (including multiple plants in the same corporation).
- · User registration with definition of access level for each module.
- · Registration of customers and suppliers.
- · Insertion of a new project.

Feasibility and Risk Analysis

The feasibility and risk analysis module covers all supply risks, as well as offers a tool for the feasibility decision addressing supply risks.

- · Checklists with various perspectives of risks associated with developments.
- · Individual analysis of each risk perspective.
- · Totalization of all risks of a supply for feasibility decision.
- · Analysis and graphs of Feasibility X Risks

Project Planning and Management

The planning, management, and control modules allow users to configure, execute, and assign all activities, assignees, and deadlines, with real-time alerts, progress reports, and monitoring, including::

- · Configurable list of activities.
- · Determination of the "critical path" of the project.
- · Gantt charts based on project activities, assignees, deadlines, and progress.
- · Link between preceding activities to ensure consistency of delivery dates.
- · Automatic update of each activity, including notification of completion.
- · Sending email notification alerts for each completed activity.
- · Automatic task update in all modules and functions.
- · Automatic verification of the status of activities before the completion of the project.
- · Activity management report for each individual user, members, or teams.
- · Dashboard with the project planning KPI's.

Product and Process Data Management

The modules of Product and Process Data Management store and manage all engineering data for each project. From these modules, users have consistent control over any engineering data changes throughout the product lifecycle.

- · Parts and Parts Family Management.
- · Product Characteristics/Process Parameters.
- · Documents related to the product under development.
- · Control of CAD/CAM/CAE images and data (including 3D) with visualization capabilities.
- · Preliminary BoM Bill of Materials for Procurement.
- · ECR Engineering Change Request with approval workflow.
- · Project Management with multiple parts (Performed in the APQP ToDo module)

Product Development

The product development modules support all project requirements throughout the product lifecycle, including:

- · PDM Product Data Management.
- · Design FMEA according to the FMEA AIAG/VDA Handbook, including FMEA-MSR (Monitoring System Response)
- · DVP & R Design Verification Plan & Report.
- · Prototype Control Plan.



FMEA Handbook - AIAG/VDA

Seven-step approach with automatic definition of AP (Action Priority), action management and reporting to easily identify risks and recommended actions for development DFMEA, PFMEA and FMEA MSR:

- Full compliance with the current requirements of the FMEA AIAG/VGA Handbook.
- · Easy migration of FMEAs developed according to the AIAG 4th Edition to FMEA AIAG/VDA.
- · It includes the new criteria of Severity, Occurrence and Detection
- · Help system for the inclusion of data in each column of the AIAG/VDA FMEA.
- · Automatic AP definition (Action Priority)
- · Robust and consistent approach to FMEAs by Foundation, Family or Specific Parts
- · Structure analysis library (Step 2) for better consistency and increased productivity
- · Capability to copy data between FMEAs already developed to new FMEAs
- · Direct access to the database of non-conformities and lessons learned (NCRs and Global 8D)
- · Preventive and corrective actions with task management, alerts and email notifications.
- · Analysis of consistency between FMEAs, Control Plan, Flowchart and Characteristic Matrix.
- · Support for RFMEA (Reverse FMEA) in manufacturing processes implemented in production
- · Task management report for individual users, for specific teams, or all users.
- · AIAG/VDA FMEA forms printed on standard or large size paper for better viewing.

Manufacturing Process Development

The modules of manufacturing process development support the product production according to the specific requirements of the automotive industry, including:

- · Management of product/production process data
- · Process Flow Diagram
- · Characteristics Matrix (process parameters/product characteristics and interactions).
- · Control Plan (Prototype, Pre Launch, Safe Launch and Production).
- · Reaction Plans, Setup Instructions, Work Instructions, Quality Alerts and Visual Aids.
- · Setup Records, Inspection Records and Statistical Process Control.

APQP Requirements and Core Tools

ISOQualitas.PLM® has several modules to ensure compliance with the IATF-16949 standard and the automotive Core Tools requirements. All activities, from product concept to the end of its useful life, are addressed in a logical, consistent and easy-to-use way, which includes:

- · APQP Planning (Phases, Activities, Responsible and Deadlines).
- · Project and Process FMEAs (according to the FMEA VDA/AIAG Handbook 1st Edition)
- · Team Feasibility Commitment.
- · Process flow diagrams and Characteristic matrix.
- · Process Control Plan (Phases: Prototype, Pre-Launch and Production including Safe Launch).
- · Work instructions with production alert within the Safe launch deadline.
- · MSA Measurement Systems Analysis (Stability, Bias, Linearity, R&R variable and attribute).
- · Statistical Process Control and Preliminary Process Capability.
- · Dimensional/Material/Performance and Appearance Inspection Results.
- · Gated Management including APQP phases checklists.
- · Production Parts Approval Process PSW (According to PPAP Manual 4th Edition).
- · Specific requirements of the VDA2 6th Edition.

