# *Generic Methodology for the Implementation of Automated Device Management Systems*

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***Abstract*** *— Organizations establish maintenance programs to ensure instruments and other devices are maintained, properly configured, and periodic calibrations are performed. Typically, a combination of computerized maintenance system and manual data collection and entry are used. The whole process is prone to errors as it depends on individuals manually performing each step. The generic methodology presented in this article can be followed to implement an automated device management system in any manufacturing organization. The methodology may be employed in new installations as well as retrofits in existing operations, as long as compatible devices are used*

***Key Terms*** *— Automation, Calibration, Device Management, Maintenance*

## INTRODUCTION

Automated systems control industrial processes by monitoring and actuating the system to effect the desired changes. Instruments measure physical variables to monitor process conditions. Actuators execute commands from the controller to change process conditions until they meet predefined set-point parameter conditions.

When installed, repaired or replaced instruments and actuators, must be configured to operate according to the particular conditions of the process. Also, since accurate measurements are critical, instruments must be periodically calibrated to ensure optimal performance.

Device management systems can be used to optimize the maintenance process, ensuring the correct configuration setup is used, eliminating calibration errors, reducing execution times, and automatically saving maintenance records into the system. Health and safety benefits can also be obtained as automating the process can also reduce technicians' exposure to hazardous conditions in the field.

## RESEARCH OBJECTIVES

The objectives of the design project are to:

- Provide a generic framework that organizations can follow to implement an automated device management system
- Discuss financial considerations to help organizations justify the investment
- Eliminate the guesswork of how to maintain regulatory compliance by presenting a Computer System Validation (CSV) strategy for the implementation
- Introduce equipment components and communications infrastructure required for the implementation
- Present follow-up scenarios to leverage on the implementation for additional benefits

## RESEARCH CONTRIBUTIONS

The use of automated device management systems is not new. They have been commercially available for many years. Corporations around the world have implemented and use them every day to great success.

However, the implementation project itself, from conceptualization to actual production use, is a complex endeavor that requires significant research, preparation, and planning. Organizations in highly regulated industries, such as pharmaceuticals, must ensure that the implementation is carried out in a manner that fully complies with regulations.

The main contribution of this design project is that it establishes a framework that corporations can follow to implement an automated device management system. It describes the implementation process in detail so organizations understand what is involved, helps them prepare better, and avoid surprises. The guideline can be tailored to fit the organization needs and can be scaled up or down as necessary. It also helps them justify the cost of the project to earn critical upper management buy-in. In addition, the framework reduces project time and costs, especially in the planning stages.

## RESEARCH BACKGROUND

The following theoretical concepts are important in the discussion of the implementation methodology.

### Automation

Automation refers to the conversion of industrial processes and production operations from a manual process, to an automated or mechanized process. It involves the use of specialized equipment and devices to perform a predetermined sequence of operations with little or no human labor.[1]

Automation primary goals are:

- Improve product quality and uniformity, minimize cycle times and effort, and reduce labor costs
- Improve quality by enabling processes repeatability
- Improve productivity by reducing manufacturing costs
- Reduce human involvement and human error

An automated system is a distributed control system (DCS) used to control processes at a manufacturing site. Its system architecture provides multiple Input/Output interfaces and system controllers distributed throughout the plant site that are interconnected with other control system components such as databases, application and operator's workstations, and smart field devices.

### Sensors and Transducers

Sensors or instruments measure physical process variables that are related to the condition that the system is intended to control. The transmitter then relays that information to the controller. The controller receives the information, compares it against the desired behavior (set point), computes corrective actions based on a model of the system's response, and actuates the system to effect the desired change.[4]

### Intelligent Devices

Intelligent or smart devices have internal microprocessors that allow them to store information and change their configuration parameters dynamically.[3]

They use standardized communication protocols like HART® (Highway Addressable Remote Transducer) and FOUNDATION™ Fieldbus. These protocols establish digital, two-way, multi-drop communication among intelligent devices as a Local Area Network (LAN) for advanced process control.

Field-based systems integrate the use of workstations, Ethernet control network, controllers, and intelligent field devices (Figure 1).

