

TECTURA LIFE SCIENCES

HIGHLIGHTS

- BALANCE THE COST OF COMPLIANCE WITH BOTTOM LINE DEMANDS
- INCREASE SPEED TO MARKET
- EFFECTIVE MANAGEMENT FORMULATION, PACKAGING AND PRICING
- IMPROVE QUALITY MANAGEMENT THROUGHOUT YOUR PROCESSES
- COMPLY WITH INDUSTRY AND GOVERNMENT REGULATIONS
- ENSURE TRACEABILITY FOR LOT AND SERIAL CONTROL
- UTILIZE ELECTRONIC SIGNATURES FOR END-TO-END VISIBILITY

FEATURES

- MANUFACTURING SPECIFICATION
- RECIPE ADMINISTRATION
- SEQUENCE PLANNING
- LOT MANAGEMENT
- TRADING UNIT STRUCTURE / BOTTLING
- ELECTRONIC SIGNATURE AND AUDIT TRAIL
- QUALITY MANAGEMENT
- VENDOR RATING
- TEXT MODULE



Industry Solution For Chemical and Pharmaceutical Companies built on Microsoft Dynamics NAV

With its industry solution Tectura® Life Sciences based on Microsoft Dynamics® NAV, Tectura provides industrial and commercial companies from areas such as pharmaceuticals, fine chemicals, cosmetics, biotechnology, medical technology, and dietary supplements with a solution designed to meet the general and regulatory requirements specific to the industry.

The Tectura Life Sciences solution was developed in combination with both industry experts and industry users resulting in a commercially available application that addresses their unique and specific requirements. Built using technology standards and leveraged to meet industry specifications – Tectura Life Sciences covers all business areas: from Purchasing, Sales, Production, Financial Accounting, Quality Control, Vendor Rating, Raw Material Data Management, Laboratory Systems, Resource Management, Warehouse Management, and Logistics, to Marketing and Distribution.

The solution excels in its use of seasoned standard software that has been deployed around the world. Additionally, the constant transfer of know-how and the intensive dialogue between technology and user market have shaped it into a practice-oriented product that has been thoroughly tried and tested.

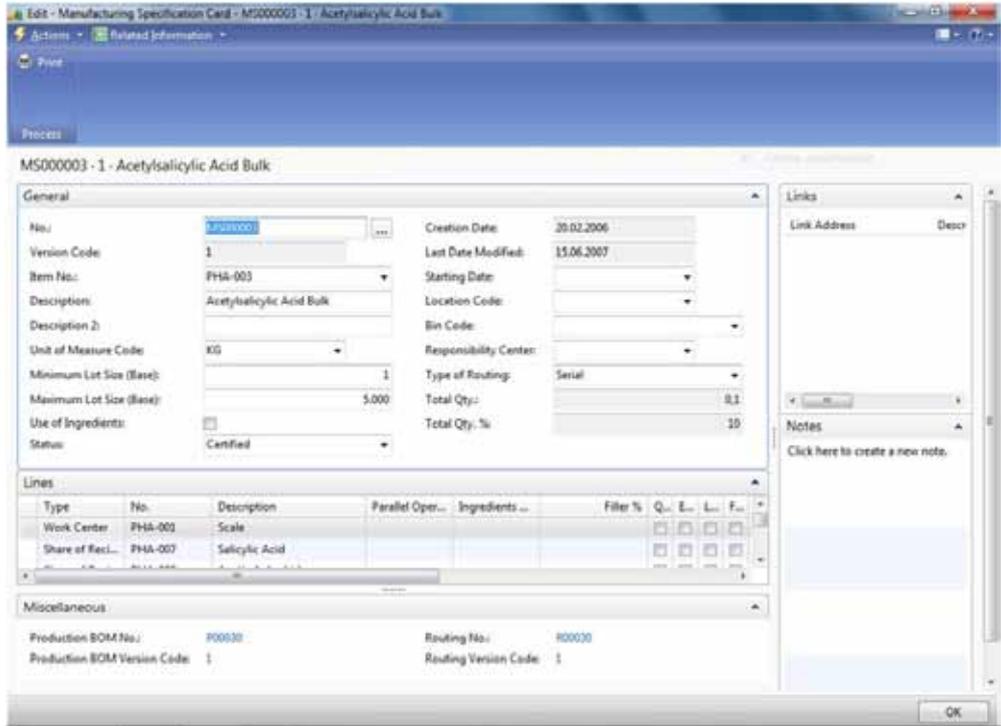


FIGURE 1: MANUFACTURING SPECIFICATION CARD

THE BEST POSSIBLE SUPPORT FOR THE SALES DEPARTMENT

Order Network

The order network is a hierarchically structured overview that displays the logistical interconnection of sales orders and the dependent manufacturing and purchase orders. It is an important controlling agent for coordination and planning when it serves as a basis for decision-making in interdepartmental meetings that occur on a regular basis. This display allows for the early detection of possible production variances such as missing raw materials or insufficient machine capacity; the on-time delivery

performance can be optimized and inventory can be reduced.

