



## ADDING CONSISTENCY, QUALITY AND COMPLIANCE TO MANUFACTURING IN A VALIDATED ENVIRONMENT

### PREDICTIVE DIAGNOSTICS MINIMIZE BATCH IMPACT

New technologies designed to help meet the demands of FDA 21 CFR Part 11 are significantly improving accuracy and increasing reliability in the pharmaceutical and life sciences industries. Predictive diagnostics from critical plant assets give early warning of impending issues, allowing you to take action and avert problems to minimize batch impact.

AMS™ Suite: Intelligent Device Manager delivers critical information to maintenance technicians and control room operators for faster action that can prevent unexpected upsets and reduce the overall cost of maintenance. A predictive maintenance environment allows you to better manage maintenance tasks and produce quality products. In fact, 9 of the top 10 pharmaceutical manufacturers use AMS Device Manager.

### MEETS RIGOROUS REGULATORY DEMANDS

Emerson embraces Good Automated Manufacturing Practice (GAMP) methodology that improves efficiency of project execution and enhances manufacturing

quality. GAMP4 compliance requires Change Management and documentation of configuration settings for smart instruments. AMS Device Manager easily improves record-keeping processes and streamlines maintenance activities. With the Audit Trail, working in a validated environment no longer requires extensive efforts to confirm that field instruments and valves are properly installed and configured.

### TOOLS FOR A VALIDATED ENVIRONMENT

- Easy-to-follow validation templates for total system validation
- Full Audit Trail tracking by location (Tag Name) and Asset (Device ID)
- Electronic signature of device configuration changes
- Calibration Management including reporting, scheduling, and capturing As Found/As Left data
- Security options and privileges to provide appropriate system access
- Proven compliance



AMS Suite: Intelligent Device Manager powers PlantWeb through predictive and proactive maintenance of intelligent field devices to improve availability and performance.



## Intelligent Device Manager



### SIMPLIFY VALIDATION WITH AMS DEVICE MANAGER

#### TEMPLATES EASE VALIDATION PROCESS

AMS Device Manager validation templates provide a base point for the validation of an AMS Device Manager system by a knowledgeable engineer. These templates include:

- Quality Plan, Functional Design Specification (FDS), and modular test protocols that include test scripts and test reports for IQ, OQ and PQ.
- Definitions and descriptions in a modular format and layout so unused capabilities can be easily removed from the documentation.
- Generic phrases so you can easily replace content with your specific project phrases.
- The FDS and Quality Plan include guideline comments and use color-coded text to emphasize areas that are typically project-specific.

Emerson can assist you with setting up these services. Contact your local Emerson representative for more information.

#### OUR CUSTOMERS SAY IT BEST

*"The PlantWeb® installation was built under FDA validation guidelines, using GAMP as the project execution methodology. AMS Suite software was used to streamline the validation process. Loop testing can be performed by one engineer using the software, instead of the traditional team approach with one control room engineer and one or more field engineers. In addition, the software automatically generates and stores the evidence that the loop test has been performed, which helps to speed up the validation process." – DSM*

*"Monitoring these critical points for baseline and calibration certification using NIST-traceable procedures allowed changing the quality control procedure from fully analytical to a process instrumentation-based system. The NIST-traceable calibration certificates must be provided as a part of the regulatory documentation in the Vitamin E facility. With our system, a calibration certificate on any instrument the control network can be printed out showing that instrument's calibration history, accuracy, date last tested, condition "as found," condition "as left," etc." – Cargill*

#### MOTIVATE YOUR TEAM BY GIVING THEM BEST-IN-CLASS CAPABILITIES

AMS Device Manager is a key component of Emerson's PlantWeb digital plant architecture for validated industries and is one of the integrated family of applications in the AMS Suite for predictive maintenance and performance monitoring.

©2007, Emerson Process Management.

The contents of this publication are presented for informational purposes only, and while every effort has been made to ensure their accuracy, they are not to be construed as warranties or guarantees, express or implied, regarding the products or services described herein or their use or applicability. All sales are governed by our terms and conditions, which are available on request. We reserve the right to modify or improve the designs or specifications of our products at any time without notice.

All rights reserved. AMS and PlantWeb are marks of one of the Emerson Process Management group of companies. The Emerson logo is a trademark and service mark of Emerson Electric Co. All other marks are the property of their respective owners.

#### Emerson Process Management

12001 Technology Drive  
Eden Prairie, MN 55344 USA  
T 1(952)828-3206  
F 1(952)828-3033

[www.assetweb.com](http://www.assetweb.com)

