



MAP Quality Engineering
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What about the Product Test Results?

**Achieving Operational Intelligence Requires
Integration of the Product Testing System**

MAP Quality Engineering Quality Data Management System (QDMS)

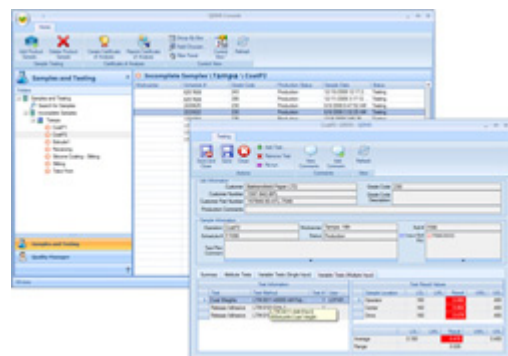
MAP QDMS™ features a robust set of testing and certification capabilities for improving the repeatability and efficiency of the laboratory, while making quality-critical data such as test results and product specifications available to manufacturing execution systems (MES), process monitoring systems (such as SPC), and ERP systems.

Key Benefits

- Operational Excellence: Connect the enterprise to the lab for greater visibility and control.
- Customer Satisfaction: Ensure product is tested and certified to the same standards in every plant.
- Continuous Improvement: Enable real-time access to, and analysis of, product test results.
- Cycle Time Reduction: Reduce product testing and release times.
- Cost Savings: Improve laboratory efficiency with reduced headcount.
- Cost Avoidance: Reduce risk of compliance failures

Key Capabilities

- Product Specifications Management.
- Product Test & Test Methods Management.
- Product Test Plan Management.
- Product Testing Management.
- Product Certification (CoA) Management.
- Integration with ERP, HMI, MES, and SPC systems.
- Multi-plant scalability.





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Overview

If you find it difficult to realize increased manufacturing efficiency in the absence of product test results, a new, MES-complementary, quality data management system may be just what you need to achieve operational intelligence that yields measurably increased efficiency.

Increasingly sophisticated manufacturing processes are dramatically increasing the demands on the product testing and certification process. The continuing search for productivity and efficiency is expanding the need for product test data beyond the traditional laboratory environment, to virtually every corner of the plant. Furthermore, increasing quality and regulatory compliance demands means that product data must be readily accessible to a growing number of users and systems across the enterprise. Failure of the product testing system to keep pace can quickly become the rate-limiting step in the quest for operational excellence (OpX).

Traditionally, laboratories have operated autonomously from the rest of the plant, and are amongst the last of the domains to be fully integrated into the manufacturing system. Thus, lab-centric systems for product testing have failed to keep up with business-centric manufacturing systems, requiring managers to make decisions with only half of the picture. Old, disconnected, laboratory information management systems (LIMS) that have been around for decades are giving way to new, integrated, quality data management systems (QDMS) that are designed to optimize the manufacturing cycle by supplying systems and decision makers across the enterprise (not just in the quality department) with timely, actionable product information.

Executive Summary

Projects aiming to achieve operational excellence must eliminate inefficiencies afflicting the entire manufacturing operation, spanning customer service, materials management, production, quality, and sales. Each of these departments is burdened by the lack of access to real-time data representing the customer contract (e.g. purchase order and shipping details), the product quality requirements and specifications, and the production status (including test results, lot disposition, and traceability). A MES-friendly solution for facilitating the product testing and certification process is now available, and its benefits are in alignment with critical corporate goals of reducing manufacturing costs, improving product quality and consistency, and improving customer satisfaction. This solution addresses product specifications management and is compatible with, and is in fact complementary to, our existing HMI/MES systems. The solution is also scalable, designed to ensure product is tested and certified to the same standards in every plant.

An investment of approximately \$25K - \$50K per plant is required. An ROI in 6-12 months is expected, and it can be realized significantly sooner in many cases. Because this solution impacts all departments, many companies share the costs equally amongst the departments. Once budgetary approval is granted, the first plant can expect to realize benefits within 90 days. Deployment to subsequent plants may require as little as 15 days. The increasing competitiveness of today's economic climate makes it even more important to eliminate systemic inefficiencies, and thus compels forward-thinking companies to act promptly. Leading manufacturers deserve a better solution, and so do their customers.



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QDMS Considerations

Storing and Managing Product Specifications

"We are having difficulty determining where the best place is to store and manage product specifications. Our integrator says this should be done within the MES, but this does not seem to be the most logical place."

Solution

A QDMS is a much better choice for management of product specifications because product specifications are dependant on the product test plan. It is not reasonable to make changes to specifications in the absence of the applicable test plan, and vice-versa. MES typically do not provide for test plan management, while the entire testing and disposition process within a QDMS is built around the test plan. Additionally, product specifications are a pre-requisite to product certification (the production and management of certificates of analyses). Product certification is clearly best performed within the QDMS, as it is the culmination of business rules carefully defined within the QDMS.