FLEXIBLE AND ACCURATE CONTROL OF PRODUCTION

Tectura Life Sciences offers extensive functionalities to configure Manufacturing Specifications, Recipes, Bills Of Materials (BOMs), and Work Plans.

Manufacturing Specification

The Manufacturing Specification adds an input template to Microsoft Dynamics NAV (SEE FIGURE 1) that allows for the compilation of all necessary materials and work steps



according to the production plan in a single overview. Additionally, the free creation of work and process instructions is possible directly in the Manufacturing Specification via an integrated text module. Of course, Manufacturing Specifications are version controlled and subject to strict password control.

BOMs and Recipes

Inventory component (BOM) information is among the most important data structures that production companies have to track and maintain. When a certain item is produced, the ordering of material or its gathering from the inventory is ultimately based on the BOMs.

While BOMs generally refer to a discrete final product, recipes are the basis for the manufacturing of certain quantities of a process product. Recipes can be stored in the system either in percentage or proportionate terms. Main recipes with additional parts are recalculated automatically. BOMs and recipes may also be used in combination, as is needed for bottling or packaging processes.

Routing

A routing describes the production process relating to the individual work steps, including respective work and setup times analogous to the BOM. The necessary raw materials and corresponding quality checks can be assigned for every operation through

according allocations. Lead and setup times can be configured within the system independent from the routings. This includes fixed lead times, for example for mixers and dryers.

PRODUCTION PLANNING AND CONTROL

Apart from the multi-stage determination of gross or net demand in Microsoft Dynamics NAV, the industry solution Tectura Life Sciences offers several additional planning functionalities that ensure cost optimized resource utilization in the production process. For example, with the help of the integrated sequence planning, taking account of freely definable planning parameters, a minimization of set-up times as well as optimum resource utilization and transparency can be achieved in the production.

Through the display of the inter-process or inter-departmental order network, disturbance variables such as a lack of raw materials or insufficient machine capacities can be detected early on. With the help of these control resources, delivery punctuality can also be optimized and stock inventories can be reduced.

Sequence Planning

Time and again, everyday operations in production control are characterized by short-term changes due to unplanned machine failure and unexpected customer orders which

necessitate high planning flexibility and transparency.

Taking into account freely defined planning parameters; the integrated sequencer can be used to minimize setup times while optimizing utilization and transparency of production processes.

Sequence planning is especially useful for the scheduling of bottleneck machines, in order to be able to use the available production time as efficiently as possible.

The core piece of the optimization is the machine scheduling that is capable of displaying complete production lines while also allowing for observation and planning directly at the machine. Orders can be easily postponed or moved from one machine to another. In addition, the result of order-specific maturity checks running in the background can be displayed in traffic light colors. This so-called traffic light control guarantees an overview of critical orders at all times (SEE FIGURE 2).

Graphical extension for sequence planning

Incorporating all the functions of Tectura Life Sciences, the graphic extension Tectura® Graphical Extension makes for more transparent visualization of data using different colors. The production orders are integrated directly into the graphic interface which allows for the easy rescheduling of orders by drag & drop.

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Graphical display of complex data assists in simplifying data analysis to support key business decisions.

Maintenance and Setup Jobs

Setup jobs are created directly from a setup matrix containing information on the changes between of item groups, items, or tools. Both setup and maintenance jobs can be assigned to or separated from production orders. The system offers the ability to compare tool setup times parallel to production.

Inventory Check

During scheduling and sequence optimization, a quick inventory check is possible that verifies whether or not the respective material is in stock and contains information on what measures, if any, have to be taken.

Detailed Planning and Schedule

Rough cut planning is followed by fine tuning. A variety of overviews help you identify problems in advance and allow for the initiation of counter-measures.

