

Upgrading Your DeltaV™ Validated System

This document describes how Emerson makes DeltaV upgrades easier and more reliable.

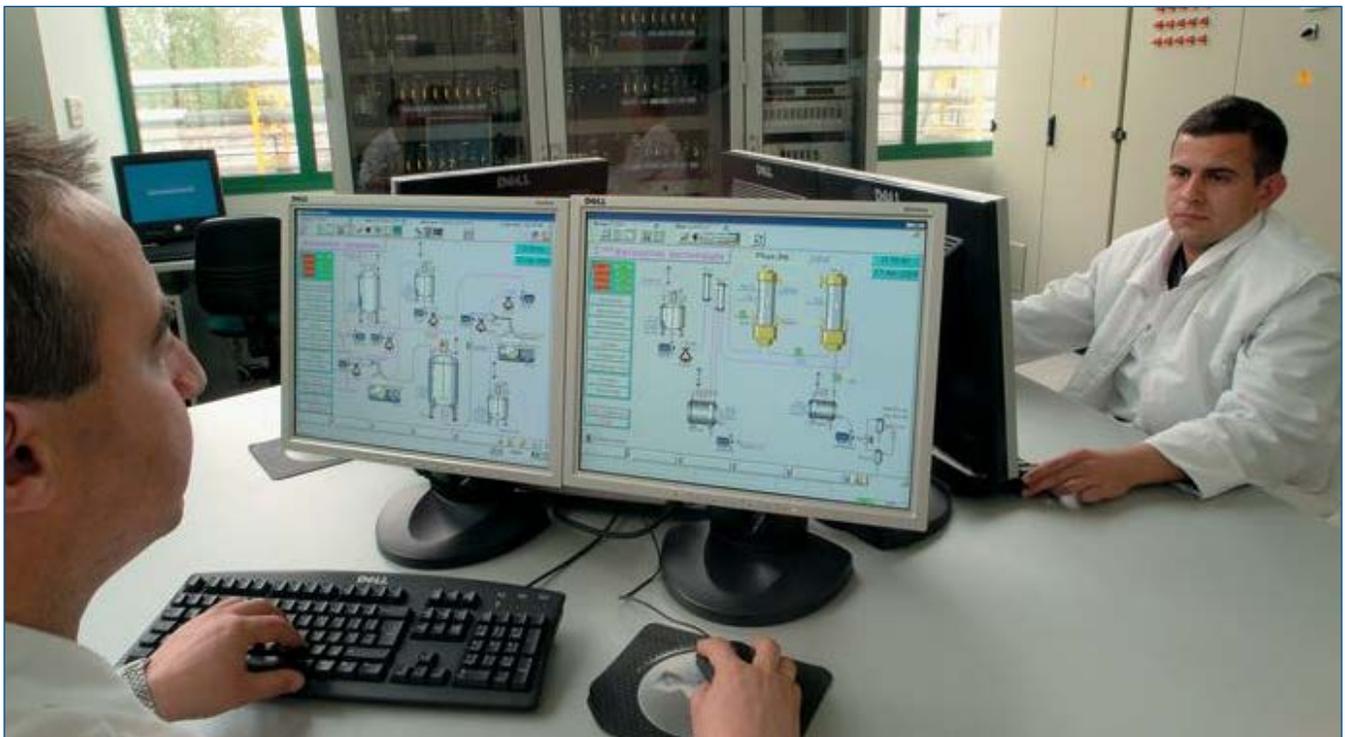


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Introduction

How do I upgrade my validated DeltaV system?

Does this sound familiar? Our clients frequently ask Emerson how to handle upgrades to their validated DeltaV systems. The answer depends on many factors including your company’s philosophy and policies, how the DeltaV system is used, and the specifics of the upgrade. In the software world, generally, an upgrade can be a risky proposition. The good news is that Emerson has taken steps to alleviate the risk and reduce the effort for you.

Overview of the DeltaV System and Validation

The DeltaV system is a digital process automation system with a proven track record in the FDA-regulated industries¹. It is an integrated system that includes an operator interface, continuous control, batch control, and historian in one system with one configuration database.

The DeltaV system itself is a commercial off-the-shelf (COTS) product. GAMP calls this Category 3, or “Non-Configured” software². Emerson is responsible for developing, testing, and evolving the product. When using a product like the DeltaV system in a validated environment, the client evaluates the functionality of the product to verify that it meets the requirements and qualifies the supplier.

The DeltaV system in your facility also includes custom application software configured specifically for your plant. Depending upon the level of customization GAMP calls this Category 4, “Configured”, or Category 5, “Custom”, software. For this application software, the team that develops your application should follow a Software Development Life Cycle (SDLC) such as GAMP and include testing of the custom configuration. The team should also be following good engineering practices such as those outlined in ASTM E25003.

The table below may help to illustrate the different parts of the system and their respective GAMP software categories.