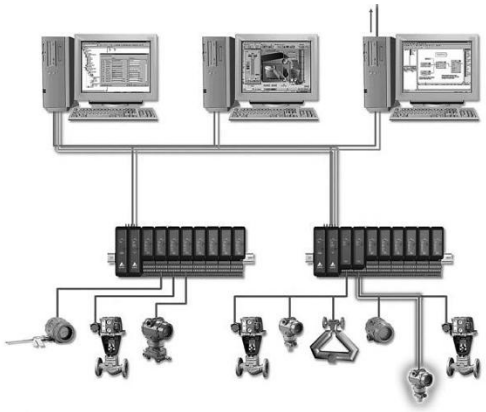

**Figure 1**
**Field Base System**

## DEVICE MANAGEMENT SYSTEM

The automated Device Management System (DMS) can be installed as a single-station system or as a multi-station, distributed system. The single-station system maintains the DMS application and database at a workstation, with no associated client stations. A distributed DMS is a client/server deployment with multiple DMS Client Stations accessing a common database at a DMS Server and all connected devices in the distributed system. See Figure 2 for a high-level illustration of the system's major components.

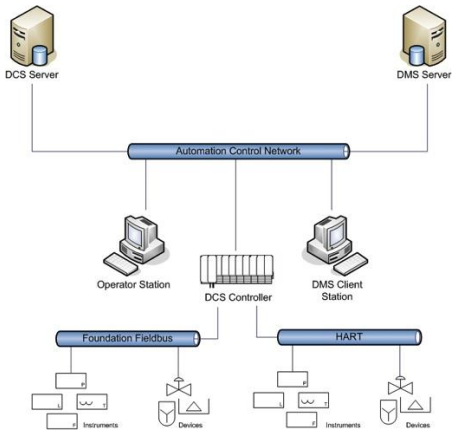


**Figure 2**
**High-Level System Overview Diagram**

The Automation Control Network is a closed-system backbone that provides bus technology communication to all DCS controllers and other system components. The Foundation Fieldbus and HART networks interconnect field devices to DCS controllers.

### DMS Basic Functionality

The DMS provides tools to configure, calibrate, document and diagnose Foundation Fieldbus and HART intelligent devices from a single application. The DMS is also able to store configuration information of conventional, non-intelligent devices although it is not able to communicate or manage them remotely as is the case with intelligent devices.

To communicate with the devices the DCS and DMS need to have the correct version of each instrument's Device Description files (DD). DD files are similar to computer system driver files and contain the information necessary for the systems to communicate with the devices.

The DMS provides the following functionality:

- Display and modify instrument configurations, compare configurations and transfer values among configurations
- Save and monitor events using "Audit Trail": configuration changes, user administration, device status and alarms, test and calibration activities, and database maintenance activities
- Secured database storage of device configuration and calibration data
- Use of electronic signatures to register user made configuration changes
- Restricts access to system functionality based on user security permissions
- Monitor device current status, conditions, and diagnostic information.
- Monitor device alarms

### Device Configuration

When first installed the DMS must collect the current configuration of all existing intelligent field devices in the DCS. There are several ways to do this. The "Scan all Devices" option will synchronize the DMS database with the configuration data of all the existing devices at once. Alternatively, the "Scan Device" option would individually synchronize selected devices. The "Scan New Device" option would synchronize all new devices into an existing configuration set.

Device configuration includes identification information, basic setup and other more advanced pieces of information. Identification information includes: manufacturer, model, revision, serial number, and site asset tag number. Basic setup information is related to the behavior of the device and includes: units of measure, upper limit, lower limit, and other connection parameters. [4]

An important feature of the DMS is the "Compare Configurations" option. It can be used to compare existing configurations, create new configurations based on existing ones, and manage changes to existing configurations.

### Device Calibration

DMS automates device calibration by creating and maintaining calibration routes, procedures, and schedules. Multiple calibration tasks can be combined into a single calibration route.

