

ISO/TS 16949

Automated Solution

To deal with all the below listed challenges, SoftExpert has designed a configurable, easy-to-use, and integrated solution to help companies comply with ISO/TS 16949 and ISO 9001.

SoftExpert Excellence Suite is a web-based management system, designed to help you meet ISO/TS requirements easily and effortlessly. It will also help your organization make better decisions in managing the content and the processes that drive your business.

The following are some examples of how SoftExpert addresses key ISO/TS16949 compliance issues:

Module	ISO/TS 16949 Compliance and Requirements
<p>Product Quality Advanced Planning Production Part Approval Process</p>	<ul style="list-style-type: none">• Provides complete documentation on company products as well as process specifications.• Provides a complete database of parts, revisions, and characteristics.• Guarantees control plan for processes producing bulk materials.• Automates document revision and automatically identifies changes.• Identifies and controls special product and process characteristics.• Provides a high quality product and helps to keep scheduled deadlines while reducing any related costs.• Sends all APQP documents to customers through the Internet with electronic signatures of Submission Warrant and APQP results.• Automatically creates APQP documents, FMEAs and Control Plans.• Ensures simple and effective control of new product development.• Generates APQP schedules in spreadsheets and Gantt charts.• Assures full compliance with 8D and 5 steps.• Builds PPAP templates for each customer to meet unique document requirements.• Submits or receives any of the PPAP documents to/from customer.• Manages all documents and tasks in the APQP and PPAP processes, allowing the team to focus on customer related matters.• Manages and controls the entire PPAP including appearance approval, test results, process flow charts, measurement studies, design records, and others.

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<p>Document and Content Management [ECM/EDM]</p>	<ul style="list-style-type: none">• Manages the creation, revision, approval, and distribution of quality documents, records, and others.• Improves the control of role-based security rights for access to documents and contents.• Documents the Quality Management System.• Increases productivity by creating an electronic review and approval process and automating workflow steps based on document type, process area, and change level.• Reduces the risk of deviations resulting from employee access to outdated or obsolete procedures and work instructions.• Files, procedures, records, etc. are centralized and controlled according to company policies.
<p>Nonconformance Management Corrective and Preventive Actions Customer Complaint Management</p>	<ul style="list-style-type: none">• Manages a closed-loop corrective and preventive action process with electronic workflow and built-in effectiveness checks.• Identifies and records Process or audit problem causes.• Ensures specific problems and their causes are corrected.• Assesses the effectiveness of corrective actions.• Nonconforming products are controlled in order to prevent inadvertent use or installation.• Formalizes nonconforming product review and control.• Guarantees that appropriate corrective action is decided upon and implemented.• Ensures that responsibility for corrective action is clearly defined.• Keeps records of all complaints and follow-up actions.• Corrects any deficiencies before products or processes fail.• Maintains records of defects, investigation of their cause, and corrective actions.• Enforces consistent and harmonized processes and procedures across the organization.
<p>Audit Management</p>	<ul style="list-style-type: none">• Improves auditing program efficiency by providing a streamlined and fully electronic approach to managing audit schedules, documenting findings, generating and distributing reports, and tracking and monitoring corrective actions.• Allows planning of all audits.• Results of audits are communicated to management and all findings are corrected and recorded.• Manages any required corrective action.• Ensures corrective actions are carried out on time.