GAMP Category	Examples
Category 1: Infrastructure	Microsoft Windows Explorer, SQL Server.
Category 3: Non-Configured	DeltaV Explorer, Control Studio, Recipe Studio, Function Blocks.
Category 4: Configured	Control and Equipment Module Instance, Phase Class Instance.
Category 5: Custom	Control and Equipment Module Classes, Phase Classes, Recipes, Custom Dynamos, Custom Displays, Soft Phases.

Commonly, validation of a new DeltaV system might involve:

- Evaluating DeltaV and qualifying Emerson as a supplier,
- Developing the configuration software following an SDLC such as GAMP,
- Commissioning and qualifying the system, and
- Maintaining the system in a validated state. Typically, the system is subject to change control and configuration management procedures.

¹As of September 2011, Emerson has a total installed base of over 9300 DeltaV systems, with more than 1300 of those being in the LSF (Life Sciences, Food & Beverage) industries.

²GAMP 5 – A Risk-Based Approach to Compliant GxP Computerized Systems, Good Automated Manufacturing Practice, ISPE 2008.

³ASTM E2500, American Society for Testing and Materials Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment, ASTM August 2007.

Just as with any other change after your system is validated, upgrading DeltaV hardware or software and migrating your configuration are subject to your company's change control and configuration management policies and procedures. It requires evaluating the impacts of the change. A formal risk analysis⁴ can help you decide upon the level of retesting required for the existing configuration software.

Emerson's Approach to Migration

Emerson's goal is to ensure that functionality and behavior are preserved from one release to another. With every release, Emerson provides a utility to migrate your existing DeltaV configuration. Emerson considers the migration tool an integral part of the DeltaV system and develops it using the same sound development practices, including extensive testing.

DeltaV Design and Implementation

Emerson defines product functionality in documents called direction statements, each of which includes a section for migration requirements. For each release, Emerson requires that your systems' existing functionality be preserved after upgrading. Implementation of migration functionality follows our standard development practices and is executed as part of the standard product development.

Additionally, starting with upgrades to DeltaV v10.3, systems with the Version Control and Audit Trail (VCAT) functionality enabled are automatically able to see which database objects versions were incremented solely as a result of an upgrade to the DeltaV system. This makes it easy to differentiate changes made by user configuration modifications versus those made as part of enhanced or new functionality in the DeltaV system itself.

DeltaV Testing

Test plans and test cases are developed for all features including migration. Migration upgrade testing is significant and integral portion of the overall release testing activities. This testing includes:

- Comparing system behavior before and after the migration,
- Comparing data consistency before and after the migration, and
- Ensuring correct behavior during the migration.

Prior to each release, Emerson executes a series of regression test cases to verify that configurations behave the same after migration as they did on previous releases. Emerson migrates and executes regression tests on copies of real customer configurations. These configurations come from a variety of industries and vary in size from small applications (hundreds of DSTs) to large applications (thousands of DSTs). These configurations come from batch systems, continuous systems, systems integrated with alliance products and systems that rely on external interfaces.

Finally, we test systems with customers and/or customer systems external to the test labs. This testing is performed to check wider varieties of implementations will behave correctly.

Releases and Release Notes

For each revision, Emerson provides release notes that describe new functionality, enhanced functionality, known issues, and resolved issues. By reviewing the release notes, you can evaluate the changes in the DeltaV system and analyze any potential impacts to your configuration. Often, there is little or no impact. Release Notes are available to you before you decide whether to upgrade.

⁴Several references are available on risk analysis including GAMP 5 – A Risk-Based Approach to Compliant GxP Computerized Systems, Good Automated Manufacturing Practice, ISPE 2008 – Appendix M3.

Evaluating the Revalidation Effort

If you are planning to upgrade your validated DeltaV system, recognize that your company has qualified Emerson as a trusted supplier of the DeltaV product. Emerson has developed and tested the tools for the upgrade and migration as an integral part of the DeltaV product. Remember to leverage the work that Emerson has done in order to minimize your revalidation efforts. Consider the following steps:

1. **Review the release notes:** The release notes define what has changed. If you are upgrading a system by more than one release, you will want to look at the release notes for each. Remember that you can get copies of the release notes prior to receiving your software.

2. **Perform a gap analysis for the changes between the current and the desired revision:** Determine whether any hardware changes are required. Evaluate how the new release will impact your configuration. Often, it has little or no effect.

If requested, Emerson can provide an analysis of your configuration and the potential impact of migrating to ensure that you didn't miss something from the release notes.

3. **Perform a risk analysis Evaluate the risks of the upgrade:** Remember that the DeltaV system including the migration utility is a commercial off-the-shelf (COTS), or GAMP category 3 non-configured product. Emerson has a sound development methodology that includes extensive testing of embedded software, such as the operating system, and testing of all features including the migration utility. Often, this type of product is considered lower-risk.