Providing Other Systems Access to Information within QDMS

"We use our MES to deliver manufacturing information to the operator, including some of the critical product specifications that are helpful during machine setup. How will our MES, and other systems, be able to access the product specifications, and other information, within QDMS? "

Solution

MAP QDMS comes with the following Wonderware® Archestra™ Industrial Application Server™ objects that enable complementary systems to utilize information within QDMS:

- 1) Product Specifications.
 - Can be accessed by HMI, MES, and SPC systems.
- 2) Alarms for control, specification, and warning limit violations.
 - Can be accessed by the HMI to alert an operator of a problem and potentially reduce scrap and rework.
 - Can be accessed by corrective action / preventive action (CAPA) systems to notify the appropriate person of the alarm.
- 3) Product disposition status.
 - Can be accessed by corrective action / preventive action (CAPA) systems to notify the appropriate person of the approval or rejection of a lot.
 - Can be accessed by inventory control and/or accounting systems to allocate finished goods inventory accordingly.
 - Can be accessed by materials management systems to trigger the release of a rush shipment (improve on time shipment metrics).



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Storage of Company-Critical Information

“We are currently using Excel and, in some cases, Access, to store our test results. We even have several instances where we store test data in our SPC system. We understand that these are inadequate and irresponsible solutions to use as a data repository for company-critical data such as product test results.”

Solution

MAP QDMS is built on a Microsoft® SQL Server™ database, so all data within QDMS can be reliably backed up following your existing IT procedures for backing up enterprise databases. Perhaps more importantly, enterprise databases such as Microsoft SQL Server offer advanced disaster recovery capabilities.

Analysis and Reporting

“Getting data out of our current system for analysis and reports takes hours, sometimes days. Often, we have to manually enter product test results into Excel or Access in order to create reports our customers require. Eliminating this duplicate data entry will save a tremendous amount of time.”

Solution

Because MAP QDMS is built on an open-architecture SQL Server database, all data within QDMS is readily available using any ODBC-capable analysis and reporting tool. Additionally, MAP QDMS comes with a SQC module that is fully-integrated with NWA Quality Analyst™ to enable the quick generation of preformatted reports and to enable ad-hoc analysis using real time data (not data that is days or weeks old by the time it is assembled). It takes mere seconds to produce a full analysis of every lot of product “A” shipped to customer “XYZ” over the past year.

Enterprise Visibility

“Our lack of timely visibility into product quality problems causes increased scrap, increased product variability, increased cycle times, and lost production capacity. In addition to the direct costs of poor quality arising from these situations, there is an associated lost revenue opportunity.”

Solution

Given the proper security, QDMS enables users to see the status of any sample, in any plant, in real time. The QDMS SPC module enables managers and/or engineers to quickly perform virtually any analysis, including comparing the results of today’s production of product “A” in plant 1 versus the same product made today in plant 2.

Genealogy and Traceability

“We need the results of a test performed on work in process (WIP), made at a production step prior to the final step, to appear on the CoA. We don’t want to have to re-test the product again at the final step in order for all necessary test result to appear on the CoA.”



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“Our company’s inability to efficiently retrieve product data, with genealogy records, significantly increases our exposure to liabilities in a product recall situation.”

Solution

QDMS provides robust genealogy capabilities that track the lot numbers of materials consumed and produced at each step of the process. The lot numbers of consumed and produced materials can be manually entered directly into QDMS, scanned into QDMS (e.g. bar code), or acquired automatically from your MES/ERP. This traceability enables QDMS to produce finished goods CoAs that include test results from tests performed on semi-finished materials – even if the lot number of the finished material is different than the semi-finished material.

Automatic Data Collection from Lab Equipment

“The efficiency of our lab would improve if we could automatically collect data from the scales and other equipment in our lab.”

Solution

MAP QDMS can be connected to most lab equipment that has a serial output. This enables the automatic collection of data without needing to write the result on paper and/or manually enter results into QDMS. Additionally, QDMS plug-ins can be configured to communicate with more complex equipment such as an Instron™ communicating through GBIP.

Test Plan Management

“The efficiency of our lab would increase if the lab technicians did not have to look up in a hardcopy binder what tests need to be performed every time a sample comes into the lab. Increasing lab efficiency is important to us because it directly reduces production cycle time.”

Solution

When a sample is brought to the lab for testing, MAP QDMS tells the technician exactly what tests are required. The list of required tests is dependant on the product being made, the step in the process it originated from, and the customer for which it is being made.

Work Instruction Access

“The efficiency of our lab would increase if the lab technicians could access the work instruction for the applicable test method without having to go look it up in a hardcopy binder. Increasing lab efficiency is important to us because it directly reduces production cycle time.”

Solution

When a sample is brought to the lab for testing, MAP QDMS tells the technician exactly what tests need to be performed, and provides a hyperlink to open the applicable work instruction, in a view only format, from the controlled document library (or folder) on the network.

Sampling/Testing Frequencies



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“The tests that are required on a given sample are also dependant on the chronology of the sample. Will QDMS automatically adjust test plans based on the applicable sample frequency?”

