Process-Oriented SAP® Validation with Integrated Risk Assessment

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ABSTRACT

For the pharmaceutical industry, process-oriented SAP validation with integrated risk assessment is an important topic. SAP validation assures an SAP system is implemented exactly as planned. Risks concerning product quality, patient safety and data security must be identified and reduced or eliminated. This corresponds to the GAMP 5 goal of “a risk-based approach to compliant GxP computerized systems.” Some of the major innovations in GAMP® 5 include:

- Integration of the process view
- Increased integration of risk assessment
- More involvement of suppliers

Of course, GAMP 4 included these items as well, but they have gained greater importance in GAMP 5.

The business process view and risk management in particular are key factors in the introduction of an SAP system. In this respect, it is useful to integrate the SAP implementation methodology with validation requirements.

In concrete terms, this means analyzing the processes, including their GxP risks and then taking a risk-based approach to the project execution rather than looking at the software and its individual functions as a starting point. From a validation point of view, GxP risks are at the forefront in risk management. From an overall project view, it makes sense to assess business risks and such elements as SOX requirements in equal measure.

With regard to a higher integration of suppliers, it is advisable to use the tools that are provided by the supplier to enhance the quality of a system implementation. Three tools can be used for process-oriented SAP validation: ARIS Design Platform, SAP Solution Manager and HP Quality Center.

ARIS integrates risk management and supports the analysis and optimization of existing business processes and the definition of the target business processes.

The well-respected SAP Solution Manager is known for supporting the implementation of SAP systems through the defined method. At the same time, its use enhances quality and reduces implementation time.

Two tools can be used to implement the test strategy. Testing can be supported by the SAP Solution Manager’s functionality alone, or HP Quality Center can be integrated as well. This provides an additional level of detail in defining the test specifications, along with enhanced analysis options.

In this white paper, you will learn more about using these tools together and taking a process-oriented approach to SAP validation with integrated risk assessment. In addition IDS Scheer Consulting offers Pharma.PerformanceREADY, the first consistently process-oriented turn-key solution based on preset SAP best-practice processes, enabling rapid and cost-effective SAP implementation and continuous optimization for companies in the pharmaceuticals industry. Pharma.PerformanceREADY also uses the process-oriented methodology for SAP validation described in this white paper.

A consistent approach to project and validation methodology that integrates suppliers is the way to achieve the greatest level of efficiency during validation.
In a process-oriented validation, ARIS and its integrated methodology directly and sustainably support many validation phases. At the same time, a change control management for the complete life cycle is implemented.

**FULLY INTEGRATING THE V-MODEL INTO PROJECT PROCEDURES**

Efficient validation during SAP implementation requires that validation activities will be integrated as much as possible into normal project processing. Ultimately, this is also one of the objectives of GAMP 5. Unfortunately, this important aspect is often overlooked and instead validation projects are set up separate from the implementation project.

The better the project model is integrated with the validation model, the more efficient the validation is. This means planning validation requirements into each phase of the project and integrating them into the project methodology. This is described in concrete terms for each phase in the following sections.
SPECIFICATION PHASE: PROCESS MODELING AND RISK CLASSIFICATION

In process-oriented SAP implementation, it is absolutely essential that process owners, key users and system implementers agree on the planned target processes. After all, these are the user requirements, i.e., the requirements the process owners really need.

In this respect, the first step is to record all the scenarios that are relevant to the company in a company-wide process map. They are usually grouped into management processes, core processes and support processes. The next step is detailed step-by-step analysis and definition of the individual processes. Represented graphically, it looks like Figure 2.

The blueprints and the risk analysis can be automatically generated from the business process models.

The results of the blueprint workshops (specification phase), the target processes are described in detail and the functional processes, roles and responsibilities, and system mapping are defined. The foundation of traceability is laid in this phase by implementing a tracing number for each scenario and process. The existing GxP requirements or GxP risks must be considered when target processes are recorded. They should be mapped, for example, with corresponding reference to the requirements of the EU GMP guide. Integrating the GxP risks into the specification phase is an essential requirement of the risk-based approach. The risks covered by the SAP system and by organizational measures are made transparent.

