AXSource® QUALITY DELIVERED | QCS D365 Solution for Life Sciences | Microsoft Solutions Partner

Enhancing Microsoft Dynamics for the Life Sciences Industry

Introduction

Life Sciences - The Challenge

Companies in the pharmaceutical and life sciences industry face a high level of scrutiny with regards to compliance and how these worldwide standards are enforced. These businesses must adhere to a range of strict regulatory requirements and guidelines, set by various governing bodies, to verify the quality and safety of products they manufacture and/or market.

Government agencies often introduce new regulatory requirements for companies to follow. As a result, pharmaceutical and life sciences companies need an Enterprise Resource Planning (ERP) system that is flexible and inexpensive to validate in order to demonstrate that their business processes meet industry standards, regardless of how recently the regulatory changes are introduced. ERP systems are built to help organizations optimize efficiency and to achieve operational excellency through the automation of core business practices. They are the foundation of business operations and provide visibility into the company's core processes in order to help executives make informed strategic decisions. Standard ERP systems are not designed to demonstrate compliance for life sciences companies, off the shelf and typical Pharma ERP systems are not integrated with Microsoft applications such as Outlook, etc. These systems must be specifically designed to incorporate the best practices from both the industry and configured to meet company's business requirements. Using best practices facilitates industry and government compliance with requirements such as cGMP, IEEE, ISO standard, IFRS, Sarbanes-Oxley, or Basel III. To comply with regulatory standards, the life sciences industry has been forced to integrate different software solutions when their ERP does not meet their day-to-day business requirement or use QMS tools outside the ERP.

Microsoft Dynamics Combined with D365QCS™

Microsoft Dynamics 365 Finance and Operations (D365FO) is a Tier 1 ERP solution used by a variety of manufacturing and distribution companies across the globe. D365QCS™ is a Quality and Compliance add-on software solution that bridges the requirements gap and design elements missing from the standard D365FO functionality that are specifically required for life sciences companies. The idea behind developing on the Dynamics platform is driven by the desire to manage the stringent challenges of life sciences industries and eliminate the unnecessary use of independent tools with a standard ERP product. Moreover there are means for ERP to be integrated to production and control equipment required for manufacturing of medical products.

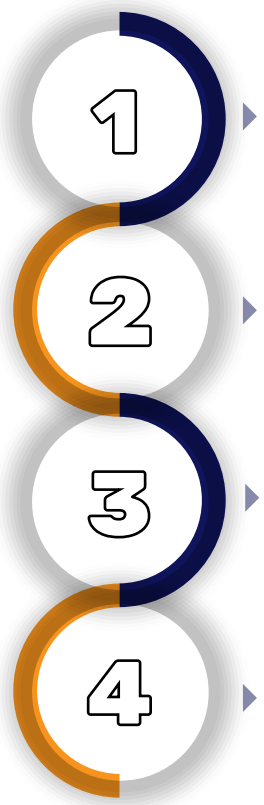
Through D365OCS™, you are guaranteed quality, accuracy in reporting, clarity in compliance and comfort in resolving financial burdens. Microsoft Dynamics combined with D365QC™ brings an 'all-in-one' comprehensive ERP solution that is especially meant for the explicit needs of life sciences industry, making Microsoft Dynamics the most competitive ERP in the market for Life Sciences. It adds specific features for life sciences to Dynamics 365 and enhances its standard functionality to make it a complete and fully integrated solution.

This complete ERP solution streamlines production as well as quality management through its built in functionality that ensures compliance with global GMP regulations including FDA 21 Code of Federal Regulations (CFR) Part 11, Health Canada and EU compliance requirements. Since many companies in the Life Sciences industry go through rapid growth, it is imperative for an ERP solution to be able to scale quickly. The right ERP solutions should reduce the cost of compliance by identifying and eliminating the areas of the business with manual limitations. The aim for D365QCS™ is to simplify business processes and eliminate excessive operational costs while ensuring compliance with regulatory requirements set by various governing bodies.

Designed by Life Sciences Experts for the Life Sciences Industry

D365QCS™ was designed and developed by regulatory experts with years of experience in the Life Sciences industry managing Quality Practices and adhering to regulations set by the FDA and Health Canada in the area of Pharmaceutical Drugs, Natural Health Products, Cosmetics and Medical devices. The quality system is designed to support Good Manufacturing Practices (GMP) and ICH guidelines. It provides a user-friendly interface of templates, configurations and processes to deliver and ideal ERP solution for the Life Sciences industry. It is one integrated system designed to manage the three essential needs of an organization—quality, regulatory compliance, and business efficiency.

