



AgileDoc[®] Elements

Controlled Data Management

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AgileDoc® Elements

Overview

Manufacturing sites face constant challenges maintaining accurate, up-to-date information. Whether driven by regulatory requirements or simply a desire to maintain good practices, users spend considerable effort managing critical product, process and system documentation. While word processing documents and spreadsheet files provide a convenient means for recording information, they lack structure, security and traceability required for robust information management. Furthermore, file based solutions are difficult to integrate with data-driven organizations.

AgileDoc® Elements ensures data integrity by managing information in a secure, configurable environment. AgileDoc Elements incorporates a Microsoft SQL Server database engine to capture critical data as well as the associated system configuration. The Configurator enables system administrators to define data models and field input rules. Authorized users enter information through desktop web browsers. When applied in conjunction with the AgileDoc report engine, AgileDoc Elements is well-suited to augmenting information that already exists in a variety of disparate databases. Several example use cases are summarized below.

System Lifecycle (SLC) Management

The configuration associated with manufacturing automation and information systems is generally controlled using formal lifecycle methodologies. Change control information and annotation associated with documenting these systems can be managed through AgileDoc Elements and automatically linked

to relevant system modules. Typical data models include document information, revision histories, text narratives and parameter aliases or descriptions.

Product Lifecycle Management (PLM)

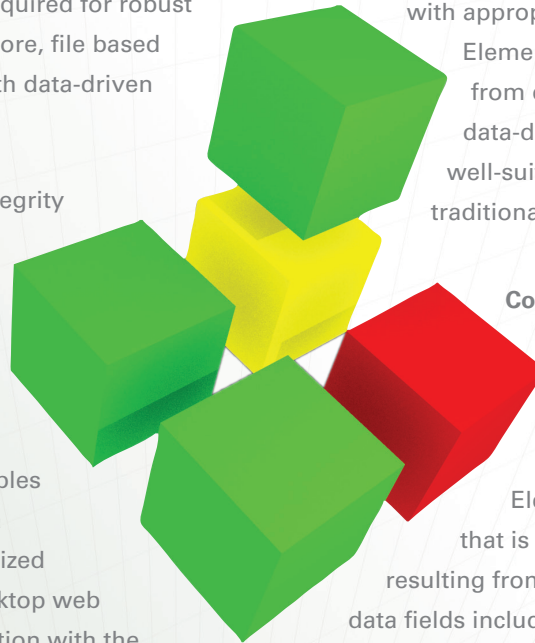
Good Manufacturing Practice requires that all manufacturing information related to PLM be managed with appropriate security and traceability. AgileDoc Elements can enable organizations to move from document or file-centric records to a data-driven approach. AgileDoc Elements is well-suited to moving beyond spreadsheets and traditional document management systems.

Corrective Action and Preventative Action (CAPA)

CAPA procedures and systems are critical to regulatory compliance and quality system standards. AgileDoc Elements can be used to capture annotation that is typically required for user interventions resulting from manufacturing exceptions. Example data fields include electronic signatures, tracking numbers, deviation category and incident status.

Functional Requirements Specifications (FRS)

Lifecycle management methodologies mandate full traceability from requirements through testing. Requirements are, however, often captured in word processing documents that make it difficult to generate and maintain traceability matrices. AgileDoc Elements enables the full lifecycle, from the definition of the requirements to test scripts, to be managed through an integrated system in order to ensure completeness and traceability.