The plan table is structured as a matrix: In an overview of machines and time units, it shows all production orders in one view. The existing drill-down function allows users to extract all desired detailed information from the matrix immediately: Across several manufacturing departments or broken down to the individual machine – per day, week, or even month – an overview of utilization in percent, by

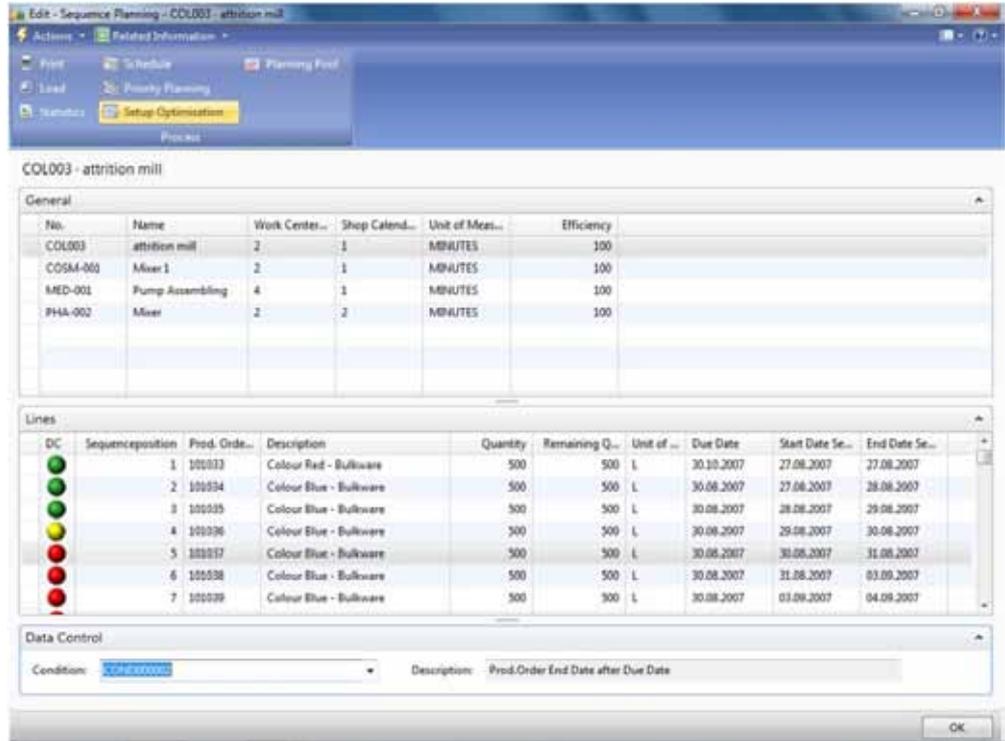


FIGURE 2: TRAFFIC LIGHT CONTROL IN SEQUENCE PLANNING

the hour, or even by free capacity is displayed.

The setup overview reveals the number of necessary personnel.

Calculation

A pre-calculation based on material costs, production time costs and indirect costs can be done directly at the item in relation to the lot size that is to be produced. You can determine which values may be changed in the calculations and which overhead rates – whether in percentages or as fixed costs - are to be taken into consideration. The calculated production costs can be added to the

acquisition costs of the item (for example for the determination of the stock value).

Similar to other industrial branches, cost optimization is one of the declared aims of life sciences. A concurrent calculation allows for the visualization and recognition of discrepancies between pre-calculation in the planning phase and post-calculation after the completion of the production process. With the help of lot size calculation, the changing relationship between quantity and unit costs for larger quantities can be displayed in a matrix.



LOT TRACING FROM PURCHASES TO DELIVERY

Lot Tracing

Tectura Life Sciences ensures continuous lot tracing, even if lots are combined. All movements, the usage and the origin of a lot are available at the click of a button. This forward and back lot traceability provides an overview of the complete delivery and production chain. It immediately becomes easy to comprehend where a certain lot was delivered and which raw material lots by which vendors were used during production. Optionally, even internal movements within the warehouse (commissioning or storage) as well as changes in the lot data (status change or a change of the expiration date) can be traced.

