OPENTEXT™

Optimizing Quality Assurance with Quality Manager™

Quality Manager™ is an integrated business tool that helps companies to effectively manage complex quality data and processes in accordance with regulatory requirements. Designed to seamlessly integrate with existing IT infrastructures, Quality Manager can enable quality control to become fundamental to all business processes, while lowering cost and reducing complexity.

Improving Efficiency and Compliance

Quality Manager provides a comprehensive suite of functions that enables you to consistently deliver high quality products and services while maintaining efficient and regulatory-compliant production operations. It means you can better respond to customers in instances of inquiry or complaint and provides you with real-time visibility of product performance, improving the effectiveness of sales and marketing activity.

The Supplier Monitoring and Management module enables you to comprehensively and continuously examine the performance of your key suppliers. The Inspection Management module provides you with intuitive browser-based tools to handle all of your company's inspection and test result activity within batch oriented production, and ongoing monitoring for continuous processing and environmental management. The Non-Conformance Management module supports all the processes you will need to adequately rectify inferior products and non-conformances in raw materials.

Quality Manager is process-centric and highly adaptable to your particular needs, regardless of the type of manufacturing, the particular sector in which you operate or the unique tailored requirements you may have. Quality Manager offers the most comprehensive quality management solution available, while the application itself can be easily tailored to suit individual user requirements.

By leveraging existing IT infrastructures, Quality Manager fully integrates quality management into key business processes to improve quality management and quality data visibility at every stage of the manufacturing process.

INTEGRATED QUALITY MANAGEMENT SOLUTION

Quality Manager™ addresses all aspects of enterprise quality management, from non-conformance management to supplier management, inspection management and LIMS. The solution is highly process-centric and can be adapted to the very specific quality management needs of any company, whether in the discrete manufacturing or the process manufacturing sector. Quality Manager supports continuous business innovation and can improve efficiency, compliance and profitability at every stage of the manufacturing process.

QUALITY MANAGER

- Quality Inspection Workflow
- Test and Specification Management

INSPECTION MANAGEMENT

- Instrument Management
- Laboratory Information Management System (LIMS)

- Supplier Rating
- Supplier Selection
- Audit Management

SUPPLIER MONITORING AND MANAGEMENT

NON-CONFORMANCE MANAGEMENT

- Non-Conformance Tracking and Tracing
- Non-Conformance Advice and Decision
- Corrective and Preventive Actions

Quality Manager provides a comprehensive suite of functions that enables you to implement Quality Control and Quality Assurance throughout your enterprise

Supplier Monitoring and Management

Quality Manager enables you to comprehensively and continuously examine the performance of your key suppliers so that you can source raw materials and components from those key suppliers that provide and maintain the highest levels of quality, service and price. As a result, you can considerably improve lead times and inventory levels, which is critical in regulated industries like Aerospace & Defense and Pharmaceuticals. The Supplier Monitoring and Management module works hand in hand with the Inspection Management module, thereby limiting inspection costs on well performing suppliers by reducing inspection sample sizes and the number of tests conducted.

- **Supplier Selection**
  This module provides the framework for the initial classification of suppliers and their ongoing monitoring, both in terms of delivery performance and the quality of goods they supply. Suppliers are selected and ultimately classified as an 'acceptable', a 'limited acceptable' or 'non-acceptable' supplier based on the results of audits or on historical performance. The severity and frequency of subsequent inspections reflects the individual rating of each supplier and ranges from complete lot inspection to skip lot inspection.

- **Supplier Rating**
  Quality Manager supports the quantitative (based on delivery performance) and the qualitative (based on product quality) measurement and rating of suppliers. The qualitative rating uses an algorithm to factor in non-conformities and any required corrective actions, and ERP data can be used to provide additional ratings based on quantity and price. The quality rating system is user-defined, flexible and can be based on your company's key performance indicators, such as item, on-time delivery, quantity accuracy and test results. Quality ratings can be updated in real time to maintain an accurate historical view of supplier performance.

- **Audit Management**
  An audit template system further supports the selection and rating of suppliers by allowing the central documentation and management of audit information. For each auditing function (internal/external) in your company, audit templates can be created to allow the efficient entry of audit results and documents and the scheduling of follow up actions. Based on the audit data, provisional or definitive approval can be granted to suppliers. For an approved supplier (or plant), a tailored monitoring system can also be created to ensure ongoing compliance.