At the beginning of each calibration route the user downloads the calibration procedures for the devices selected into field calibrators. These field calibrators automate the actual calibration process and capture the calibration information. The system maintains "as found/as left" records for each maintenance activity on each device. At the end of the route all calibration information is uploaded from the calibrator directly into the system.[5]

## IMPLEMENTATION METHODOLOGY

The implementation procedure may be tailored to the particular industry requirements of the implementation organization. For instance, the methodology presented considers the highly regulated requirements of a pharmaceutical operation. If the DMS is to be implemented at a facility with less rigorous requirements, the procedure still works by simplifying the whole process and by reducing or eliminating QA's involvement and the validation requirements.

### Assumptions

There following assumptions to be considered as part of the methodology:

- The DCS is already installed and operational
- Compatible smart devices are already installed or will be upgraded prior to the DMS implementation

### Project Team Assembly and Responsibilities Definitions

The project team is comprised of a multi-disciplinary group of individuals, each contributing knowledge and expertise towards a common goal. The team's main responsibility is to appropriately assess the needs of the site, translate them into system requirements, implement the system and maintain its operation.

Table 2 lists personnel requirements and their responsibilities for the implementation. Personnel requirements may be adjusted as required depending on the size and regulatory requirements of the implementation.

**Table 2**
**Implementation Team**

| Team Personnel | Responsibility |
|---|---|
| Maintenance Engineer | Equipment installation, configuration, calibration and maintenance.<br>Implementation Tasks:<br>• Change control origination and tracking<br>• Validation deliverables review and approval<br>• SOP development<br>• Test protocol execution |
| Automation Engineer | Automated system setup, configuration and maintenance.<br>Implementation Tasks:<br>• DMS installation and configuration<br>• DCS/DMS workstation installation and configuration<br>• Device configuration import and setup |
| Computer System Validation Representative | Develop documented evidence to demonstrate system consistently performs as designed.<br>Implementation Tasks:<br>• Validation deliverables development<br>• Test Protocol development<br>• Documentation and evidence safekeeping |
| Quality Assurance Representative | Industry regulations interpretation. Ensure regulatory requirements compliance.<br>Implementation Tasks:<br>• SOP review and approval<br>• Validation deliverables review and approval |

Input from other operational areas of the site may be required. This extended team of the implementation project may include subject matter experts from production areas, financial, environmental, and health and safety departments.

If members of the team lack expertise and knowledge of DMS system it is highly recommended to arrange for training as required. Training can be as formal and specific as external courses or as simple as internal self-study sessions.

### System Assessment

The first task the implementation team must accomplish is to assess the current state of the system. Crucial pieces of information to be collected include:

- DCS software and version
- DCS Workstations model numbers, hardware specifications, installed software and versions
- Network system architecture including automation control network and existing Foundation fieldbus and HART networks
- Smart devices in use, type of device, manufacturer, model number

### Description of the Implementation

After the current state is defined and mapped out the next step is to define the scope of the new system:

- DMS software to implement
- Overall size of the implementation: number of users, devices, and calibrators
- Implementation approach: by operational area or by device type (thermal, pressure, flow) or full implementation
- Requirements for upgrades to existing DCS software, workstations, controllers and other hardware
- Potential compatibility issues with existing network architecture
- Requirements for upgrade existing devices and acquisition of new devices

The team must carefully consider schedule, budget, personnel availability and skill sets, timing of other projects and initiatives at the site, and constraints associated with existing component interfaces. These may affect the scope and plan for the implementation.

The implementation plan must include specific deliverables for each milestone, a clear definition of the scope of each step, and contingency plans in case the schedule begins to slip.

### Change Request Development

Implementation in highly regulated industries requires that changes are carried out in controlled fashion to comply with regulations and maintain validation status of existing systems. To achieve this organizations follow change management procedures.

Implementation of a DMS requires the creation of a change request where impact assessment by all concerned parties is documented. The change request must specify:

- Full description of the intended implementation, including the current state and the proposed changes
- Impact assessments from subject matter experts from: maintenance, production, automation, validation, QA, environmental, and health and safety
- Detailed implementation plan of all project activities. Each task must specify what it will accomplish, resources required to accomplish it, key person(s) responsible, criteria for successful completion (e.g., “user acceptance”) and area owner’s approval requirements

### Pilot System Development

A pilot system can help the team confirm that the desired functionality is achievable. Development options for the pilot system include:

- A single workstation performing DMS server and client functions or a 1 server – 1 client setup.