Controlled Data Management

Data integrity maintained throughout the system configuration lifecycle

Intuitive web application for data entry and access

Immediate data entry validation

Structured Configurator to define data hierarchies and entry fields

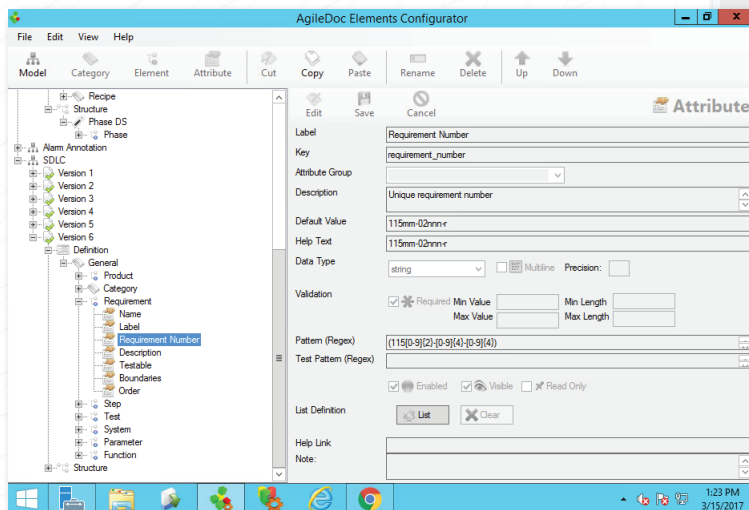
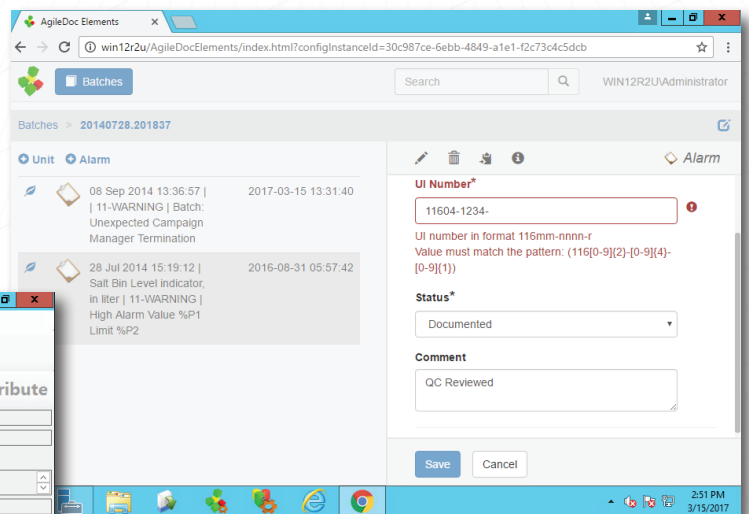
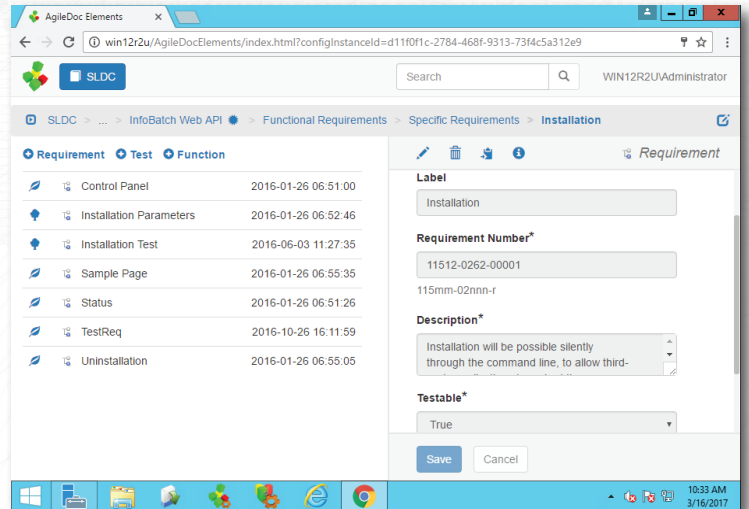
Reusable data object definitions

Enforce data entry workflow through data structure definition

Configuration and data version control

Complete traceability for configuration and data entry

Straight-forward data access from third party applications and reporting tools



AgileDoc® Elements

Complete Solution

AgileDoc Elements is a server-based software suite that incorporates a Microsoft SQL Server database engine. Authorized users create hierarchical models through a structured Configurator. Models include object and attribute definitions, input validation rules and the hierarchical structure presented to AgileDoc Elements Web users. Models are managed under strict version control, ensuring traceability and data integrity as the system is adapted to changing business requirements.

Authorized users interact with AgileDoc Elements through desktop web browsers. Users can create folders according to configured models, enter and edit data with complete traceability, and label data sets according to the specified version rules. Graphical input validation and a fast search engine ensure a satisfying user experience.

Once data is entered through the AgileDoc Elements database, it is immediately available to external applications through a set of simple optimized database queries. For example, a single query can return all of the required annotation for a specific version of a lifecycle document such as a Detailed Design Specification (DDS).

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SOFTWARE MODULES

4501	AgileDoc Elements Software Bundle
4510	AgileDoc Elements Database
4520	AgileDoc Elements Configurator
4550	AgileDoc Elements Web Application
4002	AgileDoc Report Server

SERVER PREREQUISITES

Server-class PC
Windows Server 2008 R2 (64-bit) or Windows Server 2012 R2 (64-bit)
Microsoft SQL Server 2008, 2012 or 2014
Microsoft Internet Information Services (IIS) v7.0 +
Supported Internet Browsers:
Internet Explorer 11 or later
Google Chrome
Mozilla Firefox