Inspection Management

Quality Manager's Inspection Management module provides you with intuitive browser-based tools to manage all your company's inspection and test result activity within batch oriented production, and ongoing monitoring activities for continuous processing and environmental management. This includes receiving inspections, Work-in-Progress (WIP) inspections, process control inspections, storage inspections, finished goods inspections, field inspections and environmental inspections. The module enables you to centralize your quality procedures and processes while increasing the control and efficiency of your inspections. Quality Manager works seamlessly with your ERP system to significantly automate many of your inspection operations, and reduce error prone reliance on manual data management processes.
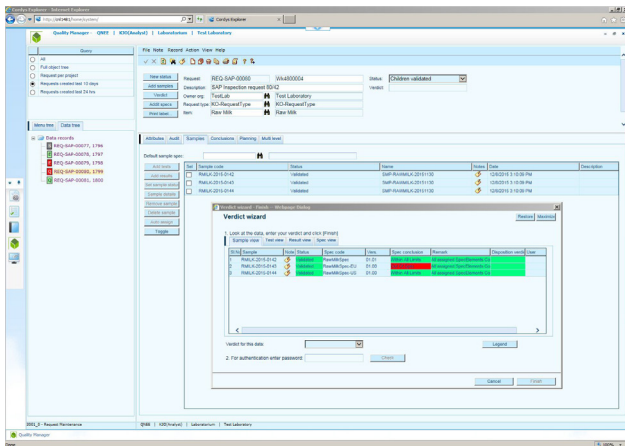
- **Quality Inspection Workflow**
  The Quality Inspection Workflow function supports the efficient routing and processing of all inspections and covers all required steps for a specific request from registration and assignment via result entry and validation through to reporting and invoicing. This structure ensures the consistency of all inspection activities across the organization and makes sure that inspections are appropriately scheduled and triggered for execution in Quality Manager.

- **Test and Specification Management**
  The Inspection Management module standardizes test profiles including the specification of tests and test methods, the processing of test results and acceptance criteria. Inspectors are provided with a list of required tests for each specification together with user-friendly data capture templates. The data capture templates automate calculations such as tensile strength, reducing errors and saving time, and enable comments and relevant documents or graphics to be filed alongside the test results for future reference.

- **Instrument Management**
  The system includes functions to manage the periodic calibration and maintenance of testing equipment, including the automatic flagging of any test results undertaken with incorrectly calibrated or under-maintained equipment.

- **Laboratory Information Management System (LIMS)**
  Quality Manager offers manufacturing companies an enterprise-wide LIMS solution that can efficiently measure and monitor the quality of products and the results of tests at every stage of the manufacturing process.

Non-Conformance Management

Quality Manager's Non-Conformance Management module ensures that all appropriate actions are taken in response to inferior products and non-conformances. By providing the means to better understand the processes that resulted in their occurrence, and identifying the product units affected, Quality Manager can ensure that non-conformances are quickly identified, tracked and fully documented, thus supporting optimal disposition and reducing the chance of recurrence. The module automates the routing of any recommendations and dispositions according to the defined rules and established business models. The module is fully integrated with the Inspection Management and Supplier Performance Management modules. For example, when a non-conformance is identified during an inspection, a supplier's rating is automatically updated and the appropriate action initiated.

- **Non-Conformance Tracking and Tracing**
  This module enables you to identify nonconformance at any stage of the goods flow, from the receipt of goods/raw materials from a supplier, through regular inspection checks in distribution and replenishment processes, to the actual production line or as the result of an audit. The system enables the physical control of the movement, storage and subsequent processing of non-conforming products. Any non-conformances can be tracked through an assigned defect code, reject reason and a red tag that will accompany the lot until disposition is made.
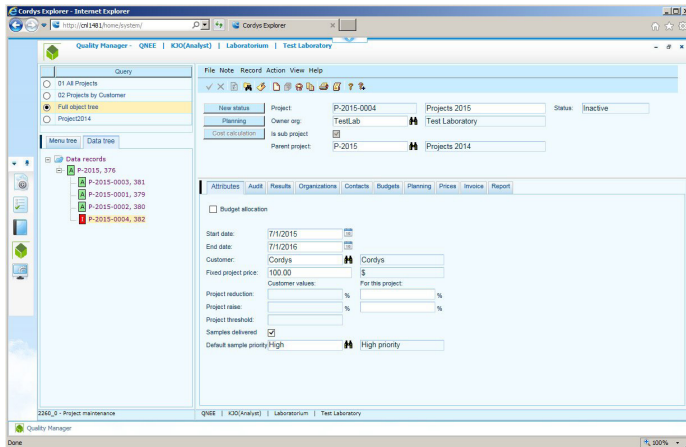
- **Non-Conformance Advice and Decision**
  Non-conformances can be segregated and reviewed by designated quality control personnel. Alternatives for disposition can be considered, such as repair, rework, reclassification, scrapping or other appropriate processing. After assessment, the disposition advice can be documented and the disposition process initiated, with reference to a Material Review Board for both material and financial disposition.