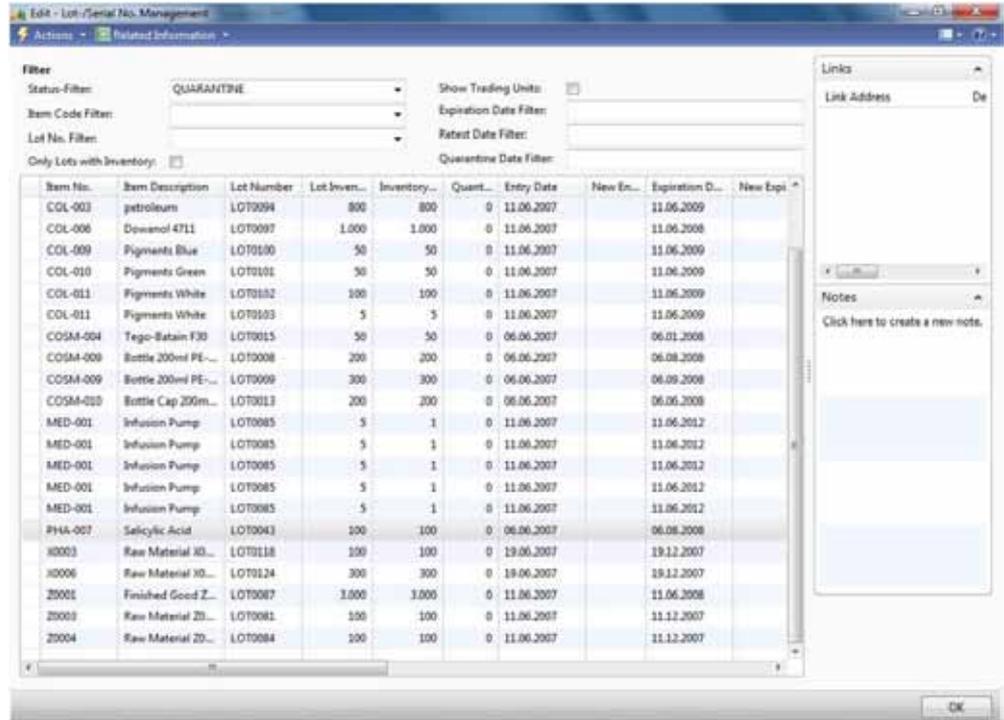


FIGURE 3: RELEASE OF SERIES, LOTS, AND TRADING UNITS

Trading Unit Structure, Bottling, and Base Products

A display of several trading units of a product in one item or even in several items is possible. Through filling and refilling orders new trading units can automatically be created or passed on to the respective departments. Any desired packaging materials and ancillary storage equipment can be assigned in the process.

Release of Series, Lots, and Trading Units

The availability of inventory and the material flow are regulated and controlled based on freely definable quality statuses. Lots and trading units

can be released and locked independently or receive another predefined status. For example, all inventories due to expire within the next three months can be earmarked for inspection. (SEE FIGURE 3)

Inventory Posting Authorization

The implementation of inventory postings can be tied to different conditions. For example, under certain conditions lot and serial number postings or reservations are only possible depending on the type of movement, the lot or serial number status, the location or bin, the item category or the registered user and his/her authorizations.

Automatic Lot Number

The system can assign the lot number automatically according to predefined rules. Furthermore, the lot numbers of products can be passed on automatically to subsequent lots in the transaction, bottling, or packaging processes. The cutting and bottling of finished products is integrated into the lot and serial number administration and is user-friendly.

SALES

Today, in most cases, the delivery or the whole order handling already represents part of the validation requirement. Over and above the



standard of Microsoft Dynamics NAV, various reservation and order picking strategies can be optionally fulfilled. These also include sales restrictions due to legislation. Automatic batch assignment according to the FEFO principle (First Expired, First Out) or the definition of single batch deliveries is also possible. Various batch logistics functions, for example the definition of customer specific lot expiry dates, provide a maximum of functionality.

Discount and Incentives

The system also allows the filing of discounts and incentives. For example, when a specified amount of items is sold, sometimes additional free items are added to the delivery or a certain percentage of the delivery is not calculated into the total bill for the customer.

Contingency Management

Contingency Management is control of shipping specific product to a pre-defined level. The system administers quantitative delivery limitations over a certain period of time. For example, a contingency group (customers or contacts) will not receive more than a predetermined quantity of an item (or a contingency item group) within a certain period of time. In addition, the delivery of free items can be regulated.