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<p><u>Competencies and Training Management</u></p>	<ul style="list-style-type: none"> • Identifies training needs. • Keeps appropriate records of all employee training, skills, and experience. • Automates employee qualification and training control. • Ensures employee performance is regularly appraised and recorded. • Guarantees that employees executing tasks directly affecting product quality are properly trained. • Controls the effectiveness of previously conducted training.
<p><u>Measurement Systems Analysis</u></p>	<ul style="list-style-type: none"> • Provides all the necessary tools for managing measurement systems within the organization. • Compares equipment performance before and after being repair. • Ensures complete analysis through the use of graph charts, such as average/range, errors, whiskers chart, scatter, histogram, linearity, and others. • Provides guidance for developing a formal gage management system. • Allows fixed and variable calibrations.
<p><u>Gage Calibration Management</u></p>	<ul style="list-style-type: none"> • Ensures all instruments are calibrated and have not exceeded their expiry date. • Guarantees all instrument calibration is up to date at time of use. • Arranges the instruments into a particular group or type for easy management. • Plans and record periodic inspections. • Guarantees all equipment validation controls. • Assures measurement uncertainty and equipment capabilities are divulged and known by all. • Identifies equipment which does not need to be calibrated. • Ensures equipment measurements comply with national and international standards.
<p><u>Statistical Process Control</u></p>	<ul style="list-style-type: none"> • Verifies process capability and product characteristic acceptability. • Ensures that the required process and product characteristics are monitored and measured. • Documents procedures to implement and control the identified statistical techniques.
<p><u>Material and Product Inspection [LIMS]</u></p>	<ul style="list-style-type: none"> • Ensures Incoming materials are inspected or verified before use. • Keeps records of all inspections. • Ensures final inspection is performed prior to finished product release. • Maintains a record of the results of supplier evaluations and follow-up actions.

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<p>Failure Mode and Effect Analysis</p>	<ul style="list-style-type: none"> • Automatically calculates the risk priority number (RPN) and the severity of the analyzed process aspects. • Conducts FMEA risk analysis to manage potential issues. • Defines FMEA for product design, process, or situation-specific issues. • Automatically stores FMEA processes on all revisions performed and pinpoints any alteration recorded from each revision analysis. • Provides managerial reports which display detailed information on most common failure causes in all products and processes. The number and effectiveness of preventive/corrective actions are also recorded in system reports.
<p>Asset Maintenance Management [CMMS]</p>	<ul style="list-style-type: none"> • Guarantees equipment preventive maintenance management. • Keeps records of all maintenance work. • Ensures unique identification of each piece of equipment. • Keeps equipment calibration and maintenance records. • Documents equipment instructions supplied by the manufacturer. • Assures that equipment operates within specifications. • Provides maintenance schedule to ensure no equipment is overlooked.
<p>Risk Management</p>	<ul style="list-style-type: none"> • Creates well structured documentation relating to all aspects of each risk element. • Provides complete support for defining teams and training for those responsible for risk management. • Provides management risk monitoring tools on complete analytical chart.
<p>Performance Management [BSC]</p>	<ul style="list-style-type: none"> • Provides numerous comparative and performance charts. • Automatically detects and warns of performance deviations. • Records and controls action plans. • Analyzes causes and effects (strategy map). • Automates graphical scorecards & dashboards displaying KPI metrics. • Increases visibility and transparency with personalized dashboards, integrated reporting tools, and automatic report distribution to management.
<p>Business Process Management [BPM]</p>	<ul style="list-style-type: none"> • Ensures production (and installation) processes are defined, planned, and documented. • Guarantees that production is carried out under controlled conditions: documented instructions, in-process controls, process and equipment approval, and criteria for workmanship. • Guarantees processes are monitored and controlled. • Allows individuals, groups, business units and suppliers to be added to any process and ensures that they receive notification of tasks in their respective queue. • Allows the building and management of business processes through the creation of process maps and process flows for all non-manufacturing processes.

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Project and Service Management

- Ensures projects are initially planned then approved.
- Estimates initial project time, costs, and deliverables.
- Identifies, documents, and reviews and approves all project changes and modifications.
- Assures critical path assessment.
- Keeps record of all project meetings.
- Manages task requests from all departments – from large macro-projects down to the smallest routine tasks.
- Displays the entire project portfolio and applies key performance indicators for organizational strategic alignment.
- Manages the entire life-cycle of electronic documentation, including the drafting, approval, and release steps for viewing, revision, and canceling.
- Ensures project tasks are performed and verified.