



**Good Automated
Manufacturing Practice
(GAMP[®])**

Compliance Guide

Overview

In February of 2008, the International Society for Pharmaceutical Engineering (ISPE) published a set of guidelines for manufacturers and users of automated systems in the pharmaceutical industry called "The Good Automated Manufacturing Practice Guide for Validation of Automated Systems in Pharmaceutical Manufacture (GAMP® 5)."

According to ISPE, the focus of GAMP® 5 is to "provide a cost effective framework of good practice to ensure that computerized systems are fit for intended use and compliant with applicable regulations."

GAMP® 5 divides automated system software components into five categories. Each of these categories relates to evaluating specific aspects of automated systems.

Datalogic's machine vision system can be used to provide automated control of production and quality inspection systems. This document will explain how the machine vision system's program development software capabilities relate to the applicable GAMP categories.

Impact Software

Datalogic's vision program development software (Impact Software) consists of two main modules, Vision Program Manager (VPM) and Control Panel Manager (CPM). For Datalogic's smart cameras, these modules run on a personal computer (client) which is networked with the cameras. On the M-Series system, the software modules run on the M-Series processor (client) which is connected through a local network to the cameras.

VPM, the user interface, resides in and runs only on the client computer. It is used to create and maintain vision programs. Authorized users drag-and-drop the inspection tools to create the desired inspection. One of the tools (the Basic tool) also allows custom programming. The vision programs reside in and control the hardware. Once a vision program is complete and running on the hardware, the VPM user interface is required to run only when making changes to the vision program.

CPM is used to create user-designed control panels which provide a human-machine interface that displays inspection data and allows an operator to adjust parameters and settings in vision programs. Two of the controls (the Basic and Scriptor controls) also allow custom programming. Control panels connect to one or more cameras but reside in and run only on the client computer. The host to client connection can be one-to-many or many-to-one. That is, a single control panel can connect to multiple hosts and multiple control panels can connect to a single host.

GAMP 5 Categories

The guidelines in categories four and five apply to programming capabilities within VPM and CPM.

Category 4: Configured Products

- Configured products provide standard interfaces and functions that enable configuration of the application to meet user-specified business processes.
- Configuration using a vendor-supplied scripting language should be handled as custom components (Category 5).

VPM and CPM both provide standard graphical drag-and-drop technology to create the inspection or user-interface application. All except three of the tools and controls have a specific set of configurable functions and properties. Inspection applications using these standard tools are covered under Category 4.

Category 5: Custom Applications

- These applications are developed to meet the specific needs of the regulated company.

- Implicitly includes internal application macros, LIMS language customizations, VBA spreadsheet macros.

Since the Basic tool in VPM, and the Basic and Scriptor controls in CPM, use an internal scripting language, inspection applications containing these tools or controls are treated as custom components and are covered under Category 5.

Validation

It is important to remember that any changes to inspection and control systems must be validated to insure that they conform to the applicable regulation. GAMP 5 requires validation if there could be an impact on patient safety, product quality, or data integrity.