



Auditing Practices within the DeltaV System

This whitepaper discusses DeltaV system auditing practices by regulated industries.



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Introduction

The FDA requires that Emerson Process Management and all other companies selling products and services to the food and pharmaceutical industries pass extensive evaluations by our customers before being considered as a vendor. Because of this, several of our pharmaceutical customers have audited the DeltaV development process. The auditors have delved into the details of the DeltaV development process to verify that Emerson Process Management follows a sound development methodology and that quality is built into the DeltaV system. These audits have covered every aspect of the development process, including management of the Systems Division quality program, software and hardware design, implementation, and testing standards and procedures, change control and configuration management, pipeline, software quality metrics, disaster/contingency planning, release control and training.

Audit Update

All audits of the DeltaV development process to date have been very successful. As expected in any audit, there have been minor findings; however, in each case the auditors indicated that they were impressed with the DeltaV development process and the development team. Comments have included, “overall we were very pleased”, and “this has been one of our most pleasant audit experiences.”

Emerson Process Management has a track record of proven validatable products for applications regulated by the FDA’s Good Manufacturing Practices (GMPs). Emerson Process Management takes great pride in the outstanding quality of these products. Like the processes for Provox and RS3, the DeltaV development process is registered to ISO-9001, a recognized standard for quality management systems. The DeltaV system, with its “built-for-batch” architecture, powerful functionality, and easy, cost effective engineering and operator interfaces is gaining widespread acceptance in the food and pharmaceutical industries.

Furthermore, Emerson Process Management believes that end users and vendors should continue to work together to improve the ways regulatory requirements are met while allowing each to focus on core businesses. To demonstrate our commitment to this relationship Emerson Process Management was the only control system vendor Field Test Site in March of 1999 for the Parental Drug Association (PDA) Supplier Auditing Task Force. The PDA task force, composed of representatives from major pharmaceutical manufacturers, is chartered to develop an industry standard audit process and a common repository of audit reports that is widely accessible to end-users in regulated industries. Another task force goal is to alleviate the auditing burden for both pharmaceutical and computer system manufacturers.



Available Documentation

If you are a GMP regulated customer who needs to qualify Emerson as a vendor, the following documentation is available to you:

- Systems Division Company Background
- ISO9001 Certificate
- Systems Division Quality Manual
- Emerson Annual Report

If your company requires an audit of the DeltaV development process, please contact your local representative to begin scheduling a visit to our site in Austin.