The results of the blueprint workshops are in ARIS defined target process containing all the information from which the necessary user requirement specifications arise. Thus, the URS documents can be created directly (and fully automatically) from the process definitions.
A huge advantage to this approach is the close interaction of project targets and process definitions with simultaneous consideration of the risks. The URS and risk classifications needed for validations fall away automatically.

**RISK MANAGEMENT**

From a validation perspective, GxP risks are the most relevant when it comes to allocating risks. From a business perspective, it is important to consider business risks and/or SOX risks as well. Doing this it is advised to use the basic regulatory requirements.

![GMP requirements catalogue](image)

![Figure 4: Requirement catalogs based on the regulations](image)

A first risk classification of the business processes will be done during the blueprint phase when analyzing if and which risks exist. Afterwards, during additional risk analysis workshops, the appropriate measures of risk mitigation will be will be defined.
The result of the analysis of GxP risks and the measures identified to minimize risk (e.g., increased need for testing, organizational solution, no significant risk, etc.) affect the depth of later testing. This process-related view generates a unique reference to the respective process activity and the assigned technical functionality. It is automatically synchronized into the test plan for subsequent tests, as described in the next section.

The risk analysis for business risks (or SOX requirements) results in appropriate controls that must be implemented later in the processes and provide continuous risk reduction.

INTEGRATION OF BUSINESS PROCESSES IN SAP SOLUTION MANAGER

After the required target processes are determined, they are stored in the same structure in SAP Solution Manager. Synchronization between ARIS and SAP Solution Manager makes the work easier and ensures consistency between the requirements (defined in ARIS) and mapping in the system (transactions in the SAP Solution Manager).
The important thing is that the SAP Solution Manager is able to support the entire development and verification process on this basis. Here’s how:

**Document storage**
SAP Solution Manager comes with document management capabilities. Documents can either be incorporated directly into SAP Knowledge Warehouse or simply referenced via a link to another document management system (e.g., SAP DMS). Metadata is used to assign various statuses to the files. Documents can be signed electronically, although the functionality is somewhat limited (in contrast, for example, to SAP DMS). In any case, it can be used to store the specification documents (URS including risk classification, functional specifications, risk analyses and development specifications) securely and in a process-oriented manner. This ensures traceability.

**Configuration and development**
Because of the defined processes and the functional specifications generated, customizing takes place during the implementation phase. For regulatory reasons it won’t do to say, “You can just look it up in the system whenever you want.” But also from a qualitative point of view, it makes sense to document which processes and process steps have been customized. SAP Solution Manager supports this phase of the project as well. Depending on the affected process or process step, you can simultaneously customize and document the customization at the process level or process-step level. Customizing can take place automatically and be furnished with notes or comments.

**Training sessions**
Finally, process-related training sessions can be stored in SAP Solution Manager to ensure consistent documentation.

**TESTING IN SAP SOLUTION MANAGER**
The largest and most important part of the validation expenses occurs apart from the specification phase in the test phase (verification phase). They mainly consist of functional testing and integration testing (user acceptance testing).

The functional tests check each individual function within a process. Every possible variant (within the process) is to be tested for each function. The functional tests, including their reference to risk analysis, are stored accordingly, in a process-oriented way. The test scenarios and test cases (each type or phase, and function or process) can be stored in SAP Solution Manager and standardized for subsequent rollouts or the change-control process.
Test plans with corresponding test packages are created in Solution Manager to conduct tests. Using them supports test management for monitoring and progress monitoring, as well as traceability of functional requirements, from risk assessment to the performed test.

