

cc | quality management

USER ABILITY TO CUSTOMIZE QUALITY PARAMETERS

MANAGEMENT OF DIFFERENT TEST PROCEDURES

CUSTOMER AND VENDOR SPECIFIC TEST PLANS

IN PROCESS OR SCHEDULED TESTING INTEGRATED VENDOR RATING TRACK QUALITY MANAGEMENT THROUGHOUT SUPPLY CHAIN

SIMPLIFY LOT-| SERIAL NO. MANAGEMENT USER DEFINED PARAMETERS FOR VENDOR ASSESSMENT



COMPANY PORTRAIT



COSMO CONSULT specialises in the implementation and system management of **industry and business solutions** based on cutting-edge software technologies. We deliver industry-oriented complete solutions for midsize businesses in the manufacturing, service and retail industries by providing an extensive range of industry-specific and special solutions based on **Microsoft Dynamics** and **QlikView**.

We offer our customers over 18 years of national and international project experience in the implementation of Microsoft Dynamics NAV (previously Navision) and Microsoft Dynamics AX (previously Axapta) ERP solutions. We are also experts in the Microsoft Dynamics CRM customer relationship management system and the Microsoft SharePoint document management and portal system, which can be integrated seamlessly into the ERP system environment. We therefore deliver fully integrated software systems for use in all areas of the company. With the aid of the QlikView business intelligence solution, our customers are able to access all of their company data in a structured and manageable format at any time.

An **implementation method** tailored to the project is a prerequisite for successful software implementation. For over 15 years, we have placed our trust in proven implementation methods when implementing our software projects, such as **SureStep** for successful ERP project implementation and the **agile implementation methodology** for rapid results when realising business intelligence (BI) projects.

At COSMO CONSULT, people are our focus. After all, it is people who decide whether our software is efficient or inefficient, who judge its strengths and weaknesses, who experience joy or frustration when using it and ultimately determine if it is a success. That's why we provide:

Business Software for People

built on Microsoft Dynamics NAV

HIGHLIGHTS

- Track quality management throughout supply chain
- User ability to customize quality parameters
- Simplify lot management with quality visibility
- Integrated vendor rating
- User defined parameters for vendor assessment
- In process or scheduled testing

FEATURES

- Management of different test procedures
- Customer and vendor specific test plans
- Order-specific testing
- Test-kit testing
- Optimization of testing (skip-lot)
- Vendor management
- Lot-/serial no. Management
- Lot-/serial no. Status option
- Stability testing
- Regulatory affairs tracking and field security
- Inventory overview
- Inventory list with item inventory by status
- Error categorisation
- Vendor/item setup
- Vendor rating

Globalisation and the resulting internationalisation of markets have forced companies to adjust the quality of their products and services continuously to the needs of their customers in order to remain competitive.

The solution cc|quality management and vendor rating, built on Microsoft® Dynamics NAV, manages all necessary tests, test devices and test documentation – during purchase, production and final inspection. Information about the quality of a product can be made available for all stages of the manufacturing process.

Quality Management and Quality Assurance are the gold standard for distribution and production companies to differentiate themselves in the market by meeting or exceeding customer expectations. If you cannot test and track your product quality from product receipt to production to distribution and then customer acceptance, then it did not happen. cc|quality management allows you to decide what, when and how you test and document.

Because a stable supply chain is the foundation for an increased competitiveness, vendor rating is another crucial component of quality management. cc|vendor rating ensures the optimization of processes related to the acquisition of materials and services.

MANAGING INVENTORY

cc|quality management is an integrated part of a company's supply chain. Microsoft Dynamics NAV delivers many strong features to manage inventory, but some new controls have been added to be compliant with standards and legal requirements

RELEASE OF GOODS

Goods are tracked by lot or serial number and are controlled by a status. Incoming shipments are assigned a predefined status related to tracking number, for example, a "quarantine" status for unapproved material. Release procedures are available for existing inventory to control the availability of lot or serial number. If a lot experiences a quality problem, the impacted quality could be split into a partial lot. User-defined statuses are possible, which provide more controls than lot release or rejection. In addition, with the included module Regulatory Affairs an approval procedure with eSignature function is configurable.

INVENTORY POSTING PERMISSION

Depending on warehouse location, user, or lot/serial status, rules can be defined to control inventory movements. For example, to prevent cross-



built on Microsoft Dynamics NAV

contamination lots are assigned with conditional release for a restricted area. And in the next step, the system controls if a user is allowed to post a certain lot into the restricted area. Or a rule can be defined to keep materials under quarantine and separated from existing stock until approved. In preventing unauthorized use, a predefined rule controls inventory movement before it becomes critical in manufacturing or delivery.

