

SYSTECH SIMPLICITY Configurable Software Explained

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Introduction

Systech has developed products for the pharmaceutical, medical device, healthcare and other industries for more than three decades. Productized, configurable and expandable packaging technology has been a key asset in helping clients successfully implement solutions to meet the changing market requirements, compliance regulations and a broad range of packaging environment challenges.

Systech has gone through the work of taking its experience with hundreds of customers and thousands of line implementations and putting it into a repeatable methodology for the myriad of environments encountered. This paper explains the documentation packages that are included with Systech's products and how the packages are aligned with the Good Automated Manufacturing Practice (GAMP) V-Model.

Configurable, Not Custom

Systech produces "off-the-shelf", configurable product that does not rely on customized or made-to-order components, and is considered a GAMP 5, Category 4 Configured Product. The benefits of deploying configurable rather than customized software are well documented. These benefits are accentuated in environments where the required functionality of this software is subject to change. 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.



Figure 1: Lifecycle for GAMP 5 Category 4 Configured Products

Design and build a solution for now that is expandable over time.





Proven Model - Modular Approach

Utilizing our patented Item Process Stream (IPS) Engine technology, Systech enables rapid and consistent deployments by productizing solution standards across common packaging use cases. By offering standardized solutions and documentation packages, deployment ease and repeatability are maximized. This approach is also advantageous when considering long-term maintenance, upgrade and support.

Systech's solutions are based on a modular approach. Each deployment contains a core set of functions used for serialization, independent of the packaging line. These functions include but are not limited to:

- **Rework Operations** Manual rework operations to build new parents, repack children, remove children, add children, etc.
- **Reports** A reporting engine to view historical batch and serialization data. Reports can be viewed on the HMI, printed or saved/exported in multiple different formats such as PDF.
- **Master Data Download** Allows you to leverage the master data contained in the ERP system to add new products into the Systech system.
- **Packaging Work Order Download** Allows you to leverage packaging work orders contained in the ERP system to manage work released into the Systech system.
- **Suspend/Resume** Allows you to suspend a running batch on the packaging line and resume it at a future time.

Systech has developed a library of prepackaged modules to meet a wide array of packaging scenarios and serialization requirements. These Packaging Integration Modules (PIMs) can then be added to the core solution to meet the requirements of the packaging line. Each module can be standalone or added with other modules allowing clients to design and build a solution for now that is expandable over time. Modules can be reused across multiple deployments to minimize risks, costs and downtime.

Solutions Library

The Systech Solutions Library supports over 250 serialization workflows on various types of packaging operations across the unit, bundle, case and pallet levels. Utilizing the Systech solution library has several advantages as clients are provided with a solution that is:

- **Proven** Each packaging module is pre-designed based on Systech's best practices to provide clients with stable and proven solutions.
- **Efficient** Packaging Modules enable speedy and efficient deployments through the use of document templates.
- **Consistent** Pre-built configurations enforce consistency across global deployments and support global scalability.
- Compliant Pre-written test protocols assist clients in Installation/Operation Qualification (IOQ) efforts during initial implementation or upgrades to meet industry regulations and standards.
- **Traceable** Our requirements traceability matrix demonstrates proof that test scripts address all areas defined in design/configuration specifications and assists in impact assessment for upgrades.

Contents of a PIM Standards Package

Each PIM standards package provides pre-built documentation and configuration templates that are utilized by Systech and our partners to create the documentation package and configuration for the specifics of the deployment. These include:

Solution Summary	A catalog of solution summaries is available that describes the functionality of the PIM, available options and the hardware required. This is intended to be used during the sales phase.
Design & Interface Specification	Serves as the functional specification for the PIM. 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.
Configuration Specification	Describes how the PIM is configured. Includes printer driver configuration, vision tool configuration, PLC tag configuration and IPS Engine configuration details.
Connection Drawings	Provides the OEM with information on how to wire the components of the PIM.
Station Design Drawings	Provides the OEM with information on how to mount the camera and lighting for each vision station.
How To Implementation Guides	Provides guidance and a work instruction to Systech engineers and partners on how to put the configuration components together in a consistent and proper method.
Validation Specification	IOQ protocols assist clients with their validation process.
Requirements Traceability Matrix	Provides traceability from Systech requirements to Design/Configuration specifications to IOQ protocols.



Figure 3: Mapping of Systech Requirements to Design/Config Spec's to IOQ Protocols

Global Requirements Traceability Matrix

A Global Requirements Traceability Matrix (RTM) has been added as a new product offering for the PIM library. The Global RTM is a single, "off-the-shelf" document that maps Systech requirements through the design specifications, configuration specifications and IOQ protocols for each solution in the PIM library.

The Global RTM provides the client with several benefits:

- Provides clarity and visibility throughout the Systech documentation package.
- Demonstrates proof that the IOQ protocols are addressing all areas defined in the design and configuration specifications.
- Assists in impact analysis during software upgrades.

How the Systech Documentation Package Fits into the V-Model

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 and 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.



Figure 4: Systech Documentation Alignment to V-Model (Line Level Example)

Figure 4 provides an illustration of how the Systech documentation aligns with the V-Model at the line level. The items highlighted in gray indicate a Systech deliverable. The items highlighted in green indicate a client responsibility. Client responsibilities would include developing a User Requirements Specification (URS) and mapping those requirements to the Systech requirements defined in the Systech RTM. In addition, the client would be responsible for developing a Performance Qualification (PQ) protocol as well as mapping it to the requirements of the URS.

Validation

Systech assists in the client's validation process by delivering Installation and Operational Qualification (IOQ) protocols. Clients are responsible for executing the IOQ protocols. Clients can execute the IOQ protocols as-is, but often leverage the Systech protocols into their broader validation plan. Although Systech staff does not execute or approve IOQ testing, they are available onsite to assist our clients with answering questions and providing operational training.

Systech does not deliver Performance Qualification (PQ) protocols as this testing involves qualifying the system within the client's standard operation procedures (SOPs).

How to Use the Global Requirements Traceability Matrix

The use of the Global RTM is optional. It is designed to be used for:

- Clients who do not have a URS. In this scenario, the clients can leverage the Systech requirements as the basis for creation of their user requirements related to the serialization system. This serves as a subset of the overall client URS, which would be the responsibility of the client to produce.
- Clients who have a URS and want to reduce their effort in producing a traceability matrix. In this scenario, the client would reduce their effort in producing a traceability matrix by just performing a one-time mapping of their URS requirements to the Systech requirements.

Since this is an "off-the-shelf" document, mapping the Systech requirements in the Systech Global RTM to requirements in a client specific URS is not within the scope. The Systech requirements can be provided upfront so clients can perform a one-time mapping of their URS requirements to the Systech requirements in the Global RTM. Once a client has performed this one-time mapping, the Systech RTM can be accepted on all future projects.

Summary

This paper has defined both Systech's documentation packages and how they align with the GAMP V-Model. Through direct feedback from our clients, we continue to provide products and services that assist our customers in meeting their packaging and regulatory needs in the simplest, most cost-effective quality manner. We encourage our clients to provide direct feedback on any topics contained in this document.



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