Alithya

FULLSCOPE IS NOW PART OF ALITHYA

EDGE for Operations

Benefits

ACCELERATES AND STREAMLINES PROCESSES to reach resolutions quicker and more efficiently.

LEVERAGES QUALITY DATA AND RESULTS across the enterprise to provide key visibility and to alert appropriate stakeholders to quality problems as they arise.

ADDRESSES CRITICAL QUALITY AND REGULATORY COMPLIANCE REQUIREMENTS for industries which are regulated by FDA, OSHA, EFSA, EMA, HC etc.

ADDRESSES CGMP RELATED GAPS in Microsoft Dynamics 365 for Finance and Operations.

HELPS STANDARDIZE AND CENTRALIZE THE INVESTIGATIVE PROCESS resulting in lower cost of regulatory compliance, process efficiency gains and better overall product quality.

ENSURES COMPLIANCE WITH REGULATIONS while increasing product quality, customer satisfaction and market penetration.

IMPROVES QUALITY PROCESSES leading to reduced cost, more efficient material handling and mitigated risks

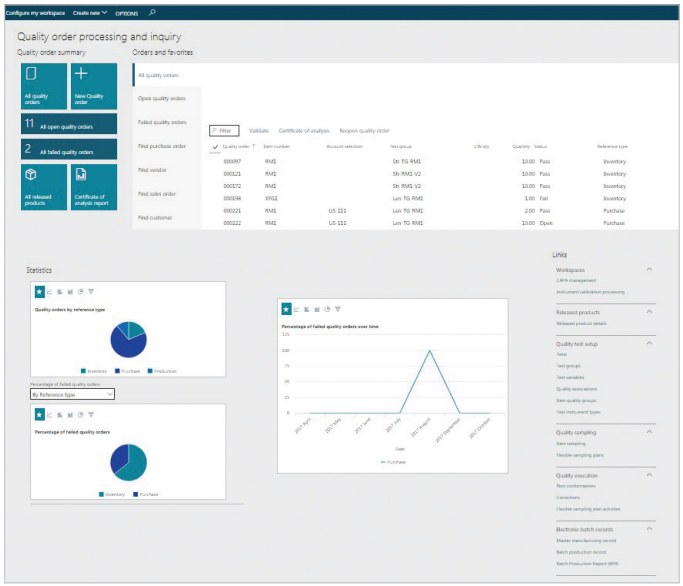
DRIVES CONTINUOUS IMPROVEMENT with closed-loop processes

EDGE FOR OPERATIONS IS AN INTEGRATED SOLUTION SET THAT ENHANCES MICROSOFT DYNAMICS 365 FOR FINANCE AND OPERATIONS

EDGE for Operations

From regional companies to international conglomerates, manufacturers of all types face distinct challenges arising from expanding regulatory requirements, quality testing demands and complex sales channels. To help meet these challenges, Fullscope offers EDGE for Operations for life sciences, pharmaceuticals, medical devices, food and beverage, commodity, industrial, specialty, agricultural, chemical and discrete manufacturers.

EDGE for Operations is a critical component required to run your business operations and to meet the requirements and regulations that confront you daily



EDGE for Operations elevates your quality results to a position of importance. The Quality order processing workspace consolidates the information you need so key visibility to quality problems can drive important decisions in your organization.