QM PERMISSIONS

Some specific decisions made for key quality processes require additional access rights setup. Depending on permission rules, the system allows or prevents changes to quality data or access to certain decisions. For example, releasing of pharmaceuticals is permitted for the qualified person only, but to release non-pharmaceuticals is possible for an eligible group of users.

EXPANDED INVENTORY OVERVIEW

The complete inventory of the company in a single overview makes investigation easy and fast. Key quality information is right next to inventory details in the overview.

INVENTORY LIST

For planning and further investigations, the inventory list provides an overview with details about availability, demand and usage history. Users are able to drill down with one click to related sources in purchase, manufacturing and sales. The current stage of the supply chain is centralized in a single view.

CUSTOMER SPECIFICATION

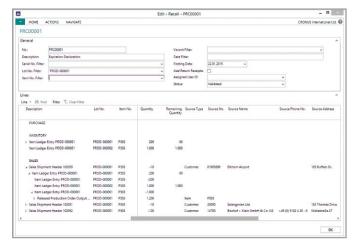
cc|quality management deals not only with corporate specifications but also with customer specifications. Customers may require slight adjustments with respect to the way products are tested, or the acceptable limits for the tests that are performed. On one hand the system can create a distinct sample and test it using the customer specification. On the other hand it provides automatically compared results for existing samples with customer specifications. Locating produced materials that match customer specifications is fast and easy for somebody out of or in the quality department as well.

EXTENDED TRACEABILITY

The system tracks any material that will be used for consumption and any products that are created as output, through all stages of production, processing and distribution. The monitored data is extended by key quality information such as status changes.

PRODUCT RECALLS

In case of a product recall, lot explosion capabilities provide the complete monitored supply chain of a product. All details starting from purchase through inventory and manufacturing up to delivery are exploded and displayed in an overview (SEE FIGURE: Product Recall). The customers to whom a certain lot has been delivered will be identified. When the recall is issued a recall letter can be printed for each of the impacted customers. Expected return receipts are created and monitored.

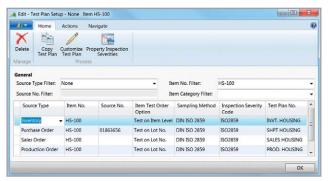


PRODUCT RECALL

built on Microsoft Dynamics NAV

PROCESS-ORIENTED TESTS

Whether for an incoming goods test, a final inspection test or a shipping test, with cc|quality management a variety of test plans can be created and assigned per vendor, per work stage and/or per customer. For instance, the testing of a pre-production sample may determine if the vendor components meet acceptance requirements (SEE FIGURE: Process-oriented Test Plan Setup).



PROCESS-ORIENTED TEST PLAN SETUP

QUALITY IN THE PURCHASING PROCESS

When the purchasing department is looking at the procurement of materials from suppliers, they will have been given some guidance by the manufacturing department, research and development, or the quality department. This includes a variety of information about the item to be sourced, such as physical description, dimensional measurements, chemical composition, performance specifications, and standards to conform to. In addition to the industry solutions of COSMO CONSULT, cc|quality management deals with specifications to check any part or raw material before it is used.

INBOUND QUALITY INSPECTION

The quality process starts sometimes together with purchasing and before the item even enters the plant. cc|quality management records the provided Certificate of Analysis related to the received lot or serial number. The system handles incoming good inspections and allows specific instructions for the warehouse and quality control department depending on the item that is being received.

INSPECTION ON THE LINE

When a manufacturing company creates finished goods, it cannot afford to wait until the items are coming off the end of the production line before they are inspected. To address early in the process the needed production issues, the system can perform a quality check on operations in order to correct problems. This can reduce the loss of raw material and the overall time that the production process is shut down. For example, the system creates inspections during the process to test the item at certain stages to ensure that the product is within the manufacturing tolerances. In products based on assembly manufacturing, many inspections can be performed sothat components are tested as the final product is being assembled to ensure that the finished product will be fault free.

FINISHED GOODS INSPECTION

When the finished item comes off the production line, the system can inspect the output to ensure that it conforms to specifications. The final check could include not only the finished good itself but the packaging used to ship or other additions.

INSPECTION IN THE WAREHOUSE

For some items, storage for a period of time can alter the characteristics of the product. Goods can be affected by environmental conditions, so that some





built on Microsoft Dynamics NAV

characteristics are no longer within the stipulated tolerances. Related to the item, warehouse inspections are created after a certain period to ensure that goods are still able to be used or the expiry date needs to be adjusted.

ELEMENTS OF QUALITY CONTROL

The well-established testing feature is at the core of cc|quality management. From incoming goods through manufacturing to shipping, the system follows the complete materials management every step of the way. For a comprehensive quality control system, different elements are available.

TEST DEVICE ADMINISTRATION

Test devices, or monitoring and measuring devices, are "tools" that implement tests in the manufacturing process. Among the features of test device administration are deadline and schedule monitoring for test devices (e.g. calibration schedule monitoring). This test device testing guarantees that only test devices that have the required properties are used. As part of quality control, test orders can be created for test devices.