In an integration test, the focus is on the integrative aspect across multiple processes. End-to-end scenarios help with this. These scenarios describe the essential business processes across multiple processes. An example would be the contract-to-cash process, which can include such processes as “create and confirm sales order,” “pharmaceutical production,” “shipping,” and “invoicing and payment.” Ultimately, these end-to-end scenarios reflect user requirements from a validation point of view, which must be tested at the top level of the V-model (user-acceptance tests) during the verification phase. The integration tests are seen as the most important tests from the SAP implementation view. They conclusively test the overall interplay of the various processes and the different SAP modules. Furthermore, they show how the new processes optimize the overall process.

ARIS Test Designer supports the definition of the test sequences during integration tests visually and methodologically. The path to be followed is simply marked in Test Designer, and the corresponding processes are synchronized in SAP Solution Manager (or alternatively in HP Quality Center).

The end-to-end scenarios and the resulting integration tests are the most important methods to demonstrate to future users of the system the full integration of the modules and data flows. This requires a high degree of transparency like that offered by ARIS Test Designer.

The test scenarios and test cases (each type or phase, and function or process) are stored in Solution Manager as individual test plans with various test packages. Standardizing these scenarios and the tests defined for them is recommended for subsequent roll outs or the change control process.

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The clear risk-based test strategy, supported by modern tools, leads to optimal results.
OPTIONAL: USE OF HP QUALITY CENTER AS A TESTING TOOL

Optionally, HP Quality Center can be used as additional support for testing activities. It offers additional opportunities to store detailed test specifications, perform test analyses and repeat tests in different variants if necessary. Complete defect handling is also integrated, allowing workflows to be used to correct errors or follow up a change request. This offers tremendous advantages in projects, keeping track of heterogeneous test teams and supporting testing activities. The defined process structure can be synchronized between Solution Manager and HP Quality Center to ensure traceability and a uniform look.

Figure 9: Synchronizing SAP Solution Manager with HP Quality Center

QUALIFICATION OF THE SUPPORTING TOOLS

By using the tools ARIS, SAP Solution Manager and HP Quality Center as described in the previous chapters, the following activities are supported:

- Definition of URS, functional specifications and risk assessment
- Methodological support of SAP implementation
- Support of risk analysis and if necessary allocating and monitoring the controls
- Document storage
- Automatic generation of documentation (customizing documentation)
- Support for testing activities
- Traceability

Thus, these tools are also relevant to quality. For many projects, this is considered to be too high of an investment. But in a risk-based approach, the qualification need not take place to the same degree as validation of the SAP system, because the tools for implementation and validation in turn are one more level away from the qualitative impact on the pharmaceutical end products. They strongly influence the development process, but ultimately they have only an indirect impact on the traditional risks to safety and quality posed by pharmaceutical products. In this respect, qualifications should be carried out, but only at reasonable expense. Carrying out a qualification results in a formal documentation as well as in an improved usage of the supporting tools. This requires conducting the normal qualification phases (similar to the V-model), beginning with a short user requirement specification or intended use and including risk assessment, customizing documentation that refers (only) to URS requirements as well as appropriate tests for the critical settings. In this process, focusing on the key technical issues arising from a good risk analysis is worthwhile.
FULLY INTEGRATED V-MODEL

The project and validation phases show us that the original GAMP 5 V-model has resulted in a model that is fully integrated into the implementation project. The process-oriented methodology is operative throughout the entire “upper section” of the V-model. The support provided by SAP Solution Manager comes somewhat later, supporting of course the more technical phases of customizing. This fully integrates the V-model into the standard implementation methodology.

Figure 10: Support by ARIS and SAP Solution Manager process methodology

REFERENCES

- SAP: Einhaltung der US FDA Verordnung Title 21 CFR PART 11 für die Life Science Industrie [Complying with US FDA Title 21 CFR Part 11 for the life sciences industry], SAP AG, 2005
- APV: Empfehlung zur elektronischen Signatur [Electronic signature recommendation], APV News 04/2007
- GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems, February 2008
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