Features

APPROVED CUSTOMER LIST (ACL)	Many process and non-process manufacturers find they need to limit the sale of certain products to specific customers. A manufacturer that produces a privately labeled product for a specific customer needs to insure that those products are not ordered and shipped to a wrong customer. If you have customers who are slow-payers or non-payers, you may need to limit the sale of only non-expensive products. You may also need to comply with Know-Your-Customer regulations. This feature allows you to define an approved customer list and create a configuration so that only those products can be sold to a customer where a previously established relationship exists. **Benefits:** An ACL can help save search time and reduce errors (like shipping the wrong product to the wrong customer, a very costly mistake) and can help lead to improved customer satisfaction by meeting/exceeding their expectations.
BATCH PRODUCTION RECORD (BPR) OR ELECTRONIC BATCH RECORD (EBR) OR DEVICE HISTORY RECORD (DHR)	FDA 21 CFR § 111.255 requires the creation of a batch production record (BPR) every time a regulated product is produced. A BPR must include complete information relating to the production and control of each batch, lot or unit of a regulated product. When applied to process industry products, it is usually referred to as a BPR. When applied to discrete manufacturing, and specifically to individually serialized products or piece-based products, it is referred to as a device history record (DHR). DHRs are regulated by FDA 21 § CFR 820.184. **Benefits:** A BPR or DHR documents the single specification used in production with its unique characteristics. An electronic batch record (EBR) contains the unique manner of production, ingredients, characteristics, processes, quality test results and batch attributes of both the finished product and the ingredients.
CUSTOMER-SPECIFIC CERTIFICATE OF ANALYSIS	A Certificate of Analysis (COA) is a signed document provided to customers who require documentation of purchased items. The COA describes specific tests performed to confirm the quality of a given item lot. Microsoft Dynamics 365 for Finance and Operations provides the ability to create a basic COA from the quality order, including tests performed, the tolerance/outcome allowed for each test and results of the tests on a sample of that item lot. EDGE for Operations enhances this standard capability by providing a mechanism to create Customer-specific COAs. This feature provides a way to group customers for COA-related purposes and set up customer-specific COA requirements. Additionally, support has been added to offer multiple methods to create and print customer-specific COAs, including from quality orders, sales order packing lists, inventory batches and inventory management menus. **Benefits:** Better customer reporting supports improved customer service.
CORRECTIVE ACTION / PREVENTIVE ACTION (CAPA)	USDA, FDA and CGMP requirements mandate a repeatable, systematic failure investigation and root cause analysis process. This feature provides a formal, closed-loop process for managing your non-conformities or defects to identify those issues and prevents them from reoccurring. **Benefits:** CAPA helps standardize and centralize the investigative process, and can result in lower cost of regulatory compliance. Other benefits include process efficiency gains and better overall product quality.
ENHANCED DIGITAL SIGNATURES (ESIG)	EDGE for Operations enhancements to Electronic Signature are designed to extend standard Microsoft Dynamics 365 for Finance and Operations with capabilities needed to comply with the requirements of FDA 21 CFR 11.200 and 11.300. Additionally, we built out-of-the box electronic signature requirements related to quality orders, instrument calibration, CAPA, and production order processing. **Benefits:** eSignature enhancements provide the ability to comply with current FDA regulations. Also, the electronic signature requirements provided for you reduces your implementation costs.
ENHANCED NON-CONFORMANCE PROCESS	A non-conformance describes products that do not comply with the predefined performance or quality standard. Often, a non-conformance is referred to as a NCMR (Non-Conforming Material Report). In many businesses, a non-conformance is reported and researched prior to a CAPA ever being entered and only results in a CAPA if the problem is deemed serious enough to justify the extra effort. The EDGE for Operations enhancements to the Non-Conformance Process are designed to extend standard Microsoft Dynamics 365 for Finance and Operations functionality. This feature includes updates to the Non-Conformance and Correction data sources and related reports. Additionally, this enhancement includes the ability to group Operations and Diagnostics together so that they can be added to a Non-Conformance quickly in an effort to streamline the process. **Benefits:** The Enhanced Non-Conformance Process expands the user's ability to better track details directly from a non-conformance and streamlines the non-conformance process for better efficiency. Other benefits include improved product quality and reduced regulatory noncompliance costs.

FLEXIBLE SAMPLING

Process-related companies are faced with overwhelming testing requirements of incoming materials. With vendor certifications, plus using flexible sampling and testing techniques, this feature allows you to apply more stringent testing requirements and frequency to vendors and suppliers who may require more attention. As a vendor develops a more proven track record to consistently provide products that meet your quality requirements, the sampling requirements can be eased, including the option to introduce skip lot sampling as required. Additionally, on the production side, as confidence grows in manufacturing processes, costly testing requirements can be reduced and adjusted.