TEST PLANNING

Test Properties

In cc|quality management, test properties will initially be used to create master template data to be the basis for the testing course. Test properties describe the characteristics that will be tested for items or lots. One or more test properties can be assigned to a test procedure. Expected or acceptable ranges are set up for each test property.

Test Procedure

Test procedures serve to combine the multiple properties and to differentiate between counting and

measuring examinations. Using test procedures, test properties can be combined into organized groups. For example, a chemical test could be necessary both for incoming goods and for "In Process" tests. Since normally other test properties also need to be tested here, individual test procedures can be created. Depending on the test procedure, deviating test devices, default, and tolerance values can be assigned to test properties, as needed.

Test Plan

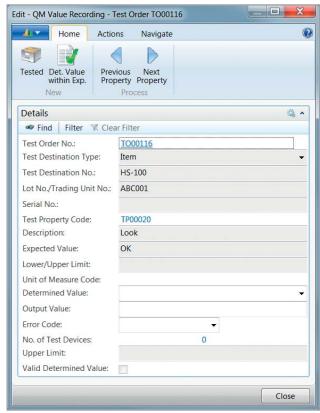
In cc|quality management the test plans define how an item is to be inspected. The plan also establishes how the inspection is to take place, the item characteristics to be inspected and the required test equipment that is needed for the inspection. The test plan includes the test properties, respective of the item specifications. These items have to be checked and are transferred to testing. Test plans are version and date controlled to ensure historical accuracy.

TEST ORDERS

A test order is created by the system or user at certain breakpoints of the business process. A number of events can trigger an automatic test but most are caused by a movement of materials, such as a goods receipt or a goods issue. A test is based on a lot or serial number, where a lot or serial number is a trigger to inspect a specific item. When a test order is performed the results of the inspection are recorded for the test properties. The lot or part can be accepted as being within tolerance or can be rejected if the inspection finds that the results do not reach the prescribed specification (test plan) for a certain characteristic. When the test order is complete, a usage decision can be made as to whether the material can be accepted, conditionally released or rejected. After the quality department has made a usage decision the test order can be closed (SEE FIGURE: Test Order - Value Recording).



built on Microsoft Dynamics NAV



TEST ORDER - VALUE RECORDING

TEST ACCURACY CONTROL

The test accuracy control is regulated by DIN ISO 2859 that describes the test accuracy plan (normal, reduced, enhanced test) according to which items can be rated. Test accuracy control can be easily displayed in cc|quality management.

SKIP-LOT FUNCTION

The logic of the skip-lot function determines the test guidance method that will be employed for a given vendor, based on an assessment of earlier tested deliveries. A change from one test guidance method table to another must not necessarily result in a classification on a level immediately above or below the current one. The possibility to skip one or more levels does exist. The according logic that specifies the circumstances of such a change between

test guidance method tables may be freely defined according to the agreements made with the vendors.

STABILITY TEST

The stability testing is able to provide evidence on how the quality of a material or product varies with time under the influence of environmental factors, such as temperature. This kind of testing is used for frequent checks on properties of components, semi-finished goods, and products under specific inventory conditions, and determines how the item changes throughout a testing schedule within a defined date range. This can be done using similar or different properties for each test over a planned period of time.

ERROR CATALOGUE

Error codes contain high level information about error cause and error action. These codes can be assigned during testing to provide a better, more structured way of categorising quality problems.

built on Microsoft Dynamics NAV

VENDOR RATING

CORE FEATURES OF THE VENDOR RATING

Vendor rating is not only the foundation of the process to award contracts but is also the continuous monitoring of vendor performance. It ensures that a high quality standard is achieved — especially in the areas operating sequentially to materials management.

The rating is based on points that are awarded for certain criteria – including "hard" and "soft" criteria. These criteria can be weighted individually. The individual scores then become a part of the overall rating in accordance with the prior weighting.

VENDOR ITEM SETUP

Frequently, individual items are essential for the rating of a vendor. The setup can be defined for every individual vendor whether or not the delivered item should enter into the respective overall vendor rating.

VENDOR RELATED RATING

Based on the deliveries, vendors can be rated according to "hard" and "soft" criteria.

For every delivery the following "hard" criteria are available to determine a weighted rating score for any single item:

- Quality of the Product
- Quantity of the Shipment (= Quantity Deviations)
- Schedule Deviations

Audits, self-assessments and visit reports contribute to the weighted rating score as "soft criteria".

VENDOR CLASSIFICATION

Vendor classification allows the classification of vendors into various categories (A, B, C, etc.) according to a combined delivery and vendor related evaluation.



cc | quality management and vendor rating built on Microsoft Dynamics NAV

Space for your own notes			