Key Benefits of D365QCS™



1. Incorporates and streamlines quality management systems with the addition of security features at required checkpoints that support compliance and process monitoring.
2. Eliminates the time and expense to implement multiple software tools by providing the required functionality in a comprehensive, all-in-one ERP solution.
3. Enables cost reductions, supports on-going maintenance and multiple validations as regulations are updated; and
4. Allows the organization to roll out a proven and validated solution that streamlines the regulatory implementation process without an overwhelming of decisions regarding customization.

From compliance to automation and finally integration, the product can solve every issue to greatly reduce burden of additional tools or manual record keeping. With access to our regulatory experts, we can easily design according to regulations any required GMP process company requires (e.g. CoAs, Calibration & Equipment Controls).

Features Overview

Product Recall Management

For accessing the details required to file regulatory notifications, identify impacted customers/patients, hold further sales/inventory movements and monitor progress (effectiveness) , it is vital to know the exact product configuration details. With recall management:

- Know the most efficient way of managing recalls.
- Perform recall management for multiple products.
- Eliminate any risk of non-compliance and
- Simplify agency notifications

CAPA Management

CAPA Management system helps companies coordinate corrective and preventative procedures online. Each CAPA is tracked and traced to non-conformances identified throughout the company processes.

CAPA works to identify the quality problems in all phases production. It provides a sense of reassurance to the regulatory bodies and agencies and shows that the company is capable of hosting and resolving issues effectively. Lastly, it can also demonstrate to the regulatory bodies that the problem has been properly resolved.
D365QCS™ CAPA management system will improve the identification and response mechanism in order to provide a continuous quality improvement process. The system is capable of:

- Identifying a failing situation or event
- Initiating a non-conformance report
- Issuance of a corrective action and preventive action (CAPA)
- Record Investigation and root causes of failed events
- Access step by step documentation
- Simplify review & regulatory compliance.

Electronic Batch Records (eBR)

Accountability is a vital component of quality management and FDA compliance and is crucial for the life sciences industry. The cGMP (Current Good Manufacturing Practice) regulations by FDA encourage companies to have Electronic Batch Records systems that can employ accountability and functional discipline at each stage of production.

D365QCS™ creates unique electronic batch records for each product separately and captures the manufacturing and environmental details from the raw materials or components. The feature allows finishing the final packaging with e-signatures. The system uses data such as:

- Manufacturing details
- Date of manufacturing
- Data for quantity release
- Limits of production
- Accountability of product
- Automated tracking

Enhanced eSignature (eSIG)

Generate and use eSignatures enables the business to cut down on time inefficiencies and increase accurate results. Even though eSignatures are not mandatory when hand written signatures are employed, validated e-signature are required when auto approvals are performed for GMP tasks. The benefit of this feature includes.

- Avoid time-consuming handwritten signatures.
- Maintain internal efficiency.
- Maintain security and authority.
- Cost effective solution.
- Support paperless approach.
- Support GMP compliance

Computer System Validation (CSV) Tool Kit

D365QCS™ is a validated with Microsoft Dynamics ERP. There are requirements to conduct verification and validation (V&V) once the system is installed at our customer sites with unique customer business requirements. CSV procedure automates the process of V&V for our clients. As FDA and other global regulatory bodies mandate the software validation process, this Tool Kit saves time. The CSV Tool Kit will assist in:

- Reduce time to V&V on-site for our clients.
- Shorten commercial time.
- Support internal staff training for on-going maintenance.
- Provide procedures for on-going validation to remain compliant and
- Ensure GAMP5 standards are met and meets 21 CFR Part 11 compliance

Regulatory & Quality Reporting

Generate quick reports that give you the advantage of having actionable insight on the manufacturing procedure and performance. We invite a favorable ambiance of continuous growth and improvement with our regulatory and quality reporting mechanism.

- Prepare the industry compliance documents.
- Be aware of quality related issues.
- Make operational adjustments.
- Embrace the element of feedback.

Environmental Monitoring

As per the government regulations, it is mandatory for life sciences companies to identify key areas of production to be monitored whether they be facility, equipment or personnel. With environmental monitoring feature, we promise:

- Quality assured environment
- Simplified compliance

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