- **Corrective and Preventive Actions**
  The Non-Conformance Management module also enables appropriate Corrective and/or Preventive Action Plans (CAPA). It enables you to investigate the cause of the non-conformance by analyzing all relevant processes, work operations, quality records and customer complaints. After determining the production units that were involved, including the production time interval, the specific production machine and the product lots involved, all means for documenting the nonconformity are available and the appropriate CAPA Plans can be put in place and relevant processes and controls can be initiated and controlled.

Application Management and Control

Quality Manager is process-centric and highly adaptable to your particular needs, regardless of the type of manufacturing, the particular sector in which you operate or the unique tailored requirements you may have. The module includes features for defining organizational structure to enable access by different types of user to be automatically controlled, including authorization for specific menu functions and features. User-exits or API's (Application Program Interface) provide the necessary communications to third-party applications, while an XML interface foresees in communication

Quality Assurance throughout your Enterprise

By leveraging existing IT infrastructures, Quality Manager fully integrates quality management into key business processes to improve quality management and quality data visibility at every stage of the manufacturing process. The solution includes a number of functions that ensure a high level of quality assurance. E-records are implemented via an audit trailing mechanism that satisfies international regulations, such as FDA and FAA. Critical data entered into the system is checked through a robust and diligent authentication process. User's business models define the way that Standard Operating Procedures (SOPs) are implemented, and control is exercised over the access rights of employees through the user's business models and business rules. Quality Assurance is implemented throughout Quality Manager to support and control core regulations, such as ISO 9000:2000, ISO 17025, ISO 14000, FDA 21 cfr. part 11, GxP.

Dynamic Business Rules define the users who are authorized to maintain particular information for specific objects. This is further supported by multilevel validation, which ensures that more than one appropriately skilled employee is required for an activity requiring validation.

SOPs that are used for automatic Test and Specification assignments are fully tested before they are validated and used in operations. The authorization system ensures that any required activity is always conducted by suitably qualified employees. This ensures, for example, that only analysts who are qualified to conduct a certain test and record its results are scheduled to do so. Control samples can be defined and are automatically added to test work lists. Their results are interpreted according to Shewhart, Cusum or SPC procedures and graphically presented.

Version control enables the management of critical data like test definitions, methods, specifications and other SOPs, while a tight status control mechanism prevents updating after validation. Control samples are used to assure the proper conducting of tests, while instrument management detects and prevents the use of equipment that is not maintained or calibrated according to defined procedures.

Quality Manager ensures that 100 per cent traceability is maintained for the entire life cycle of a product. Requirements are user-defined and can include attributes such as item, supplier, PO number, lot number, batch number and serial number.

from third-party applications to Quality Manager. Finally, software customizations, business rules and business models are all updated automatically when the software is upgraded to later versions.

- **Flexible Attributes**
  Flexibute Management is a set of functions that enable the addition of user defined data definitions and screen layouts. The feature enables Quality Manager to be tailored to the specific business needs of your company, and to the specific needs of individual users.

- **Project Management**
  Quality Manager contains a set of functions that enable the definition and maintenance of specific projects for quality control purposes. The module allows projects and sub-projects to be defined and can include information of tariffs, pricing agreements, customer contacts and participating organizations.

- **Formatting Functions**
  Quality Manager offers Formatting Functions that enable you to generate and manage the format and layout for codes and names that are used in dynamic functions such as inspection requests, samples, non-conformance cases, invoices and reports.

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