- Single device type – A single device type is selected (e.g.: temperature). This setup is recommended for phased implementations by device type
- Multiple device types – A single device of each type is selected (e.g.: temperature, pressure, flow). This setup is recommended for implementations employing more than one device type, in particular whole site projects encompassing all existing device types

**Equipment and Applications Acquisition**

Purchasing requirements of hardware and software items may be extensive and must be carefully considered to ensure all required components are available during the implementation. The list should include specific models, versions, configuration settings, and information about manufacturer support, licensing, and maintenance agreement details.

Hardware:

- Workstations and required upgrade components: memory, hard drives
- Smart devices (Foundation fieldbus, HART compliant)
- Field calibrators
- Computerized calibration standards
- Network, data communication equipment, cabling

Software:

- DMS server application and central database with the appropriate number of user licenses
- DMS client application
- All necessary drivers for application interfaces, network protocols, automation controllers, and all field devices

**Configuration and Testing**

DMS configuration is performed as part of the test execution of the validation process (see section "Validation Strategy"). System components are installed during the installation qualification (IQ), system functionality is verified during the operational qualification (OQ), and fulfillment of functional requirements is verified during the functional testing.

CSV personnel must develop test protocol documents for each testing phase describing:

- Prerequisites for execution or predecessor test protocols (if any)
- Detailed executions instructions and steps including the expected results
- Acceptance criteria for determining pass or fail
- Instructions to handle execution discrepancies

The following system components should be installed during the IQ:

- DMS Server Application and system's database
- DMS Client Application

The following activities will be executed during the OQ:

- Synchronize the DMS database with the configuration data of all the existing devices ("Scan all Devices")
- Enter conventional devices configuration
- Create calibration test schemes for devices to be tested

The following activities will be executed during the Functional Testing:

- Synchronize the DMS database with the configuration data of all the existing devices
- Configure a new device ("Scan Device")
- Compare existing configurations, create new configurations based on existing ones, manage changes to existing configurations ("Compare Configurations")
- Replace a device
- Perform full loop calibration test for each type of device to be tested using the field calibrator:

- Store calibration route list of devices to calibrate
- Store test schemes for the selected devices
- Execute the calibration test schemes when connected to the device
- Store the test results
- Upload the information to the DMS

**Standard Operational Procedure Development**

Standard Operational Procedures (SOPs) help people perform processes correctly and consistently, reduce variations, facilitate training, and encourage continuous improvement.

The following SOPs must be developed or updated for the DMS implementation:

- DMS System Administration – Provides the instructions to operate the system. It should include instructions for adding and replacing devices, importing device configurations, creating analog device configurations, definition of device calibration schemes, creating calibration routes, adding devices to calibration routes, check-in and check-out of calibration routes, and instructions for checking status, audit trail review, configuration comparisons, reporting, and DD files maintenance
- Device Calibration – Calibration SOPs should already exist at an operational facility. It is very likely that there is at least one SOP for each device type, e.g.: one calibration SOP for temperature devices, another one for pressure devices, and so on. The existing calibration SOPs for the devices in the scope of the implementation must be updated to describe the instructions to perform automated calibrations. The updated instructions will describe how to load checked-out calibration routes onto the calibrator, connection to the device, use of automated calibration standards, steps to perform the calibration, and upload of calibration route results
- Asset Management System (AMS) related SOP – This SOP describes how to manage work orders. Originally, device calibration work orders would be documented manually and the result would be manually keyed into the AMS [2]. After the implementation of the DMS the process of documenting work orders would happen at varying degrees of human intervention and level of automation according to the scope of the project. Existing SOPs must be updated accordingly

**End User Training**

System users must be fully educated so they understand how the DMS system will be integrated into the device maintenance program. All users must be trained to take full advantage of the system's capabilities.

DMS user training will be based on the operational procedures developed and updated as part of the project. An option to consider is to select a group of power users to receive more intensive hands-on training. These "power users" can provide additional user support after the go-live.