MSA – Measurement System Analysis

Management and execution of measurement system studies, according to the MSA - Measurement Systems Analysis manual:

- · Management of control systems including the calibrations management according to the ISO-17025 standard.
- · Stability, Bias and Linearity Studies.
- · R&R Study Variables (X-R and ANOVA methods).
- · R&R Study Attributes (Cohen Method and Gray Band).



Process Capability Study

The capability and process studies module meets the requirements of Statistical Process Control (SPC) Reference Manual - AIAG, which includes

- · Evaluation of process stability (X-R Chart, X-σ Chart, and X-MR).
- · Evaluation of the Sample Distribution: Normal, Lognormal, Exponential, Weibull and Real (Kernel).
- · Process capability indexes: Cp/Cpk, Pp/Ppk; Cm/Cmk, PPM, etc.

Production Part Approval Process PPAP e VDA2

The product approval processes modules include all requirements of PPAP 4th Edition, and the VDA2-PPA 2020 Edition, including:

- · Dimensional Inspection Results, Material and Performance (and Other tests for VDA2).
- · Part Submission Warrant PSW and VDA2 PPA according to the 6th Edition.
- · Appearance Approval Report.

Manufacturing Execution Support

The Manufacturing Execution Support after the product and process development phases benefits from the full integration of ISOQualitas.PLM®, sharing the same engineering database to be used on the shop floor in a consistent and reliable manner. The Manufacturing Execution support modules include:

- · Registration and management of production batches.
- · Inspection records with automatic SPC analysis.
- · Quality Certificates.
- · Access to Work Instructions with alerts during Safe Launch.
- · Continuous process monitoring SPC.
- · Analysis of Run@Rate and Time/Costs.
- · Production Non-Conformity Records.
- · Reverse FMEA support on manufacturing processes.
- · Full integration with ISOQualitas.ACT®software to support shop floor activities.
- · Shop Floor Layout
- · Tooling Maintenance

CAPA and Global 8D

ISOQualitas.PLM® has several modules for handling corrective, preventive, and problem solving actions as an integral part of the manufacturing support process. This enables the management, implementation, and validation of the problem solving process (Global 8D) and the recording of non-conformances (NCRs) throughout the product lifecycle. The following modules are included:

NCRs Modules

- · Registration of non-conformities.
- · Non-conformance and history search system with NCR management charts.
- · Management of corrective and preventive activities and actions (on-screen and e-mail alerts).

Problem Solving Modules

- · Registration and management of problem solving process Global 8D.
- · Management of corrective/preventive activities and actions (on-screen and e-mail alerts).

Management and Quality Control of Incoming Goods

In the modules of receiving goods control, the data of incoming materials are recorded and shared, which avoids duplication of data entry, in addition to ensuring that the data is consistent and reliable. The Raw Materials Management modules include:

- · Registration and management of materials received from suppliers.
- · Notification via email to the inspector about batches pending inspection and approval.
- · Skip Lot sampling plans (configurable as per organization's criteria) and inspection instructions.
- · Receipt and control of inspection records from suppliers.
- · Registration of non-conformities NCRs and request for troubleshooting from the supplier Global 8D.



Total Shop Floor Support

ISOQualitas.ACT® is a manufacturing execution system (MES) that extends ISOQualitas.PLM® to the shop floor to support companies looking for a paperless, engineering-integrated solution to ensure productivity, quality production and compliance to the lead times.

With ISOQualitas.ACT[®], operators, inspectors and auditors on the shop floor receive process instructions directly at their workstations and have a variety of tools to support production and feedback of process results during product manufacturing.

ISOQualitas.ACT® includes the data defined in ISOQualitas.PLM® during the APQP development and is available on the shop floor through an easy-to-use interface suitable for operators.

ISOQualitas.ACT® has specific modules to record and report quality control events and results during manufacturing as required by automotive standards and elevating the production environment to industry 4.0.

System Requirements and Implementation Options

Hardware e Software - Server

Processor: 1x8Gb - 3.2 Ghz recommended RAM: 8Gb minimum, (16Gb recommended)

HD set space: 5Gb minimum, (10Gb recommended)

Operating System: Microsoft Windows Server 2008R2, 2012, 2016,2019 and 2022.

Hardware & Software - Workstation

Processor: Intel / AMD - minimum 3.20 Ghz - 32/64 bit (64 bit recommended)

RAM: 4Gb minimum (8Gb recommended) Screen resolution: 1280 X 768px minimum

Operating System: Microsoft Windows 7, 8, 8.1, 10 and 11 – 32/64 bit - Microsoft .NET Framework 4.8

Lower than recommended settings may affect processing performance.

Server-side Deployment (On-Premise or Cloud)

Database Server: MS-SQL Server 2008 or higher, including MS-SQL Server Express, installed on the local or cloud server (Microsoft Azure recommended).

ISOQualitas.PLM installation application in the Server option and ISOQualitas.SQLAdmin, included in the installation package for the configuration of the MS-SQL Server database.

Workstation Installation

ISOQualitas.PLM installation application in the Workstation option.

Request a Free Trial Today

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