Systech PIMs:
A Powerful Way to Jumpstart Your GAMP 5 Documentation Needs

When deploying a new or upgraded pharmaceutical packaging solution, drug manufacturers and CMOs must conform to the regulatory requirements of the markets they serve. The regulatory agencies of the major markets of the world, and many others that are smaller markets, require adherence to Good Automated Manufacturing Practice (GAMP). GAMP is a set of guidelines published by the International Society for Pharmaceutical Engineering (ISPE) for users and designers of automation systems in the pharmaceutical industry aimed at ensuring pharmaceutical products have the required quality. Pharmaceutical serialization solutions are components with the larger pharmaceutical packaging automation systems so following GAMP guidance is essential.

Systech solutions are classified within GAMP 5 as "Category 4, Configured Products." That classification establishes the level of documentation and testing rigor necessary when system changes are made. Configurable serialization software is designed with elements that can be assembled and realigned to quickly accommodate changing demands. In contrast, customized solutions are rigid, making them difficult and costly to modify. When requirements change with customized solutions, it will be necessary to reengage vendors and incur expensive rewrite, revalidation, and re-training costs.

Utilizing our patented Item Process Stream (IPS) Engine technology, Systech solutions enable rapid and consistent deployments by "productizing" solution standards across a wide range of packaging use cases. Standardized solutions allow us to offer standardized documentation packages, which maximizes deployment ease and repeatability. This approach is also advantageous when considering long-term maintenance, upgrade and support.

Packaging Integration Modules (PIMs)

Systech has developed a library of prepackaged modules that meet a wide array of packaging scenarios and serialization requirements. These Packaging Integration Modules (PIMs) can be added to the core solution to meet the requirement of a particular, packaging line. Systech PIMs are a powerful way to jumpstart your GAMP 5 documentation needs. Each module can be stand-alone or added with other modules, allowing clients to design and build a solution for now and expandable over time. Modules can be reused across multiple deployments to minimize risks, cost, and downtime.

Example of PIM modules supporting multiple markets:
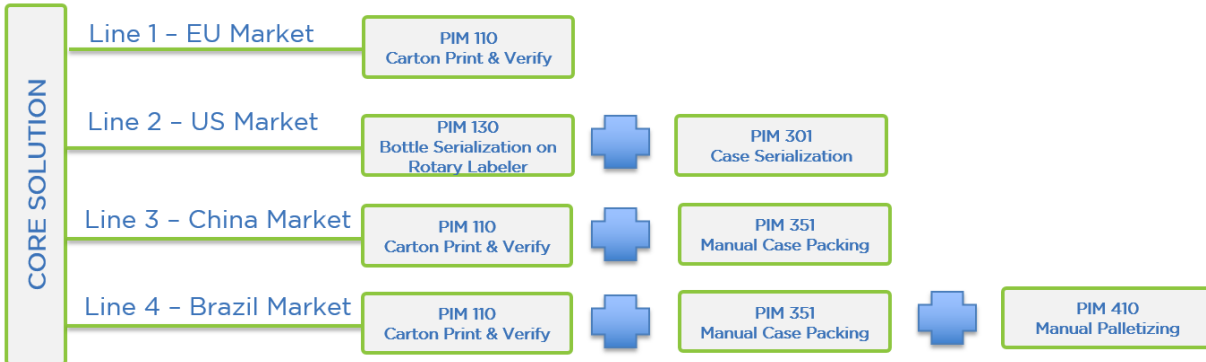
A comprehensive deliverable package that defines the design, configuration, and testing of the serialization solution is provided for each packaging line. The standard deliverable package includes:

Core Line Detail Design Specification	Serves as the functional specification for the core line serialization solution. Describes the line architecture, start/end packaging lot processes, suspend/resume packaging lot processes, QA and in-lot rework operations, audit log, reports, archives, and security.
Core Line Configuration Specification	Describes how the core line serialization solution is configured. Includes class and product configuration.
Core Line Validation Specification	IOQ test protocols for the functions and configuration of the core line serialization solution assists clients with their validation process.
PIM Design & Interface Specification	Serves as the functional specification for the module. Describes the detailed functions of the module and how to interface to it. Includes process flows, station descriptions, exception handling, timing diagrams, I/O assignments, signal descriptions, device communication, alarms, and counters.
PIM Configuration Specification	Describes how the PIM is configured. Includes printer driver configuration, vision tool configuration, PLC tag configuration, and IPS Engine configuration details.
PIM Validation Specification	IOQ test protocols for the functions and configuration of the PIM assist clients with their validation process.
Connection Drawings	Provides the OEM with information on how to wire the Systech components.
Hardware Drawings	Provides the OEM with information on how to mount Systech components and panels.
Vision Integration Module	Provides the OEM with information on how to mount the camera and lighting for each vision station.

Systech's documentation packages are aligned with the V-Model lifecycle for GAMP 5, Category 4 Configured Products. Documentation packages are modular and delivered for each product in the Systech product stack.

For UniTrace and UniSight Guardian deployments, Systech delivers a Detailed Design Specification (DDS) document that represents the contents of both the Functional Specification and Configuration Specification in the V-Model lifecycle. A Validation Specification document is also delivered, which represents the Installation Qualification (IQ) and Operational Qualification (OQ) in the V-Model lifecycle.

For line level deployments, Systech delivers a core documentation package and a documentation package for each PIM deployed on the packaging line. The core documentation package is focused around the core functions of the serialization system. It includes a Core Line DDS which represents the Functional Specification, a Core Line Configuration Specification, and a suite of Validation Specification documents that represent the IQ and OQ in the V-Model lifecycle.

For each PIM, Systech delivers a Design & Interface Specification (D&I Spec) which serves as the Functional Specification, a Configuration Specification, and Validation Specification that represents the IQ and OQ in the V-Model lifecycle. The scope of a PIM documentation package is limited to the functions performed within the respective PIM.

PIMs are just one of the ways Systech helps to jumpstart GAMP 5 validation requirements. Contact us for a complete explanation of the ways a Systech solution can fill all your needs.