**Go-Live**

After completing all validation activities, SOPs are in place, end users have been trained, and the Validation Report is approved, the DMS system is ready for its go live and use in production. Planning and preparation are necessary for this step of the process go over smoothly.

The implementation team must coordinate the system roll out and go-live date with management and the site's operation areas way ahead of time. The objective is to cause the least amount of disruptions to normal operations as possible.

After these preparations are made, the proper announcements must be made for site personnel to be aware of the go-live date.

**Validation Strategy**

Computer System Validation (CSV) is a technical discipline used to ensure that computer systems perform according to their intended purpose. The objective of the process is to produce documented evidence that systems fulfill what they were designed to do in a consistent and reproducible manner.

A full system validation package consists of the following documents:

- Validation Plan - Defines the objectives of the Validation and the activities, procedures and responsibilities for accomplishing the objectives of the Validation. The Validation Plan should also deal with the approach for maintaining the validation status
- Functional Requirement - Defines clearly and precisely what the user wants the system to do and states any constraints (e.g. regulatory) under which the system must operate. The requirement document addresses the "what" of the system
- Design - Provides a technical description of "how" to achieve the functionality described in the Functional Requirement. Design documentation must address the following topics (either in separate documents or any combination):
    - System Overview - A high level description of the system, including basic functions, features, interfaces with other systems and general system architecture
    - System Configuration - Detailed technical information about the system hardware and software components
    - System Specifications - Detailed specification showing how the system performs the functions documented in the Functional Specifications
- Testing, which includes:
    - Test Plan - Describes the overall test strategy, including: extent of testing rationale, description of test execution process, requirements for documentation and evidence handling, overall sequence and dependency of test activities, successful test completion criteria, roles and responsibilities, handling of discrepancies, and requirements for the test summary report
    - Installation qualification (IQ)
    - Operational qualification (OQ)
    - Functional testing
    - Test Summary Report - Review of all testing activities against the expectations set in the Test Plan. It summarizes the results of the test activities that were performed demonstrating that the system is fit for its intended use. The report must include: list of all test cases executed, test discrepancies and justifications for any problems not fixed, and description of the system configuration used in testing
- System operational, administration and security SOPs - Documented procedures for users, system administrators, and other administrative related functions (see section "Standard Operational Procedure Development" for details). Other important topics to address in SOPs are Backup & Restoration, Disaster Recovery Plan and the Business Continuity Plan
- Validation Report - Consists of a review of all activities and documents against the expectations set in the Validation Report. It also includes evidence that any deviations from the plan have been addressed. The Validation Report is a

documented approval of system acceptance by the stakeholders. Once approved the system is considered ready for production use

The extent of the validation should be justified based on an evaluation of risk. Criteria to consider during the risk evaluation include:

- Regulatory and business requirements related to the intended use of the system
- Criticality of the system data
- Impact of the system on the overall quality and existing quality control strategies
- Complexity of the system

If there is a validation package for the DCS the implementation system of the DMS may not require development of all the validation elements previously described. It may be appropriate to update existing DCS documentation, such as requirements and design. This could simplify and expedite the validation process.

## Financial Justification

Justifying cost is always a challenging aspect of a project. The main objective is to demonstrate and convince management that the investment required will ultimately cover the initial expense and bring financial benefits over a period of time.[6]

The immediate financial benefit obtained from the implementation of a DMS is savings in operating and maintenance costs. These savings are mostly related to the reduction in time required to configure and calibrate instruments. In addition, as much as 50% of maintenance time is actually spent on paperwork and manually recording calibration results. DMS eliminates manual entry of calibration data by automatically uploading the results from the smart calibrator into the system's database.

The following tables (Tables 3-5) show typical savings related to the reduction in execution time of configuration and maintenance activities by comparing manual versus DMS execution. The sample cases consider a site operation consisting of 300 devices and a $60 technician's hourly rate.