Frequently, legal requirements and/or agreements impose delivery

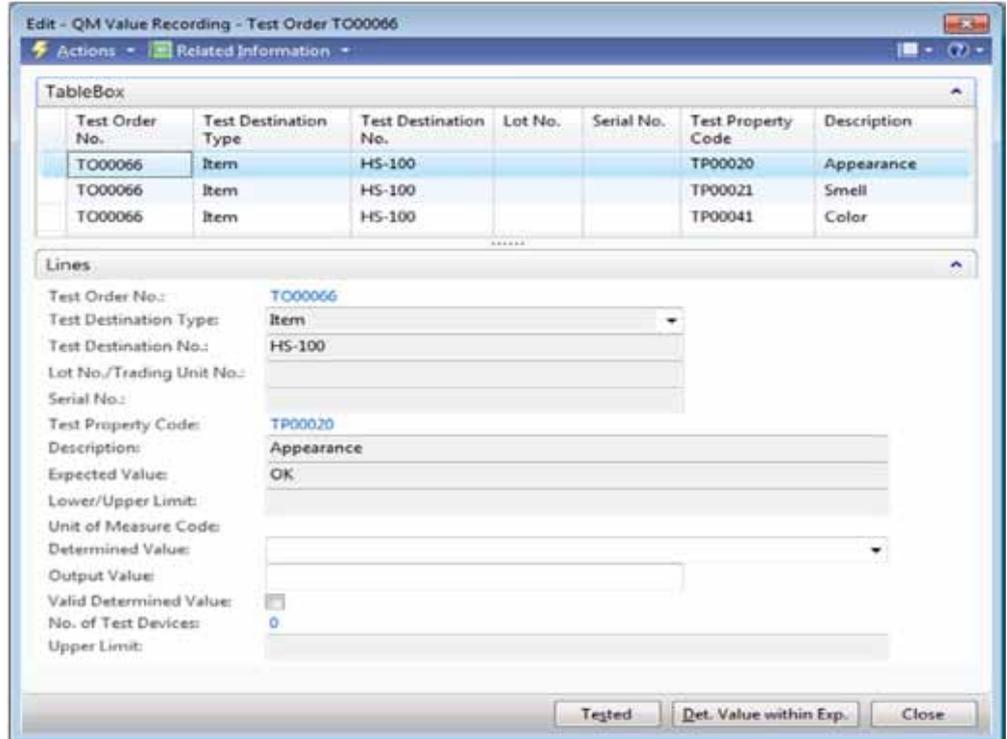


FIGURE 4: ELECTRONIC SIGNATURE

limitations. Therefore, these delivery limitations are referenced in the according documents.

Additionally, this module allows the limitation of the free delivery of samples. It keeps track of how many samples are delivered to a customer or contact within a certain, predefined timeframe. As soon as the quota is reached within that period, the system reports this condition and prevents all additional postings.

Delivery or Sales Limitations

While the Contingency Management refers to the item quantity, delivery

and purchase limitations are restrictions that concern what category of customer or type of location the items or final products can be shipped. For example, prescription medicines may only be delivered to pharmacies and hospitals. The system regulates the compliance with these restrictions and requirements by reporting and preventing the posting.

DATA SECURITY AND AUDIT TRAIL

For the easy verification of master data changes, the user is interrogated and checked to ensure his or her authorization to change this master



data record. The “four eye verification” is used as a form of double check. Here, the data to be verified according to this principle can be freely selected. As opposed to the standard logic in Microsoft Dynamics NAV, access authorizations can even be granted for individual fields. The change verification fulfills the requirements of the electronic signature (SEE FIGURE 4). Furthermore, all changes in the database are automatically documented by the existing Audit Trail functionality with time stamp, data, and user information, so that changes carried out can be ordered to the corresponding operation and tracked at any time.

QUALITY MANAGEMENT AUTHORIZATIONS

Standards set up authorizations for functions are critical to the Good Manufacturing Practice (GMP) –for example the release of manufacturing or test orders or the change of lot data. These can depend on the user ID, the role ID, the item or the selected item category.

COMPLEX QUALITY MANAGEMENT

The benefit of having Quality Management integrated into production and lot control is a single source traceability and validation.

