



MAXLife

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MAXLife: Life Sciences for Microsoft Dynamics AX and SharePoint

BENEFITS

- ◆ Comply with 21 CFR Part 11 and Part 820.
- ◆ Simplify Compliance with FDA regulations.
- ◆ Continuously Improve Product Quality and Safety.
- ◆ Increase Traceability and Security.
- ◆ Manage Documents Electronically.
- ◆ Automate and Optimize Business Processes.
- ◆ Accelerate Corrective Action Timelines.
- ◆ Identify and Understand Non-Conformance Trends.
- ◆ Minimize Risk and Maximize Safety.

MAXLife is an industry-specific software package for life sciences companies that produce and distribute products that are regulated by the FDA. With MAXLife, Life Sciences companies can take advantage of a fully integrated Quality and Compliance Management system that enables you to improve product quality and safety, reduce organization risk, and increase customer satisfaction. MAXLife supports requirements including 21 CFR Part 11, Part 820, Electronic Signatures, CAPA, SOPs, GMPs, Materials Control, and more!

ELECTRONIC BATCH RECORDS (EBR)

MAXLife provides Electronic Batch Record capabilities that reduce manual processing and operating costs by tracking Batch Records electronically, having them go through a life cycle of approvals, security, and workflows along the way. MAXLife eliminates costly paperwork errors, speeds up information distribution and collaboration, and enables strategies for improving quality and efficiency.

LIFE SCIENCES QUALITY PORTAL

MAXLife features document management and quality control capabilities, simplifying compliance with complete document lifecycle capabilities, including automated workflows, audit trails, and full versioning support. MAXLife helps companies address the regulatory requirements of FDA 21 CFR Part 11, as well as SOP management, clinical document management and a range of quality functions including CAPA, audits management, non-conformance and complaint management.

ELECTRONIC STANDARD OPERATING PROCEDURES (SOP) MANAGEMENT

All Life Sciences companies need to manage standard operating procedures (SOPs) with change control. MAXLife's Electronic Standard Operating Procedures Management feature provides companies the ability to do all of that electronically—with change control and FDA 21 CFR Part 11 compliance—in a web-based environment.

ELECTRONIC SIGNATURES

A key approach to the separation of duties for a Life Sciences company is having technology solutions that require two-deep sign-off on critical data changes or transaction entries. MAXLife enables companies to increase control over their system changes with the ability to add Electronic



“With MAXLife, Ivancic i sinovi will utilize key quality control and compliance management features specific to pharmaceutical manufacturing. Quality incident and non-conformance management processes will be streamlined and automated with MAXLife’s Corrective Action Preventive Action (CAPA) capabilities, enabling Ivancic i sinovi to correct and prevent issues, measure outcomes, and continuously monitor the system. Ivancic i sinovi will also be able to track and analyze all of their costs related to performing quality processes with Cost of Quality Management, enabling them to reduce the cost of quality while maintaining product safety.”

- Pharmaceutical Manufacturer Chooses MAXLife for Microsoft Dynamics AX

FAST FACTS

- ◆ IT services company with offices in North America and Europe.
- ◆ Focused 100% on Microsoft Dynamics, SharePoint, and surrounding technologies.
- ◆ Microsoft Partner since 1999; 500+ customers across 37+ countries.
- ◆ Microsoft Gold Certified Partner since 2003.
- ◆ ISV with Two Products that have Passed Certified for Microsoft Dynamics (CfMD) Testing.
- ◆ Microsoft Dynamics Emerging ISV for Food Safety and Life Sciences Quality Management.
- ◆ Hybrid Delivery Model Reduces Costs.
- ◆ Microsoft Dynamics Cloud Partner.
- ◆ AMR Industry Certified in Process Manufacturing.
- ◆ One of the Top VARs of 2011 and 2012.
- ◆ Established, trusted partnership with Microsoft.

Signatures anywhere in the software. Electronic Signatures supports an unlimited number of signers, groups, steps that can be applied to controlled fields, documents, and processes. MAXLife also has the ability to attach electronic signature reason codes and comments to change history, and provides controls to help companies meet the requirements of FDA 21 CFR Part 11.

CAPA INCIDENT MANAGEMENT

With MAXLife, Life Sciences companies can generate a CAPA request that routes through review, root cause, corrective action taken, and verification stages. This Corrective Action tracking software generates multiple reports automatically, providing an effective mechanism for tracking the source and costs of problems. MAXLife helps ensure that a company is compliant, effective and efficient.

MATERIALS CONTROL WORKBENCH

The MAXLife Materials Control Workbench enables Life Sciences companies to access and view any material lot and / or serial number, the status of that material, and all of the locations of that material - at the click of a button! And, if you need to notify vendors, customers or internal team members of a potentially adverse situation or investigation, you can quickly send out an email within the MAXLife Materials Control Workbench notification center.

ABOUT MERIT SOLUTIONS

We understand that it is important that you work with someone who knows your industry and can help you overcome your unique business challenges.

Merit Solutions has more than twelve years of experience deploying business management solutions for Life Sciences manufacturers and distributors. We have worked with hundreds of Life Sciences companies - from small medical device to global pharmaceutical manufacturers - to help them overcome the industry-specific challenges they face.

Merit Solutions helps customers transform their business through process optimization, change management consulting, and innovative IT consulting and development services. Our clients are mid-sized to global enterprise organizations that want to leverage Microsoft Dynamics and surrounding technologies to increase efficiency, reduce costs, and improve service – while maintaining profitable growth.

Merit Solutions is a Gold Certified Partner with Microsoft Dynamics AX and Microsoft SharePoint ISV solutions for Life Sciences and Food and Beverage companies. Merit Solutions is AMR Research Industry Certified in Process Manufacturing for Microsoft Dynamics AX. We have recently been recognized as one of Accounting Today's VAR 100, one of the 2011 VAR Stars, and had two products named in the Top 15 Add-Ons for Microsoft Dynamics. Merit Solutions is a Microsoft Excellence Partner for working successfully and collaboratively with customers and partners across the world.

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