**Table 3**
**Device Configuration Savings**

| Configuration | Manual | DMS |
|---|---|---|
| Connect Field Communicator | 2 | 0 |
| Configure device parameters | 20 | 5 |
| Document changes and events | 20 | 0 |
| Trip to field location and returning items | 15 | 0 |
| **Total minutes** | **57** | **5** |
| Minutes of savings per device | | 52 |
| Total hours saved (300 devices) | | 260 |
| Configuration Savings ($60 per hour) | | $15,600 |
| Savings per device | | $52 |

**Table 4**
**Device Calibration Savings**

| Calibration | Manual | DMS |
|---|---|---|
| Pull test requirement for each instrument | 2 | 0 |
| Attach calibrator and apply test scheme | 10 | 10 |
| Record readings and calculate accuracy | 5 | 0 |
| Document changes and events | 15 | 0 |
| Trip to field location and returning items | 15 | 15 |
| **Total minutes** | **47** | **25** |
| Minutes of savings per device | | 22 |
| Total hours saved (300 devices) | | 110 |
| Calibration Savings ($60 per hour) | | $6,600 |
| Savings per device | | $22 |

**Table 5**
**Device Replacement Savings**

| Device Replacement | Manual | DMS |
|---|---|---|
| Identify replacement | 2 | 2 |
| Locate replacement | 5 | 5 |
| Remove failed instrument | 10 | 10 |
| Install replacement | 10 | 10 |

| Device Replacement | Manual | DMS |
|---|---|---|
| Configure replacement | 20 | 5 |
| Document changes and events | 20 | 0 |
| Trip to field location and returning items | 15 | 15 |
| **Total minutes** | **82** | **47** |
| Assuming replacement of 10% of total devices | | 30 |
| Minutes of savings per device | | 35 |
| Total hours saved (30 devices) | | 18 |
| Device Replacement Savings ($60 per hour) | | $1,050 |
| Savings per device | | $35 |

Also, the system's potential reduction in production operations downtime is significant. Financial planning departments at manufacturing operations maintain figures detailing the dollar cost of production disruptions. Depending on the size of the operation losses can run from thousands to millions of dollars per hour of downtime. These numbers can be used as economical justification by identifying areas where device breakdowns would cause the greatest losses. Presenting the case that the DMS implementation would help avert that type of loss can be a very persuasive argument.

Some organizations may require a more formal economical justification approach. The most commonly used methods are:

- Net Present Value (NPV)
- Payback Method
- Profitability Index (PI)
- Internal Rate of Return (IRR)

These methods are based on the concepts that the present value of a dollar is higher than in the future and that the expected cash flows (expenses) from each year is discounted from the company's desired rate of return.

### Future Benefits

The immediate objective of the DMS implementation presented in this methodology is to improve the preventive maintenance process. However, the documented data and evidence in the system's central database is very valuable.

By analyzing the data it is possible to implement a predictive maintenance program. The data can help to identify maintenance practices that are unproductive, or areas of the plant that have chronic maintenance problems.

Devices that show patterns in performance degradation may suffer from systemic errors such as installation problems - indicating an opportunity to reduce maintenance work by correcting the root cause of the errors. Conversely, if a device shows no deterioration in performance between routine calibrations, maintenance work can be reduced by extending the intervals between services.

Predictive intelligence improves plant performance by delivering accurate, real-time data to aid decision making. Integrated data from the instruments, alerts and events, and real-time device status information helps predict, detect and correct conditions that can lead to equipment failure. This will ultimately help prevent process upsets before they result in unplanned shutdowns.[7]

This next logical step in the life cycle of the system is possible because the DMS provides integrated information from multiple data sources, presents real-time analyses and reports of asset health and availability, and incorporates advanced device management strategies.

## CONCLUSION

The generic methodology presented in this design project provides a guideline to manufacturing organizations wanting to implement an automated Device Management System. Special emphasis was placed to include rigorous regulatory requirements for corporations in regulated industries. These can easily be bypassed in implementations at less controlled environments.

In summary, the methodology:

- Offers a comprehensive theoretical background of automation concepts
- Provides a generic framework for the implementation of a DMS
- Presents Computer System Validation (CSV) strategy for the implementation
- Describes system components
- Discusses several methods to develop economical justification to earn upper management buy-in for the project
- Presents future benefits of the project

Organizations following the methodology will understand the process, plan the project realistically, and tailor it as necessary to achieve a successful implementation.

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