Solution

MAP QDMS supports both time-based sampling and unit-based sampling, and tracks the chronology of each sample so that a different set of tests can be required based on the applicable frequency. For example, every unit of product “A” might require critical test “TM-052.” However, test “TM-733” might be required on only every third unit produced.

Certificates of Analysis - Creation

“Overhead costs allocated to CoA generation are excessive. A CoA may take as much as 30 minutes to create because we have to determine the genealogy, retrieve the applicable test results from the applicable WIP lots, and then manually enter them into a spreadsheet or Word document in order to print the CoA. Shipments are too often delayed while we wait for a CoA to be created. The manual production of CoAs also increases the chance of making errors, thus increasing our risk of customer complaints.”

Solution

MAP QDMS makes CoA generation a snap. If your CoA generation process is similar to the one described above, it is our experience that every person-hour spent generating CoAs will be reduced to 10 minutes or less with QDMS. Simply enter the product and lot number(s), check a box to identify the units being shipped, and hit the Create button. QDMS does the rest.

Certificates of Analysis – Content Management

“We have many customers that require us to put specific language on our CoAs. Sometimes, especially when we are in a hurry to release a shipment, we forget the special language and the result is a customer complaint. We are concerned that we will lose out on the opportunity for new business with existing customers due to these complaints.”

Solution

MAP QDMS also provides for true CoA content management by product, by customer, and even by customer ship-to address. Simply hit the Create button. QDMS does the rest, including placing any required customer-specific language on the CoA. Additionally, QDMS provides the CoA Clerk with any special instructions that pertain to the CoA, such as the fax numbers and/or email addresses to which to send the CoA.

Certificates of Analysis – Results Display

“We have customers that want us to summarize the results of the shipment by test, as opposed to supplying them with the result every single test that was performed.”

Solution

MAP QDMS provides two different options for displaying test results on the CoA: 1) Detail display, which shows every test result and the unit on which it was performed, and 2) Summary display, which shows the average and range of each test performed on X samples.



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Standardization

“When we produce product “A” at any plant in North America, we need to ensure that the same tests are performed, and that the same analyses and specifications appear on the CoA.”

Solution

QDMS allows test plans, specifications, and CoAs to be shared across the enterprise. In addition to making QDMS deployment faster and quality system management easier, this ensures that products are tested and certified to the same standards regardless of where they are made.

Customer and Product Information

“We already have systems to manage our customer information (names, addresses, etc.) and product information (product ID, description, etc.). We would like to continue to use our existing systems to manage this information.”

Solution

MAP QDMS connects to your existing MES/ERP system to obtain the necessary customer and product information. You will continue to use your existing systems to manage this information.

Ease of Use

“We have had a very difficult time getting the lab technicians to adopt to new technologies. Our previous attempts to implement LIMS systems in the lab have all failed to one degree or another. Because of these previous failures, the QDMS implementation project is in the spotlight.”

Solution

As a testament to QDMS ease of use, it should be noted that often times after training the lab technicians on the first shift, those technicians actually perform the training of the technicians incoming on the next shift. It’s that easy to use.

True story: After seeing QDMS for 30 seconds, a Lead Technician at one of our clients told us, “That will never work. This is going to be another waste of time and money.” The next day the same technician said to us, “I am sorry about my comments yesterday. We tried to implement systems like this in the past, and they were all just too hard to use. I thought that this was going to be just like the others. But, this (QDMS) is easy. It was clearly designed by someone who actually works in a lab. QDMS will truly make my job easier.”

Multi-Plant Deployment

“IT costs associated with maintenance of our current system at each plant, and overhead costs associated with maintaining quality system documents at each plant, are excessive.”

Solution



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Once test plans, specifications, and CoAs for product "A" are defined, they can be shared by all plants, and do not have to be re-created locally. This makes QDMS deployment faster, and reduces overhead costs associated with managing quality system documents related to product testing and certification.

Architecturally, many clients choose to locate the QDMS server at the corporate headquarters, and to provide plant access through the WAN/LAN. QDMS even supports terminal server access (a favorite deployment approach by many IT departments). QDMS is not an Internet-based product.

Implementation Timeline

"As part of the project justification, we are positioning QDMS as the solution to the ISO9000 nonconformancies that our company must address before our next audit. How long can we expect it to take to deploy QDMS?"

Solution

QDMS implementation can be broken into the following major steps:

1. QDMS installation and MES/ERP connectivity: 1-3 weeks
2. QDMS Administrator training: 2 days
3. QDMS configuration (tests, test methods, test plans, CoAs): 2-8 weeks
4. QDMS user training and dual-system pilot: 1 week
5. QDMS CoA training: 1 day
6. QDMS SPC training: 0.5 days w/o NWA QA training, 2 days with NWA QA training
7. QDMS single-system pilot: 1 week
8. QDMS launch

Duration is dependant on several things such as how many plants, how many products are made at each plant, how many tests are performed, and, most importantly, resources allocated to QDMS configuration (creation of the test plans). Often times, tests and test methods can be imported from existing systems, further shortening the deployment timeline. Deployment of QDMS to subsequent plants typically requires only 1-3 weeks.