

# COSMO Quality Assurance

Part of COSMO Quality Management Pack

## Benefits

- Helps maintain quality throughout the entire value chain
- Ensures that the product meets customer requirements
- Ensures that the processes used to test and produce products will be done correctly
- Provides prompt access to data in the event of a recall
- Traces and tracks materials from supplier receipts to the customer shipments
- Encourages quality consciousness among the workers in the factory

## Introduction

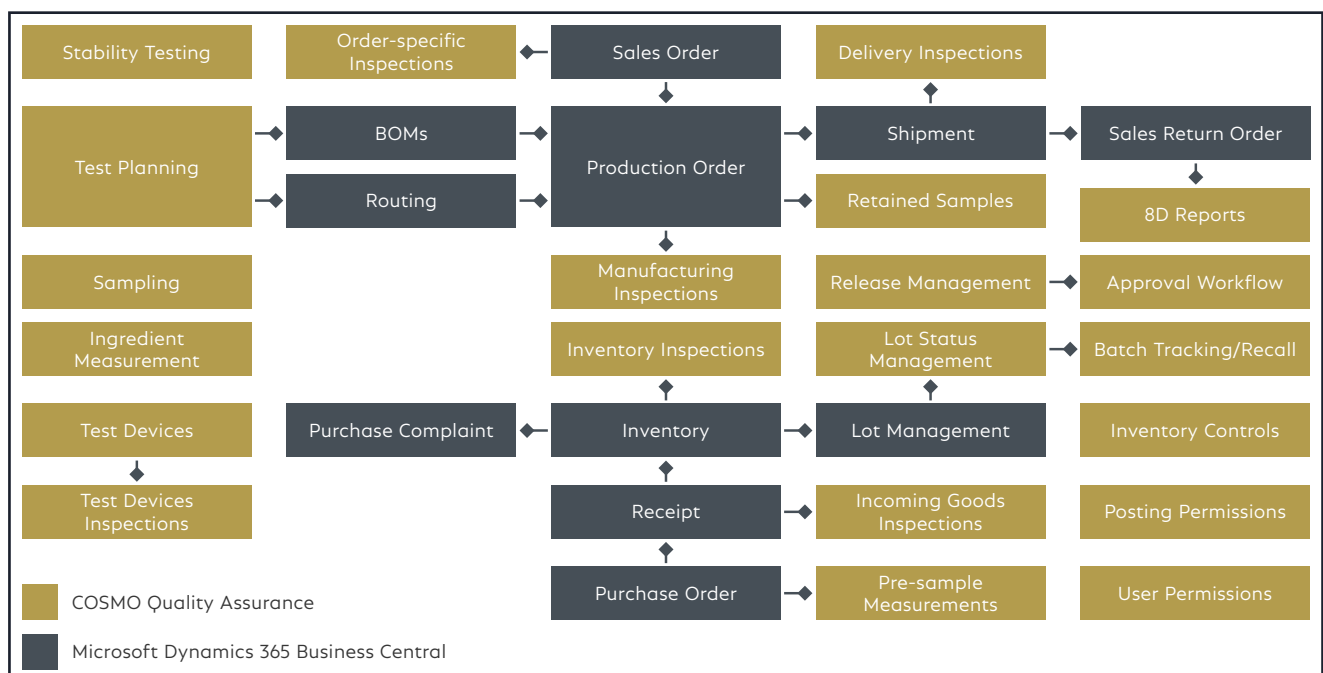
In industries such as healthcare, pharmaceuticals and food, aerospace and aviation, professional quality management is required by law. But in other industries, quality has also long been one of the central management tasks. The reason is obvious: carelessness can become really expensive for companies. Not only because of the threat of fines and compensation claims, but also because poor quality can, at least temporarily, severely weaken a company's own competitive position.

The additional software **COSMO Quality Assurance** extends Microsoft Dynamics 365 Business Central by a compliance-compliant, operational quality management.

It supports users

- to align processes according to generally applicable standards and legal requirements and
- to comply with the procedures in the long term and to document them in accordance with the regulations.

**COSMO Quality Assurance** provides support for every phase of internal value chain management (VCM): from receipt and acceptance of raw materials, through production of intermediates, to inspections of finished goods before shipment to Customers. Integration of quality control to VCM processes helps a business keep track of its quality levels at various stages. Thus, helping it to detect the quality variance at initial stages, initiate rectification procedures and reduce wastages.