Benefits: Flexible sampling offers a managed process of testing based on proven results; increases confidence and trust with vendors and your own manufacturing processes; helps reduce costs (labor, testing, lab, WIP inventory), and helps increase inventory turns by reducing the amount of inventory normally held for quality testing.

INSTRUMENT CALIBRATION

Certain test instruments used during quality control processes must be regularly calibrated. Calibration is the process of evaluating and adjusting the precision and accuracy of measurement equipment and is usually defined as a performance comparison against a standard of known accuracy. Proper calibration of an instrument allows people to have a safe working environment and produces valid data for future reference. Instruments that are not calibrated regularly can result in product which has incorrectly passed or failed quality control tests. This feature helps track individual test instruments through tags, supports an ongoing calibration process for test instruments and tracks usage of given test instruments against the quality orders tests. Additionally, it provides the ability to maintain calibration certificates, generate calibration labels and schedule reports.

Benefits: Instrument calibration provides better accuracy during quality testing and subsequently better quality products. Better testing leads to less redundant and destructive testing. Quality built into the process leads to potentially less recalls and better customer service. Improved quality processes can create cost reductions, reduce material handling and facilitate faster material throughput.

MASTER MANUFACTURING RECORD (MMR) OR DEVICE MASTER RECORD (DMR)

The Master Manufacturing Record is a document that specifies how each unique formulation is manufactured. It is a compilation of the effective engineering item definition and product specifications, bill of material (BOM)/formula version, route version and associated quality requirements. MMRs are regulated by FDA 21 CFR § 111 and FDA 21 CFR § 211. The Device Master Record is a compilation of the device specifications, production process specifications, quality assurance procedures, packaging and labeling specifications, and installation, maintenance and servicing procedures for every unique product configuration. DMRs are regulated by FDA 21 § CFR 820.

Benefits: MMRs document all the unique specifications for manufacturing a product and help companies comply with regulatory requirements.

PRODUCTION DISPENSING

Dispensing permits the bi-directional flow of materials with the return of remaining material after production usage, the identification of materials that must be dispensing-controlled, the assignment of authorized personnel and authorized tolerances for dispensing, and also captures the electronic signature of dispensing personnel and permits the validation of dispensing weights.

Benefits: Dispensing provides compliance with regulations to prevent cross-contamination of materials, enables accurate costing of materials to production based on dispensed usage and provides sign-offs with an electronic signature. It is visible within the Electronic Batch Record and is compliant with current Good Manufacturing Practices.

QUALITY ASSOCIATIONS FOR RETURNS AND TRANSFERS

Automatic creation of quality orders is standard functionality from various business processes. Designed for any manufacturer who uses quality management heavily, this feature adds the option to automatically trigger a quality order from a sales return or transfer while supporting all standard quality functionality such as blocking processes and destructive testing. It also adds visibility to quality elements from both the sales return and the transfer process.

Benefits: Quality associations for returns and transfers automatically generate quality orders from the returns or transfer process, which helps ensure product quality before goods are placed back in inventory.

QUICK RESULTS ENTRY

Quality testing for process-related companies can be very time consuming. Recording the results can also be cumbersome. The Quick Results Entry feature expands upon the standard quality order functionality by allowing you to enter the test results and the test quantities for all tests on a quality order using one consolidated view of the data. This allows you to optimize the quality order test results entry by providing a single access point to maintain all test results instead of going to each individual quality order test.

Benefits: Quick results entry provides a fast and efficient method to enter quality testing results. This helps increase productivity and potentially decrease data entry errors. Faster passed quality orders for raw materials and manufactured items means product is available for use or sale sooner.

Microsoft Dynamics 365 is only sold by authorized Microsoft resellers like Fullscope.
For more information, visit **www.fullscope.com** or send an email to **D365difference@fullscope.com**.