



SUCCESS STORY:

Nordmark Pharma GmbH

SAP S/4HANA migration with
GxP-compliant validation



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Initial Situation

With the end of maintenance for SAP ECC, Nordmark Pharma GmbH faced the move to SAP S/4HANA. This brought the requirement to create a foundation for future innovation and to make the potential of the new SAP generation usable. Building on an existing validation, the CSV methodology was systematically and fundamentally modernized in the project and re-established for the S/4HANA target architecture.

Until then, responsibility for requirements and specifications had rested centrally with IT. As part of the project, responsibility for validation documentation was transferred to the respective business departments as process owners. The project therefore went well beyond a technical migration: it included a complete rebuild of Nordmark's CSV documentation, based on a risk-based validation approach that focused specifically on GxP-relevant business processes and requirements.



Project Goals & Expectations

Nordmark pursued a brownfield approach: proven processes from the legacy system were to be retained, and new developments were used selectively where they offered a clear added value. For validation, this meant no classic data migration, but a structured re-documentation of the existing, GxP-relevant process landscape.

„The close and trusting collaboration with DHC helped us not only to complete the project successfully, but also to significantly mature as an organization in the area of CSV.“

Stefanie Hölscher, Project Manager, Nordmark Pharma GmbH





Solution Approach & Technologies Used

The central steering instrument of the project was the Digital Process Landscape (DPL), which systematically captured all 16 business processes and 138 detailed processes and documented the clear GxP assessment of each process. Across all project phases, the DPL formed the binding basis for a risk-based, redundancy-free validation, which significantly reduced the validation effort.

To enable the business departments in the validation context, DHC developed a project-specific CSV/validation training based on real project examples (including along the document chain from URS to FS). Support did not end with the training but continued throughout the entire project.

A particular challenge was the authorization concept: responsibility lies with the individual business areas in a decentralized way, while validation requires central, consistent documentation. This interface was clarified and documented carefully in the project. For each process, it was also defined individually where an audit trail is required and where SAP's own logging is sufficient.



Project Progress & Collaboration

With the project start, the project team grew significantly: a previously IT-centered structure became a broader, business-department-driven team. This change meant additional effort for the departments in their day-to-day work. During the testing phase, it became clear that the business departments carried the new processes independently.

The URS creation was initially planned as a tech-writing service.

In practice, reliable requirements first required additional coordination with the business departments, as they had to familiarize themselves gradually with the new system capabilities. **DHC adjusted the approach pragmatically and ran additional URS workshops**, creating a consistent and sustainable requirements basis for the subsequent specification and testing activities.

The project used the VxP Validation Platform as the central document management system for validation documentation, supporting collaboration and the digital management of validation records. As a digital validation platform, VxP simplifies identifying the currently valid documents, versioning, and traceability.

Approach





Results & Measurable Value

Go-live was successfully achieved in March 2026. Key to the successful completion were the consistent application of the DHC methodology and a clear distribution and delegation of responsibilities between Nordmark, CPRO and DHC. The validation itself was completed on schedule, before the deadline.

Working with DHC, Nordmark built significant internal validation expertise, enabling independent validation in ongoing operations.



Regulatory Compliance Aspects

A consistent GxP assessment of the processes enabled a risk-based, redundancy-free and audit-ready validation of the system.

A recurring question was the process-specific assessment of audit trail requirements. Following a fundamental decision on this, the outcome could be consistently incorporated into the documentation.



Customer Satisfaction & Relationship

Nordmark repeatedly and actively asked DHC for advice and professional guidance in the validation context during the project. This is an indicator of the trust that has developed, going well beyond pure order processing.

„With DHC we not only validated a migration – we realigned our entire CSV methodology and laid the foundation for GxP-compliant SAP operations.“

Stefanie Hölscher, Project Manager,
Nordmark Pharma GmbH



Project Manager:

karsten.schulz@dhc-gmbh.com

Arrange a free initial consultation!



Contact:



+ 49 6 81 93 666-0



consulting@dhc-gmbh.com



www.dhc-consulting.com