As a part of the integrated lab information management system, the module Quality Management allows for the administration of test properties, test schedules, and test

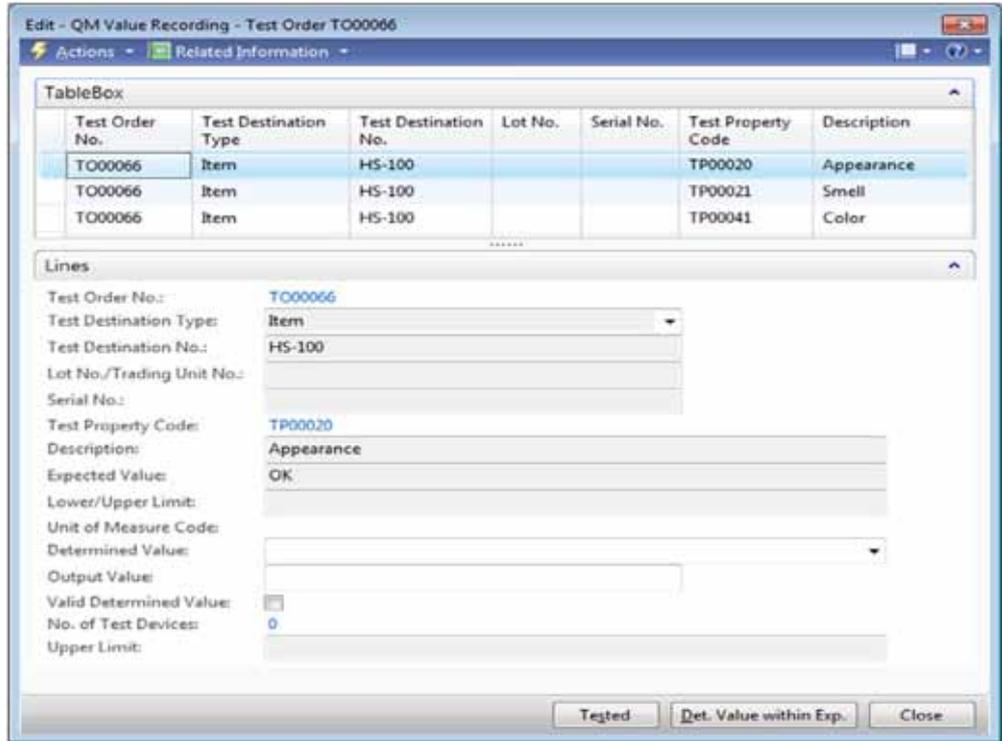


FIGURE 5: TESTORDER - VALUE RECORDING

devices. By manually or automatically creating test orders within the production chain – from goods incoming through production to goods outgoing – the necessary quality of the product is guaranteed. Since this module is also completely integrated into the lot management, lots that are being tested are secured against unauthorized access and are handled differently depending on their respective status.

Among others, the module Quality Management features the following functions:

- Integrated test accuracy control (skip-lot-method) according to DIN ISO 2859

- Automatic sample amount determination
- Documents of any format can be integrated into all test areas
- Test device management
- Retest functionality for lots (SEE FIGURE 5)

Vendor Rating

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



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

Stability Check

With the help of the stability and durability check, it can be determined how a lot reacts to various storage conditions such as temperature, light, or humidity over a certain period of time.

For this reason a stability check can be created within the system which initiates an inspection of the lot in certain intervals. These inspections occur according to a predefined test plans. The collected test results or the development of individual test properties can be printed out in a report afterwards.

TEXT MODULE

An integrated text module allows users to add extended information in the areas Purchases, Sales, Production, Service and Financial Accounting. It includes:

- Standard and free form notes and text specific to customers and creditors
- Text blocks that are automatically transmitted into documents (sales order, purchase order, manufacturing order, etc.)
- Proof-print of texts on reports

- Automatic generation of warning messages (pop-up windows) in documents
- Creation of text libraries as templates for the creation of new text blocks
- The definition of item-independent header and footer text blocks for the Purchases and Sales departments
- Specify effective timeframes for text blocks
- Creation of country and language specific texts

SUMMARY

Tectura Life Sciences solution offers rich functionality for a variety of businesses in the regulated industries. Companies can tailor the solution to meet their requirements over time by combining and adding functional modules, as needed. This allows you to take advantage of the solution as your business expands and changes.

ABOUT TECTURA

Tectura is a worldwide provider of business consulting services providing sustainable value through consulting, software and IT implementation. Our clientele include mid-sized companies and larger enterprises throughout the Americas, EMEA, and Asia Pacific. With team members in 20+ countries, Tectura applies its comprehensive industry knowledge and unparalleled experience in collaboration with our clients to deliver business and technology strategies and solutions designed to achieve their business performance goals.

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Version: LS2009SP1.201007-B

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