

## 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.

## 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 industries<sup>1</sup>. 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" software<sup>2</sup>. 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 software configured specifically for your plant. For this software, the team that develops your application should follow a Software Development Life Cycle (SDLC) such as GAMP and include testing of the configuration. The team should also follow good engineering practices such as those outlined in ASTM E2500<sup>3</sup>. DeltaV users may categorize components of their configured software in terms of complexity and novelty, which may feed into risk assessment and mitigation approaches.

The DeltaV upgrade utility is developed and tested as part of the DeltaV product, so the utility can also be considered as Category 3. Usually, users will review the Release Notes, perform a risk assessment for the upgrade, and potentially do some retesting based on the assessment.

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 analysis<sup>4</sup> can help you decide upon the level of retesting required for the existing configuration software.

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<sup>1</sup> Emerson has a total installed base of over 14,000 DeltaV systems, with more than 1700 of those being in the LSF (Life Sciences, Food & Beverage) industries.

<sup>2</sup> GAMP 5 – A Risk-Based Approach to Compliant GxP Computerized Systems, Good Automated Manufacturing Practice, Second Edition, ISPE 2022.

<sup>3</sup> ASTM E2500, American Society for Testing and Materials Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment, ASTM 2012.

<sup>4</sup> Computer Software Assurance for Production and Quality System Software, Draft Guidance for Industry and Food and Drug Administration Staff, US Food & Drug Administration, September 22, 2022.

## 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

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.

Systems with the Version Control and Audit Trail (VCAT) functionality enabled have the ability 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 in the DeltaV system itself.

### DeltaV Product Testing

Test plans and test cases are developed for all DeltaV features including migration. Testing of the migration upgrade functionality is a 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.

In addition, DeltaV Knowledge Base Articles (KBAs) can be considered since they may drive decisions about changes and retesting. By engaging Emerson to assist with an upgrade, you can benefit from Emerson's KBA Analysis Tool to maximize the efficiency of the search.

## 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. In addition, DeltaV Knowledge Base Articles (KBAs) may provide helpful information.

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 and 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 configured software—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 other 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. Sometimes, 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, which could include 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 certified engineers, trained on standard tools and internal processes, 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 evaluation, preparation and execution<sup>5</sup>. Using an experienced partner like Emerson to assist with upgrades can minimize risk and reduce engineering and cut-over time. In addition, by engaging Emerson, you can benefit from a standard approach with access to Emerson best practices and shared knowledge and from Emerson tools including the KBA Analysis Tool to optimize the search of KBAs and Test Studio to help standardize and align test execution requirements to customers' requirements.

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<sup>5</sup> <https://www.emerson.com/documents/automation/service-data-sheet-deltav-upgrade-service-en-67694.pdf>

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