QCS
D365 Solution for Life Sciences

An Integrated Approach to Compliance for Life Sciences Companies

Product Features

FDA 21 CFR Part 11 & GMP Compliant

Electronic Signatures Capability

Corrective Action & Preventive Action (CAPA)

Deviations Control

Quality Orders & QA Inspections

Enhanced Lot/Batch & Component Traceability

Recall Management & Effectiveness

Audit Trail

Controlled Document Management

Computer System Validation (CSV)

QCS™ is Built on Microsoft D365 for Operations

- Enhance your Investment: D365 for Operations (Dynamics AX) combined with QCS™ delivers an upgraded and fully integrated solution that serves the complex requirements of companies in Life Science companies
- QCS™ was designed and developed by in-house regulatory experts to ensure compliance with FDA 21 Code of Federal Regulations (CFR) Part 11 and global GMP regulations
- Allows for leveraging of system wide business data for quality management and quality improvement initiatives

Make Compliance Your Business Advantage

- Compliant processes ready for implementation
- Eliminate the use of unnecessary quality management software solutions and paperwork with your ERP
- Reduces cost, supports efficiency and cGMP compliant
- A validated solution with huge savings in costs compared to a separate validation effort with multiple partners
- Meets FDA, Health Canada and EU compliance requirements

Good Manufacturing Practices (GMP) Made Easy

- **Electronic Batch Records:** Capture manufacturing and environmental details from raw material /components thru to finished packaging complete with e-signatures
- **Electronic Signatures:** authorize and maintain security at sign-off points necessary in production & quality control
- **CAPA:** manage non-conformances & deviations with on-line CAPA
- **Recall Management:** most effective control of recalls
- **Quality Management:** Issue quality orders for quality control and Inspections
- **Computer System Validation:** ensure accuracy, reproducibility, reliability, security, integrity and performance
- AXSource® offers full range CSV services for any solution interfaced with QCS™

Features Overview

QCS

www.D365QCS.com

Electronic Signatures (e-Signatures)	• Enables compliance with industry and government regulations, including 21 CFR Part 11 • Apply preventive controls on changes to validated software • Setup authorized approvers with various security levels • Maintain authorizations electronically and save time; eliminate hardcopy records
Electronic Batch Records	• Complete management of production & quality control inputs during manufacturing reducing paperwork • Complete control of GMP records, procedures and documentation to support compliance from raw materials, components, in-process, bulk, packaging, labeling and finished goods • Record of unique production parameters necessary to meet cGMPs for your products • Access deviation control feature for non-conformances during production • Formula management and yield determinations; line clearance • Leverages ERP data removing duplication & any redundancies • Enables compliance with industry & GPP regulations, including 21 CFR Part 11
Material Control and Recall Management	• Complete traceability for all material lot/serial numbers • Control of raw material, component, and product traceability processes • Management of material status at various point of production and quality control • Hold/quarantine management to expedite recalls and product withdrawals • Control of raw material, in-process and finished goods expiry and retesting requirements for risk mitigation
Corrective and Preventive Action (CAPA)	• Meets regulatory requirements for a compliant quality management system • Assignment of Quality Assurance investigators with automated workflow and approval processes and detailed documentation archiving • Maintain detailed records on corrective action and preventive actions taken • Tracking of non-conformances, deviations and audit non-conformances to prevent future occurrences • Eliminates purchase of supplementary document management software with your ERP • Allows identification of quality trends for compliance
Controlled Document Management	• Reduces time, effort, and costs associated with manual and paper-based processes • Integrated quality control and product safety document management solution for batch records, DMRs, CAPA, SOPs, audits, complaints, GMPs and more • Reduces cost of ownership with ERP and quality management solution integration

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