For custom, or GAMP category 5, software within the DeltaV configuration—such as graphics, control module classes, phase classes, and recipes—the DeltaV system migrates the software for you. The DeltaV release notes help you determine potential risk areas so that you can evaluate if, based on your company's philosophy, any revalidation effort is required.

For GAMP category 5 software outside of the DeltaV configuration—such as soft phases and custom interfaces—you should carefully examine the applications to determine possible impacts from DeltaV changes and/or operating system changes. Often, customers determine that custom applications such as these are higher-risk and may warrant more extensive retesting.

In summary, the revalidation effort will depend on the specific impacts to your configuration and on your company's policies.

Executing the Upgrade

As you execute the upgrade, remember to:

- **Involve all relevant stakeholders early in the process:** It is important to involve all relevant stakeholders (operations, quality, automation, management, etc.) in your upgrade process beginning with the planning phase. Understanding the expectations of those whose approvals will be required and getting their agreement with the process that will be followed at the beginning of the upgrade will help to avoid unnecessary delays and unexpected surprises during the actual upgrade.
- **Break it into steps:** Based on the risk analysis, determine any changes or testing that may be required. High-risk areas, such as custom interfaces with other systems, require more attention than low-risk areas. In some cases (for example, if you are not taking advantage of new functionality), you may determine that no retesting or revalidation is required.
- **Follow your company's software development lifecycle (SDLC):** If any new configuration is added to take advantage of new features, development must follow your SDLC. If you need to change existing configuration, follow your change management and configuration management procedures.
- **Perform the upgrade and migration on a "test" system:** Depending on the results of your risk analysis, you may want to try the upgrade and migration on an offline DeltaV system such as your development or training system. This approach may minimize the impact on your process by reducing testing on the live system. It can also provide a benchmark on the time required for the upgrade. If new hardware or computers are part of the upgrade, consider staging the new elements off-line to allow for testing and validation using them. This allows for quicker swapping out of the new hardware during the actual upgrade, minimizing down time and risk.

- Determine when the upgrade will occur. Knowing when your upgrade is and what the allowable duration for it may be enables the proper planning of the activities associated with your upgrade. Treat your upgrade as a project so that enough time is included for the planning phase. Proper planning is a key factor to ensuring a successful upgrade.
- Create a test plan (if required). Remember that the operating system, service packs, DeltaV product software and DeltaV configuration migration tools are all tested as part of the Emerson software development process and may be considered low-risk areas. Focus your resources on the high-risk areas that were identified in your risk analysis.
- Get help if you need it Emerson can provide assistance with planning and executing your upgrade. We have extensive industry experience and comprehensive service offerings to ensure that your migration is low-risk, complies with your company's change management procedures, and allows you to take advantage of the latest DeltaV platforms.

In summary, take advantage of the tools and services that Emerson provides to minimize your effort, and focus your resources on high-risk areas.

Upgrade and Migration Services

Emerson offers a wide range of services to assist with your upgrade including:

Project Management

- Low-risk, turnkey migration project management for the complete effort, from analyzing the issues/opportunities through completing Installation Qualification and Operation Qualification testing required in order to meet your change management requirements.
- Project Management Institute (PMI) certified and experienced project managers who follow Emerson's proven Common Project Execution management and implementation methodologies.
- Required resource analysis, acquisition, and management.
- Schedule planning assistance, creation, review and management, including online or "hot" cutovers to minimize or eliminate plant down time.
- Monitoring, control, and reporting of quality, cost, and schedule in order to minimize project implementation risk.

Planning

- Evaluation of the hardware and software upgrade requirements to go from the current release to the new release.
- Detailed roadmap indicating the migration prerequisites for floor space, wiring, hardware cutover, software upgrades, platform migrations, configuration migration, etc.
- Review of applicable technical Knowledge Base Articles from Emerson Process Management and DeltaV release notes for known issues, resolved issues, and new and enhanced functionality for all releases between your current revision and the targeted revision.
- Consultation regarding the newest features and enhancements contained in the new version of software.
- Consultation regarding data management and integration with existing or new third-party applications such as LIMS or ERP.
- Impacts of all proposed changes on test plans and test execution.
- Installation impacts on facility.

Execution

- Assistance writing and executing upgrade and test procedures.
- Migration and testing of the physical installation of the new hardware and the removal of older versions.
- Migration and testing of your configuration on a DeltaV system at Emerson, which can include:
 - Testing that existing functionality works on the new release,
 - Compatibility with and integration of existing and/or new third-party application, and
 - Testing of any desired modifications.
- Design, implementation, and testing of new configuration items to take advantage of added features.
- On-site upgrade and test support.
- Comprehensive commissioning and qualification testing execution.
- Comprehensive reporting of all work done and any issues addressed.

To learn how comprehensive SureService solutions can help to address your upgrade needs, contact your local Emerson sales office or representative or visit our web site at <http://www2.emerson.com/en-us/brands/sureservice/applicationservices/systemupgradeservice/pages/systemupgradeservice.aspx>.

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