Overview COSMO Quality Assurance

## Traceability

Should products or materials stray from their specifications, the manufacturer must, first, become aware of the issue, and second, be able to track where the deviation occurred. Traceability functions in Dynamics 365 Business Central enhanced by **COSMO Quality Assurance** offers various functions to ensure that this is the case, including audit functions, document changes to master data and every step in the value chain. Traceability is ensured from receipt of materials through production to delivery.

As customers and regulatory agencies require manufacturers to deliver accurate history of individual lots or serial numbers within a short period of time, bi-directional tracking allows manufacturers to localize the problem and to perform adequate product recalls.

## Product recalls

Timing is everything in the case of a recall. If business processes are performed using paper and pen or spreadsheets, going back through data to find which batch went wrong could take hours, maybe even days. If manufacturers need to recall an item, customers and authorities cannot wait that long. **COSMO Quality Assurance** quickly finds and isolates the critical lots or serial numbers that prompted the recall and keep them from entering the production phase.

## Quarantine and release management

Disposition of materials and products is supported by a status at lot/serial number level throughout the entire value chain. Starting with an initial status at receipt, material may be assigned to quarantine status or restricted use. Managing quarantine with status is not dependent on warehouse configurations. Material of the same lot might be stored at multiple locations, but lot integrity in view of disposition is ensured by the status. The module provides an unlimited number of possible statuses with configurable functions and controls. Approval workflows enable authorized persons to make decisions on further disposition by changing lot/serial number status. To ensure audit trail, status changes are traceable and approvals are logged.

To ensure lot integrity, the module can split lots for segregated disposition. For instance, if only a portion of a lot is to be restricted for use, the quantity of the material that was assigned another status is then segregated from the original lot. In combination with **COSMO Process Manufacturing**, the module is able to deal with individual dispositions to trading units (in the sense of sublots).

In short, **COSMO Quality Assurance** can establish reliable processes for assigning a disposition to materials and products in accordance to local regulatory requirements and the requirements of daily business.

## First-piece inspection

The module issues and manages first-piece inspections to help ensure lots meet requirements at ordering. For this purpose, inspections against given specification are performed before a purchase order is released.

## Incoming goods inspection

The receiving process is enhanced by this module to perform inspections, sampling, and putting material in quarantine for pending disposition. From here, the module helps decide and control further disposition of the material and tracks non-conforming material. The inspection is scheduled with goods receipt and informs subsequent departments when the inspection is expected to begin and to end.

Managing variability starts with a purchase order for raw material with specific product characteristics. At the time of receipt, samples are taken, inspected and validated against a set of tolerances or targets. Once received, lot/serial numbers and disposition status can be assigned to inventory so that material can be tracked throughout the manufacturing process.

Materials may be released based on the supplier's certificate of analysis without further inspections. These certificates can be recorded and are then retrievable for review.

Enhanced by **COSMO Vendor Rating**, rated quality completes the calculated delivery performance to help organizations build strong supplier relationships.

## Manufacturing Inspection

Quality requirements must be met throughout the whole of the intended shelf life of the product or material. Tracking quality requirements during production often becomes a chore, what with the need to record the disposition of materials at multiple inspection points, capture test results, record defects, and track items requiring rework. The module streamlines the entire process and enables users to identify defective raw material or intermediates at the point of use rather than at receipt, which helps to report the issue promptly.

To expect quality output from the production department, a business needs to keep a close check on the quality levels at its various stages of production. Materials can be examined during the production before proceeding to the next operation, and intermediates can be inspected and released before further use. Depending on the configuration, inspections are scheduled along operational steps with expected start and ending date-time. Downstream operations can improve their planning by knowing when inspections are expected to be completed. If an adjustment needs to be made during the production process, configurable controls allow authorized individuals, verified by approval workflow, to change operational data for use in production.

## Customer specification

Manufacturers are often required to deliver finished products to customers that meet order-specific requirements. A raw material might meet one process specification, but it might not meet another. **COSMO Quality Assurance** provides full visibility into available raw materials inventory and their product characteristics, so that manufacturers can deliver products that meet customer requirements.

## Effizientes Reklamationsmanagement

In many respects, products and materials with limited shelf life demands increased attention in inventory, planning and production. In order to reduce both economic risks and risks at future use, batches of such products are tracked and labelled according to shelf life. **COSMO Quality Assurance** includes built-in functionalities to manage shelf life and to control when materials and products are past their expiration dates.

For instance, inventory can be monitored on expiration and retest date to reexamine lot/serial number tracked inventory. The result is less waste from expired inventory. Already expired inventory can be excluded from planning calculation and is then not used to cover demand.

## Stability testing

Manufacturers in general, and process manufacturers in particular, routinely conduct stability studies on raw material or on their own produced goods. For instance, it could be appropriate to establish initial shelf life dating through either long-term stability study. **COSMO Quality Assurance** supports such stability studies by creating tests based on defined specifications:

## Test Device Management

Monitoring and measuring devices, which are necessary to perform quality inspections, are managed as test devices in **COSMO Quality Assurance**. The individual devices are recorded with equipment data. Together with test properties and other details, the test devices define instructions to perform quality inspections.

Regular calibration/qualification orders can be created based on a predefined interval or by exception. Based on a specified plan including quantitative and qualitative characteristics, calibration tasks are created, their results are recorded and are then accessible at any time.

## Approval with Authentication

Approvals workflow increases visibility and improves reaction time while adhering to the regulatory requirements. For instance, BOMs, recipes and routings are approved using single authentication or four-eyes approval. When any changes are made to these master data, authorized approvers are requested to sign for it. Such approvals with authentication can be integrated into various processes in purchasing, warehousing, production, quality management and sales. Authentication policies are configurable according to regulatory requirements:

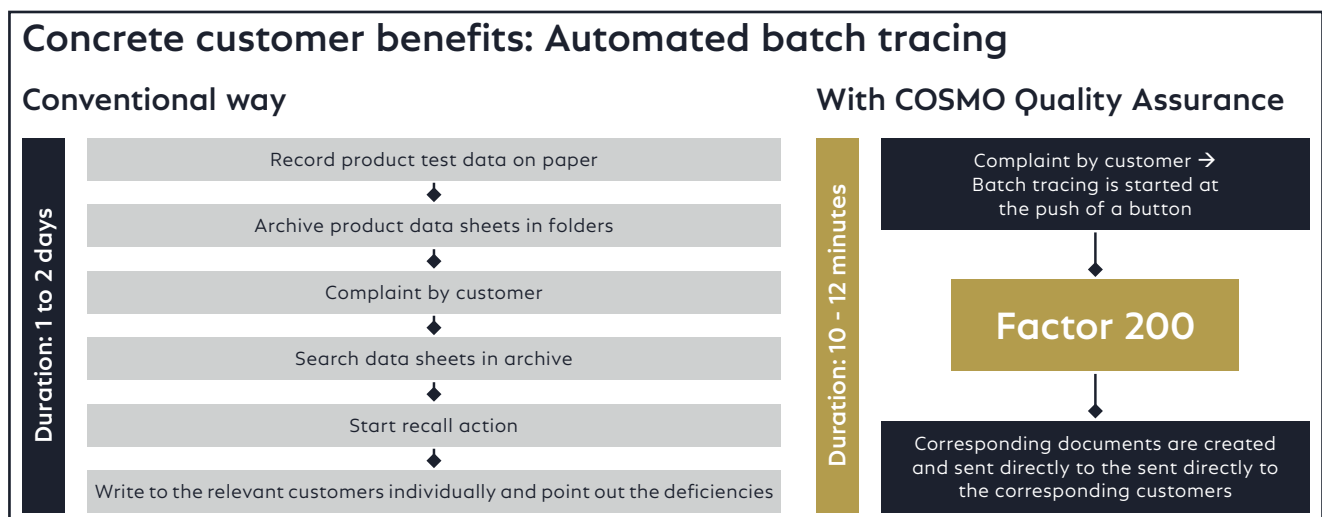
## Conclusion

Manufacturers need quality control and assurance functionality as a native, embedded part of Dynamics 365 Business Central. To encourage teams to exhibit knowledge, collaboration and confidence in quality practice, it is recommended that quality management be integrated in an ERP system. The exchange of knowledge and the collaboration that will inevitably take place between teams is priceless.

Adding **COSMO Quality Assurance** is taking Dynamics 365 Business Central a step ahead to improve quality practice across the entire value chain.

## COSMO Vendor Rating

To evaluate supplier's performance based on a pre-defined rating system, COSMO CONSULT offers an add-on for Dynamics 365 Business Central. Both suppliers and individual deliveries can be evaluated according to various criteria, ensuring that the reliability of a supplier can be qualified at any time. **COSMO Vendor Rating** involves assigning weights to different important measures of performance, such as delivery, quality and qualitative criteria. Once the weights are determined, the performance measure is multiplied by the weight and the result is totaled to get the rating.



Today, quality checks are carried out at the various stages of production so that deviations from the standard are detected at an early stage, even before the end product leaves the factory. The computer aided quality management (CAQ) system that has been introduced documents all quality checks before, during and after production.



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